ARNOLD & PORTER LLP

IP/Technology Update Series

IP/Technology Year in Review and Forecast for 2013: *Protecting Your Company's IP Position*

PATENT LAW

Wednesday, January 30, 2013

ARNOLD & PORTER LLP

IP/Technology Update Series

IP/Technology Year in Review and Forecast for 2013: *Protecting Your Company's IP Position*

PATENT LAW

Wednesday, January 30, 2013
8:00 – 10:00 a.m. (PST)

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Tab 1: Agenda

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IP/Technology Update Series

IP/Technology Year in Review and Forecast for 2013: *Protecting Your Company's IP Position*

PATENT LAW

Wednesday, January 30, 2013

8:00 – 10:00 a.m. (PST)

Agenda

8:00–8:05 a.m.	**Introduction**
8:05–9:50 a.m.	**Presentation and Discussion**

Speakers:

Jennifer Sklenar, Partner, Arnold & Porter LLP, Los Angeles

Monty Agarwal, Senior Counsel, Arnold & Porter LLP, San Francisco

Mike Berta, Partner, Arnold & Porter LLP, San Francisco

Tom Magnani, Partner, Arnold & Porter LLP, San Francisco

9:50–10:00 a.m.	**Question-and-Answer Session**

1.5 hours of CA CLE credit, other states pending.

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Tab 2: Presentation

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IP/Technology Year in Review and Forecast for 2013: Protecting Your Company's IP Position – Patent Law

Jennifer Sklenar
Monty Agarwal
Mike Berta
Tom Magnani

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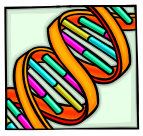
Patent Eligible Subject Matter

- Application of laws of nature (*Mayo*)

  $E=mc^2$

- Aspects of human genes (*Myriad*)



Patent Eligible Subject Matter

"There is no patent. Could you patent the sun?"

-- Dr. Jonas Salk

Mayo v. Prometheus, 132 S. Ct. 1289 (2012)

- Prometheus' patent claims: methods to assist doctors determine appropriate dosage of thiopurine drugs to treat patients with autoimmune diseases,
- Mayo entities began using/selling its own test
- Relevant law of nature: relationship between concentration in the blood of certain thiopurate metabolites and likelihood dosage will be effective or result in side-effects

Mayo v. Prometheus, 132 S. Ct. 1289 (2012)

Competing legal principles

- "'[L]aws of nature, natural phenomena, and abstract ideas' are not patentable." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).
- " [A]n *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Id.* at 187.

Competing public policy

- Grant of a patent should not tie up laws of nature and inhibit future innovation.
- Those who make discoveries and innovate should be rewarded with a patent.

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Mayo v. Prometheus, 132 S. Ct. 1289 (2012)

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Mayo v. Prometheus, 132 S. Ct. 1289 (2012)

"The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, **do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe the answer is no**. . . **[A]ny additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community** . . . ."

ASM v. Myriad Genetics – Supreme Court 2013

- Claims involve aspects of BRCA 1 and BRCA 2 breast cancer genes
- Myriad had history of aggressive enforcement of rights against other suppliers of diagnostic test
- Petition filed by group of doctors represented by the American Civil Liberties Union and Public Patent Foundation
- Question 1: "Are human genes patentable"

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ASM v. Myriad Genetics, 689 F.3d 1303 (Fed. Cir. 2012)

- After remand from Supreme Court in view of *Mayo*
- 2-1 decision authored by Judge Lourie
- Reversed in part and affirmed in part on patent-eligible subject matter issues in view of *Mayo*

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ASM v. Myriad Genetics, 689 F.3d 1303 (Fed. Cir. 2012)

- Composition of matter claims relating to BRCA 1 and BRCA2 genes are patent eligible
- Method claim directed to screening potential cancer therapeutics by assessing changes in cell growth rates of transformed cells is patent-eligible
- Method claims directed to "comparing" or "analyzing" DNA sequences are patent ineligible

Myriad Genetics – Composition of Matter Claims

- Isolated BRCA1 and BRCA2 genes
- Shorter molecules corresponding to a DNA sequence that occurs to the BRCA genes
- cDNA molecules corresponding to BRCA1 and BRCA2 genes

Myriad Genetics – Composition of Matter Claims

- Isolated BRCA1 and BRCA2 genes
  - Judge Lourie: held patent eligible as manmade composition of matter; *Mayo* is irrelevant
  - Judge Moore: concurred but primarily because of settled expectations, including USPTO 2001 Examination Guidelines, estimated 2645 issued patents claiming isolated DNA, Congress' failure to act
  - Judge Bryson: dissented; "Myriad is claiming the gene itself" because isolated genes are "not materially different"
  - Government : advocated patent ineligibility based upon "magic microscope" test

Myriad Genetics – Composition of Matter Claims

- Shorter molecules corresponding to a DNA sequence that occurs in the BRCA genes
  - Judge Bryson dissented
- cDNA molecules corresponding to BRCA1 and BRCA2 genes
  - Judge Bryson concurred (3-0)
  - Government advocated for patent eligibility

Myriad Genetics – The appropriate analogy?

CLS Bank Int'l v. Alice Corp, App. No. 2011-1301 (Fed. Cir. 2012)

- a. What test should the court adopt to determine whether a computer-implemented invention is a patent ineligible "abstract idea"; and when, if ever, does the presence of a computer in a claim lend patent eligibility to an otherwise patent-ineligible idea?
- b. In assessing patent eligibility under 35 U.S.C. § 101 of a computer-implemented invention, should it matter whether the invention is claimed as a method, system, or storage medium; and should such claims at times be considered equivalent for § 101 purposes?

Patent Exhaustion

- *Monsanto v. Bowman* – Supreme Court 2013

Bowman – Supreme Court 2013

- Monsanto holds various composition of matter and method claims directed to Roundup Ready® technology
- Roundup Ready® seeds sold with Technology Agreement limiting seed use to one growing season and prohibiting replanting
- Monsanto permits crops to be sold to grain elevators as a commodity
- Bowman (IN farmer) purchased seed from local grain elevator and replanted for several seasons

Bowman – Federal Circuit 2012

- Monsanto sued, claiming patent infringement
- Bowman defended based on patent exhaustion
- District Court granted summary judgment of infringement and entered judgment in amount of $84,456.20

Bowman – Federal Circuit 2012

Held: Conditional sale precludes application of patent exhaustion, as in *McFarling* and *Scruggs*

"Even if Monsanto's patent rights in the commodity seeds are exhausted, such a conclusion would be of no consequence because once a grower, like Bowman, plants the commodity seeds containing Monsanto's Roundup Ready® technology and the next generation of seed develops, the grower has created a newly infringing article."

Joint Patent Infringement of Method Claims

Monty Agarwal

Summary

- On August 31, 2012, the Federal Circuit issued an en banc opinion in two related cases involving the joint infringement of method claims: *Akamai Technologies, Inc. v. Limelight Networks, Inc.* and *McKesson Technologies, Inc. v. Epic Systems Corp.*
- In a 6-5 decision, a divided court expanded the theory of induced infringement by holding that all steps of a method claim need not be practiced by a single entity for purposes of induced infringement.
- The Federal Circuit's decision is sweeping in that it represents a shift away from the "single entity" rule and opens the door to claims of induced infringement by two or more actors. At the same time, the decision is narrow because the Federal Circuit passed on the issue of direct joint infringement (as opposed to induced infringement). Joint direct infringement claims still require a single actor, with limited exceptions.
- The Federal Circuit's decision will likely save and strengthen some interactive method claims that previously may have been difficult to enforce in light of the "single entity" rule.
- As patents issue for interactive methods, joint infringement situations are more likely.

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Joint Infringement

- What is joint infringement?
- How to spot a joint infringement claim?
- What does the new decision say about joint infringement?

Infringement Theories

- **Direct Infringement**:
  - "**[W]hoever** without authority makes, uses or sells any patented invention … infringes the patent." (35 U.S.C. § 271(a))
  - All elements must be practiced by a ***single entity***.
- **Induced Infringement**:
  - "**Whoever** actively induces infringement of a patent shall be liable as an infringer." (35 U.S.C. § 271(b))
  - No induced infringement without a direct infringement.
  - A single actor induces another actor to practice all elements of claim.

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Joint Infringement

- All elements are practiced, but ***single entity does not practice*** all elements.
- One actor practices some of the steps of a patented method and another actor practices remaining step(s).
- Joint infringement arises because:
  - The invention is multi-party or interactive.
  - Economics allow for contracting out step of the claims.
  - The manner in which the claims are drafted.

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Akamai v. Limelight Background

- Distributed system for storing and serving web content.
- Akamai sues Limelight, who offers competing service, for infringement of method claim.

34. A content delivery method, comprising:
distributing a set of page objects…
tagging at least some of the embedded objects…
in response to a client request for an embedded object of the page:
resolving the client request …
returning to the client an IP address ...

Limelight does not do the "tagging" step.

This step is undertaken by Limelight's customers.

Limelight gives customers the instructions on how to tag.

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Akamai v. Limelight Background

- Jury awards Akamai $40 Million
- District Court undoes the verdict, ruling no infringement because of divided infringement.
  - No single actor does all the steps of the method.
- CAFC Panel: No infringement
- "Joint infringement requires (i) an agency relationship, or (ii) a contractual obligation:
  - "This court therefore holds as a matter of Federal Circuit law that there can only be joint infringement when there is an agency relationship between who performed the method steps or when one party is contractually obligated to the other to perform the steps. Neither is present here."
  - Concerns about multi-party claims "can usually be offset by proper claim drafting."

Akamai v. Limelight Background

- "Proper" claim drafting?

34. A content delivery method, comprising:
distributing a set of page objects…
tagging at least some of the embedded objects…
in response to a client request for an embedded object of the page:
resolving the client request …
returning to the client an IP address ...

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Akamai v. Limelight Background

- "Proper" claim drafting?

34. A content delivery method, comprising:
distributing a set of page objects…
~~tagging~~ at least some of the embedded objects…
in response to a client request for an embedded object of the page:
resolving the client request …
returning to the client an IP address ...

Could this have been written to avoid a joint infringement problem?
"Receiving tagged information about"

McKesson v. Epic Systems Background

- McKesson's patented method relates to personal patient medical records.
- Epic makes software and sells it to health care providers who use it to interact with their patients.
- McKesson sues Epic for inducing infringement.

1. A method of automatically and electronically communicating between [health care provider] and [users] …
   initiating a communication by one of the [user/patients]
   enabling communication …
   Electronically comparing…
   Returning the response...

Epic argues there is no single infringer that directly infringes and therefore no inducement liability.

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McKesson v. Epic Systems Background

- District court grants renewed motion for summary judgment of no induced infringement.
- McKesson appeals, Federal Circuit affirms.
- A "doctor-patient relationship does not by itself give rise to an agency relationship or impose on patients a contractual obligation such that the voluntary actions patients can be said to represent the vicarious actions of their doctors."
- Absent an agency or contractual obligation to perform, McKesson failed to demonstrate that any single party directly infringed, and therefore no liability for induced infringement.

Issues Presented En Banc

Akamai

- If separate entities each perform separate steps of a method claim, under what circumstances would that claim be directly infringed and to what extent would each of the parties be liable?

McKesson

- If separate entities each perform separate steps of a method claim, under what circumstances, if any, would either entity or any third party be liable for inducing infringement or for contributory infringement?
- Does the nature of the relationship between the relevant actors matter (e.g., service provider/user; doctor/patient)?

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The Decision

- Decided August 31, 2012
- 6-5 En Banc Decision
  - Radar, Lourie, Bryson, Moore, Reyna and Wallach joined per curiam opinion
- Substantial Dissents
  - Judge Linn, joined by Dyk, Prost, O'Malley
  - Judge Newman

The En Banc Decision

- **Concerned about too much liability**:
  - Court is clearly concerned about "extending [direct infringement] liability in that manner would ensnare actors who did not themselves commit all the acts … and had no way of knowing that others were acting in a way that rendered their collective conduct infringing."
- **Concerned about too little liability**:
  - "Parties that jointly practice patented invention can often arrange to share performance…"
  - "sometimes that is the natural way that a particular method will be practiced"
  - "the patentee has no remedy, even though the patentee's rights are plainly being violated by the actors' joint conduct"

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The En Banc Decision: Joint Direct Infringement

- Although the holding was limited to induced infringement, the Federal Circuit stated:
- "To be sure, the court has recognized that direct infringement applies when the acts of infringement are committed by an agent of the accused infringer or a party acting pursuant to the accused infringer's direction or control."

The En Banc Decision: Joint Induced Infringement

- For a method claim, a party that does not perform all steps of the claim can be liable for infringement if :
  - One party can be liable for induced infringement when the party:
  - (1) knew of the patent
  - (2) performed the steps of the method **or** induced others to perform, and
  - (3) those steps were actually performed

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The Dissents: Judge Newman

- "This en banc court has split into two factions, neither of which resolves the issues of divided infringement."
- "The court should acknowledge that an all-purpose single-entity requirement is flawed, and restore direct infringement to its status as occurring when all of the claimed steps are conducted, whether by a single entity or in interaction or collaboration."
- "Today's new rule of inducement-only liability serves no public interest, no innovation need. The consequences of the technology communities are uncertainty, disincentive, and new potential for abuse."

The Dissents: Judge Linn

- "In its opinion today, this court assumes the mantle of policy maker. It has decided that the plain text of § 271(a) and (b) fails to accord patentees certain extended rights that a majority of this court's judges would prefer that the statute covered."
- "Congress knows how to create alternative forms of infringement."

Bottom Line

- Federal Circuit has chipped at away single entity rule and expanded induced infringement liability.
- Resurrects multi-party patent claims.
- Change is sweeping as a matter of doctrine, but may be limited because of limitations of induced infringement doctrine.
- Majority believes knowledge requirement for induced infringement will curtail abuse.
- Future will tell how this expanded liability is used in litigation.

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2012 Patent Litigation Update: Reasonable Royalties post-*Uniloc*

Mike Berta

arnoldporter.com

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Reasonable Royalty Damages: Overview

- 35 USC §284: patent holder is statutorily entitled to "in no event less than a reasonable royalty for the use made of the infringement by the infringer"
- Running royalty versus lump-sum payment
- Running royalty amount = royalty rate x base

- Increasing focus: what is the right base?

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Calculating a Base for Royalty Damages

- Apportionment and the Entire Market Value rule
- Idea of apportionment for components has a long lineage
  - *Livingston v. Woodworth*, 56 U.S. 546 (1853)
  - *Seymour v. McCormick*, 57 U.S. 480 (1853)
- What is a component?
- How to prove proportional value of component?

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Application of EMV Rule

- Applies to a “component”
- Is this the same as a “feature”?
- *Cornell University v. Hewlett-Packard Co.*

Cornell University v. Hewlett-Packard Co.

609 F. Supp. 2d 279 (N.D.N.Y. 2009) (Rader, C.J., sitting by designation)

- When does EMV not apply?
- When the prerequisites for the EMVR aren't met, the best conceptual product base is "the smallest possible measure of sales"
- "The logical and readily available alternative was the smallest salable infringing unit with close relation to the claimed invention," *Id.* at 288
- Any time damages theory goes beyond this, EMVR must be invoked
- For more on Chief Judge Rader as policeman, *see* Ravi Mohan, *Analysis of the Entire Market Value Rule in Complex Technology Litigation: Arduous Royalty Base Determinations, Unjust Damage Rewards, and Empirical Approaches to Measuring Consumer Demand*, 27 SANTA CLARA COMPUTER & HIGH TECH. L.J. 639 (2011).

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When the EMV Rule Applies: Methodology

- Prior Models:
  - Sliding scale – pick your base and "adjust" rate accordingly
  - Demand for component shown by documents referring to component
- Proof issues:
  - Question of fact?
  - Battle of experts?
  - Any gatekeeping?

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Uniloc: Cleaning up the EMV Rule

***Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292 (Fed. Cir. 2011)**

- Microsoft copy-protection features various Word and Windows products found to infringe plaintiff patent
- Jury awarded $388 million in damages; district court had denied *in limine* on plaintiff damages expert, but granted new trial on damages
  - ($10 per-product baseline) x (number of products sold)
  - 25-percent rule
  - Did not expressly rely on MSFT revenue numbers
- Federal Circuit affirms grant of new trial on damages, but offers guidance on EMV Rule (and throws out 25% Rule)

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EMV Rule Under *Uniloc*

- Reaffirms legitimacy of EMVR
  - *Garretson v. Clark*, 111 U.S. 120 (1884)
- But, its use was inappropriate
  - Jury presented with evidence that Microsoft made $19 bn from infringing products as a "check" on the damages figure and as cross of defendant's expert.
  - Total revenue "cannot help but skew the damages horizon for the jury, regardless of the contribution of the patented component to this revenue."
- EMVR only available where component is proven to be the basis of customer demand
- Total revenue only admissible where EMV Rule applies

EMV Rule in 2012: *Laser Dynamics*
694 F.3d 51 (Fed. Cir. 2012)

- Involved alleged infringement by a feature of an optical disk drive in a laptop computer
- *Laser Dynamics* expands on EMV rule limitations:
  - Expressly adopts that damages should be based on the "smallest salable unit" and that the EMV rule is an exception to this requirement
  - Not enough to be "valuable, important or even essential" component, even if entire product would be unviable without allegedly patented feature
  - Must show that "the presence of that functionality is what motivates customers"

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Arguably Open Questions from *Laser Dynamics*

- What is sufficient proof of customer demand?
- Interplay between lump sum licenses and derived rates for running royalties?
- What is the smallest salable unit?

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Apple, Inc. v. Motorola, Inc.

No. 11-8540, 2012 WL 1959560, at *6 (N.D. Ill. May 22, 2012) (Posner, J., sitting by designation)

- Judge Posner tosses almost all substantive expert testimony
- Proof of customer demand: A customer survey must actual answer the relevant damages questions – a list of "important features" and some long division is not enough to assign a value to a particular feature in a multi-component product
- Other highlights:
  - Asking your own engineers about design-around costs is either unreliable or not expert testimony
  - Experts must use methods they would use "with an identical issue outside the litigation context"
- On appeal: Fed. Cir. briefing due March 13, 2013.

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Honeywell Int'l, Inc. v. United States

No. 02-1909, 2012 WL 6115817, at *31, *36 (Ct. Fed. Cl. Dec. 5, 2012)

- Patent allegedly covered a method for enabling a full color cockpit display that was night-vision goggle compatible
- Court rejected plaintiff and defendant damages expert testimony
- Among other things, plaintiff's justification of the relatively modest damages in light of pricing for entire C-130 aircraft violated EMV rule; reliance on press releases regarding importance of night vision technology insufficient to meet *Laser Dynamics* hurdle

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Multimedia Patent Trust v. Apple, Inc.

No. 10-2618, 2012 WL 5873711, at *4-*6 (S.D. Cal. Nov. 20, 2012)

- *Daubert* proceedings on damages regarding alleged infringement of video compression patents
- Court distinguished a fixed per-unit running royalty from a percentage-based royalty rate; former does not *per se* violate EMV rule
- However, reference to percentage royalty rate as a "check" violates *Uniloc/LaserDynamics*
- Existence of lump sum licenses was not sufficient justification for discussing entire market value of products covered by license, but converting a lump sum license to a fixed per-unit rate could be justified

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Fractus, S.A. v. Samsung Electronics Co., Ltd.

No. 09-203, 2012 WL 2505741, at *21-*23 (E.D. Tex. June 28, 2012)

- Patent related to cell phone antenna technology
- Expert discussed value of antenna as proportion of value of cell phone and applied royalty rate to calculated proportional value of antenna, even though antenna appeared to be the smallest salable unit
- "Model did not improperly invoke the entire market value rule" – *Uniloc* and *Cornell* distinguished where total overall revenues not referenced and where expert explained that he was not intending to use value of phone as the royalty base, but was instead using the calculated proportional value of the phone as the base
- This distinction may not be viable post-*Laser Dynamics*

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AVM Techs., LLC v. Intel Corp.

No. 10-610, 2013 WL 126233, at *2 (D. Del. Jan. 4, 2013)

- *Daubert* motion on damages for alleged infringement of patents involving dynamic logic circuits
- Plaintiff based damages on purported "smallest salable unit," *i.e.*, a microprocessor, relying on *Laser Dynamics*
- Defendant relied on *Lucent* to argue that plaintiff should have apportioned value of patent, regardless of what smallest salable unit was
- Court acknowledged certain tension between *Lucent* and *Laser Dynamics* and preliminarily indicated, based on the facts of the case, that plaintiff here may well have to prove that the patented feature drives demand

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Lessons from 2012 on Damages

- Where there is a divisible, salable component that practices a patented invention, there appears to be an increasingly higher threshold for using (or introducing) any other revenue information
- However, even using the smallest salable unit may not be proper and apportionment may be required, if the patented feature is still a minor part of the salable unit
- Reliable, relevant licenses can address these issues

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Implied Patent Licensing via Legal Estoppel:

What the Left Hand Gives, the Right Hand May Not Take Away

Thomas A. Magnani

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What is an implied license by legal estoppel?

- When a patentee is barred from asserting a patent because it would derogate from an earlier license granted to the "infringer" expressly covering different patents

Why should you care?

- The doctrine has been expanding in recent years
- It can affect the value of patents in your portfolio or that you may be considering acquiring
- You MAY be able to prevent inadvertent implied licensing in future deals

AMP v. US, 389 F.2d 448 (Ct. Cl. 1968)

- Licensor granted license to practice "Subject Invention"
- Licensor later acquired earlier filed, *dominant* patent
- Licensor sued licensee on the dominant patent

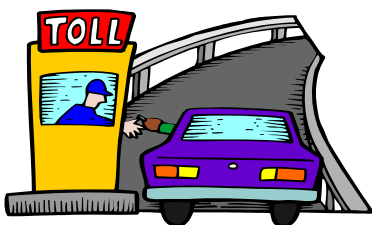
Held: Licensor estopped from asserting dominant patent

TransCore v. Electronic Transaction Consultants Corp., 563 F.3d 1271 (Fed. Cir. 2009)

- TransCore and Mark IV settled earlier patent litigation with a covenant not to sue (CNS) by TransCore to Mark IV covering several patents
- CNS stated it "shall not apply to any other patents issued as of the effective date of this Agreement or to be issued in the future"
- ETC installed and tested E-Z Pass systems purchased by ISTHA from Mark IV

TransCore v. Electronic Transaction Consultants

- TransCore sued ETC on 4 patents, 3 of which were included in the CNS
- Remaining patent was *dominant* over 1 of the patents covered by the CNS and was pending at the time CNS was executed



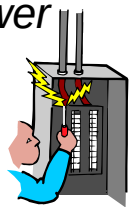
TransCore v. Electronic Transaction Consultants

Held: ETC had an "E-Z Pass" to the dominant patent via legal estoppel

Exclusion of all other patents from CNS did not permit TransCore to derogate from the CNS

General Protecht Group, Inc. v. Leviton Manufacturing Co., 651 F.3d 1355 (Fed. Cir. 2011)

- Leviton and GPG settled earlier litigation with CNS from Leviton to GPG covering two patents
- CNS expressly limited to only two patents
- Leviton was later granted two *narrower* continuations of those patents



General Protecht Group, Inc. v. Leviton Manufacturing

- Leviton sued GPG on the two *narrower* continuations

Held: Narrower continuations are included in the CNS

Even though the prior patents could be infringed without infringing continuations

Absent clear indication of mutual intent to the contrary

Intel Corporation v. Negotiated Data Solutions, Inc., 2012 WL 6554690 (Fed. Cir. 2012)

- Intel and National cross-licensed each other under all patents with a first effective filing date prior to expiration of Agreement
- National assigned 3 patents to Vertical Networks
- Vertical filed broadening reissue applications
- After Agreement expired, Vertical assigned original patents and reissue applications to N-Data

Intel Corporation v. Negotiated Data Solutions

- Reissue applications issued
- N-Data sued an Intel customer (Dell) on the reissues
- Intel intervened, seeking DJ that reissues were covered by the National cross-license

Held: In the absence of contrary language, patent license that is not directed at specific claims, field of use, etc. will extend to the full invention that is the subject of that patent

Includes reissues (citing 35 USC § 251)

Drafting Tips for Licensors

- Clearly disclaim all implied licenses, by legal estoppel or otherwise
- Avoid granting license to "inventions disclosed" in patents
- Require licensee to acknowledge that no license granted to any other patents, whether or not infringed by practice of licensed patents
- Expressly exclude all continuations, reissues, and divisionals, if that is the intent

Drafting Tips for Licensees

- Better not to rely on legal estoppel
- Conduct due diligence to determine necessary patents from licensor's portfolio
- Seek license to all inventions disclosed in licensed patents
- Include continuations, reissues, and divisionals
- Seek warranties that no other licensor patents or applications cover licensed invention
- Include all current and future patents necessarily infringed by practice of licensed patents

Questions

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Tab 3: Speaker Biographies

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Jennifer Sklenar

Partner

Ms. Sklenar is a partner in the firm's intellectual property practice group. She focuses her practice on patent litigation and counseling, particularly in the medical device and biotech fields. She has managed all aspects of litigation and has significant in-court experience. In addition, Ms. Sklenar has experience drafting and negotiating license agreements and has counseled clients on intellectual property matters for corporate transactions.

Ms. Sklenar is consistently recognized by *Law & Politics* magazine as a Southern California Super Lawyer "Rising Star" in the field of intellectual property litigation.

Representative Matters

- *GE Healthcare*. Serves as counsel in pending patent and contract litigation brought by Enzo Biochem involving labeled nucleic acids and their detection. Obtained summary judgment of non-infringement of patent claims.
- *GE Healthcare.* Serves as counsel in pending patent litigation against AntiCancer involving fluorescent detection technology.
- *GE Healthcare. Served as counsel in patent litigation against NeuroGrafix involving MRI technology. The case was settled favorably.*
- *GE Healthcare.* Served as counsel in patent litigation against MMP involving medical database and paging technology. The case was settled favorably.
- *GE Healthcare.* Served as counsel in patent litigation against SonoSite involving ultrasound technology. The cases were settled favorably.
- *Hologic*. Serves as counsel in pending patent litigation against Enzo involving labeled nucleic acids.

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Practice Areas
Intellectual Property

Education
JD, *with distinction*, Hofstra University School of Law, 1994
BS, Northwestern University, 1991

Admissions
California
New York
US District Court for the Central District of California
US District Court for the Southern District of California
US District Court for the Northern District of California
US District Court for the Eastern District of New York
US District Court for the Southern District of New York
US District Court for the Western District of New York
US District Court for the Northern District of Texas
US Court of Appeals for the Federal Circuit
US Patent and Trademark Office

- *Hologic*. Serves as counsel in pending patent litigation against Smith & Nephew involving intrauterine tissue removal technology.
- *Hologic*. Served as counsel in patent litigation against IZI involving mammography technology. Prevailed at trial in obtaining jury verdict of infringement.
- *The Trustees of Columbia University in the City of New York and The Board of Trustees of the Leland Stanford Junior University*. Served as counsel in patent and contract litigation brought by MedImmune involving recombinant monoclonal antibody technology. The case was settled favorably.
- *Advanced Bionics (subsidiary of Boston Scientific Corporation).* Served as counsel in patent and trade secret litigation brought by Advanced Neuromodulation Systems involving implantable spinal cord stimulation technology. The case was settled favorably.

Monty Agarwal

Senior Counsel

Monty Agarwal is senior counsel in the firm's intellectual property group and is based in the San Francisco office. Mr. Agarwal specializes in representing technology, consumer product and other businesses, in commercial and intellectual property litigation, including patent, trademark, trade secret and copyright litigation. Mr. Agarwal also provides strategic counseling to businesses on a broad range of intellectual property and commercial issues, including IP portfolio evaluation and license compliance audits and arbitrations. Mr. Agarwal has tried cases before judges and juries in federal and state courts, and has also presented to the Ninth Circuit Court of Appeals. Mr. Agarwal also has substantial experience in the use of alternative dispute procedures, including arbitration and mediation. He has worked particularly with clients in the IT, electronics, semiconductor, medical device, and food and drug industries.

Mr. Agarwal is a member of the Board of Directors of the Bar Association of San Francisco and a Commissioner on the Judicial Nominees Evaluation Commission of the State Bar of California. He has served as the president of the South Asian Bar Association of Northern California, as the Chair of the Board of Directors of the Asian Law Caucus, and has been honored for his pro bono asylum work by the Lawyers Committee for Civil Rights of the San Francisco Bay Area. In 2008, he was presented a Unity Award by the Minority Bar Coalition and also recognized by the National Asian Pacific Bar Association as one of its "Best Lawyers Under 40." Before law school, he was a Peace Corps volunteer in the mountain villages of Lesotho, Southern Africa.

Representative Matters

- Prevailed in stopping use of infringing trademark for dietary supplement manufacturer.
- Oversaw royalty audit of drug manufacture to ensure compliance with patent licenses.

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Practice Areas
Intellectual Property Litigation

Education
JD, *cum laude*, Georgetown University Law Center, 1997
MS in Foreign Service, Georgetown University, 1997
BA, Emory University, 1990

Admissions
California
US Court of Appeals for the Ninth Circuit
US District Court for the Northern District of California
US District Court for the Southern District of California
US District Court for the Northern District of Illinois
US District Court for the Central District of California
US Court of Appeals for the Federal Circuit

- Defended light emitting diode manufacturer against claims of design patent infringement.
- Secured multimillion dollar recovery in arbitration relating to patent licenses for medical laser systems.
- Defended plastics manufacturer from product liability claims arising out of use of polymer packaging.
- Defended designer of programmable gate arrays from masks works infringement claims.
- Prosecuted trademark infringement claims on behalf of manufacturer of encryption hardware and software.
- Prosecuted patent, copyright and trademark infringement, trade secret misappropriation and unfair competition claims relating to high capacity disk drives.
- Prosecuted actions for copyright and trademark infringement against counterfeit software distributors.
- Prosecuted commercial dispute involving disposable medical systems for intravenous therapies.

Rankings

- *Diversity & The Bar* 2009 as one of National Asian Pacific American Bar Association's (NAPABA) "Best Lawyers Under 40"

Professional and Community Activities

- Board of Directors, Asian Law Caucus
- Member, Board of Directors of the Bar Association of San Francisco
- Commissioner, Judicial Nominees Evaluation Commission of the State Bar of California

Articles

- Monty Agarwal and James S. Blackburn ""False Patent Marking" Suits: How Judges And IP Rights Holders Can Respond To New Litigation Trend" Washington Legal Foundation August 6, 2010
- Monty Agarwal "The Case Must Go On" *Los Angeles Daily Journal*, February 2009

Presentations

- Monty Agarwal "Old Rules, New Medium: What Lawyers Need to Know About Legal Ethics In An Era of Social Media." Marin County Bar Association Annual CLE Fair, November 6, 2010
- Monty Agarwal, James S. Blackburn and Ryan M. Nishimoto "IP/Technology: 2010 Midyear Update" Arnold & Porter LLP, Palo Alto, CA, June 8, 2010

Advisories

- "Ninth Circuit Rejects Tax Withholding as Litmus Test for Copyright "For Hire" Status" Apr. 2010
- "Federal Circuit Ruling Raises the Bar for Fraud in Trademark Cases Before the TTAB" Sep. 2009
- "Second Circuit Rules Sale of Trademarked Keywords Satisfies "Use" Requirements of Lanham Act" Apr. 2009
- "Federal Circuit Clarifies Test for Business Method Patents" Nov. 2008
- "Federal Circuit Eliminates "Point of Novelty" Test for Design Patent Infringement" Sep. 2008

Multimedia

- Monty Agarwal, Michael A. Berta, Beth H. Parker and Robert P. Taylor. "WEBCAST: Key Recent U.S. Supreme Court and Federal Circuit Court Decisions That Impact Patent Law" June 22, 2011.
- Monty Agarwal, Todd A. Lorenz, Joseph A. Micallef and Beth H. Parker. "WEBCAST: Trends and Developments in Patent Law" January 26, 2011. *(also available as a Podcast)*
- Monty Agarwal, James S. Blackburn, Sean Morris, Beth H. Parker, John C. Ulin and Suzanne V. Wilson. "WEBCAST: IP/Technology: 2010 Midyear Update" June 08, 2010. *(also available as a Podcast)*

Michael A. Berta

Partner

Michael Berta is a partner in the intellectual property group of Arnold & Porter LLP and is based in the San Francisco office. Mr. Berta focuses his practice on intellectual property litigation, with experience in both patent and trade secret litigation across a wide range of technologies, including data storage systems and software networking hardware and software, microprocessor and flash memory architecture, pharmaceuticals, medical devices, and consumer products. Mr. Berta has tried cases before judges and juries in federal court and before the International Trade Commission.

Representative Matters

- Represented hardware, software and web-based services companies including Google and Hewlett-Packard in patent litigation in multiple jurisdictions, including the Eastern District of Texas.
- Represented various pharmaceutical companies in ANDA patent litigation in United States District Courts of Delaware and New Jersey, both at trial and in preliminary injunction proceedings.
- Represented various pharmaceutical and life sciences companies, including Medicis Pharmaceutical, Affymetrix, Ventana Medical Systems, Arcturus Engineering Neopharm, VISX (now AMO) and Cell Therapeutics in patent, trade secret, and drug development litigation involving technologies such as transdermal delivery systems, DNA/RNA microarrays, DNA probes, laser capture microdissection, and oncological pharmaceuticals.
- Represented companies in the semiconductor industry, including Sun Microsystems, SMIC, SanDisk, Numerical Technologies and Nanya Technology in patent and trade secret litigation involving semiconductor manufacturing technology, DRAM architecture, flash controller

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Practice Areas
Intellectual Property
Litigation

Education
JD, *cum laude*, Georgetown University Law Center, 1997
BA in Economics, University of California, San Diego, 1993

Admissions
California
District of Columbia
US District Court for the Northern District of California
US District Court for the Southern District of California
US District Court for the Central District of California
US District Court for the District of Columbia
US Court of Appeals for the Federal Circuit
US International Trade Commission

technology, and server architecture.

- Represented Crocs in district court, before the ITC and with Customs in design and utility patent matters against import shoe manufacturers.
- Represented RealNetworks in DMCA/antitrust action involving DVD technology.
- Represented Global VR in copyright and trade dress action over coin-operated video golf.
- Other clients have included LeapFrog Enterprises, Fortinet, Digital Oilfield, Platinum Equity, the California Lottery, the McClatchy Company, UTStarcom and NetSuite.

Articles

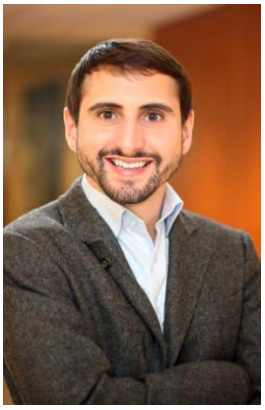
- Michael A. Berta "Weighing Generic Litigation In The ITC" Law360, April 28, 2011

Advisories

- "The America Invents Act: An Overview of Patent Reform" Sep. 2011
- "Generic Litigation in the ITC: A New Trend?" Apr. 2011

Multimedia

- Michael A. Berta and Louis S. Ederer. "VIDEOCAST: Brand Enforcement Strategies - The ITC as An Effective Anti-Counterfeiting Tool" August 23, 2011. *(also available as a Podcast)*
- Monty Agarwal, Michael A. Berta, Beth H. Parker and Robert P. Taylor. "WEBCAST: Key Recent U.S. Supreme Court and Federal Circuit Court Decisions That Impact Patent Law" June 22, 2011.



Thomas A. Magnani

Partner

Tom Magnani focuses primarily on intellectual property licensing and counseling and on structuring technology and commercial transactions for companies and investors in a broad range of industries, including media and entertainment, e-commerce, life sciences, consumer products, and information technology. Mr. Magnani has provided strategic advice to clients in connection with a wide variety of intellectual property-related transactions, including research and development collaborations, mergers, asset acquisitions, public offerings, venture capital financings, copyright, trademark, and patent licenses, software licenses, distribution and supply arrangements, and sponsorship deals. Working closely with the firm's litigation practice, Mr. Magnani has developed particular experience in the settlement of complex intellectual property disputes.

In addition, Mr. Magnani counsels clients on compliance with advertising laws, including those regulating sweepstakes, skills contests, unsolicited e-mail and privacy. He also advises clients on antitrust concerns that arise in the context of business transactions.

While in law school, Mr. Magnani served on the editorial board of the *Berkeley Technology Law Journal* and earned a Boalt Hall Law and Technology Certificate.

Mr. Magnani was recently selected by the *Daily Journal* as one of the top IP attorneys in California and he was named one of the "Best LGBT Lawyers Under 40" by the National LGBT Bar Association. He was also recognized as a Northern California Rising Star from 2009 through 2012, and named the "'Hidden Gem' Intellectual Property Attorney" by *The Recorder* in October 2006.

Representative Matters

- Representing three leading research universities in

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Practice Areas
Intellectual Property
Technology / IP Transactions and Licensing
Telecommunications, Internet, and Media
Consumer Protection and Advertising

Education
JD, Order of the Coif, UC Berkeley School of Law, 2000
BS in Biology and Environmental Studies, *summa cum laude*, Phi Beta Kappa, Tufts University, 1997

Admissions
California
US Patent and Trademark Office

structuring and negotiating a settlement of class action copyright infringement lawsuits, brought by the Authors Guild, and five major publishers against Google regarding Google's digitization of the universities vast library holdings in connection with the Google Book Search Project.

- Participating in the negotiation and documentation of a $612.5 million license and settlement between Research In Motion Limited and NTP, Inc. resolving a widely-publicized patent dispute over RIMs BlackBerry handheld devices.
- Negotiating and drafting video game and merchandise license agreements on behalf of The Saul Zaentz Company (d/b/a Middle-earth Enterprises), holder of film, stage, and merchandising rights in *The Hobbit* and *The Lord of the Rings*.

Mr. Magnani's representative clients include Amazon.com, Autodesk, The Clorox Company, CustomInk, The Doheny Eye Institute, Fullpower Technologies, The Saul Zaentz Company (d/b/a Middle-earth Enterprises), and TigerLogic Corporation. He has represented clients in deals with Boeing, Boston Scientific, Electronic Arts, Google, Johnson & Johnson, Nestlé, New Line Cinema, Nike, Siemens, Paramount, Sony, Universal Pictures, Vivendi Universal Games and Warner Bros., among others.

Rankings

- *Northern California Super Lawyers* 2009-2012 "Rising Star"
- *Daily Journal* 2010 "Top Intellectual Property Lawyers"

Professional and Community Activities

Professional Activity

- American Bar Association, member of the Computer Games and Virtual Worlds Committee
- Licensing Executives Society
- State Bar of California, IP Section, Licensing Committee
- Bay Area Lawyers for Individual Freedom

Community Activity

- Frameline, Board of Directors
- StartOut

ARNOLD & PORTER LLP

Tab 4: Practice Overview

ARNOLD & PORTER LLP

Tab 5: Supporting Materials

United States Court of Appeals for the Federal Circuit

MONSANTO COMPANY AND MONSANTO TECHNOLOGY LLC,
Plaintiffs-Appellees,

v.

VERNON HUGH BOWMAN,
Defendant-Appellant.

2010-1068

Appeal from the United States District Court for the Southern District of Indiana in case no. 07-CV-0283, Judge Richard L. Young.

Decided: September 21, 2011

PAUL R. Q. WOLFSON, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC, for plaintiffs-appellees. With him on the brief were SETH P. WAXMAN and GREGORY H. LANTIER; and DAVID B. JINKINS, Thompson Coburn LLP, of St. Louis, Missouri. Of counsel were DANIEL C. COX and JEFFREY A. MASSON, Thompson Coburn, LLP, of St. Louis, Missouri.

MARK P. WALTERS, Frommer Lawrence & Haug LLP, of Seattle, Washington, for defendant-appellant. With him on the brief were DARIO A. MACHLEIDT; and EDGAR H. HAUG, of New York, New York.

TIMOTHY C. MEECE, Banner & Witcoff, Ltd., Chicago, Illinois, for amicus curiae Lexmark International, Inc.

Before BRYSON, LINN, and DYK, *Circuit Judges*.

LINN, *Circuit Judge*.

This case presents the court with another question of patent infringement by farmers planting the progeny of genetically altered seeds covered by U.S. patents. Here, Plaintiffs-Appellees, Monsanto Company and Monsanto Technology LLC (collectively "Monsanto"), sued Defendant-Appellant, Vernon Hugh Bowman ("Bowman"), in the United States District Court for the Southern District of Indiana alleging infringement of U.S. Patent Nos. 5,352,605 ("'605 Patent") and RE39,247E ("'247E Patent"). *Monsanto Co. v. Bowman*, 686 F. Supp. 2d 834 (S.D. Ind. 2009). The district court granted summary judgment of infringement in favor of Monsanto. *Id.* at 840. Bowman appeals. For the reasons discussed below, this court affirms.

I. BACKGROUND

Monsanto invented and developed technology for genetically modified "Roundup Ready®" soybeans that exhibit resistance to N-phosphonomethylglycine-(commonly known as "glyphosate") based herbicides, such as Monsanto's Roundup® product. The '605 and '247E Patents cover different aspects of this Roundup Ready® technology.

A. The '605 Patent

On October 4, 1994, the United States Patent and Trademark Office ("PTO") issued the '605 Patent to Monsanto for "chimeric genes for transforming plant cells using viral promoters." The invention of the '605 Patent relates to the use of viral nucleic acid from the cauliflower mosaic virus ("CaMV"), a virus capable of infecting plant cells, as a vector for incorporating new genetic material into plant cells (a "transformation" of the plant cells). To accomplish this transformation, the CaMV promoter region is isolated from the CaMV genome and combined with a heterologous protein-encoding DNA sequence, forming a chimeric gene to be expressed in the plant cell. Monsanto alleges infringement of claims 1, 2, 4, and 5 of the '605 Patent. Representative claims 1 and 4 cover:

> **1.** A *chimeric gene* which is expressed in plant cells comprising a promoter from a cauliflower mosaic virus, said promoter selected from the group consisting of a CaMV (35S) promoter isolated from CaMV protein-encoding DNA sequences and a CaMV (19S) promoter isolated from CaMV protein-encoding DNA sequences, and a structural sequence which is heterologous with respect to the promoter.
>
> **4.** A *plant cell* which comprises a chimeric gene that contains a promoter from cauliflower mosaic virus . . . .

'605 Patent, col.15 ll.52-59, 64-65 (emphases added).

B. The '247E Patent

On August 22, 2006, the PTO reissued U.S. Patent No. 5,633,435 ("'435 Patent") as the '247E Patent for

"glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases [("EPSPS")]." The invention of the '247E Patent involves the transformation of plant cells—using, for example, the CaMV promoters disclosed in the '605 Patent—to transform plant cells with novel protein-encoding gene sequences that encode for EPSPS, a glyphosate-tolerant enzyme. These genetically modified plants express EPSPS and exhibit glyphosate resistance. '247E Patent, col.1 ll.15-46. The advantage of this technology, which can be incorporated into a variety of crops, is that farmers can treat their fields with glyphosate-based herbicide to control weed growth without damaging their crops. Monsanto alleges infringement of seventeen claims of the '247E Patent. Representative claims 103, 116, 122, 128, 129, and 130 cover:

> **103.** A *recombinant, double-stranded DNA molecule* comprising in sequence:
>
> (a) a promoter which functions in plant cells to cause the production of an RNA sequence;
>
> (b) a structural DNA sequence that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence of SEQ ID NO:70; and
>
> (c) a 3' non-translated region that functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence;
>
> where the promoter is heterologous with respect to the structural DNA sequence and adapted to cause sufficient expression of the encoded EPSPS enzyme to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule.

> **116.** A glyphosate-tolerant *plant cell* comprising a DNA sequence encoding and EPSPS enzyme having the sequence of SEQ ID NO: 70.
>
> **122.** A *seed of the plant* of claim 116, wherein the seed comprises the DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO: 70.
>
> **128.** A glyphosate[-]tolerant *plant cell* comprising the recombinant DNA molecule of claim 103.
>
> **129.** A *plant* comprising the glyphosate[-]tolerant plant cell of claim 128.
>
> **130.** A *method for selectively controlling weeds* in a field containing a crop having planted crop seeds or plants comprising the steps of:
>
> (a) planting the crop seeds or plants which are glyphosate-tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant . . .
>
> (b) applying to the crop and weeds in the field a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop.

'247E Patent, col.164 ll.15-29; col.165 ll.18-20, 30-32, 45-55; col.166 ll.3-5 (emphases added to reflect breadth of coverage).

C. Monsanto's Technology Agreement

Since 1996, Monsanto has marketed and sold Roundup Ready® soybean seeds under its own brands, and licenses its technology to seed producers who insert the

Roundup Ready® genetic trait into their own seed varieties. Monsanto's licensed producers sell Roundup Ready® seeds to growers for planting. All sales to growers, whether from Monsanto or its licensed producers, are subject to a standard form limited use license, called the "Monsanto Technology Agreement" or "Monsanto Technology/Stewardship Agreement" (both referred to hereinafter as the "Technology Agreement"). J.A. 284-315. Monsanto's Technology Agreement covers a variety of its patented agricultural biotechnologies, including Roundup Ready® soybeans. Both the '605 Patent and the '435 Patent (reissued as the '247E Patent) are listed as "applicable patents" licensed under the Technology Agreement.

Under the Technology Agreement, the licensed grower agrees: (1) "to use the seed containing Monsanto gene technologies for planting a commercial crop only in a single season"; (2) "to not supply any of this seed to any other person or entity for planting"; (3) "to not save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting"; and (4) "to not use this seed or provide it to anyone for crop breeding, research, generation of herbicide registration data, or seed production." Monsanto's Standard Form Technology Agreements, 1998-2007, J.A. 284-315. Monsanto restricts the grower's use of the licensed Roundup Ready® seed to a single commercial crop season because the patented Roundup Ready® genetic trait carries forward into each successive seed generation.

Although the express terms of the Technology Agreement forbid growers to sell the progeny of the licensed Roundup Ready® seeds, or "second-generation seeds," for planting, Monsanto authorizes growers to sell second-generation seed to local grain elevators as a commodity, without requiring growers to place restrictions on grain elevators' subsequent sales of that seed. Commodity seeds are a mixture of undifferentiated seeds harvested

from various sources, including from farms that grow Roundup Ready® soybeans and those that do not, although nearly ninety-four percent of Indiana's acres of soybeans planted in 2007 were planted using herbicide resistant varieties. Damages Report at 2, *Monsanto v. Bowman*, No. 07-cv-0283 (S.D. Ind. Sept. 30, 2008), ECF No. 62-7. Before this court, Monsanto has twice eschewed any reading of the Technology Agreement to prohibit unrestricted seed sales to grain elevators as a commodity. First, Monsanto stated in its appeal brief that "[a] licensed grower who has harvested a soybean crop from Roundup Ready® seeds obtained in an authorized manner *may sell that crop* to be used as feed *or otherwise as a commodity*." Appellee Br. 7 (emphases added). Again, at oral argument, when asked by the panel whether a grower "exceed[s] the license by selling to the grain elevator without securing some promise from the grain elevator not to sell the seeds for planting," Monsanto's attorney responded: "No, I don't think the grower is exceeding his authority there . . . that is a channel of commerce that Monsanto has authorized." Oral Arg. at 19:34-20:14, *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/all/bowman.html. Based on Monsanto's statements, the only permissible reading of the Technology Agreement for purposes of this appeal is that it authorizes growers to sell seed to grain elevators as a commodity.

D. Bowman's Activities

Pioneer Hi-Bred ("Pioneer") is one of Monsanto's licensed seed producers. In 2002, Pioneer sold Pioneer Hi-Bred® brand seeds containing the Roundup Ready® technology to Bowman, a grower in Knox County, Indiana. In making the sale, Pioneer required Bowman to execute the "Pioneer Hi-Bred Technology Agreement," which contains language and restrictions identical to the Technology Agreements discussed above. *See* J.A. 673. Bowman

purchased from Pioneer and planted seeds containing the Roundup Ready® technology each year, beginning as early as 1999. Bowman planted Roundup Ready® seeds as his first-crop in each growing season during the years 1999 through 2007. Consistent with the terms of the Technology Agreement, Bowman did not save seed from his first-crop during any of those years.

In 1999, Bowman also purchased commodity seed from a local grain elevator, Huey Soil Service, for a late-season planting, or "second-crop." Because Bowman considered the second-crop to be a riskier planting, he purchased the commodity seed to avoid paying the significantly higher price for Pioneer's Roundup Ready® seed. That same year, Bowman applied glyphosate-based herbicide to the fields in which he had planted the commodity seeds to control weeds and to determine whether the plants would exhibit glyphosate resistance. He confirmed that many of the plants were, indeed, resistant. In each subsequent year, from 2000 through 2007, Bowman treated his second-crop with glyphosate-based herbicide. Unlike his first-crop, Bowman saved the seed harvested from his second-crop for replanting additional second-crops in later years. He also supplemented his second-crop planting supply with periodic additional purchases of commodity seed from the grain elevator. Bowman did not attempt to hide his activities, and he candidly explained his practices with respect to his second-crop soybeans in various correspondence with Monsanto's representatives.

In winter 2006, Monsanto contacted Bowman, seeking to investigate his planting activities. On October 12, 2007, Monsanto sued Bowman in the Southern District of Indiana alleging infringement of the '605 and '247E Patents. On November 2, 2007, Monsanto investigated eight of Bowman's fields, totaling 299.1 acres, and confirmed that Bowman's second-crop soybean seeds (the progeny of the commodity seeds) contained the patented

Roundup Ready® technology. The Technology Agreement signed by Bowman extended only to seeds purchased from Monsanto or a licensed dealer; thus, Bowman's use of the commodity seeds was not within the scope of the agreement. Monsanto did not allege infringement or breach of the Technology Agreement with respect to Bowman's planting of first-generation seeds purchased from Pioneer.

On September 30, 2009, the district court granted summary judgment of infringement and entered judgment for Monsanto in the amount of $84,456.20. Am. Final J. and Order Granting Pls.' Rule 59 Mot., *Bowman*, No. 07-cv-0283 (May 12, 2010), ECF Nos. 130, 131. Bowman appeals, and this court has jurisdiction under 35 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

This court reviews a district court's order granting a motion for summary judgment *de novo*. *See, e.g.*, *Leviton Mfg. Co. v. Universal Sec. Instruments, Inc.*, 606 F.3d 1352, 1358 (Fed. Cir. 2010).

B. Patent Exhaustion

Bowman argues that Monsanto's patent rights are exhausted with respect to all Roundup Ready® soybean seeds that are present in grain elevators as undifferentiated commodity. According to Bowman, the "[s]ales of second-generation seeds by growers to grain elevators, and then from grain elevators to purchasers (like Bowman) are authorized according to the terms of Monsanto's [T]echnology [A]greement[], and are thus exhausting sales . . . under the Supreme Court's analysis in *Quanta* [*Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008)]." Appellant Br. 23.

Bowman further argues that if the right to use patented seeds does not include the unlimited right to grow subsequent generations free of liability for patent infringement, then any exhaustion determination "is useless." Appellant Br. 31. Bowman urges the court to hold, under *Quanta*, that each seed sold is a "substantial embodiment" of all later generations, thus adopting a "robust" exhaustion doctrine that encompasses the progeny of seeds and other self-replicating biotechnologies. According to Bowman, "[t]he Supreme Court disapproved undermining the exhaustion doctrine by categorically eliminating its application [to] method patents [and t]his [c]ourt should not condone effectively eliminating the doctrine for self-replicating products." Appellant Br. 31.

Monsanto counters that licensed growers' sales of second-generation seeds to grain elevators as commodity seeds did not exhaust Monsanto's patent rights in those seeds "[b]ecause of the express condition [in the Technology Agreement] that the progeny of licensed seed never be sold for planting." Appellee Br. 32. According to Monsanto, "a grower's sale of harvested soybeans to a grain elevator is not an 'authorized sale' when it results in those soybeans subsequently being planted." *Id.*

Monsanto argues that, even if there was exhaustion with respect to commodity seeds, Bowman is nevertheless liable for infringement by planting those seeds because patent protection "is independently applicable to *each* generation of soybeans (or other crops) that contains the patented trait." *Id.* 15-16. *See Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006); *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002). Monsanto contends that "under Bowman's analysis, patent protection for self-replicating inventions would be eviscerated." Appellee Br. 20. Monsanto further cites *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), a Plant Variety Protection Act ("PVPA") case, for the propo-

sition that patent exhaustion in seeds, if applicable, must be limited to the seeds sold. In *J.E.M.*, in explaining the differences between seed variety protection under the PVPA and utility patents, the Court stated: "Most notably, there are *no exemptions for* research or *saving seed under a utility patent*." *Id.* at 143 (emphases added).

In *McFarling* and *Scruggs*, the court dealt with unauthorized planting of second-generation seeds. In *McFarling*, one of Monsanto's licensed growers, McFarling, violated the terms of his Technology Agreement by saving 1500 bushels of Roundup Ready® soybeans from his harvest during one growing season, and replanting those seeds in the next season. 302 F.3d at 1293. McFarling repeated this activity, without paying any license fee in either year for the saved seed, which retained Monsanto's Roundup Ready® technology. *Id.* McFarling defended against Monsanto's patent infringement allegation on the ground that, *inter alia*, the conditions in the Technology Agreement "violate[d] the doctrine of patent exhaustion and first sale." *Id.* at 1298. This court held, based on *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (Fed. Cir. 1992), that the conditions in Monsanto's Technology Agreement were valid and legal and did not implicate the doctrine of patent exhaustion. *McFarling*, 302 F.3d at 1298-99. In any event, the court stated, "[t]he 'first sale' doctrine of patent exhaustion . . . [wa]s not implicated, as the new seeds grown from the original batch had never been sold. The price paid by the purchaser 'reflects only the value of the 'use' rights conferred by the patentee.'" *Id.* at 1299 (citing *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997)).

In *Scruggs*, Scruggs purchased Roundup Ready® soybean seeds from one of Monsanto's authorized seed companies and never executed the Technology Agreement. 459 F.3d at 1333. Scruggs planted the purchased seeds, harvested them, and replanted the second-generation

seeds containing the Roundup Ready® trait. *Id.* Scruggs asserted the doctrine of patent exhaustion as one of many defenses, and the court held that it was inapplicable: "There was no unrestricted sale because the use of the seeds by seed growers was conditioned upon obtaining a license from Monsanto." *Id.* at 1334.

Thus, the doctrine of patent exhaustion did not bar the infringement claims in *McFarling* or *Scruggs*. Similarly, here, patent exhaustion does not bar an infringement action. Even if Monsanto's patent rights in the commodity seeds are exhausted, such a conclusion would be of no consequence because once a grower, like Bowman, plants the commodity seeds containing Monsanto's Roundup Ready® technology and the next generation of seed develops, the grower has created a newly infringing article. *See, e.g.*, '247E Patent, col.164 ll.15-29. "The fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology. Applying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder." *Scruggs*, 459 F.3d at 1336. The right to use "do[es] not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094, 1102 (Fed. Cir. 2001). The court disagrees with Bowman that a seed "substantially embodies" all later generation seeds, at least with respect to the commodity seeds, because nothing in the record indicates that the "only reasonable and intended use" of commodity seeds is for replanting them to create new seeds. *See Quanta*, 553 U.S. at 631. Indeed, there are various uses for commodity seeds, including use as feed. While farmers, like Bowman, may have the right to use commodity seeds as feed, or for any other conceivable use, they cannot "replicate" Monsanto's patented technology by planting it in the ground to create newly infringing ge-

netic material, seeds, and plants. *See, e.g.*, '247E Patent, col.164 ll.15-29; col. 165 ll.18-20, 30-32, 45-48.

C. Notice Under 35 U.S.C. § 287(a)

1. Waiver

Bowman argues that Monsanto cannot recover pre-Complaint damages because it did not provide actual notice and did not mark or require growers to mark second-generation seeds in compliance with 35 U.S.C. § 287(a). Section 287(a) provides that a patent owner may recover damages for patent infringement only after providing actual notice to the accused infringer or constructive notice through marking the patented article or its package with the applicable patent number(s). 35 U.S.C. § 287(a); *Dunlap v. Schofield*, 152 U.S. 244, 247-48 (1894). Bowman argues that, although he did not expressly cite § 287(a) at the district court, Monsanto's failure to provide notice formed one of his primary arguments on summary judgment, and that he should be entitled to leniency as a *pro se* litigant.

Monsanto counters that Bowman waived this argument by failing to raise it at the district court. Monsanto argues that even if not waived, Monsanto complied with § 287(a) because Monsanto gave Bowman actual notice of infringement in a 1999 letter and again in the Technology Agreement, and alternatively put Bowman on constructive notice by marking and requiring all seed partners to mark first-generation seeds containing Monsanto's patented technology.

This court holds that Bowman did not waive his lack of notice argument under § 287(a) because he argued before the district court that Monsanto failed to put any growers or grain elevators on notice of its patent rights

with respect to commodity grain. For example, Bowman argued that "Monsanto did not take the necessary steps to keep their patented grain from being mixed with non-patented grain at the grain elevators." Def.'s Resp. to Pls.' Mot. Summ. J. at 2, *Bowman*, No. 07-cv-0283 (Nov. 18, 2008), ECF No. 73. He contended that "if Monsanto is going to complain about farmers using the age old practice of buying commodity grain for seed; they could have . . . had their Technology Agreements require farmers to sell their patented grain to pre-approved grain dealers who would keep Monsanto's patented traits separate . . . ." *Id.* at 3. While Bowman did not cite § 287(a) as the legal basis for this "lack of notice" contention, this court holds that, as a *pro se* litigant, he alleged facts and proffered argument sufficient to preserve the issue for appeal.

2. Actual Notice

Monsanto sent Bowman a letter on June 11, 1999, specifically notifying Bowman of its patents covering Roundup Ready® soybeans and informing Bowman that the "[p]lanting of seed that is covered by a patent would be making the patented invention and using the patented invention." Supp. Auth. of May 25, 2011. This letter was in the district court record attached to Bowman's memorandum in opposition to Monsanto's motion for summary judgment. *See Bowman*, No. 07-cv-0283 (Nov. 18, 2008), ECF No. 73-2. The letter (1) identified the allegedly infringing product (Roundup Ready® soybeans), (2) enclosed a Technology Agreement identifying the patents covering the Roundup Ready® soybeans, (3) explained that Bowman would infringe the identified patents by planting any unlicensed Roundup Ready® seeds, and (4) informed Bowman that he could not pay a fee to save Roundup Ready® seeds, but may license seeds only through the purchase of new seeds subject to the Technology Agreement. *Id.* This letter is an "affirmative com-

munication to the alleged infringer of a specific charge of infringement by a specific accused product or device," *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1345 (Fed. Cir. 2001) (internal citation omitted), and it is "sufficiently specific to support an objective understanding that the recipient may be an infringer," *Funai Electric Co. v. Daewoo Electronics Corp.*, 616 F.3d 1357, 1373 (Fed. Cir. 2010).

The fact that this letter does not specifically mention commodity seeds is of no import because the specific accused products are not commodity seeds as a class, but rather Monsanto's Roundup Ready® seeds. Bowman planted Roundup Ready® seeds with actual notice that Monsanto considered this activity to infringe its patents. Because Bowman received actual notice under § 287(a) as of June 11, 1999, the court need not reach the issue of constructive notice through marking. Accordingly, Monsanto may recover damages under § 287.

III. CONCLUSION

For the foregoing reasons, this court affirms the district court's holding that patent exhaustion does not apply to Bowman's accused second-crop plantings.

AFFIRMED

COSTS

Each party shall bear its own costs.

United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, AND KATHLEEN RAKER,
Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant,

and

MYRIAD GENETICS, INC.,
Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, AND MICHAEL K. YOUNG,

IN THEIR OFFICIAL CAPACITY AS DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION,
Defendants-Appellants.

2010-1406

Appeal from the United States District Court for the Southern District of New York in Case No. 09-CV-4515, Senior Judge Robert W. Sweet.

Decided: August 16, 2012

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Before LOURIE, BRYSON, and MOORE, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* LOURIE.
Opinion concurring in part filed by *Circuit Judge* MOORE.
Opinion concurring in part and dissenting in part filed by *Circuit Judge* BRYSON.

LOURIE, *Circuit Judge*.

Myriad Genetics, Inc. and the Directors of the University of Utah Research Foundation (collectively, "Myriad") appeal from the decision of the United States District

Court for the Southern District of New York holding that an assortment of medical organizations, researchers, genetic counselors, and patients (collectively, "Plaintiffs") have standing under the Declaratory Judgment Act to challenge Myriad's patents. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 669 F. Supp. 2d 365 (S.D.N.Y. 2009) ("*DJ Op.*"). Myriad also appeals from the district court's decision granting summary judgment that all of the challenged claims are drawn to non-patentable subject matter under 35 U.S.C. § 101. *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) ("*SJ Op.*"). We affirm in part and reverse in part.

This appeal has returned to us as, a petition for certiorari having been filed from our decision of July 29, 2011, the Supreme Court of the United States granted the petition, vacated our decision, and remanded the case to us for further consideration in light of its decision in *Mayo Collaborative Services v. Prometheus, Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012). *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012). We invited and received briefing by the parties and interested amici and held oral argument on July 20, 2012. Our decision on remand follows. It both decides the issues that were before us in the original appeal and evaluates the effect of *Mayo* on those issues.

On the threshold issue of jurisdiction, we affirm the district court's decision to exercise declaratory judgment jurisdiction because we conclude that at least one plaintiff, Dr. Harry Ostrer, has standing to challenge the validity of Myriad's patents. On the merits, we reverse the district court's decision that Myriad's composition claims to "isolated" DNA molecules cover patent-ineligible products of nature under § 101 because each of the claimed molecules represents a nonnaturally occurring

composition of matter. We also reverse the district court's decision that Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates of transformed cells is directed to a patent-ineligible scientific principle. We affirm the court's decision, however, that Myriad's method claims directed to "comparing" or "analyzing" DNA sequences are patent ineligible; such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.

BACKGROUND

Plaintiffs brought suit against Myriad, challenging the patentability of certain composition and method claims relating to human genetics. *See DJ Op.*, 669 F. Supp. 2d at 369-76. Specifically, Plaintiffs sought a declaration that fifteen claims from seven patents assigned to Myriad are drawn to patent-ineligible subject matter under 35 U.S.C. § 101: claims 1, 2, 5, 6, 7, and 20 of U.S. Patent 5,747,282 ("the '282 patent"); claims 1, 6, and 7 of U.S. Patent 5,837,492 ("the '492 patent"); claim 1 of U.S. Patent 5,693,473 ("the '473 patent"); claim 1 of U.S. Patent 5,709,999 ("the '999 patent"); claim 1 of U.S. Patent 5,710,001 ("the '001 patent"); claim 1 of U.S. Patent 5,753,441 ("the '441 patent"); and claims 1 and 2 of U.S. Patent 6,033,857 ("the '857 patent").

The challenged composition claims cover two "isolated" human genes, *BRCA1* and *BRCA2* (collectively, "*BRCA1/2*" or "*BRCA*"), and certain alterations, or mutations, in these genes associated with a predisposition to breast and ovarian cancers. Representative composition claims include claims 1, 2, and 5 of the '282 patent:

> 1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.

> 2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.
>
> 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.

'282 patent col.153 l.55 – col.154 l.56.[1] SEQ ID NO:2 depicts the amino acid sequence of the BRCA1 protein, and SEQ ID NO:1 depicts the nucleotide sequence of the *BRCA1* DNA coding region; the latter sequence is colloquially referred to as cDNA. *Id.* col.19 ll.48-50.

All but one of the challenged method claims cover methods of "analyzing" or "comparing" a patient's *BRCA* sequence with the normal, or wild-type, sequence to identify the presence of cancer-predisposing mutations. Representative method claims include claims 1 of the '999 and '001 patents:

> 1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises *analyzing* a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or *analyzing* a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.

'999 patent col.161 ll.17-25 (emphases added).

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[1] In addition to representative claims 1, 2, and 5 of the '282 patent, other claims to isolated DNA molecules at issue in this appeal include: claims 6 and 7 of the '282 patent; claims 1, 6, and 7 of the '492 patent; and claim 1 of the '473 patent.

> 1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises [] *comparing* a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.

'001 patent col.155 ll.2-17 (emphasis added).[2]

The final method claim challenged by Plaintiffs is directed to a method of screening potential cancer therapeutics. Specifically, claim 20 of the '282 patent reads as follows:

> 20. A method for screening potential cancer therapeutics which comprises: growing a *transformed eukaryotic host cell* containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said *transformed eukaryotic host cell* in the absence of said compound, determining the

[2] The claims currently before us that recite methods of "analyzing" or "comparing" *BRCA* sequences are: claims 1 of the '999, '001, and '441 patents and claims 1 and 2 of the '857 patent.

> rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.

'282 patent col.156 ll.13–24 (emphases added).

The challenged claims thus relate to isolated gene sequences and diagnostic methods of identifying mutations in these sequences. To place this suit in context, we take a step back to provide background on the science involved, including the identification of the *BRCA* genes, and the Plaintiffs' connections to the invention and to Myriad.

I.

Human genetics is the study of heredity in human beings.[3] The human genome, the entirety of human genetic information, contains approximately 22,000 genes, which form the basis of human inheritance. The majority of genes act by guiding the production of polypeptide chains that form proteins. Proteins in turn make up living matter and catalyze a variety of cellular processes.

Chemically, the human genome is composed of deoxyribonucleic acid ("DNA"). Each DNA molecule is made up of repeating units of four nucleotide bases—adenine ("A"), thymine ("T"), cytosine ("C"), and guanine ("G")—which are covalently linked, or bonded,[4] together via a sugar-

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[3] The district court's opinion, *SJ Op.*, 702 F. Supp. 2d at 192-203, contains a detailed and comprehensive discussion of the science involved in this case. We repeat only the basics here.

[4] Covalent bonds are chemical bonds characterized by the sharing of electrons between atoms in a molecule.

phosphate, or phosphodiester, backbone. DNA generally exists as two DNA strands intertwined as a double helix in which each base on a strand pairs, or hybridizes, with a complementary base on the other strand: A pairs with T, and C with G. Figure 1 below depicts the structure of a DNA double helix and the complementary pairing of the four nucleotide bases, represented by A, T, C, and G.

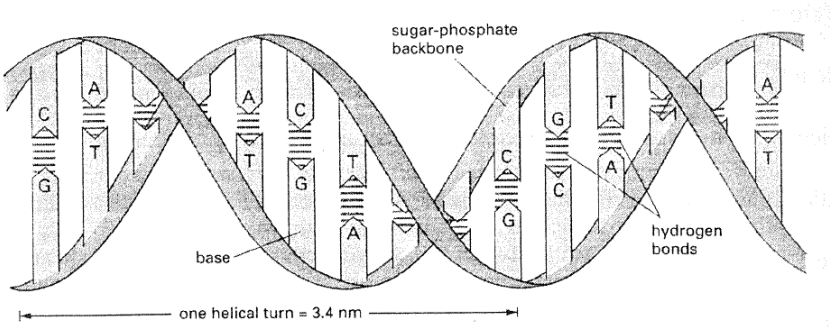

Figure 1

The linear order of nucleotide bases in a DNA molecule is referred to as its "sequence." The sequence of a gene is thus denoted by a linear sequence of As, Ts, Gs, and Cs. "DNA sequencing" or "gene sequencing" refers to the process by which the precise linear order of nucleotides in a DNA segment or gene is determined. A gene's nucleotide sequence in turn encodes for a linear sequence of amino acids that comprise the protein encoded by the gene, *e.g.*, the *BRCA1* gene encodes for the BRCA1 protein. Most genes have both "exon" and "intron" sequences. Exons are DNA segments that are necessary for the creation of a protein, *i.e.*, that code for a protein. Introns are segments of DNA interspersed between the exons that, unlike exons, do not code for a protein.

The creation of a protein from a gene comprises two steps: transcription and translation. First, the gene sequence is "transcribed" into a different nucleic acid

called ribonucleic acid ("RNA"). RNA has a chemically different sugar-phosphate backbone than DNA, and it utilizes the nucleotide base uracil ("U") in place of thymine ("T"). During transcription, the DNA double helix is unwound and each nucleotide on the non-coding, or template, DNA strand is used to make a complementary, single-stranded RNA molecule that mirrors the coding DNA strand, *i.e.*, adenine on the template DNA strand results in uracil in the RNA molecule, thymine results in adenine, guanine in cytosine, and cytosine in guanine. The resulting "pre-RNA," like the DNA from which it was generated, contains both exon and intron sequences. Next, the introns are physically excised from the pre-RNA molecule, followed by "splicing" the exons to produce a messenger RNA ("mRNA"). Figure 2 below shows the steps of transcribing a gene that contains three exons (exon 1-3) and two introns (intron 1 and 2) into a pre-RNA, followed by RNA excising the introns and splicing of the exons to produce an mRNA containing only exon sequences.

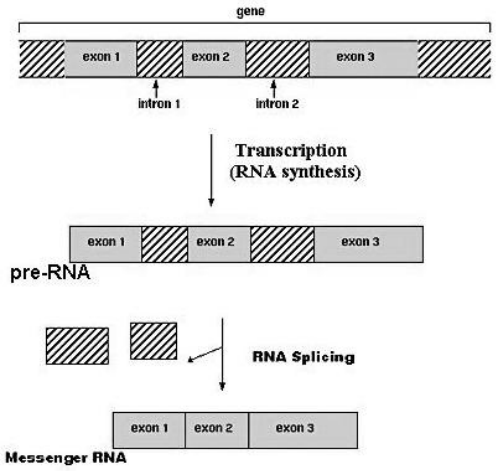

Figure 2

Following transcription and splicing, the resulting mRNA is "translated" into the encoded protein. Genes, and their corresponding mRNAs, encode proteins via three-nucleotide combinations called codons. Each codon triplet corresponds to one of the twenty amino acids that make up all proteins or a "stop" signal that terminates protein translation. For example, the codon adenine-thymine-guanine (ATG, or AUG in the corresponding mRNA), encodes the amino acid methionine. The relationship between the sixty-four possible codon sequences and their corresponding amino acids is known as the genetic code. Figure 3 below represents an mRNA molecule that translates into a protein of six amino acids (Codon 1, AUG, methionine; Codon 2, ACG, threonine; Codon 3, GAG, glutamic acid; Codon 4, CUU, leucine; Codon 5, CGG, arginine; Codon 6, AGC, serine), and ends with one of the three stop codons, UAG.

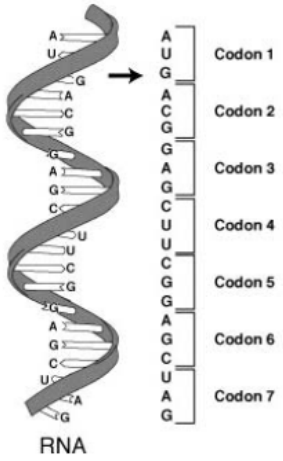

Figure 3

Changes, or mutations, in the sequence of a human gene can alter the production, structure, and/or function of the resulting protein. Small-scale changes include point mutations in which a change to a single nucleotide

alters a single amino acid in the encoded protein. For example, a base change in the codon *G*CU to *C*CU changes an alanine in the encoded protein to a proline. Larger scale variations include the deletion, rearrangement, or duplication of larger DNA segments—ranging from several hundreds to over a million nucleotides—and can result in the elimination, misplacement, or duplication of an entire gene or genes. While some mutations have little or no effect on the body's processes, others result in disease or an increased risk of developing a particular disease. DNA sequencing is used in clinical diagnostic testing to determine whether a gene contains mutations associated with a particular disease or disease risk.

Nearly every cell in the human body contains an individual's entire genome. DNA in the cell, called "native" or "genomic" DNA, is packaged into twenty-three pairs of chromosomes. Chromosomes are complex structures comprising a single extended DNA molecule wrapped around proteins called histones, as shown in Figure 4 below.

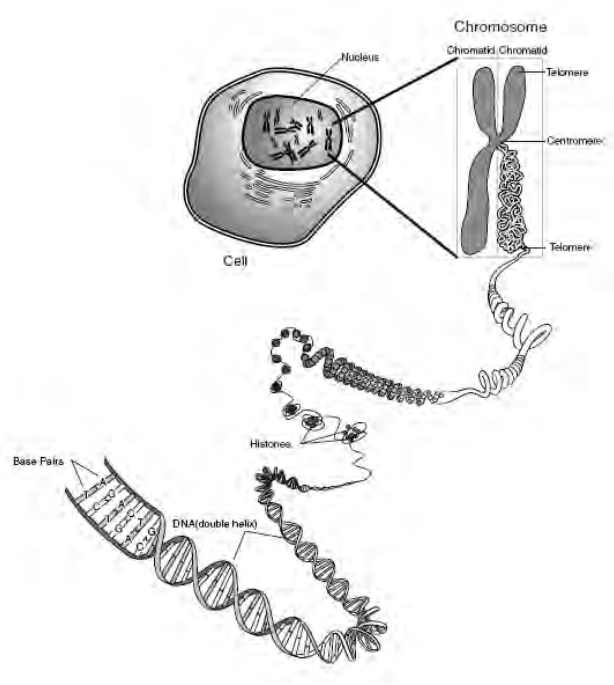

Figure 4

Each chromosome contiguously spans millions of bases and encompasses many discrete genes. Humans have twenty-two pairs of autosomal chromosomes, numbered one to twenty-two according to size from largest to smallest, and one pair of sex chromosomes, two X chromosomes in females and one X and one Y chromosome in males.

Genomic DNA can be extracted from its cellular environment using a number of well-established laboratory techniques. A particular segment of DNA, such as a gene, can then be excised or amplified from the DNA to obtain the isolated DNA segment of interest. DNA molecules can also be synthesized in the laboratory. One type of synthetic DNA molecule is complementary DNA ("cDNA"). cDNA is synthesized from mRNA using complementary base pairing in a manner analogous to RNA

transcription. The process results in a double-stranded DNA molecule with a sequence corresponding to the sequence of an mRNA produced by the body. Because it is synthesized from mRNA, cDNA contains only the exon sequences, and thus none of the intron sequences, from a chromosomal gene sequence.

II.

Certain mutations in the *BRCA* genes correlate with an increased risk of breast and ovarian cancer. The average woman in the United States has around a twelve to thirteen percent risk of developing breast cancer in her lifetime. Women with *BRCA* mutations, in contrast, face a cumulative risk of between fifty to eighty percent of developing breast cancer and a cumulative risk of ovarian cancer of between twenty to fifty percent. Diagnostic genetic testing for the existence of *BRCA* mutations is therefore an important consideration in the provision of clinical care for breast or ovarian cancer. This testing provides a patient with information on her risk for hereditary breast and ovarian cancers, and thus aids in the difficult decision regarding whether to undertake preventive options, including prophylactic surgery. Diagnostic results can also be an important factor in structuring an appropriate course of cancer treatment, since certain forms of therapy are more effective in treating cancers related to *BRCA* mutations.

The inventors of the patents in suit identified the genetic basis of *BRCA1*- and *BRCA2*-related cancers using an analysis called positional cloning. Relying on a large set of DNA samples from families with inherited breast and ovarian cancers, the inventors correlated the occurrence of cancer in individual family members with the inheritance of certain marker DNA sequences. This allowed the inventors to identify, or "map," the physical

location of the *BRCA* genes within the human genome and to isolate the *BRCA* genes and determine their exact nucleotide sequences. This in turn allowed Myriad to provide *BRCA* diagnostic testing services to women.[5]

III.

Myriad, however, was not the only entity to implement clinical *BRCA* testing services. Starting in 1996, the University of Pennsylvania's Genetic Diagnostic Laboratory ("GDL"), co-directed by plaintiffs Haig H. Kazazian, Jr., M.D. and Arupa Ganguly, Ph.D., provided *BRCA1/2* diagnostic services to women. By 1999, however, accusations by Myriad that GDL's *BRCA* testing services infringed its patents forced the lab to stop providing such services.

The first sign of a dispute came in early 1998. At that time, Dr. Kazazian recalls a dinner with Dr. Mark Skolnick, inventor and Chief Science Officer at Myriad. At the dinner, Skolnick informed Kazazian that Myriad was planning to stop GDL from providing clinical *BRCA* testing in light of Myriad's patents. A month or two later, in May 1998, Kazazian received a letter from William A. Hockett, Director of Corporate Communications at Myriad. The letter stated that Myriad knew that Kazazian was currently providing *BRCA1* diagnostic testing services, and that Myriad, as patent holder of five U.S. patents covering the isolated *BRCA1* gene and diagnostic

[5] Myriad filed the first patent application leading to the patents in suit covering isolated BRCA1 DNA and associated diagnostic methods in August 1994. The first resulting patent, the '473 patent, issued on December 2, 1997. Myriad filed the first application leading to the patents in suit covering isolated BRCA2 DNA and associated diagnostic methods in December 1995, and the first such patent, the '492 patent, issued on November 17, 1998.

testing, was making available to select institutions a collaborative license. Attached to the letter was a copy of Myriad's collaborative agreement, which proposed severely limiting GDL's testing services to certain tests for patients of Ashkenazi Jewish descent. Plaintiff Harry Ostrer, M.D, a researcher at New York University ("NYU") School of Medicine, received the same letter and collaborative agreement in May 1998, although his laboratory did not, at the time, provide such testing services. Rather, Ostrer sent patient samples to GDL for *BRCA* genetic testing.

Months later, in August 1998, Dr. Kazazian received a second letter, this time from George A. Riley of the law firm O'Melveny & Myers LLP. The letter identified by number five Myriad patents "covering, among other things, the BRCA1 gene sequence . . . and methods for detecting alterations in the BRCA1 sequence." J.A. 1145. The letter also indicated that it "has come to Myriad's attention that you are engaged in commercial testing activities that infringe Myriad's patents," and that "[u]nless and until a licensing arrangement is completed . . . you should cease all infringing testing activity." *Id.* The letter noted, however, that the cease-and-desist notification did not apply to research testing "for the purpose of furthering non-commercial research programs, the results of which are not provided to the patient and for which no money is received from the patient or the patient's insurance." *Id.*

In June 1999, Robert Terrell, the General Counsel for the University of Pennsylvania, received a similar cease-and-desist letter from Christopher Wight, Myriad's General Counsel. The letter stated, "It has come to our attention that Dr. Haig H. Kazazian, Jr. of the University of Pennsylvania is continuing to willfully engage in commercial BRCA1 and BRCA2 genetic testing activities, in

violation of the University of Pennsylvania's previous assurances that such commercial testing activities would be discontinued." J.A. 2890. Terrell responded to Wight by letter on September 10, 1999, stating that "the University agrees that it will not accept samples for BRCA1 research testing from third parties." J.A. 2891. Kazazian thus informed Dr. Ostrer that GDL would no longer be accepting patient samples for *BRCA* testing from him or anyone else as a result of the patent infringement assertions made by Myriad. As a result, Ostrer started sending patient samples for *BRCA* genetic testing to Myriad, which became (and remains today) the only provider of such services in the United States.

During this period, Myriad also initiated several patent infringement suits against entities providing clinical *BRCA* testing. Myriad filed suit against Oncormed Inc. in 1997 and again in 1998, *Myriad Genetics v. Oncormed*, Nos. 2:97-cv-922, 2:98-cv-35 (D. Utah), and the University of Pennsylvania in 1998, *Myriad Genetics v. Univ. of Pa.*, No. 2:98-cv-829 (D. Utah). Both lawsuits were later dismissed without prejudice after each defendant agreed to discontinue all allegedly infringing activity.

None of the plaintiffs besides Drs. Kazazian, Ganguly, and Ostrer, allege that Myriad directed any letters or other communications regarding its patents at them. Rather, the other researchers and medical organization members state simply that knowledge of Myriad's vigorous enforcement of its patent rights against others stopped them from engaging in clinical *BRCA* genetic testing, although they have the personnel, expertise, and facilities as well as the desire to provide such testing. The patient plaintiffs state that they have been unable to obtain any *BRCA* genetic testing or their desired *BRCA* testing, either covered by their insurance or at a price

that they can afford, because of Myriad's patent protection.

Like the other researchers, Dr. Kazazian states that if Myriad's patents were held invalid, he and Dr. Ganguly would be able to resume *BRCA* testing within a matter of a few weeks. He notes, however, that this is only if they "decided to resume BRCA testing." J.A. 2852. Ganguly concurs, stating that if the patents were invalidated, "I would immediately consider resuming BRCA testing in my laboratory." J.A. 2892. Dr. Ostrer[6] also indicates that his lab has all the personnel, facilities, and expertise necessary to undertake clinical *BRCA* testing and emphatically states that his lab "would immediately begin to perform BRCA1/2-related genetic testing upon invalidation of the Myriad patents." J.A. 2936-38.

IV.

After Plaintiffs filed suit, Myriad moved to have the case dismissed, alleging that the Plaintiffs lacked standing to bring a declaratory judgment suit challenging the validity of its patents. The district court disagreed,

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[6] On July 27, 2011, two days before we issued our initial, now-vacated decision in this case, Myriad notified the court that Dr. Ostrer was leaving NYU to assume a position at the Albert Einstein College of Medicine and Montefiore Medical Center, effective August 29, 2011. In response, Plaintiffs submitted a supplemental declaration from Dr. Ostrer stating that, in his new position, he still seeks to undertake BRCA diagnostic testing, still has the resources and expertise to conduct such testing, and would immediately do so if Myriad's patents were invalidated. Following remand from the Supreme Court, we have also received from Myriad a related "suggestion of mootness" and motion to remand or dismiss. We declined the suggestion and denied the motion. We now review this case on the facts and arguments briefed and presented to us.

however, holding that the Plaintiffs had established Article III standing under the "all the circumstances" test articulated by the Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). *DJ Op.*, 669 F. Supp. 2d at 385-92. The court first found that Myriad had engaged in sufficient "affirmative acts" based on the company's assertion of its "right to preclude others from engaging in *BRCA1/2* genetic testing through personal communications, cease-and-desist letters, licensing offers, and litigation," the result of which was "the widespread understanding that one may engage in *BRCA1/2* testing at the risk of being sued for infringement liability by Myriad." *Id.* at 390. Myriad's actions, the court concluded, had placed "the Plaintiffs in precisely the situation that the Declaratory Judgment Act was designed to address: the Plaintiffs have the ability and desire to engage in *BRCA1/2* testing as well as the belief that such testing is within their rights, but cannot do so without risking infringement liability." *Id.*

In so holding, the court rejected Myriad's argument that there must be some act directed toward the Plaintiffs, noting that Myriad had, in fact, taken affirmative acts toward plaintiffs Dr. Kazazian and Dr. Ganguly. *Id.* at 387-88. The court also rejected Myriad's arguments that the cease-and-desist letter sent to plaintiff Kazazian was too old to support declaratory judgment jurisdiction and that the legal actions brought against third parties could not be considered in the jurisdictional analysis. *Id.* at 388-89. The court concluded that rigid adherence to either of these requirements would be inconsistent with *MedImmune*'s mandate that the court assess the facts alleged under all the circumstances. *Id.*

The district court also found that the Plaintiffs had alleged sufficient meaningful preparations for infringement to establish declaratory judgment jurisdiction. *Id.* at 390-

92. With respect to the researchers, the court held it was sufficient that they were all "ready, willing, and able" to begin *BRCA1/2* testing within the normal course of their laboratories' research, rejecting Myriad's argument that they needed to allege specific preparatory activities. *Id.* at 390-91. The court also rejected Myriad's argument that plaintiffs Kazazian and Ganguly testified only that they would "consider" engaging in allegedly infringing activities, concluding that the proper focus of the inquiry is whether they are meaningfully prepared, not whether they have made a final, conclusive decision to engage in such activities. *Id.* at 391 n.18.

The parties then moved for summary judgment on the merits of Plaintiffs' § 101 challenge to Myriad's patent claims. The district court held for Plaintiffs, concluding that the fifteen challenged claims were drawn to non-patentable subject matter and thus invalid under § 101. *SJ Op.*, 702 F. Supp. 2d at 220-37. Regarding the composition claims, the court held that isolated DNA molecules fall within the judicially created "products of nature" exception to § 101 because such isolated DNAs are not "markedly different" from native DNAs. *Id.* at 222, 232 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). The court relied on the fact that, unlike other biological molecules, DNAs are the "physical embodiment of information," and that this information is not only preserved in the claimed isolated DNA molecules, but also essential to their utility as molecular tools. *Id.* at 228-32.

Turning to the method claims, the court held them patent ineligible under this court's then-definitive machine-or-transformation test. *Id.* at 233 (citing *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd on other grounds*, *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010)). The court held that the claims covered "analyzing" or "comparing" DNA sequences by any method, and

thus covered mental processes independent of any physical transformations. *Id.* at 233-35. In so holding, the court distinguished Myriad's claims from those at issue in *Mayo* based on the "determining" step in the latter being construed to include the extraction and measurement of metabolite levels from a patient sample. *SJ Op.*, 702 F. Supp. 2d at 234-35 (citing *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1350 (Fed. Cir. 2010), *rev'd,* 132 S. Ct. 1289 (2012)). Alternatively, the court continued, even if the claims could be read to include the transformations associated with isolating and sequencing human DNA, these transformations would constitute no more than preparatory data-gathering steps. *Id.* at 236 (citing *In re Grams*, 888 F.2d 835, 840 (Fed. Cir. 1989)). Finally, the court held that the one method claim to "comparing" the growth rate of cells claimed a basic scientific principle and that the transformative steps amounted to only preparatory data gathering. *Id.* at 237.

Myriad appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

I. Declaratory Judgment Jurisdiction

A.

The first question we must address is whether the district court correctly exercised declaratory judgment jurisdiction over this suit. The Declaratory Judgment Act provides that, "In a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The phrase "a case of actual controversy" in the Act refers to the types of "cases" and "controversies" that are justici-

able under Article III of the U.S. Constitution. *Aetna Life Ins. v. Haworth*, 300 U.S. 227, 239-40 (1937).

Although no bright-line rule exists for determining whether a declaratory judgment action satisfies Article III's case-or-controversy requirement, the Supreme Court has held that the dispute must be "definite and concrete, touching the legal relations of parties having adverse legal interests," "real and substantial," and "admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune*, 549 U.S. at 127 (quoting *Aetna Life*, 300 U.S. at 240-41). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

In applying *MedImmune*'s all-the-circumstances test to a declaratory judgment action, we are guided by the Supreme Court's three-part framework for determining whether an action presents a justiciable Article III controversy: standing, ripeness, and mootness. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008). In this case, the parties have framed the jurisdictional issue as one of standing. *See MedImmune*, 549 U.S. at 128 n.8. ("The justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of injury from occurring, can be described in terms of standing . . . or . . . ripeness." (internal citations omitted)).

"[T]he irreducible constitutional minimum of standing contains three elements." *Lujan v. Defenders of Wildlife*,

504 U.S. 555, 560 (1992). "First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Id.* (internal citations and quotations omitted). "Second, there must be a causal connection between the injury and the conduct complained of–the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant . . . .'" *Id.* (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)). "Third, it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Id.* at 561 (quoting *Simon*, 426 U.S. at 38, 43).

"Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law." *MedImmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1378 (Fed. Cir. 2005), *overruled on other grounds*, *MedImmune*, 549 U.S. at 130-31. Following *MedImmune*, this court has held that, to establish an injury in fact traceable to the patentee, a declaratory judgment plaintiff must allege both (1) an affirmative act by the patentee related to the enforcement of his patent rights, *SanDisk Corp. v. STMicroelecs., Inc.*, 480 F.3d 1372, 1380-81 (Fed. Cir. 2007), and (2) meaningful preparation to conduct potentially infringing activity, *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008). We review the exercise of declaratory judgment jurisdiction in light of a particular set of facts *de novo*. *SanDisk Corp.*, 480 F.3d at 1377.

B.

Myriad challenges the district court's jurisdictional decision on the grounds that Myriad and the Plaintiffs do not have adverse legal interests and that Plaintiffs have

failed to allege a controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Specifically, Myriad argues that Plaintiffs have failed to allege any "affirmative acts" by Myriad within the past ten years relating to the patents in suit or directed at any Plaintiff. According to Myriad, the district court erred by relying on "stale communications" directed at Drs. Kazazian, Ganguly, and Ostrer over a decade ago, as well as ten-year-old licensing and litigation activities directed at third parties, and thus exercised jurisdiction based solely on Plaintiffs' subjective fear of suit, arising from rumor and innuendo in the research community.

Plaintiffs respond that they have standing under *MedImmune*'s all-the-circumstances test because, not only are they undisputedly prepared to immediately undertake potentially infringing activities, but also Myriad took sufficient affirmative acts with respect to the patents in suit. Regarding the latter, Plaintiffs assert that Myriad sued, threatened to sue, or demanded license agreements from every known institution offering *BRCA* clinical testing, including university labs directed by plaintiffs Kazazian, Ganguly, and Ostrer, forcing each to cease such testing. And, according to Plaintiffs, the awareness of Myriad's vigorous assertion of its patent rights still continues to suppress their ability to perform clinical *BRCA* testing, placing Plaintiffs in the very dilemma the Declaratory Judgment Act was intended to address: they must either proceed with *BRCA*-related activities and risk liability for patent infringement, or refrain from such activities despite believing Myriad's patents are invalid.

Under the facts alleged in this case, we conclude that one Plaintiff, Dr. Ostrer, has established standing to maintain this declaratory judgment suit. All Plaintiffs claim standing under the Declaratory Judgment Act based on the same alleged injury: that they cannot un-

dertake the *BRCA*-related activities that they desire because of Myriad's enforcement of its patent rights covering *BRCA1/2*.[7] Only three plaintiffs, however, allege an injury traceable to Myriad; only Drs. Kazazian, Ganguly, and Ostrer allege affirmative patent enforcement actions directed at them by Myriad. Of these three, Dr. Ostrer clearly alleges a sufficiently real and imminent injury because he alleges an intention to actually and immediately engage in allegedly infringing *BRCA*-related activities. We address each in turn.

Although *MedImmune* relaxed this court's more restrictive "reasonable apprehension of suit" test for declaratory judgment jurisdiction, *SanDisk*, 480 F.3d at 1380, it did not alter "the bedrock rule that a case or controversy must be based on a *real* and *immediate* injury or threat of future injury that is *caused by the defendants*," *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008). Accordingly, following *MedImmune*, this court has continued to hold that declaratory judgment jurisdiction will not arise merely on the basis that a party learns of the existence of an adversely held patent, or even perceives that such a patent poses a risk of infringement, in the absence of some affirmative act by the patentee. *SanDisk*, 480 F.3d at 1380-81. Thus, without defining the outer boundaries of declaratory judgment jurisdiction, we have held that

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[7] Certain patients also allege an injury based on their inability to gain access to affordable *BRCA* genetic testing because of Myriad's patent dominance of such services. While denial of health services can, in certain circumstances, state a judicially cognizable injury, *see Simon*, 426 U.S. at 40-41, Plaintiffs have not pressed this as an independent ground for standing. Moreover, we fail to see how the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing.

"where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise . . . ." *Id.* at 1381; *see also Prasco*, 537 F.3d at 1338 ("A patentee can cause . . . an injury [sufficient to create an actual controversy] in a variety of ways, for example, by creating a reasonable apprehension of an infringement suit, [or] demanding the right to royalty payments." (internal citations omitted)).

In this case, Myriad demanded a royalty under its patents from Dr. Ostrer based on his clinical *BRCA*-related activities. In May 1998, Myriad's Director of Corporate Communications sent Ostrer a letter proposing a collaborative license. The letter stated that Myriad was aware that Ostrer was either currently providing, or was interested in initiating, *BRCA1* diagnostic testing services and that Myriad, as holder of U.S. patents covering the *BRCA1* gene and diagnostic testing of *BRCA1*, was making available to his institution, NYU Medical Center, a limited collaborative license. The collaborative license required NYU to make a payment to Myriad for each non-research *BRCA* test performed.

At the same time, as Ostrer was aware, Myriad was asserting its patent rights against other similarly situated parties, a fact to be considered in assessing the existence of an actual controversy under the totality of circumstances. *See Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 901 (Fed. Cir. 2008). Soon after Ostrer received Myriad's letter, Dr. Kazazian informed him that, because of Myriad's assertion of its patent rights against him, GDL would no longer be accepting patient samples for *BRCA* genetic testing. Myriad's assertion of its patent rights against Kazazian escalated into a patent infringement suit by Myriad against the University of Pennsyl-

vania, which was later dismissed without prejudice after the University agreed to cease all accused *BRCA* testing services. Myriad also sued Oncormed for patent infringement based on its *BRCA* genetic testing services. As a result of Myriad's patent enforcement actions, Dr. Ostrer was forced to send all patient samples to Myriad, now the sole provider of *BRCA* diagnostic testing services.

Dr. Ostrer, on the other hand, maintains that he could have proceeded with his *BRCA*-related clinical activities without taking a license from Myriad. This assertion is based on his belief that the patents Myriad claims cover such activities are invalid because genes are patent-ineligible products of nature. Acting on his belief, Ostrer seeks in this lawsuit a declaration of his right to undertake *BRCA*-related clinical activities without a license. Accordingly, Myriad and Dr. Ostrer have taken adverse legal positions regarding whether or not Ostrer can engage in *BRCA* genetic testing without infringing any valid claim to "isolated" *BRCA* DNAs or methods of "analyzing" or "comparing" *BRCA* sequences, as recited in Myriad's patents. *See Aetna Life*, 300 U.S. at 242 (holding declaratory judgment jurisdiction existed when "the parties had taken adverse positions with respect to their existing obligations" on an insurance contract).

Dr. Ostrer has also alleged a controversy of sufficient reality and immediacy, *MedImmune*, 549 U.S. at 127; he has alleged a concrete and actual injury traceable to Myriad's assertion of its patent rights, *see Lujan*, 504 U.S. at 560. First, Ostrer seeks to undertake specific *BRCA*-related activities—*BRCA* diagnostic testing—for which Myriad has demanded a license under specific patents—those that cover the isolated *BRCA* genes and *BRCA* diagnostic testing. Thus, Ostrer does not request "an opinion advising what the law would be upon a hypothetical state of facts," *Aetna Life*, 300 U.S. at 241, but rather

whether his proposed *BRCA* testing services are covered by valid patent claims to "isolated" *BRCA* genes and methods of "comparing" the genes' sequences. Second, Ostrer not only has the resources and expertise to immediately undertake clinical *BRCA* testing, but also states unequivocally that he will immediately begin such testing. In contrast to Ostrer, who alleges an actual and imminent injury for purposes of standing, Drs. Kazazian and Ganguly allege only that they will "consider" resuming *BRCA* testing. These "'some day' intentions" are insufficient to support an "actual or imminent" injury for standing "without . . . any specification of *when* the some day will be." *Lujan*, 504 U.S. at 564. As a result, Drs. Kazazian and Ganguly do not have standing.

Myriad seeks to avoid this result based on the timing of its enforcement actions. Specifically, Myriad argues that time has extinguished the immediacy and reality of any controversy, relying on language that hearkens back to our pre-*MedImmune* reasonable apprehension of suit test. *See, e.g.*, Appellants' Br., 2010 WL 4600106, at 26 ("[A] patentee's ten-year silence presumptively extinguishes any reasonable objective fear of suit."). We disagree. In many cases a controversy made manifest by a patentee's affirmative assertion of its patent rights will dissipate as market players and products change. In this case, however, the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed despite the passage of time.[8]

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[8] Myriad's analogy to laches is also unconvincing. Laches bars the recovery of pre-filing damages; it does not preclude a patent action for prospective relief, the type of relief sought here. *See A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1041 (Fed. Cir. 1992) (*en banc*) ("[L]aches bars relief on a patentee's claim only with respect to damages accrued prior to suit.").

Myriad's active enforcement of its patent rights forced Dr. Ostrer, as well as every other similarly situated researcher and institution, to cease performing the challenged *BRCA* testing services, leaving Myriad as the sole provider of *BRCA* clinical testing to patients in the United States. Since that time, neither the accused activities nor the parties' positions have changed. First, Myriad does not allege that genetic testing technology has changed in any way that renders its past assertions of its patent rights irrelevant to Ostrer's currently proposed *BRCA* testing. Rather, the patents cover, as Myriad asserted in the late 1990s, the basic components of any such test: the isolated *BRCA* genes and the diagnostic step of comparing the genes' sequences.

Second, ever since Myriad's enforcement efforts eliminated all competition, Myriad and Ostrer have not altered their respective positions. Ostrer, still laboring under Myriad's threat of infringement liability, has not attempted to provide *BRCA* testing; yet, as a researcher, he remains in the same position with respect to his ability and his desire to provide *BRCA* testing as in the late 1990s. Furthermore, nothing in the record suggests that any researcher or institution has successfully attempted to compete with Myriad, or that Myriad has in any way changed its position with regard to its patent rights. Just as active enforcement of one's patent rights against others can maintain a real and immediate controversy despite the passage of time, *see Micron*, 518 F.3d at 901, so too can the successful assertion of such rights when the relevant circumstances remain unchanged. Thus, consistent with the purpose of the Declaratory Judgment Act, Ostrer need not risk liability and treble damages for patent infringement before seeking a declaration of his contested legal rights. *See MedImmune*, 549 U.S. at 134.

Myriad also argues that the record refutes Ostrer's claim that he has been restrained from engaging in *BRCA*-related gene sequencing. Specifically, Myriad argues that since Myriad published its discoveries of the *BRCA1* and *BRCA2* genes in October 1994 and March 1996, respectively, over 18,000 scientists have conducted research on the *BRCA* genes and over 8,600 research papers have been published. Furthermore, according to Myriad, plaintiff Wendy Chung concedes that her lab currently conducts sequencing of *BRCA* genes. Yet, both Drs. Chung and Ostrer state that, although they conduct gene sequencing, they are forbidden from informing their research subjects of the results of their *BRCA* tests without first sending the samples to Myriad. Accordingly, Ostrer is restrained from the *BRCA*-related activity that he desires to undertake: clinical diagnostic testing.

Myriad's communications with Dr. Ostrer confirm this understanding. The licensing letter Myriad sent to Ostrer proposed a collaborative agreement giving NYU the right to perform "Research Tests" without payment to Myriad. J.A. 2967. "Research Tests" are defined as tests that further "non-commercial research programs, the results of which *are not provided to the patient* and for which no money is received." J.A. 2965 (emphasis added). In contrast, the agreement requires payment to Myriad for each "Testing Service" performed, with "Testing Services" defined as "medical laboratory testing . . . for the presence or absence of BRCA1 mutations for the purpose of determining or predicting predisposition to, or assessing the risk of breast or ovarian cancer in humans." J.A. 2966-67. Thus, Myriad's patent enforcement actions never targeted the non-clinical *BRCA* research now cited by Myriad, and Ostrer's ability to perform such research does not address the injury asserted here.

Finally, Myriad argued in its reply brief and at oral argument that Plaintiffs' declaratory action will not afford them the relief they want, a requirement for standing. *Lujan*, 504 U.S. at 560-61; *see also MedImmune*, 549 U.S. at 127 n.7 ("[A] litigant may not use a declaratory-judgment action to obtain piecemeal adjudication of defenses that *would not finally and conclusively resolve* the underlying controversy."). Specifically, Myriad asserts that because Plaintiffs have challenged just fifteen composition and method claims, while admitting that other unchallenged claims to *BRCA* probes and primers will still prevent them from engaging in *BRCA* sequencing, a favorable decision will not redress the Plaintiffs' alleged injury. Again, we disagree.

The Supreme Court has required only that it is "likely," rather than "merely 'speculative,'" that the alleged injury will be "redressed by a favorable decision." *Lujan*, 504 U.S. at 561. The Court has not required certainty. For example, in *Village of Arlington Heights v. Metropolitan Housing Development Corp.*, the Court held that the plaintiffs had standing to challenge a suburb's exclusionary zoning ordinance, as the ordinance stood as "an absolute barrier" to the housing development Metropolitan Housing Development Corp. ("MHDC") had contracted to provide in the village. 429 U.S. 252, 261 (1977). The Court noted that injunctive relief, while removing the "barrier" of the ordinance, would not "guarantee" that the housing would be built since MHDC still had to secure financing, qualify for federal subsidies, and carry through with construction. *Id.* The Court nevertheless recognized that "all housing developments are subject to some extent to similar uncertainties," and concluded that it was sufficient that there was a "substantial probability" that the housing development would be built. *Id.* at 261, 264.

In this case, Myriad's challenged composition and method claims undisputedly provide "an absolute barrier" to Dr. Ostrer's ability to undertake *BRCA* diagnostic testing activities, and a declaration of those claims' invalidity would remove that barrier. *See id.* at 261. Moreover, while there may be other patent claims directed to *BRCA* probes and primers that prevent Ostrer from performing *BRCA* diagnostic testing free of infringement liability, Myriad has failed to direct us to any specific unchallenged claim that will have that effect. And Plaintiffs' counsel stated at the first oral argument in this case that his clients can sequence the *BRCA* genes without using *BRCA* probes and primers. Oral Arg. at 34:07-25, 34:53-35:29 *available at* http://www.cafc.uscourts.gov/oral-argument-recordings/2010-1406/all. Accordingly, we decline to construe the asserted claims and decline to hold on this record that Dr. Ostrer's proposed *BRCA*-related activities would infringe unchallenged claims to primers and probes. We thus conclude that it is likely, not merely speculative, that Dr. Ostrer's injury will be redressed by a favorable decision.

Although we affirm the district court's decision to exercise declaratory judgment jurisdiction over this case, we do so on narrower grounds. The district court failed to limit its jurisdictional holding to affirmative acts by the patentee directed at specific Plaintiffs, *see SanDisk*, 480 F.3d at 1380-81, erroneously holding all the Plaintiffs had standing based on "the widespread understanding that one may engage in *BRCA1/2* testing at the risk of being sued for infringement liability by Myriad," *DJ Op.*, 669 F. Supp. 2d at 390. We disagree, and thus we reverse the district court's holding that the various plaintiffs other than Dr. Ostrer have standing to maintain this declaratory judgment action. Simply disagreeing with the existence of a patent on isolated DNA sequences or even

suffering an attenuated, non-proximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. *See MedImmune*, 549 U.S. at 127. The various organizational plaintiffs in this suit in particular were not the target of any enforcement action or offered license agreements by Myriad and had made no preparation to undertake potentially infringing activities. They accordingly suffered no injury and thus lack standing to bring this action. *See Prasco*, 537 F.3d at 1338-42; *Cat Tech*, 528 F.3d at 880-81.

Having found one plaintiff with standing to maintain this declaratory judgment action, *see Horne v. Flores*, 129 S. Ct. 2579, 2592-93 (2009), we may turn now to the merits of Myriad's appeal of the district court's summary judgment decision, which held all fifteen challenged composition and method claims invalid under § 101.

II. Subject Matter Eligibility

Under the Patent Act, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The Supreme Court has consistently construed § 101 broadly, explaining that "[i]n choosing such expansive terms . . . modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Chakrabarty*, 447 U.S. at 308).

The Supreme Court, however, has also consistently held that § 101, although broad, is not unlimited. *Id.* The Court's precedents provide three judicially created exceptions to § 101's broad patent-eligibility principles: "'Laws

of nature, natural phenomena, and abstract ideas' are not patentable." *Mayo*, 132 S. Ct. at 1293 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)). The Court has also referred to those exceptions as precluding the patenting of mental processes, *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), and products of nature, *Chakrabarty*, 447 U.S. at 313 ("[T]he relevant distinction for purposes of § 101 is . . . between products of nature . . . and human-made inventions."). The Court has explained that, although not required by the statutory text, "[t]he concepts covered by these exceptions are 'part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.'" *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

Plaintiffs challenge under § 101 Myriad's composition claims directed to "isolated" DNA molecules, its method claims directed to "analyzing" or "comparing" DNA sequences, and its claim to a method for screening potential cancer therapeutics. We address each in turn. Before reviewing the applicability of the Supreme Court's *Mayo* holding to the claims of the Myriad patents, however, it is important to state what this appeal is not about. It is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent—that is the basic right provided by a patent, *i.e.*, to exclude others from practicing the patented subject matter. It is also not whether the claims at issue are novel or nonobvious or too

broad. Those questions are not before us. It is solely whether the claims to isolated BRCA DNA, to methods for comparing DNA sequences, and to a process for screening potential cancer therapeutics meet the threshold test for patent-eligible subject matter under 35 U.S.C. § 101 in light of various Supreme Court holdings, particularly including *Mayo*. The issue is patent eligibility, not patentability.

We would further note, in the context of discussing what this case is not about, that patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights. But disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress, and other general questions relating to patentability and use of patents are issues not before us. As will be seen, on the limited questions before us, we conclude that the composition claims and the screening claim involving growing a transformed host cell meet the standards for patent eligibility, while the claimed methods for "analyzing" or "comparing" do not.

A. Composition Claims: Isolated DNA Molecules

i.

The principal claims of the patents before us on remand relate to isolated DNA molecules. *Mayo* does not control the question of patent-eligibility of such claims. They are claims to compositions of matter, expressly authorized as suitable patent-eligible subject matter in § 101. As to those claims, the issue of patent-eligibility remains, as it was on the first appeal to this court, whether they claim patent-ineligible products of nature. We hold that they do not. The isolated DNA molecules before us are not found in nature. They are obtained in

the laboratory and are man-made, the product of human ingenuity. While they are prepared from products of nature, so is every other composition of matter. All new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials. For example, virtually every medicine utilized by today's medical practitioners, and every manufactured plastic product, is either synthesized from natural materials (most often petroleum fractions) or derived from natural plant materials. But, as such, they are different from natural materials, even if they are ultimately derived from them. The same is true of isolated DNA molecules.

ii.

Myriad argues that its challenged composition claims to "isolated" DNAs cover patent-eligible compositions of matter within the meaning of § 101. According to Myriad, the district court came to a contrary conclusion by (1) misreading Supreme Court precedent as excluding from patent eligibility all "products of nature" unless "markedly different" from naturally occurring ones; and (2) incorrectly focusing not on the differences between isolated and native DNAs, but on one similarity: their informational content. Rather, Myriad argues, an isolated DNA molecule is patent eligible because it is, as claimed, "a nonnaturally occurring manufacture or composition of matter" with "a distinctive name, character, and use." Appellants' Br., 2010 WL 4600106, at 41-42 (quoting *Chakrabarty*, 447 U.S. at 309-10). Myriad contends that isolated DNA does not exist in nature and that isolated DNAs, unlike native DNAs, can be used as primers and probes for diagnosing cancer. Moreover, Myriad asserts that an ultimately-derived-from "products of nature" exception not only would be unworkable, as every composition of matter is, at some level, composed of natural materials, but also would be contrary to this court's

precedents, the PTO's 2001 *Utility Examination Guidelines*, and Congress's role in enacting the patent laws. Regarding *Mayo*, Myriad argues that the Supreme Court's decision did not address or alter the established patent-eligibility test for composition claims, such that the standards announced in *Chakrabarty* still govern this appeal. To the extent that the general principles discussed in *Mayo* bear on the DNA claims, Myriad maintains that isolated DNA represents a nonnatural, man-made invention distinct from the lack of human ingenuity underlying the method claims there at issue.

Plaintiffs respond that claims to isolated DNA molecules fail to satisfy § 101 because such claims cover natural phenomena and products of nature. According to Plaintiffs, Supreme Court precedent establishes that a product of nature is not patent eligible even if, as claimed, it has undergone some highly useful change from its natural form. Rather, Plaintiffs assert, to be patent eligible a composition of matter must also have a distinctive name, character, and use, making it "markedly different" from the natural product. In this case, Plaintiffs conclude that because isolated DNAs retain part of the same nucleotide sequence as native DNAs, they do not have any "markedly different" characteristics. Furthermore, according to Plaintiffs, the isolated DNA claims preempt products and laws of nature, excluding anyone from working with the *BRCA* genes and the genetic information they convey. Under *Mayo*, Plaintiffs assert that any structural differences relative to the chromosomal *BRCA* genes do not add "enough" to the underlying natural genetic sequences to render Myriad's isolated DNA molecules patentable under § 101.

The government as amicus curiae does not defend the longstanding position of the PTO, a government agency, that isolated DNA molecules are patent eligible, arguing

instead for a middle ground. Specifically, the government argues that DNA molecules engineered by man, including cDNAs,[9] are patent-eligible compositions of matter because, with rare exceptions, they do not occur in nature, either in isolation or as contiguous sequences within a chromosome. In contrast, the government asserts, isolated and unmodified genomic DNAs are *not* patent eligible, but rather patent-ineligible products of nature, since their nucleotide sequences exist because of evolution, not man.

At the first oral argument, the government illustrated its position by way of a so-called "magic microscope" test (an invention in and of itself, although probably not patent-eligible). Oral Arg. at 46:50-47:50. According to the government's test then, if an imaginary microscope could focus in on the claimed DNA molecule as it exists in the human body, the claim covers ineligible subject matter. The government thus argued that because such a microscope could focus in on the claimed isolated *BRCA1* or *BRCA2* sequences as they exist in the human body, the claims covering those sequences are not patent eligible. In contrast, the government contended, because an imaginary microscope could not focus *in vivo* on a cDNA sequence, which is engineered by man to splice together non-contiguous coding sequences (*i.e.*, exons), claims covering cDNAs are patent eligible.

In sum, although the parties and the government appear to agree that isolated DNAs are compositions of matter, they disagree on whether and to what degree such molecules fall within the exception for products of nature.

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[9] According to the government, several of the composition claims at issue in this suit, including claim 2 of the '282 patent, are limited to cDNA and thus patent eligible. We agree.

As set forth below, we conclude that the challenged claims to isolated DNAs, whether limited to cDNAs or not, are directed to patent-eligible subject matter under § 101.

iii.

While *Mayo* and earlier decisions concerning method claim patentability provide valuable insights and illuminate broad, foundational principles, the Supreme Court's decisions in *Chakrabarty* and *Funk Brothers* set out the primary framework for deciding the patent eligibility of compositions of matter, including isolated DNA molecules.[10]

In *Chakrabarty*, the Court addressed the question whether a man-made, living microorganism is a patent-

[10] Other Supreme Court decisions cited by the parties and amici relating to patented manufactures and compositions of matter were decided based on lack of novelty, not patent-eligible subject matter. In *American Wood-Paper Co. v. Fibre Disintegrating Co.*, the Court held the challenged patent "void for want of novelty in the manufacture patented," because the "[p]aper-pulp obtained from various vegetable substances was in common use before the original patent was granted . . . , and whatever may be said of their process for obtaining it, the product was in no sense new." 90 U.S. 566, 596 (1874). Similarly, in *Cochrane v. Badische Anilin & Soda Fabrik*, the Court held that a claim to artificial alizarine covered an old and well-known substance, the alizarine of madder, which could not be patented although made artificially for the first time. 111 U.S. 293, 311 (1884); *see also id.* at 308-09 ("It is very plain that the specification of the original patent, No. 95,465, states the invention to be a process for preparing alizarine, *not as a new substance prepared for the first time*, but as the substance already known as alizarine, to be prepared, however, by the new process, which process is to be the subject of the patent, and is the process of preparing the *known product* alizarine from anthracine." (emphases added)).

eligible manufacture or composition of matter within the meaning of § 101. 447 U.S. at 305, 307. The microorganisms were bacteria genetically engineered with four naturally occurring DNA plasmids, each of which enabled the breakdown of a different component of crude oil. *Id.* at 305, 305 n.1. The bacteria, as a result, could break down multiple components of crude oil, a trait possessed by no single naturally occurring bacterium and of significant use in more efficiently treating oil spills. *Id.* at 305, 305 n.2. The Court held that the bacteria qualified as patent-eligible subject matter because the "claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* at 309-10 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

To underscore the point, the Court compared Chakrabarty's engineered bacteria with the mixed bacterial cultures found unpatentable in *Funk Brothers*, again casting this case, more relating to obviousness, in terms of § 101. *See Parker v. Flook*, 437 U.S. 584, 591 (1978); *Benson*, 409 U.S. at 67. In *Funk Brothers*, the patentee discovered that certain strains of nitrogen-fixing bacteria associated with leguminous plants do not mutually inhibit each other. 333 U.S. at 129-30. Based on that discovery, the patentee produced (and claimed) mixed cultures of nitrogen-fixing species capable of inoculating a broader range of leguminous plants than single-species cultures. *Id.* The Court held that the bacteria's cooperative qualities were, "like the heat of the sun, electricity, or the qualities of metals," the "work of nature," and thus not patentable. *Id.* at 130. The Court also held that applying the newly discovered bacterial compatibility to create a mixed culture was not a patentable advance because no species acquired a different property or use. *Id.* at 131.

The *Chakrabarty* Court thus concluded that what distinguished Chakrabarty's oil-degrading bacteria from the mixed cultures claimed in *Funk Brothers*, and made the former patent-eligible, was that Chakrabarty's bacteria had "markedly different characteristics from any [bacterium] found in nature" based on the efforts of the patentee. *Chakrabarty*, 447 U.S. at 310.

One distinction, therefore, between products of nature and human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. Specifically, the Supreme Court has drawn a line between compositions that, even if arrayed in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics. *Id.* (citing *Hartranft*, 121 U.S. at 615); *see also Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931). Applying this test to the isolated DNAs in this case, the challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature.

It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form—as distinctive chemical molecules—from DNAs in the human body, *i.e.*, native DNA. Natural DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each of those DNA molecules is condensed and intertwined with various proteins, including histones, to form a complex tertiary structure known as chromatin that makes up a larger structural complex, a chromosome. *See supra*, Figure 3. Inside living cells, the chromosomes are further encapsulated within a series of membranes and suspended in a complex intracellular milieu.

Isolated DNA, in contrast, is a free-standing portion of a larger, natural DNA molecule. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. For example, the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Similarly, *BRCA2* in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast, isolated *BRCA1* and *BRCA2*, with introns, each consists of just 80,000 or so nucleotides. And without introns, *BRCA2* shrinks to approximately 10,200 nucleotides and *BRCA1* to just around 5,500 nucleotides. Furthermore, claims 5 and 6 of the '282 patent cover isolated DNAs, *e.g.*, primers or probes, having as few as fifteen nucleotides of a *BRCA* sequence. Accordingly, *BRCA1* and *BRCA2* in their isolated states are different molecules from DNA that exists in the body; isolated DNA results from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA, imparting on that isolated DNA a distinctive chemical identity as compared to native DNA.

As the above description indicates, isolated DNA is not just purified DNA. Purification makes pure what was the same material, but was combined, or contaminated, with other materials. Although isolated DNA is removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body. Accordingly, this is not a situation, as in *Parke-Davis & Co. v. H.K. Mulford Co.*, in which purification of adrenaline resulted in the *identical* molecule, albeit being "for every practical purpose a new thing commercially and therapeutically." 189 F. 95, 103 (C.C.S.D.N.Y. 1911). Judge Learned Hand's opinion for

the district court in that oft-cited case held the purified "Adrenalin" to be patent-eligible subject matter. *Id.* The *In re Marden* cases are similarly inapposite, directed as they are to the patent ineligibility of purified natural elements—ductile uranium, 47 F.2d 957 (CCPA 1931), and vanadium, 47 F.2d 958 (CCPA 1931)—that are inherently ductile in purified form. While purified natural products thus may or may not qualify for patent under § 101, the isolated DNAs of the present patents constitute an *a fortiori* situation, where they are not only purified; they are different from the natural products in "name, character, and use." *Chakrabarty*, 447 U.S. at 309-10.[11]

Parke-Davis and *Marden* address a situation in which claimed compound A is purified from a physical mixture that contains compound A. In this case, the claimed

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[11] *In re Bergy*, relating to a purified microorganism, 596 F.2d 952, 967-68 (CCPA 1979), was once a companion case to *Chakrabarty* but was vacated by the Supreme Court and remanded for dismissal as moot when the inventors withdrew their claim from the pending application. *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980). Other CCPA cases cited by the parties and amici were not decided based on patent eligibility. In *In re Bergstrom*, the court held that pure prostaglandin compounds, PGE(2) and PGE(3), were improperly rejected as lacking novelty. 427 F.2d 1394, 1394 (CCPA 1970); *see Bergy*, 596 F.2d at 961 (recognizing *Bergstrom* as a case decided under § 102). Similarly in *In re Kratz*, the court held nonobvious claims to synthetically produced, substantially pure 2-methyl-2-pentenoic acid, a chemical that gives strawberries their flavor. 592 F.2d 1169, 1170 (CCPA 1979); *see also In re King*, 107 F.2d 618, 619 (CCPA 1939) (holding claims to vitamin C invalid for lack of novelty, as "[a]ppellants were not the first to discover or produce [vitamin C] in its pure form"); *In re Merz*, 97 F.2d 599, 601 (CCPA 1938) (holding claims to artificial ultramarine that contains non-floatable impurities invalid as not "inventive," and thus obvious).

isolated DNA molecules do not exist in nature within a physical mixture to be purified. They have to be chemically cleaved from their native chemical combination with other genetic materials. In other words, in nature, the claimed isolated DNAs are covalently bonded to such other materials. Thus, when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity that is obtained by human intervention. *See Chakrabarty*, 447 U.S. at 313 ("the relevant distinction [is] between products of nature . . . and human-made inventions"). In fact, some forms of isolated DNA may require no purification at all, because DNAs can be chemically synthesized directly as isolated molecules.

The above analysis holding the isolated DNA molecules to be patent-eligible subject matter applies to all of the asserted composition claims on appeal in this case. However, as the government has pointed out, claim 2 of the '282 patent is narrower than claim 1 and reads only on cDNAs, which lack the non-coding introns present in the genomic *BRCA1* gene.[12] While, as we have held, all of the claimed isolated DNAs are eligible for patent as compositions of matter distinct from natural DNA, the claimed cDNAs are especially distinctive, lacking the non-coding introns present in naturally occurring chromosomal DNA. They are even more the result of human intervention into nature and are hence patent-eligible subject matter. The government, as noted earlier, has agreed with that conclusion. Br. United States, 2010 WL 4853320, at 14-17.

The dissent disparages the significance of a "chemical bond," presumably meaning a covalent bond, in distin-

[12] Claims 2 and 7 of the '282 patent and claim 7 of the '492 patent recite isolated cDNA molecules.

guishing structurally between one molecular species and another. But a covalent bond is the defining boundary between one molecule and another, and the dissent's citation of Linus Pauling's comment that covalent bonds "make it convenient for the chemist to consider [the aggregate] as an independent molecular species" underlines the point. The covalent bonds in this case connect different chemical moieties to one another.

Plaintiffs argue that because the claimed isolated DNAs retain the same nucleotide sequence as native DNAs, they do not have any "markedly different" characteristics. This approach, however, looks not at whether isolated DNAs are markedly different—have a distinctive characteristic—from naturally occurring DNAs, as the Supreme Court has directed, but at one similarity, albeit a key one: the information content contained in isolated and native DNAs' nucleotide sequences. Adopting this approach, the district court disparaged the patent eligibility of isolated DNA molecules because their genetic function is to transmit information. We disagree, as it is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility rather than their physiological use or benefit. Uses of chemical substances may be relevant to the nonobviousness of these substances or to method claims embodying those uses, but the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material. The claimed isolated DNA molecules are distinct from their natural existence as portions of larger entities, and their informational content is irrelevant to that fact. We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature and, as such, are best described in patents by their structures rather than by their functions. In

fact, many different materials may have the same function (*e.g.*, aspirin, ibuprofen, and naproxen).

The district court in effect created a categorical rule excluding isolated genes from patent eligibility. *See SJ Op.*, 702 F. Supp. 2d at 228-29. But the Supreme Court has "more than once cautioned that courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed,'" *Bilski*, 130 S. Ct. at 3226 (quoting *Diehr*, 450 U.S. at 182), and has repeatedly rejected new categorical exclusions from § 101's scope, *see id.* at 3227-28 (rejecting the argument that business method patents should be categorically excluded from § 101); *Chakrabarty*, 447 U.S. at 314-17 (same for living organisms). Contrary to the conclusions of the district court and the suggestions of Plaintiffs and some amici, § 101 applies equally to all putative inventions, and isolated DNA is not and should not be considered a special case for purposes of patent eligibility under existing law. *See, e.g.*, *SJ Op.*, 702 F. Supp. 2d at 185 ("DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature."); Appellees' Suppl. Br. at 4-5 ("Unlike other chemicals, the information encoded by DNA reflects its primary biological function . . . .").

Under the statutory rubric of § 101, isolated DNA is a tangible, man-made composition of matter defined and distinguished by its objectively discernible chemical structure. Whether its unusual status as a chemical entity that conveys genetic information warrants singular treatment under the patent laws as the district court did is a policy question that we are not entitled to address. *Cf. Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, slip op. at 6 (2012) ("[W]e possess neither the expertise nor the prerogative to make policy judgments. Those

decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them."). Congress is presumed to have been aware of the issue, having enacted a comprehensive patent reform act during the pendency of this case, and it is ultimately for Congress if it wishes to overturn case law and the long practice of the PTO to determine that isolated DNA must be treated differently from other compositions of matter to account for its perceived special function. We therefore reject the district court's unwarranted categorical exclusion of isolated DNA molecules.

Because isolated DNAs, not just cDNAs, have a markedly different chemical structure compared to native DNAs, we reject the government's earlier proposed "magic microscope" test, as it misunderstands the difference between science and invention and fails to take into account the existence of molecules as separate chemical entities. The ability to visualize a DNA molecule through a microscope, or by any other means, when it is bonded to other genetic material, is worlds apart from possessing an isolated DNA molecule that is in hand and usable. It is the difference between knowledge of nature and reducing a portion of nature to concrete form, the latter activity being what the patent laws seek to encourage and protect. The government's microscope could focus in on a claimed portion of any complex molecule, rendering that claimed portion patent ineligible, even though that portion never exists as a separate molecule in the body or anywhere else in nature, and may have an entirely different utility. That would discourage innovation. One cannot visualize a portion of a complex molecule, including a DNA containing a particular gene, and will it into isolation as a unique entity. Visualization does not cleave and isolate the particular DNA; that is the act of human invention.

The Supreme Court in *Mayo* focused on its concern that permitting patents on particular subject matter would prevent use by others of, in *Mayo*, the correlation recited in the method claims. Plaintiffs argue here that they are preempted from using the patented DNA molecules. The answer to that concern is that permitting patents on isolated genes does not preempt a law of nature. A composition of matter is not a law of nature. Moreover, as indicated earlier, a limited preemption is inherent in every patent: the right to exclude for a limited period of time. 35 U.S.C. § 154(a)(1) ("Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . ."). When the patent expires, the public is entitled to practice the invention of the patent. That is true of all inventions; during the term of the patent, unauthorized parties are "preempted" from practicing the patent, but only for its limited term. The seven patents being challenged here all expire by December 18, 2015.[13] Any preemption thus is limited, very limited in the case of the present patents. Moreover, patents are rarely enforced against scientific research, even during their terms.

The remand of this case for reconsideration in light of *Mayo* might suggest, as Plaintiffs and certain amici state, that the composition claims are mere reflections of a law of nature. Respectfully, they are not, any more than any product of man reflects and is consistent with a law of nature. Everything and everyone comes from nature, following its laws. But the compositions here are not

[13] Specifically, the '441 patent will expire on August 12, 2014; the '473 patent will expire on December 2, 2014; the '999 and '001 patents will expire on January 20, 2015; the '282 patent will expire on May 5, 2015; and the '492 and '857 patents will expire on December 18, 2015.

natural products. They are the products of man, albeit following, as all materials do, laws of nature.

The dissent indicates that "elemental lithium (like other elements) would not be patentable subject matter, even if it could only be extracted from nature through an isolation process." But the isolation here is not a simple separation from extraneous materials, but conversion to a different molecular entity. And again, these facts are not before us, so we do not attempt to evaluate the patentability of one form of lithium over another. Courts decide cases; they do not draft comprehensive legal treatises. Suffice it to say, however, that if lithium is found in the earth as other than elemental lithium because it reacts with air and water to form, for example, lithium oxide or lithium hydroxide, it is a different material. A lithium compound is not elemental lithium.

It is also important to dispute the dissent's analogy to snapping a leaf from a tree. With respect, no one could contemplate that snapping a leaf from a tree would be worthy of a patent, whereas isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect. Snapping a leaf from a tree is a physical separation, easily done by anyone. Creating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort. *See Mayo*, 132 S. Ct. at 1294 ("While a scientific truth . . . is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.") (quoting *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939)).

The dissent also mentions several times in its opinion the "breathtaking[]" breadth of certain claims as grounds for objecting to their patentability. However, we do not

have here any rejection or invalidation on the various grounds relating to breadth, such as in 35 U.S.C. § 112. The issue before us is patent eligibility under § 101, not the adequacy of the patents' disclosure to support particular claims. Nor is it lack of patentability for obviousness, as the dissent intimates, that is before us.

The dissent finally attempts to analogize the creation of the isolated DNAs in this case to the removal of a kidney from the human body, indicating that the latter does not create patent-eligible subject matter, hence the claimed isolated DNAs also do not. Such an analogy is misplaced. Extracting a kidney from a body does not result in a patent-eligible composition, as an isolated gene has been and should be. A kidney is an organ, not a well defined composition of matter or an article of manufacture specified by § 101. No one could confuse extensive research needed to locate, identify, and isolate a gene with the extraction of an organ from a body. One is what patents are intended to stimulate research on and hence are properly patent eligible, and the other, while obviously essential to human wellbeing, is not what patents are understood to cover under the patent statute. An isolated DNA is properly characterized as a composition of matter under § 101; no one would so characterize an isolated body organ.

Finally, our decision that isolated DNA molecules are patent eligible comports with the longstanding practice of the PTO and the courts. The Supreme Court has repeatedly stated that changes to longstanding practice should come from Congress, not the courts. In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Court rejected the argument that plants did not fall within the scope of § 101, relying in part on the fact that "the PTO has assigned utility patents for plants for at least 16 years and there has been no indication from either Con-

gress or agencies with expertise that such coverage is inconsistent with [federal law]." 534 U.S. 124, 144-45 (2001); *see also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) ("[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997))); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (upholding a written description requirement separate from enablement based in part on *stare decisis*).

In this case, the PTO has issued patents relating to DNA molecules for almost thirty years. In the early 1980s, the Office granted the first human gene patents. *See* Eric J. Rogers, *Can You Patent Genes? Yes and No*, 93 J. Pat. & Trademark Off. Soc'y 19 (2010). It is estimated that the PTO has issued 2,645 patents claiming "isolated DNA" over the past twenty-nine years, J.A. 3710, and that by 2005, had granted 40,000 DNA-related patents relating to, in non-native form, genes in the human genome, Rogers, *supra* at 40. In 2001, the PTO issued *Utility Examination Guidelines*, which reaffirmed the agency's position that isolated DNA molecules are patent eligible, 66 Fed. Reg. 1092-94 (Jan. 5, 2001), and Congress has not indicated that the PTO's position is inconsistent with § 101. If the law is to be changed, and DNA inventions excluded from the broad scope of § 101, contrary to the settled expectation of the inventing and investing communities, the decision must come, not from the courts, but from Congress. The dissent mentions possible "adverse effects" that may occur if isolated DNAs are held to be patent eligible. But, respectfully, it is the adverse effects on innovation that a holding of ineligibility might cause. Patents encourage innovation and even

encourage inventing around; we must be careful not to rope off far-reaching areas of patent eligibility.

Accordingly, we once again conclude that claims 1, 2, 5, 6, and 7 of the '282 patent; claims 1, 6, and 7 of the '492 patent; and claim 1 of the '473 patent directed to isolated DNA molecules recite patent-eligible subject matter under § 101. *Mayo* does not change that result. In so doing, we reiterate that the issue before us is *patent eligibility*, not *patentability*, about which we express no opinion.

II. Method Claims

We turn next to Myriad's challenged method claims. This court in its now-vacated decision of July 29, 2011, had held method claims 1 of the '999, '001, and '441 patents, as well as method claims 1 and 2 of the '857 patent—all of which consist of analyzing and comparing certain DNA sequences—not to be patent-eligible subject matter on the ground that they claim only abstract mental processes. In light of the Supreme Court's decision in *Mayo*, we reaffirm that prior holding. The Court made clear that such diagnostic methods in that case essentially claim natural laws that are not eligible for patent. Without expressly analyzing the instant method claims in the context of the Court's reasoning, but in light of the Court's holding, and in view of our own prior reasoning, set forth herein below, those method claims cannot stand.

In our prior decision, however, we reversed the district court's holding that claim 20 of the '282 patent was not eligible for patent. We did so on the ground, *inter alia*, that, in addition to the step of comparing the cells' growth rates, the claim also recites the steps of growing transformed cells and determining those growth rates. We relied on the fact that those steps were transformative. Although the Court has now held that certain transformative steps are not necessarily sufficient under § 101

if the recited steps only rely on natural laws, we once again, even in light of *Mayo*, arrive at the same conclusion of patent-eligibility because at the heart of claim 20 is a transformed cell, which is made by man, in contrast to a natural material.

A. Methods of "Comparing" or "Analyzing" Sequences

Myriad argued that its claims to methods of "comparing" or "analyzing" *BRCA* sequences satisfy the machine-or-transformation test because each requires a transformation—extracting and sequencing DNA molecules from a human sample—before the sequences can be compared or analyzed. According to Myriad, the district court failed to recognize the transformative nature of the claims by (1) misconstruing the claim term "sequence" as merely information, rather than a physical molecule; and (2) erroneously concluding, in the alternative, that Myriad's proposed transformations were mere data-gathering steps, rather than central to the purpose of the claims.

Plaintiffs responded that these method claims are drawn to the abstract idea of comparing one sequence to a reference sequence and preempt a phenomenon of nature—the correlation of genetic mutations with a predisposition to cancer. And, according to the Plaintiffs, limiting the claims' application to a specific technological field, *i.e.*, *BRCA* gene sequences, is insufficient to render the claims patent eligible. Plaintiffs also assert that the claims do not meet the machine-or-transformation test because the claims' plain language includes just the one step of "comparing" or "analyzing" two gene sequences.

We renew our conclusion that Myriad's claims to "comparing" or "analyzing" two gene sequences fall outside the scope of § 101 because they claim only abstract mental processes. *See Benson*, 409 U.S. at 67 ("Phenomena of nature, . . . mental processes, and abstract intellec-

tual concepts are not patentable, as they are the basic tools of scientific and technological work."). The claims recite, for example, a "method for screening a tumor sample," by "comparing" a first *BRCA1* sequence from a tumor sample and a second *BRCA1* sequence from a non-tumor sample, wherein a difference in sequence indicates an alteration in the tumor sample. '001 patent claim 1. This claim thus recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences: one looks at the first position in a first sequence; determines the nucleotide sequence at that first position; looks at the first position in a second sequence; determines the nucleotide sequence at that first position; determines if the nucleotide at the first position in the first sequence and the first position in the second sequence are the same or different, wherein the latter indicates an alteration; and repeats the process for the next position.

Limiting the comparison to just the *BRCA* genes or, as in the case of claim 1 of the '999 patent, to just the identification of particular alterations, fails to render the claimed process patent-eligible. As the Supreme Court has held, "the prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Bilski*, 130 S. Ct. at 3230 (quoting *Diehr*, 450 U.S. at 191-92); *see also id.* at 3231 ("*Flook* established that limiting an abstract idea to one field of use . . . did not make the concept patentable."). Although the *application* of a formula or abstract idea in a process may describe patent-eligible subject matter, *id.* at 3230, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process that is claimed.

To avoid this result, Myriad attempts to read into its method claims additional, allegedly transformative steps. As described above, Myriad reads into its claims the steps of (1) extracting DNA from a human sample, and (2) sequencing the *BRCA* DNA molecule, arguing that both steps necessarily precede the step of comparing nucleotide sequences. The claims themselves, however, do not include either of these steps. The claims do not specify any action prior to the step of "comparing" or "analyzing" two sequences; the claims recite just the one step of "comparing" or "analyzing." Moreover, those terms' plain meaning does not include Myriad's proposed sample-processing steps; neither comparing nor analyzing means or implies "extracting" or "sequencing" DNA or otherwise "processing" a human sample.

Myriad claims that "comparing" and "analyzing" take on such meaning when read in light of the patent specifications. Specifically, Myriad argues that the specifications show that the claim term "sequence" refers not to information, but rather to a physical DNA molecule, whose sequence must be determined before it can be compared. That may be true, but the claims only recite mental steps, not the structure of physical DNA molecules.

Accordingly, Myriad's challenged method claims are indistinguishable from the claims the Supreme Court found invalid under § 101 in *Mayo*. In *Mayo*, the patents claimed methods for optimizing the dosage of thiopurine drugs administered to patients with gastrointestinal disorders. 132 S. Ct. at 1295. As written, the claimed methods included the steps of (a) "administering" a thiopurine drug to a subject, and/or (b) "determining" the drug's metabolite levels in the subject, wherein the measured metabolite levels are compared with predetermined levels to optimize drug dosage. *Id.* In holding that the

claims satisfied § 101, this court concluded that, in addition to the "administering" step being transformative, the "determining" step was both transformative and central to the purpose of the claims. *Prometheus*, 628 F.3d at 1357. However, the Supreme Court held that the steps of administering and determining, combined with a correlative "wherein" clause, were not sufficiently transformative of what was otherwise a claim to a natural law. That holding governs Myriad's claims to methods of "comparing" and "analyzing" DNA sequences.

Myriad's other claims do not even include a *Mayo*-like step of "determining" the sequence of *BRCA* genes by, *e.g.*, isolating the genes from a blood sample and sequencing them, or any other putatively transformative step. Rather, the comparison between the two sequences can be accomplished by mere inspection alone. Accordingly, Myriad's claimed methods of comparing or analyzing nucleotide sequences are only directed to the abstract mental process of comparing two nucleotide sequences. As such, we hold claims 1 of the '999 patent, '001 patent, and '441 patent and claims 1 and 2 of the '857 patent invalid under § 101 for claiming patent-ineligible processes.

B. Method of Screening Potential Cancer Therapeutics

Lastly, we turn to claim 20 of the '282 patent, directed to a method for screening potential cancer therapeutics via changes in cell growth rates of transformed cells. The parties agree that those transformed cells arose from human effort; *i.e.*, they are not natural products. Plaintiffs nonetheless challenge claim 20 as directed to the abstract idea of comparing the growth rates of two cell populations and as preempting a basic scientific principle—that a slower growth rate in the presence of a potential therapeutic compound suggests that the compound is

a cancer therapeutic. Plaintiffs therefore contend that claim 20 is indistinguishable from the claims held ineligible in *Mayo*. We disagree.

Claim 20 recites a method that comprises the steps of (1) growing host cells *transformed* with an altered *BRCA1* gene in the presence or absence of a potential cancer therapeutic, (2) determining the growth rate of the host cells with or without the potential therapeutic, and (3) comparing the growth rate of the host cells. Claim 20 thus recites a screening method premised on the use of "transformed" host cells. Those cells, like the patent-eligible cells in *Chakrabarty*, are not naturally occurring. Rather, they are derived by altering a cell to include a foreign gene, resulting in a man-made, transformed cell with enhanced function and utility. *See* '282 patent col.27 ll.28-33. The claim thus includes more than the abstract mental step of looking at two numbers and "comparing" two host cells' growth rates.

In *Mayo*, the Supreme Court invalidated claims directed to the relationship between concentrations of certain metabolites in the blood and the likelihood that a particular dosage of a thiopurine drug will be optimum, stating that steps of "administering" and "determining," coupled with a correlative "wherein" clause, were insufficient to differentiate the claimed method from the natural laws encompassed by the claims. In short, "to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words 'apply it'." 132 S. Ct. at 1294.

Here, claim 20 does do more; it does not simply apply a law of nature. Of course, all activity, whether chemical, biological, or physical, relies on natural laws. But, more to the point here is that claim 20 applies certain steps to

transformed cells that, as has been pointed out above, are a product of man, not of nature. The Court, in its evaluation of the *Mayo* method claims, found that the additional steps of those claims were not sufficient to "transform" the nature of the claims from mere expression of natural laws to patent-eligible subject matter. By definition, however, performing operations, even known types of steps, on, or to create, novel, *i.e.*, transformed subject matter is the stuff of which most process or method invention consists. All chemical processes, for example, consist of hydrolyzing, hydrogenating, reacting, etc. In situations where the objects or results of such steps are novel and nonobvious, they should be patent-eligible. It is rare that a new reaction or method is invented; much process activity is to make new compounds or products using established processes. Thus, once one has determined that a claimed composition of matter is patent-eligible subject matter, applying various known types of procedures to it is not merely applying conventional steps to a law of nature. The transformed, man-made nature of the underlying subject matter in claim 20 makes the claim patent-eligible. The fact that the claim also includes the steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell—patent-eligible subject matter.

Furthermore, the claim does not cover all cells, all compounds, or all methods of determining the therapeutic effect of a compound. Rather, it is tied to specific host cells *transformed* with specific genes and grown in the presence or absence of a specific type of therapeutic. Accordingly, we hold that claim 20 of the '282 patent recites patent-eligible subject matter under § 101. Whether such processes, including claim 20, meet other

tests for patentability, such as novelty or nonobviousness, is not before us.

CONCLUSION

For the foregoing reasons, we affirm the district court's decision to exercise declaratory judgment jurisdiction over this case, we reverse the district court's grant of summary judgment with regard to Myriad's composition claims to isolated DNAs, including cDNAs, we affirm the district court's grant of summary judgment with regard to Myriad's method claims directed to comparing or analyzing gene sequences, and we reverse the district court's grant of summary judgment with regard to Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates of novel, man-made transformed cells.

AFFIRMED IN PART and REVERSED IN PART

COSTS

Costs to Myriad.

United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, AND KATHLEEN RAKER,
Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant,

and

MYRIAD GENETICS, INC.,
Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, AND MICHAEL K. YOUNG,

IN THEIR OFFICIAL CAPACITY AS DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION,
Defendants-Appellants.

2010-1406

Appeal from the United States District Court for the Southern District of New York in case No. 09-CV-4515, Senior Judge Robert W. Sweet.

MOORE, *Circuit Judge*, concurring in part.

I join the majority opinion with respect to standing and the patentability of the method claims at issue. I join the majority with respect to claims to isolated cDNA sequences, and concur in the judgment with respect to isolated DNA sequences. I write separately to explain my reasoning.

I.

The Patent Act, 35 U.S.C. § 101, allows "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" to obtain a patent. The plain language of this statute only requires that an invention be "new and useful," and fall into one of four categories: a "process, machine, manufacture, or composition of matter." "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting the statutory history).

While the plain language used by Congress did not limit the scope of patentable subject matter in the statute,

the "Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Bilski v. Kappos*, 130 S. Ct. 3218, 3226 (2010) (quoting *Chakrabarty*, 447 U.S. at 309). These exceptions "rest[], not on the notion that natural phenomena are not processes [or other articulated statutory categories], but rather on the more fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Parker v. Flook*, 437 U.S. 584, 593 (1978).

Applying the judicially created exception to the otherwise broad demarcation of statutory subject matter in section 101 can be difficult. *See Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134-45 (1948) (Frankfurter, J., concurring) ("[S]uch terms as 'the work of nature' and the 'laws of nature' . . . are vague and malleable . . . . Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."). The analysis is relatively simple if the invention previously existed in nature exactly as claimed. For example, naturally existing minerals, a plant found in the wild, and physical laws such as gravity or $E=mc^2$ are not patentable subject matter, even if they were "discovered" by an enterprising inventor. *Chakrabarty*, 447 U.S. at 309.

Even when an invention does not exist in nature in the claimed state, it may still be directed to subject matter that is not patentable. For example, in *Funk Brothers*, the Supreme Court held a patent to a combination of multiple naturally occurring bacterial strains was not patentable. Although there was "an advantage in the combination," which was apparently "new and useful," none of the bacterial strains "acquire[ed] a different use" in combination. *Funk Bros.*, 333 U.S. at 131-32. The aggregation of the bacterial strains into a single product

produced "no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. . . . They serve the ends nature originally provided and act quite independently of any effort of the patentee." *Id.*

In contrast, the Supreme Court held bacteria that included extra genetic material introduced by the inventor were "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use'" and therefore patentable. *Chakrabarty*, 447 U.S. at 309-310 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)). *Chakrabarty* explained that there is no distinction between inventions based on living and inanimate objects for the purpose of the patent statute; instead, the "relevant distinction" for the section 101 analysis is "between products of nature . . . and human-made inventions." *Id.* at 312-13. Even if the invention was based on nature, and resulted in a living organism, it may fall within the scope of section 101. For example, "the work of the plant breeder 'in aid of nature' was patentable invention" because "'a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man.'" *Id.* (quoting S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930)). In *Chakrabarty*, the intervention of man resulted in bacteria with "markedly different characteristics" from nature and "the potential for significant utility," resulting in patentable subject matter. *Id.* at 310.

Funk Brothers and *Chakrabarty* do not stake out the exact bounds of patentable subject matter. Instead, each applies a flexible test to the specific question presented in order to determine whether the claimed invention falls within one of the judicial exceptions to patentability.

Funk Brothers indicates that an invention which "serve[s] the ends nature originally provided" is likely unpatentable subject matter, but an invention that is an "enlargement of the range of . . . utility" as compared to nature may be patentable. 333 U.S. at 131. Likewise, *Chakrabarty* illustrates that an invention with a distinctive name, character, and use, e.g., markedly different characteristics with the potential for significant utility, is patentable subject matter. 447 U.S. at 309-10. Although the two cases result in different outcomes, the inquiry itself is similar.

Courts applied an analogous patentability inquiry long before *Funk Brothers* or *Chakrabarty*. In one notable case, Judge Learned Hand held that purified adrenaline, a natural product, was patentable subject matter. Judge Hand explained that even if the claimed purified adrenaline were "merely an extracted product without change, there is no rule that such products are not patentable." *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911). This is because "while it is of course possible logically to call this a purification of the principle" the resulting purified adrenaline was "for every practical purpose a new thing commercially and therapeutically." *Id.* Similarly, in a case applying the Patent Act of 1952,[1] purified vitamin B-12, another natural product, was also held patentable subject matter within the meaning of section 101. *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156 (4th Cir. 1958). The Fourth Circuit explained that purified vitamin B-12 was "far from the premise of the [naturally occurring] princi-

[1] The Patent Act of 1952 was the first time patentable subject matter (the current section 101) was separated out from novelty (the current section 102). Previously, these two concepts were combined into a single section.

ple. . . . The new product, not just the method, had such advantageous characteristics as to replace the [naturally occurring] liver products. What was produced was, in no sense, an old product." *Id.* at 162-63. These purified pharmaceutical cases are both consistent with Supreme Court precedent: the purified substance was "a new thing . . . therapeutically," *Parke-Davis*, 189 F. at 103, and had such "advantageous characteristics" that what was produced by purification "was, in no sense, an old product." *Merck*, 253 F.2d at 162-63. In other words, the purified natural products were held to have "markedly different characteristics," as compared to the impure products, which resulted in "the potential for significant utility." *Chakrabarty*, 447 U.S. at 310.

In contrast, mere purification of a naturally occurring element is typically insufficient to make it patentable subject matter. For example, our predecessor court held that claims to purified vanadium and purified uranium were not patentable subject matter since these were naturally occurring elements with inherent physical properties unchanged upon purification. *See In re Marden*, 47 F.2d 958, 959 (CCPA 1931) ("[P]ure vanadium is not new in the inventive sense, and, it being a product of nature, no one is entitled to a monopoly of the same."); *In re Marden*, 47 F.2d 957 (CCPA 1931) ("ductile uranium" not patentable because uranium is inherently ductile). Likewise, claims to purified ductile tungsten were not patentable subject matter since pure tungsten existed in nature and was inherently ductile. *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928). In each of these cases, purification did not result in an element with new properties. Instead, the court held the naturally occurring element inherently had the same characteristics and utility (e.g. ductility) as the claimed invention. Consistent with *Funk Brothers* and

Chakrabarty, the claims all fell within the laws of nature exception.

As illustrated by these examples, courts have long applied the principles articulated in *Funk Brothers* and *Chakrabarty* to different factual scenarios in order to determine whether an invention, as claimed, falls into the laws of nature exception. I see no reason to deviate from this longstanding flexible approach in this case.

II.

We reconsider whether the claims at issue in this case are directed to patentable subject matter following the remand from the Supreme Court in light of its opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012) (*Prometheus*). While the *Prometheus* decision does not control the outcome in this case, it is nonetheless instructive regarding the scope of the law of nature exception. As an initial matter, the *Prometheus* discussion of laws of nature (process claims) clearly ought to apply equally to manifestations of nature (composition claims). Myriad's argument that *Prometheus* is constrained to methods is an untenable position.

As the *Prometheus* court explained: "If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself." *Id.* at 1297. *Prometheus* did not, however, overturn *Funk Brothers* or *Chakrabarty*; cases clearly more analogous to the one before us. Using the framework of *Funk Brothers* and *Chakrabarty* in conjunction with the direction of *Prometheus*, the applicable principles are: (1) laws of nature/manifestations of nature are not patentable; (2) a composition of matter with "markedly different characteristics" from that found in nature with

the potential for significant utility is directed to patentable subject matter.

Does the isolation process change the DNA from an unpatentable manifestation of nature into a patentable composition of matter? *Id.* at 1299. Does the claimed isolated DNA have markedly different characteristics with the potential for significant utility, e.g., an "enlargement of the range of . . . utility" as compared to nature? *Chakrabarty*, 447 U.S. at 309-310; *Funk Bros.*, 333 U.S. at 131.

The isolated DNA claims of the patents in suit fall into two categories. The first category of claims is directed to isolated sequences that are identical to naturally occurring gene sequences. These include claims encompassing both the isolated full length gene sequence (e.g. claim 1 of '282 patent), which are thousands of nucleotides, and claims to shorter isolated DNA strands, with as few as fifteen nucleotides, whose nucleotide sequence is found on the chromosome (e.g. claim 5 of '282 patent). The second category of claims is directed to isolated DNA sequences that are different from the naturally occurring gene sequences. These include claims to isolated cDNA molecules (e.g. claim 2 of the '282 patent), which differ from the natural gene sequence in that the introns are removed, and are the opposite (complementary) sequence of the naturally occurring RNA.

The cDNA claims present the easiest analysis. Although the plaintiffs (now plaintiff) in the suit argue, and the district court held, that cDNA falls within the "laws of nature" exception to section 101 patentability, the claimed cDNA sequences do *not* exist in nature. Moreover, since cDNA has all of the introns removed, and only contains the coding nucleotides, it can be used to express a protein in a cell which does *not* normally produce it. Of course,

the claimed isolated cDNA is inspired by nature—after all naturally occurring RNA is the template upon which cDNA is constructed. Because it is used as a template, however, cDNA has a complementary sequence of nucleotides, and therefore has a *completely different* nucleotide sequence than the RNA. Moreover, DNA has a different chemical structure than RNA, including a different base (T instead of U, respectively) and sugar units (deoxyribose instead of ribose, respectively). This results in, among other things, greater stability for the DNA sequence as compared to the RNA sequence.

cDNA sequences thus have a distinctive character and use, with markedly different chemical characteristics from either the naturally occurring RNA or any continuous DNA sequence found on the chromosome. The claimed isolated cDNA sequences are the creation of man, made using biological tools and the naturally occurring mRNA as a template. cDNA is therefore not one of the "'manifestations of . . . nature, free to all men and reserved exclusively to none'" that falls outside of the patent system. *Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros.*, 333 U.S. at 130). I decline to extend the laws of nature exception to reach entirely manmade sequences of isolated cDNA, even if those sequences are inspired by a natural template. I therefore join the majority opinion with respect to the claims to cDNA sequences.[2]

DNA sequences that have the same pattern of DNA bases as a natural gene, in whole or in part, present a more difficult issue. Unlike the isolated cDNA molecules, whose sequence is not present in nature, the isolated

[2] To the extent the claims to shorter portions of cDNA include only naturally occurring sequences found in the chromosome, for example claim 6 of the '282 patent, my reasoning is the same as for the isolated sequences of claim 5, discussed below.

DNA claims include nucleotide sequences which are found in the human body, albeit as part of a much larger molecule, the chromosome. To the extent the majority rests its conclusion on the chemical differences between genomic and isolated DNA (breaking the covalent bonds), I cannot agree that this is sufficient to hold that the claims to human genes are directed to patentable subject matter. I agree that isolated genes are a different molecule and are therefore not squarely analogous to unpatentable minerals, created by nature without the assistance of man. The claimed isolated DNA molecules, which are truncations (with different ends) of the naturally occurring DNA found as part of the chromosome in nature, are not naturally produced without the intervention of man.

I begin with the short isolated sequences such as those covered by claim 5 which is directed to "an isolated DNA having at least 15 nucleotides of the DNA of claim 1." This claim covers a sequence as short as 15 nucleotides and arguably as long as the entire gene. For this claim to be patent eligible, all of the sequences ranging from the 15 nucleotide sequence to the full gene must be patentable subject matter. The shorter isolated DNA sequences have a variety of applications and uses in isolation that are new and distinct as compared to the sequence as it occurs in nature. For example, these sequences can be used as primers in a diagnostic screening process to detect gene mutations. These smaller isolated DNA sequences—including isolated radiolabeled sequences mirroring those on the chromosome—can also be used as the basis for probes. Naturally occurring DNA cannot do this. Unlike the isolated DNA, naturally occurring DNA simply does not have the requisite chemical and physical properties needed to perform these functions.

The ability to use isolated DNA molecules as the basis for diagnostic genetic testing is clearly an "enlargement of

the range of . . . utility" as compared to nature. *Funk Bros.*, 333 U.S. at 131. In *Prometheus*, the Supreme Court held that the claims at issue were not directed to patentable subject matter because they merely "set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 132 S. Ct. at 1296-97. The claimed relationship was "a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes." *Id.* at 1297.

There is no suggestion that the human body naturally uses 15-mers as primers to synthesize DNA, or that the attendant process of "probing" a patient's DNA to detect a mutation is somehow a natural law. The ability to use a short strand of DNA as a primer or probe to determine whether a patient has a mutation is a new and important utility substantially different from the role of that DNA as it occurs in nature. Indeed, many of the plaintiffs in this case submitted declarations indicating that they wanted to either offer such testing or receive such testing. Unlike *Prometheus*, the claims to short isolated strands of DNA are not directed to the relationship between the mutation and cancer, but rather to a new tool that can be used to determine if that relationship exists. The short isolated DNA sequences have markedly different properties which are directly responsible for their new and significant utility. *Chakrabarty*, 447 U.S. at 309-10. It is not the chemical change alone, but that change combined with the different and beneficial utility that leads me to conclude that small isolated DNA fragments are patentable subject matter. *Id.* at 310.

In fact, much of the dissent's analysis with regard to the full gene would seem to support my conclusion that small isolated DNA molecules are directed to patent-

eligible subject matter. The dissent explains why the baseball bat is directed to patent eligible subject matter: "man has defined the parts that are to be retained and the parts that are to be discarded, and he has molded the retained portion into a product that bears little resemblance to that which occurs naturally." Dissent at 11-12. The exact same thing is true with regard to primer and probe claims. Man has whittled the chromosomal DNA molecule down to a 15 nucleotide sequence – defining the parts to be retained and discarded.[3] And the result is a product with a function (primer or probe) that is entirely different from the full gene from which it was obtained.[4] I conclude that the small, isolated DNA molecules are an alteration of the natural product "with markedly different characteristics from any found in nature and one having the potential for significant utility." 447 U.S. at 310.

Turning now to the longer strands of isolated DNA, isolated strands which include most or all of the gene present a more difficult case. Some of the claims at issue, for example '282 patent claim 5, are genus claims, drafted

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[3] If adding functionality to a naturally occurring molecule, for example adding a lipid chain, is a creation of man then removing functionality, for example truncating a natural DNA sequence or protein to yield smaller molecules with new properties should also be. In either case, it is the intervention of man that created a new molecule. After all, the hand of man is just as apparent in the David, created by removing stone from a block of marble, as the ceiling of the Sistine Chapel, created by adding layers of paint to an existing structure.

[4] The dissent analogizes the full BRCA gene to a slab of marble found in the earth as distinct from the sculpture carved into it – which the dissent indicates would be worthy of intellectual property protection. If the multi-thousand nucleotide BRCA gene is the slab, isn't the 15 nucleotide primer the sculpture?

broadly enough to include both short fragments as well as the entire isolated gene sequence. While I ultimately conclude that these longer isolated sequences, including the isolated gene sequence as a whole, are also patentable subject matter, I do so for a reason different than for the shorter sequences.

All of the same structural arguments apply to any length of isolated DNA so, like the shorter strands, an isolated DNA coding for a gene does have a literal chemical difference from the gene as it appears on the chromosome. Unlike the shorter strands of isolated DNA, the chemical and structural differences in the isolated gene do not clearly lead to an "enlargement of the range of . . . utility" as compared to nature. *Funk Bros.*, 333 U.S. at 131. For example, the full length gene is too large to be used as a probe. *See* J.A. 4322 (a probe is a DNA molecule usually 100-1,000 bases long). Likewise, an entire isolated gene appears unsuitable for use as a primer in genetic screening for mutations in that same gene. *See* J.A. 4323 (Primers "are complementary to an exact location of a much larger target DNA molecule."). The isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence.

If I were deciding this case on a blank canvas, I might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter. The scope of the law of nature/manifestation of nature exception was certainly enlarged in *Prometheus*. But we do not decide this case on a blank canvas. Congress has, for centuries, authorized an expansive scope of patentable subject matter. Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified

natural products for centuries. There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof.[5] As I explain below, I believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved.[6]

III.

For more than a decade the Patent Office's policy has been that "[a]n isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because . . . that DNA molecule does

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[5] *See, e.g.*, U.S. Patent 3,067,099 (claiming vancomycin, an antibiotic produced by bacteria found in soil) and U.S. Patent 4,552,701 (claiming a vancomycin fragment produced by removing a sugar unit). A natural product fragment, for example a naturally occurring antibiotic with a sugar moiety removed, is highly analogous to isolated DNA. In each case, the claimed molecule is a smaller fragment of a naturally occurring molecule, with some naturally occurring functionality removed. *See* U.S. Patent 4,552,701, col.3-4 (compare entry 2 with entries 10 and 13).

[6] My analysis of the claims at issue assumes that they do not include an isolated, full length chromosome. I do not believe that a claim to an entire chromosome, for example chromosome 17, is patentable subject matter. First, there is no indication that the chromosome in isolation has markedly different characteristics compared to the chromosome in nature. Second, unlike claims to isolated genes, there is no indication of either settled expectations or extensive property rights for claims to isolated chromosomes. This is undoubtedly due to the small number of chromosomes as compared to the number of genes.

not occur in that isolated form in nature . . . ." 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). I do not agree with the dissent's characterization of the PTO position as perfunctory. The PTO concluded that isolated DNA is patentable because it is different from what is found in nature – the process of synthesizing it or isolating it changes it. While the PTO lacks substantive rule making authority, it is not without expertise in this area. The explicit statement of the Patent Office's position on isolated DNA, however, is simply a continuation of a longstanding and consistent policy of allowing patents for isolated natural products. *See id.* (noting U.S. Patent 141,072, claiming "[y]east, free from organic germs of disease," issued to Louis Pasteur in 1873); *cf. In re Bergstrom*, 427 F.2d 1394 (CCPA 1970) (isolated prostaglandins patentable). According to the Patent Office, isolated DNA is no different from the isolated natural products of *Parke-Davis*. *See* 66 Fed. Reg. at 1093 (quoting *Parke-Davis*).

Even before the current guidelines formalized the Patent Office's position, it granted patents to human genes in the early 1980s, and subsequently issued thousands of patents on "isolated DNA." Majority at 54. In fact, claims similar to the ones at issue in this case have been the focal point of important litigation. For example, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) involved a claim to "'[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.'" *Id.* at 1203-04 (quoting U.S. Patent No. 4,703,008, claim 2). We affirmed that this claim was valid and infringed. *Id.* at 1219. Erythropoietin, also known as EPO, went on to become the biggest-selling biotechnology drug developed to that point, resulted in billions of dollars in sales, and accounted for over 50% of Amgen's revenue in 1997. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp.2d 69, 77

(D. Mass. 2001). Isolated DNA claims, at least in the case of Amgen, represent crucial and exceedingly valuable property rights.

The settled expectations of the biotechnology industry – not to mention the thousands of issued patents – cannot be taken lightly and deserve deference. This outpouring of scientific creativity, spurred by the patent system, reflects a substantial investment of time and money by the biotechnology industry to obtain property rights related to DNA sequences. The type of fundamental alteration in the scope of patentable subject matter argued in this case "risk[s] destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). I believe leaving intact the settled expectations of property owners is particularly important in light of the large number of property rights involved, both to isolated DNA and to purified natural products generally.

The Supreme Court has warned that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Id.* at 739. The settled expectations of the inventing community with respect to isolated DNA claims are built upon the broad language of the statute, judicial precedent, such as *Parke-Davis* and *Merck*, and the Patent Office's longstanding policy and practice. Neither *Funk Brothers* nor *Chakrabarty* purported to overrule either the early cases or the Patent Office's practice; indeed, as discussed *supra*, these cases weigh the same considerations as *Parke-Davis* and *Merck*. "'To change so substantially the rules of the game now,'" after more than a century of practice, "'could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision.'"

Festo, 535 U.S. at 739 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997)).

Although the Patent Office has consistently followed the same policy for a decade (and arguably a century or more), the United States, as an amicus, now argues that the Patent Office's published guidelines are incorrect and a misstatement of the law. In place of these guidelines, the government suggested that a "magic microscope" would provide a useful metaphor for guiding our section 101 analysis. The magic microscope, however, would not see the claimed DNA molecules at issue in this case. An isolated DNA molecule has different chemical bonds as compared to the "unisolated" sequence in the chromosome (the ends are different). In short, the claimed molecules cannot be seen in nature through the magic microscope. While you may be able to see the order of DNA nucleotides in the chromosome, the isolated fragment of DNA is a different molecule. Creating the claimed isolated DNA sequences therefore results in a distinctly unnatural molecule.[7] Even the dissent agrees that the isolated DNA molecules at issue require cleaving chemical bonds, though it disputes the importance of the resulting distinct

[7] This also illustrates why the government's analogies to situations dealing with elements, for example lithium, are inapposite. Even assuming the government's contention that lithium does not currently exist in isolated form in nature, it is nevertheless clear that elemental lithium, a basic building block provided by nature, at some point must have reacted with, e.g., water to form the naturally occurring lithium salts. In contrast, an isolated DNA sequence did not necessarily exist before reacting further to produce the corresponding naturally occurring chromosomal DNA. Unlike a lithium salt, the chromosome does not imply that an isolated DNA molecule of 15 nucleotides – or even a gene – necessarily previously existed as an isolated molecule in nature.

"'molecular species.'" Dissent at 7 (quoting Linus Pauling, *The Nature of the Chemical Bond* 6 (3d ed. 1960)).

The dissent claims that the Patent Office's past views are "substantially undermined by the position the government has taken in this case." Dissent at 20. The Patent Office's prior practice, however, is particularly important since it resulted in a large number of property rights over the past decades. If the government decided to change course in the Patent Office, and decline to issue new patents to isolated genes, it would not impact these existing property rights. This, however, is not what the government argues in this case. Instead the government argues for an entirely different interpretation of the law that would destroy existing property rights. Although the dissent points out that *Chakrabarty* overturned the Patent Office's practice of denying patents to microorganisms, there is a clear difference between allowing additional patent protection where none previously existed, and denying patent protection decades (or centuries) after the fact, thereby eliminating a large number of property rights. *Chakrabarty*, consistent with the broad language of the statute, allowed additional patents where none previously existed. In contrast, the government proposes to destroy existing property rights based on a judge made exception to that same broad language. This is a dramatic step that I believe is best left to the Congress.

Nevertheless, the government claims that "this is a pure question of law" and that we can therefore feel free to ignore the years of Patent Office practice and the accompanying expectations that practice created within the industry. The government argues that we should not defer to the broad language (all but unchanged since 1793) provided by Congress in the patent statute, or allow Congress to decide whether it is necessary to correct the Patent Office's practice through legislation. It is tempting

to use our judicial power in this fashion, especially when the patents in question raise substantial moral and ethical issues related to awarding a property right to isolated portions of human DNA – the very thing that makes us humans, and not chimpanzees.

The invitation is tempting, but I decline the opportunity to act where Congress has chosen not to. Congress at least implicitly approved of the Patent Office's policy of awarding patents on genes and DNA sequences. For example, Congress included, as part of the Patent Office's appropriations, language affirming the Patent Office's interpretation of section 101 to prohibit patents on human organisms. Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, § 634, 118 Stat. 3, 101. Although Congress was aware "that there are many institutions . . . that have extensive patents on human genes," 149 Cong. Rec. H7248, H7274, it explicitly declined to implement legislation to "affect any of those current existing patents." 149 Cong. Rec. E2417-01. To the contrary, it made clear that the language related to "human organisms" was not intended to change the Patent Office's policy with respect to claims to genes, stem cells, or other similar inventions.[8] Far from oblivious to the patenting of genes, Congress introduced and declined to pass several bills

[8] "What I want to point out is that *the U.S. Patent Office has already issued patents on genes*, stem cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. *My amendment would not affect the former*, but would simply affirm the latter." 149 Cong. Rec. E2417-01 (emphasis added); *see also* 157 Cong. Rec. E1177-04 (resubmitting this testimony in the context of the current patent reform legislation).

which would put a moratorium on gene patents,[9] authorize funding for the study of whether genes ought to be patentable,[10] and exempt from patent infringement anyone who uses patented genes for non-commercial research purposes or medical practitioners who use genetic diagnostic tests.[11] Congress is obviously aware of the issues presented in this case and I believe "[a]ny recalibration of the standard of [patentability] remains in its hands." *Microsoft Corp. v. i4i Ltd.*, 131 S. Ct. 2238, 2252 (2011).

The judiciary cannot engage in an *ad hoc* innovation-based analysis, which is why the exceptions to patentability apply only to the clearest cases: a new mineral discovered in the earth, or a new plant found in the wild, or $E=mc^2$, or the law of gravity. It is Congress, with "the constitutional authority and the institutional ability to accommodate fully the varied permutations of competing interests that are inevitably implicated by such new technology," *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 431 (1984), who must decide whether it is necessary to change the scope of section 101

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[9] At least one bill was introduced in Congress to put a moratorium on patents to human genes or gene sequences. *See, e.g.*, The Animal and Gene Patent Moratorium Bill (S.387 1993).

[10] The Genomic Science and Technology Innovation Act of 2002 (H.R. 3966).

[11] The Genomic Research and Diagnostic Accessibility Act of 2002 (H.R. 3967). As the bill's sponsor explained: "It is important to note that this section would not overturn the commercial rights of patent holders. If a research [organization] utilizing the exemption makes a commercially viable finding, he or she would still have to negotiate any rights to market the new discovery with the patent holder." 148 Cong. Rec. E353-03.

to exclude the kind of isolated DNA claims at issue here. It is not clear to me that *Chakrabarty*, *Funk Brothers*, or *Prometheus* leads inexorably to the conclusion that isolated DNA molecules are not patentable subject matter. I decline the invitation to broaden the law of nature exception.

Given the complicated technology and conflicting incentives at issue here, any change must come from Congress. *See Gottschalk v. Benson*, 409 U.S. 63, 72-73 (1972) (A section 101 analysis raises "considerable problems . . . which only committees of Congress can manage, for broad powers of investigation are needed, including hearings which canvass the wide variety of views which those operating in this field entertain. The technological problems tendered [by the parties] . . . indicate to us that considered action by the Congress is needed.").

IV.

"The rule that the discovery of a law of nature cannot be patented rests . . . on the . . . fundamental understanding that they are not the kind of 'discoveries' that the statute was enacted to protect." *Flook*, 437 U.S. at 593. Is an isolated kidney patentable? Probably not, but as far as I can tell nobody ever thought isolating organs from someone's body was the kind of discovery "that the statute was enacted to protect." In contrast, purifying or isolating natural products has historically been exactly the kind of discovery protected by the patent statutes. There is a century-long history of affirming patent protection for isolated and purified biological products ranging from hormones to vitamins to proteins to antibiotics. These inventions must have seemed miraculous at the time, providing previously unknown therapeutic options to treat sickness. The fact that these molecules might have existed in nature did not foreclose patent protection in

view of the extraordinary benefits accessible to man after isolation.

The Patent Office has, for more than a decade, affirmatively stated its belief that isolated DNA is patentable for the same reasons as isolated vitamins or hormones. There is no indication from Congress that this view is wrong; to the contrary, it appears Congress also believes DNA is patentable. This long-term policy of protecting isolated DNA molecules has resulted in an explosion of innovation in the biotechnology industry, an industry which, unlike the financial services industry or even the software industry, depends on patents to survive. Holding isolated DNA not patentable would destroy long settled industry expectations for no reason other than a gut feeling that DNA is too close to nature to be patentable, an arbitrary decision based on a judge-made exception. I believe that isolated DNA fragments, which have both chemical changes from the naturally occurring genomic DNA as well as new utility, are "the kind of 'discoveries' that the statute was enacted to protect." I therefore decline to extend the "laws of nature" exception to include isolated DNA sequences.

This case typifies an observation by the late Chief Judge Markey, our first Chief Judge, that "[o]nly God works from nothing. Men must work with old elements." *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) (quotation, citations omitted). Human DNA is, for better or worse, one of the old elements bequeathed to men to use in their work. The patents in this case revealed a new molecular understanding about ourselves; "the inventions most benefiting mankind are those that 'push back the frontiers of chemistry, physics, and the like.'" *Chakrabarty*, 447 U.S. at 316 (quoting *Great A.&P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 154 (1950)). We cannot, after decades of

patents and judicial precedent, now call human DNA fruit from the poisonous tree, and punish those inquisitive enough to investigate, isolate, and patent it. "Our task . . . is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted." *Id.* at 318. This inquiry does not have moral, ethical, or theological components. *Cf. id.* at 316-17 ("[W]e are without competence to entertain" arguments about "the grave risks" generated by genetic research.). "The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot." *Id.* at 317. The patents in this case might well deserve to be excluded from the patent system, but that is a debate for Congress to resolve. I will not strip an entire industry of the property rights it has invested in, earned, and owned for decades unchallenged under the facts of this case.

United States Court of Appeals for the Federal Circuit

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, HAIG KAZAZIAN, MD, ARUPA GANGULY, PHD, WENDY CHUNG, MD, PHD, HARRY OSTRER, MD, DAVID LEDBETTER, PHD, STEPHEN WARREN, PHD, ELLEN MATLOFF, M.S., ELSA REICH, M.S., BREAST CANCER ACTION, BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, LISBETH CERIANI, RUNI LIMARY, GENAE GIRARD, PATRICE FORTUNE, VICKY THOMASON, AND KATHLEEN RAKER,
Plaintiffs-Appellees,

v.

UNITED STATES PATENT AND TRADEMARK OFFICE,
Defendant,

and

MYRIAD GENETICS, INC.,
Defendant-Appellant,

and

LORRIS BETZ, ROGER BOYER, JACK BRITTAIN, ARNOLD B. COMBE, RAYMOND GESTELAND, JAMES U. JENSEN, JOHN KENDALL MORRIS, THOMAS PARKS, DAVID W. PERSHING, AND MICHAEL K. YOUNG,

IN THEIR OFFICIAL CAPACITY AS DIRECTORS OF THE UNIVERSITY OF UTAH RESEARCH FOUNDATION,
Defendants-Appellants.

2010-1406

Appeal from the United States District Court for the Southern District of New York in case No. 09-CV-4515, Senior Judge Robert W. Sweet.

BRYSON, *Circuit Judge*, concurring in part and dissenting in part:

I concur with the portions of this court's judgment that are directed to standing, the patentability of the cDNA claims, and the patentability of the method claims. I respectfully dissent from the court's holding that Myriad's BRCA gene claims and its claims to gene fragments are patent-eligible. In my view, those claims are not directed to patentable subject matter, and the court's decision, if sustained, will likely have broad consequences, such as preempting methods for whole-genome sequencing, even though Myriad's contribution to the field is not remotely consonant with such effects.

In its simplest form, the question in this case is whether an individual can obtain patent rights to a human gene. From a common-sense point of view, most observers would answer, "Of course not. Patents are for inventions. A human gene is not an invention." The essence of Myriad's argument in this case is to say that it has not patented a human gene, but something quite different—an *isolated* human gene, which differs from a

native gene because the process of extracting it results in changes in its molecular structure (although not in its genetic code). We are therefore required to decide whether the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention. The court concludes that it does; I conclude that it does not.

At the outset, it is important to identify the inventive contribution underlying Myriad's patents. Myriad was not the first to map a BRCA gene to its chromosomal location. That discovery was made by a team of researchers led by Dr. Mary-Claire King. *See* Jeff M. Hall et al., *Linkage of Early-Onset Familial Breast Cancer to Chromosome 17q21*, 250 Science 1684 (1990). And Myriad did not invent a new method of nucleotide sequencing. Instead, it applied known sequencing techniques to identify the nucleotide order of the BRCA genes.[1] Myriad's discovery of those sequences entailed difficult work, and the identified sequences have had important applications in the fight against breast cancer. But the discovery of the sequences is an unprotectable fact, just like Dr. King's discovery of the chromosomal location of the BRCA1 gene.

Of course, Myriad is free to patent applications of its discovery. As the first party with knowledge of the sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications. *See, e.g.*, '441 patent, claim 21; '492 patent, claim 22; '282 patent, claim

[1] There is some dispute over whether other inventors helped Myriad discover the BRCA sequences or discovered the BRCA2 sequence before Myriad. Because those disputes are irrelevant to the question of patentable subject matter, I refer to the discovery of the BRCA sequences as Myriad's work.

9. Yet some of Myriad's challenged composition claims effectively preempt any attempt to sequence the BRCA genes, including whole-genome sequencing. In my view, those claims encompass unpatentable subject matter, and a contrary ruling is likely to have substantial adverse effects on research and treatment in this important field.

I

As the majority and concurring opinions explain, the DNA claims at issue in this case fall into three categories: claims that cover the isolated BRCA genes (claim 1 of the '282 patent, claim 1 of the '473 patent, and claims 1 and 6 of the '492 patent); claims that cover only the BRCA cDNA (claims 2 and 7 of the '282 patent and claim 7 of the '492 patent); and claims that cover portions of the BRCA genes and cDNA as small as 15 nucleotides long (claims 5 and 6 of the '282 patent). I first address the claims to the BRCA genes.

A

In the seminal case of *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Supreme Court held that an artificial life form could be patented. In the course of its opinion, and critically for purposes of its reasoning, the Court stated that not all living things or other items found in nature were subject to patenting. The Court explained that although the language of section 101 of the Patent Act is broad, it is not the case that it "has no limits or that it embraces every discovery." *Id.* at 309. The Court then set forth the general proposition that "laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Id.* As examples, the Court noted that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter." Thus, even

though a mineral or a plant is a "composition of matter," and could be viewed as falling within a broad construction of section 101, the Court explained that those "manifestations of . . . nature" are not patentable subject matter, but are "free to all men and reserved exclusively to none." *Id.*, quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *see also Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010).

The Court in *Chakrabarty* held the artificial life form at issue in that case to be patentable because the claim was "not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" 447 U.S. at 309-10, quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887). In distinguishing between naturally occurring substances and nonnaturally occurring manufactures, the Court relied heavily on its earlier decision in *Funk Brothers*, in which the inventor discovered that certain useful bacterial strains did not exert an inhibitive effect on one another. Based on that discovery, the inventor obtained a patent on a mixed culture of those non-inhibitive strains. The Supreme Court held the product unpatentable, however, because the bacteria remained structurally and functionally the same as in their natural state. *Funk Bros.*, 333 U.S. at 131. By contrast, because Chakrabarty had produced "a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility," the Court held Chakrabarty's invention to be patentable. *Chakrabarty*, 447 U.S. at 310.

B

Myriad's claims to the isolated BRCA genes seem to me to fall clearly on the "unpatentable" side of the line the Court drew in *Chakrabarty*. Myriad is claiming the genes themselves, which appear in nature on the chromosomes of living human beings. The only material change made to those genes from their natural state is the change that is necessarily incidental to the extraction of the genes from the environment in which they are found in nature. While the process of extraction is no doubt difficult, and may itself be patentable, the isolated genes are not materially different from the native genes. In this respect, the genes are analogous to the "new mineral discovered in the earth," or the "new plant found in the wild" that the Supreme Court referred to in *Chakrabarty*. It may be very difficult to extract the newly found mineral or to find, extract, and propagate the newly discovered plant. But that does not make those naturally occurring items the products of invention.

The same is true for human genes. Like some minerals, they are hard to extract from their natural setting. Also like minerals, they can be used for purposes that would be infeasible if they remained in their natural setting. And the process of extracting minerals, or taking cuttings from wild plants, like the process of isolating genetic material, can result in some physical or chemical changes to the natural substance. But such changes do not make extracted minerals or plant cuttings patentable, and they should not have that effect for isolated genes. In each case, merely isolating the products of nature by extracting them from their natural location and making those alterations that are attendant to their extraction does not give the extractor the right to patent the products themselves.

The majority characterizes the isolated genes as new molecules and considers them different substances from the corresponding native DNA.[2] Because the native BRCA genes are chemically bonded to other genes and histone proteins, the majority concludes that cleaving those bonds to isolate the BRCA genes turns the isolated genes into "different materials." Yet there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken, but not when other atomic or molecular forces are altered.[3] A chemical bond is merely a force between two atoms or groups of atoms strong enough "to make it convenient for the chemist to consider [the aggregate] as an independent molecular species." Linus Pauling, *The Nature of the Chemical Bond* 6 (3d ed. 1960). Weaker interatomic forces will be broken when, for example, a dirty diamond is cleaned with water or another solvent, but that does not make the clean diamond a human-made invention. *See Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 12

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[2] Although I recognize that Judge Lourie and Judge Moore, while reaching the same ultimate conclusions, have taken analytical paths that differ in some respects, for convenience I will refer to Judge Lourie's opinion as the majority opinion and Judge Moore's opinion as the concurring opinion.

[3] The majority characterizes the question in this case as turning on the breaking of covalent bonds linking the BRCA genes to the rest of the DNA in chromosomes 13 and 17, but its analysis appears to place patentable weight on the breaking of other chemical bonds, such as the hydrogen bonds that are broken when separating DNA from histones or—in an example unrelated to this case—the ionic bonds that are broken when lithium is derived from a salt. It is difficult to see why differences between types of chemical bonds should matter for patentability purposes, and I see little support for such a distinction in the governing precedents.

(1931) (cleaning a shell by acid and then grinding off a layer with an emery wheel did not convert it into a different product). Nor should it make a difference for purposes of patentability if the portion of a wild plant that is collected for purposes of later regeneration is separated from the original plant by chemical means or by scissors.

If the changes in the DNA molecule that occur as part of the process of isolation render the gene claims patentable, the same analysis would seem to apply to chemical elements that do not appear in their atomic form in nature. For example, isolated lithium does not occur naturally because it reacts with air and water and thus is found in nature only as part of a chemical compound, ionically bound to other elements. Robert E. Krebs, *The History and Use of Our Earth's Chemical Elements* 48 (2d ed. 2006). Once isolated, lithium has many industrial applications, and in order to isolate lithium, it is necessary to break ionic bonds in the lithium compounds that are found in nature. But it seems plain that elemental lithium (like other elements) would not be patentable subject matter, even if it could only be extracted from nature through an isolation process.

The principles underlying that analysis apply to genetic material as well. In order to isolate the BRCA gene, it is necessary to break chemical bonds that hold the gene in its place in the body, but the genetic coding sequence that is the subject of each of the BRCA gene claims remains the same whether the gene is in the body or isolated. If we are to apply the conventional nomenclature of any field to determine whether Myriad's isolated DNA claims are "new," it would seem to make more sense to look to genetics, which provides the language of the claims, than to chemistry. Aside from Myriad's cDNA claims, its composition claims are not defined by any

particular chemical formula. For example, claim 1 of the '282 patent covers all isolated DNAs coding for the BRCA1 protein, with the protein being defined by the amino acid sequence encoded by the naturally occurring BRCA1 gene. From a molecular perspective, that claim covers a truly immense range of substances from the cDNA that is 5,914 nucleotides long to the isolated gene that contains more than 120,000 nucleotides. And the patent does not define the upper end of that range because the patent does not identify a unique nucleotide sequence for the 120,000-nucleotide-long isolated BRCA1 gene. Instead, the patent contains a sequence that is just 24,000 nucleotides long with numerous gaps denoted "vvvvvvvvvvvv." '282 patent, fig. 10. An almost incalculably large number of new molecules could be created by filling in those gaps with almost any nucleotide sequence, and all of those molecules would fall within the scope of claim 1. Included in that set are many important molecular variations to the BRCA1 gene that Myriad had not yet discovered and could not have chemically described. Yet those molecules would share only one unifying characteristic: each would code for the same protein as the naturally occurring BRCA1 gene.

From a genetic perspective, that claim covers one "composition of matter"—the BRCA1 gene. The isolated BRCA genes are identical to the BRCA genes found on chromosomes 13 and 17. They have the same sequence, they code for the same proteins, and they represent the same units of heredity. It is true that the claimed molecules have been cleaved and that they possess terminal groups that differ from those found on naturally occurring genes. The majority attaches significance to those facts. But the function of the isolated DNA molecules is attributable not to the nature of the isolation process or to the identity of the terminal groups on the molecules; the

function of the claimed molecules is dictated by the nucleotide sequence of the gene—a sequence that is determined by nature and that appears in nature exactly as it appears in the claimed isolated DNA. During the transcription phase of protein synthesis, the BRCA genes are separated from chromosomal proteins. The transcription process then proceeds from a starting point called the promoter to a stopping point often called the terminator. James D. Watson et al., *Molecular Biology of the Gene* 382, 394-96 (6th ed. 2008). The only difference between the naturally occurring BRCA genes during transcription and the claimed isolated DNA is that the claimed genes have been isolated according to nature's predefined boundaries, i.e., at points that preserve the ability of the gene to express the protein for which it is coded.

In that respect, extracting a gene is akin to snapping a leaf from a tree. Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1295 (Fed. Cir. 2010) (Dyk, J., concurring in part and dissenting in part). That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf, unless those differences imparted "markedly different characteristics" to the plucked leaf. *Chakrabarty*, 447 U.S. at 310.

Another example underscores the problem with characterizing the isolated gene as a patentable invention. A human kidney is a product of nature; it does not become a patentable invention when it is removed from the body, even if the patentee has developed an improved procedure for extracting the kidney, and even if the improved procedure results in some physical or chemical changes to the

kidney at the points where the kidney was attached to the host body. But if that is so, then why should an isolated gene be treated differently for purposes of section 101? While the isolation of a gene involves the alteration of a single molecule, it is difficult to accept that it should make a difference, for purposes of patentability, whether the isolated substance is part of a single molecule, as in the case of the BRCA genes, or part of a very large aggregation of molecules, as in the case of a kidney.

Both the majority and the concurring opinions attach significant weight to the fact that the claimed coding portions of the native BRCA genes are part of a much larger molecule and that the isolated BRCA genes, being smaller molecules extracted from the larger one, are therefore man-made inventions. But to argue that the isolated BRCA gene is patentable because in its native environment it is part of a much larger structure is no more persuasive than arguing that although an atom may not be patentable, a subatomic particle is patentable because it was previously part of a larger structure, or that while a tree is not patentable, a limb of the tree becomes a patentable invention when it is removed from the tree.

Of course, it is an oversimplification to say that something that can be characterized as "isolated" or "extracted" from its natural setting always remains a natural product and is not patentable. One could say, for example, that a baseball bat is "extracted" or "isolated" from an ash tree, but in that case the process of "extracting" the baseball bat necessarily changes the nature, form, and use of the ash tree and thus results in a manmade manufacture, not a naturally occurring product. In that setting, man has defined the parts that are to be retained and the parts that are to be discarded, and he has molded

the retained portion into a product that bears little resemblance to that which occurs naturally. The result of the process of selection is a product with a function that is entirely different from that of the raw material from which it was obtained. In the case of the BRCA genes, by contrast, nature has defined the genes as independent entities by virtue of their capacity for protein synthesis and, ultimately, trait inheritance. Biochemists extract the target genes along lines defined by nature so as to preserve the structure and function that the gene possessed in its natural environment. In such a case, the extraction of a product in a manner that retains the character and function of the product as found in nature does not result in the creation of a human invention.[4] That principle was captured by the Supreme Court's statement in *Chakrabarty* that the invention in that case was not to "a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter 'having a distinctive name, character [and] use.'" 447 U.S. at 309-10.

Cases involving the "purification" of a natural substance employ similar analysis. Our predecessor court recognized that merely purifying a naturally occurring substance does not render the substance patentable unless it results in a marked change in functionality. *In re Merz*, 97 F.2d 599, 601 (CCPA 1938) (holding that there was no right to a patent on a purer version of ultramarine, but recognizing that if a claimed article is "of such

[4] By analogy, extracting a slab of marble from the earth does not give rise to protectable intellectual property rights, but "extracting" a piece of sculpture from that slab of marble does. In the case of the BRCA gene claims, what Myriad has claimed is more akin to the slab of marble found in the earth than to the sculpture carved from it after its extraction.

purity that it differs not only in degree but in kind it may be patentable"); *see also In re King*, 107 F.2d 618, 620 (CCPA 1939) (same, for purified vitamin C); *In re Marden*, 47 F.2d 958, 959 (CCPA 1931) (same, for purified vanadium); *Gen. Elec. Co. v. DeForest Radio Co.*, 28 F.2d 641, 643 (3d Cir. 1928) (same, for purified tungsten). On the other hand, the purified natural substance is patentable if the "purification" results in a product with such distinct characteristics that it becomes "for every practical purpose a new thing commercially and therapeutically." *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911); *see also Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 161-64 (4th Cir. 1958) (holding that a purified composition of vitamin B-12 was patentable because the purification process resulted in a product that was therapeutically effective, whereas the natural form was not).

In sum, the test employed by the Supreme Court in *Chakrabarty* requires us to focus on two things: (1) the similarity in structure between what is claimed and what is found in nature and (2) the similarity in utility between what is claimed and what is found in nature. What is claimed in the BRCA genes is the genetic coding material; that material is the same, structurally and functionally, in both the native gene and the isolated form of the gene.

The structural differences between the claimed "isolated" genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form. The use to which the genetic material can be put, i.e., determining its sequence in a clinical setting, is not a new use; it is only a consequence of possession. In order to sequence an isolated gene, each gene must function in the same manner in the laboratory as it does in the

human body. Indeed, that identity of function in the isolated gene is the key to its value. The naturally occurring genetic material thus has not been altered in a way that would matter under the standard set forth in *Chakrabarty*. For that reason, the isolation of the naturally occurring genetic material does not make the claims to the isolated BRCA genes patent-eligible.

The Supreme Court's recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012), does not decide this case, but the Court's analysis is nonetheless instructive. In *Mayo*, which involved method claims, the representative claim involved the steps of administering a drug to a subject, determining a metabolite concentration in the subject's blood, and inferring the need for a change in dosage based on that metabolite concentration. *Id.* at 1295. The Court found that the method was not directed to patent-eligible subject matter because it contributed nothing "inventive" to the law of nature that lay at the heart of the claimed invention, i.e., "the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects." *Id.* at 1294. The Court examined "whether the claims do significantly more than simply describe these natural relations" and whether the "claims add *enough* to their statements of the correlations to allow the processes they described to qualify as patent-eligible processes that apply natural laws." *Id.* at 1297 (emphasis in original). In concluding that the claims did not add "enough" to the natural laws, the Court was particularly persuaded by the fact that "the steps of the claimed processes . . . involve well-understood, routine, conventional activity previously engaged in by researchers in the field." *Id.* at 1294.

Just as a patent involving a law of nature must have an "inventive concept" that does "significantly more than simply describe . . . natural relations," *Mayo*, 132 S. Ct. at 1294, 1297, a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done "enough" to distinguish his alleged invention from the similar product of nature. Has the applicant made an "inventive" contribution to the product of nature? Does the claimed composition involve more than "well-understood, routine, conventional" elements? Here, the answer to those questions is no.

Neither isolation of the naturally occurring material nor the resulting breaking of covalent bonds makes the claimed molecules patentable. We have previously stated that "isolation of interesting compounds is a mainstay of the chemist's art," and that "[i]f it is known how to perform such an isolation doing so 'is likely the product not of innovation but of ordinary skill and common sense.'" *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1302 (Fed. Cir. 2007), quoting *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). Similarly, the structural changes ancillary to the isolation of the gene do not render these claims patentable. The cleaving of covalent bonds incident to isolation is itself not inventive, and the fact that the cleaved molecules have terminal groups that differ from the naturally occurring nucleotide sequences does nothing to add any inventive character to the claimed molecules. The functional portion of the composition—the nucleotide sequence—remains identical to that of the naturally occurring gene.

The majority suggests that I have "focus[ed] not on the differences between isolated and native DNAs, but on one similarity: their informational content." In light of *Mayo*, that approach seems appropriate. The informational content of the nucleotide sequences is the critical aspect of these molecules; the terminal groups added to the molecules when the covalent bonds are broken—to which the majority and concurring opinions attribute such significance—are not even mentioned in the claims. The nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes. In my view, that structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive.

II

As noted, in addition to the BRCA gene claims discussed above, the claims at issue in this appeal include four claims to BRCA cDNA and two claims to portions of the BRCA genes and cDNA as small as 15 nucleotides long.

I agree with the court that the claims to BRCA cDNA are eligible for patenting. The cDNA cannot be isolated from nature, but instead must be created in the laboratory.[5] The end product is a human-made invention with

[5] The appellees argue that the BRCA1 cDNA can be isolated from nature, and they refer to a BRCA1 pseudogene called BRCA1P1 that is found in the human genome. However, the appellees have failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA.

distinct structure because the introns that are found in the native gene are removed from the cDNA segment. Additionally, the cDNA has a utility not present in the naturally occurring BRCA DNA and mRNA because cDNA can be attached to a promoter and inserted into a non-human cell to drive protein expression.

However, I disagree with the court as to the two claims to short segments of DNA having at least 15 nucleotides. Claim 6 of the '282 patent covers any sequence of the BRCA1 cDNA that is at least 15 nucleotides long. That claim encompasses each BRCA1 exon, even though each exon is naturally defined by transcription. Moreover, because small sequences of DNA are repeated throughout the three billion nucleotides of the human genome, the claim covers portions of the cDNA of more than 4% of human genes. It also covers portions of the DNA of nearly all human genes. Accordingly, efforts to sequence almost any gene could infringe claim 6 even though Myriad's specification has contributed nothing to human understanding of other genes. Myriad is not entitled to such broad protection. *See Mayo*, 132 S. Ct. at 1301, 1303 (examining "how much future innovation is foreclosed relative to the contribution of the inventor" and warning of the "danger" that overly broad patent claims might "foreclose[] more future invention than the underlying discovery could reasonably justify").

Myriad could easily have claimed more narrowly to achieve the utility it attaches to segments of cDNA. It contends that those segments can be used as probes and primers. DNA probes must be chemically altered or "tagged" before they can be so used, and Myriad could have claimed the tagged segments to achieve probe functionality. A claim to tagged segments would not encompass the BRCA1 exons. As to primer functionality, many

of the cDNA segments will not work. Some will be too long. Some will be too short. Some will be palindromic and fold in on themselves. Myriad could have identified a subset of the segments that work as primers, and such a claim could be patentable if it were limited to species with "markedly different characteristics from any found in nature and . . . having the potential for significant utility." *Chakrabarty*, 447 U.S. at 310. The problem with claim 6 is that it is so broad that it includes products of nature (the BRCA1 exons) and portions of other genes; its validity is not salvaged because it includes some species that are not natural. Accordingly, I would hold claim 6 unpatentable.

The other claim to a short segment of DNA, claim 5 of the '282 patent, is breathtakingly broad. That claim covers any segment of the DNA defined by claim 1, provided that the segment is at least 15 nucleotides long. Claim 1, in turn, covers any isolated DNA that codes for the BRCA1 polypeptide. Thus, claim 5 would cover not only the isolated BRCA1 gene in each of its numerous molecular variations, but also any sub-sequence of those molecules, including portions that fall in the undefined range of those molecules denoted "vvvvvvvvvvvv." Claim 5 would therefore be unpatentable for the same reasons as claim 1 and claim 6.

Of course, in light of its breadth, claim 5 of the '282 patent is likely to be invalid on other grounds, and thus a ruling as to patent eligibility with respect to that claim may be superfluous. Nonetheless, it is important to consider the effects of such broad patent claims on the biotechnology industry. While Myriad has emphasized the biotechnology industry's need of patent protection to encourage and reward research in this difficult and important field, there is another side to the coin. Broad

claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine—multiplex tests and whole-genome sequencing. New technologies are being developed to sequence many genes or even an entire human genome rapidly, but firms developing those technologies are encountering a thicket of patents. Secretary's Advisory Comm. on Genetics, Health, and Society, Dep't of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* 49-62 (2010). In order to sequence an entire genome, a firm would have to license thousands of patents from many different licensors. *See id.* at 50-51. Even if many of those patents include claims that are invalid for anticipation or obviousness, the costs involved in determining the scope of all of those patents could be prohibitive. *See id.* at 51-52; Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 Hou. L. Rev. 1059, 1076-1080 (2008) (concluding that existing studies "have focused relatively little attention on downstream product development" and that interviews accompanying those studies suggest that, though smaller than initially feared, the costs associated with the patent thicket are "quite real in the calculations of product-developing firms").

My colleagues assign significant weight to the fact that since 2001 the PTO has had guidelines in place that have allowed patents on entire human genes. They conclude that those guidelines, and the PTO's earlier practice, are entitled to deference from this court as to the question whether patents to isolated human genes constitute patent-eligible subject matter. I think the PTO's practice and guidelines are not entitled to significant weight, for several reasons.

First, as we have recognized, the PTO lacks substantive rulemaking authority as to issues such as patentability. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991). In areas of patent scope, we owe deference only commensurate with "the thoroughness of its consideration and the validity of its reasoning." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). The comments that the PTO issued at the time of its 2001 guidelines in response to suggestions that isolated human genes were not patentable are, frankly, perfunctory. *See* John M. Conley & Roberte Makowski, *Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents*, 85 J. Pat. & Trademark Off. Soc'y 301 (2003). Because those comments, at least on their face, do not reflect thorough consideration and study of the issue, I do not regard them as worthy of much weight in the analysis of this complex question.

Second, whatever force the PTO's views on the issue of patent eligibility may have had in the past has, at the very least, been substantially undermined by the position the government has taken in this case. The Department of Justice has twice filed a brief on behalf of the United States in this court taking the position that Myriad's gene claims (other than the cDNA claims) are not patent-eligible. Although the PTO did not "sign" the brief on either occasion and we are left to guess about the status of any possible continuing inter-agency disagreements about the issue, the Department of Justice speaks for the Executive Branch, and the PTO is part of the Executive Branch, so it is fair to conclude that the Executive Branch has modified its position from the one taken by the PTO in its 2001 guidelines and, informally, before that.

Finally, prior to the Supreme Court's decision in *Chakrabarty*, the PTO had determined that microorgan-

isms were not subject to patenting, but the Supreme Court gave no indication that it regarded that view as entitled to deference. Moreover, the Court gave short shrift to the Commissioner's contention (which was made the lead argument in the government's brief in that case) that the patentability of life-forms was an issue that should be left to Congress. Citing *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803), the Court explained that "Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed." *Chakrabarty*, 477 U.S. at 315. We have the same responsibility and should not shy away from deciding the issues of law that the parties have brought to us. Although my colleagues believe our analysis of the legal question in this case should be influenced by purported expectations of the inventing community based on the PTO's past practice of issuing patents on human genes, that is in effect to give the PTO lawmaking authority that Congress has not accorded it.[6] There is no collective right of adverse possession to intellectual property, and we should not create one. Our role is to interpret the law that Congress has written in accordance with the governing precedents. I would do so and would affirm the district court's rulings as to the BRCA gene and BRCA gene segment claims.

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[6] Because the asserted reliance interest is based on PTO practice and not on prior judicial decisions, this case is not analogous to *Warner Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997), or *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), where the expectations of the inventing community were based on longstanding Supreme Court precedent.

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL. *v.* PROMETHEUS LABORATORIES, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 10–1150. Argued December 7, 2011—Decided March 20, 2012

Although "laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter under §101 of the Patent Act, *Diamond* v. *Diehr*, 450 U. S. 175, 185, "an *application* of a law of nature . . . to a known structure or process may [deserve] patent protection," *id.,* at 187. But to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words "apply it." See, *e.g., Gottschalk* v. *Benson*, 409 U. S. 63, 71–72. It must limit its reach to a particular, inventive application of the law.

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the two patents at issue, which concern the use of thiopurine drugs to treat autoimmune diseases. When ingested, the body metabolizes the drugs, producing metabolites in the bloodstream. Because patients metabolize these drugs differently, doctors have found it difficult to determine whether a particular patient's dose is too high, risking harmful side effects, or too low, and so likely ineffective. The patent claims here set forth processes embodying researchers' findings that identify correlations between metabolite levels and likely harm or ineffectiveness with precision. Each claim recites (1) an "administering" step—instructing a doctor to administer the drug to his patient—(2) a "determining" step—telling the doctor to measure the resulting metabolite levels in the patient's blood—and (3) a "wherein" step—describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below

these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.

Petitioners Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) bought and used diagnostic tests based on Prometheus' patents. But in 2004 Mayo announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo contending that Mayo's test infringed its patents. The District Court found that the test infringed the patents but granted summary judgment to Mayo, reasoning that the processes claimed by the patents effectively claim natural laws or natural phenomena—namely, the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs—and therefore are not patentable. The Federal Circuit reversed, finding the processes to be patent eligible under the Circuit's "machine or transformation test." On remand from this Court for reconsideration in light of *Bilski* v. *Kappos*, 561 U. S. ___, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, *id.,* at ___–___, the Federal Circuit reaffirmed its earlier conclusion.

Held: Prometheus' process is not patent eligible. Pp. 8–24.

(a) Because the laws of nature recited by Prometheus' patent claims—the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm—are not themselves patentable, the claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations. The three additional steps in the claimed processes here are not themselves natural laws but neither are they sufficient to transform the nature of the claims. The "administering" step simply identifies a group of people who will be interested in the correlations, namely, doctors who used thiopurine drugs to treat patients suffering from autoimmune disorders. Doctors had been using these drugs for this purpose long before these patents existed. And a "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.' " *Bilski*, *supra,* at ___. The "wherein" clauses simply tell a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions. The "determining" step tells a doctor to measure patients' metabolite levels, through whatever process the doctor wishes to use. Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. Such

activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Parker* v. *Flook*, 437 U. S. 584, 590. Finally, considering the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Pp. 8–11.

(b) A more detailed consideration of the controlling precedents reinforces this conclusion. Pp. 11–19.

(1) *Diehr* and *Flook,* the cases most directly on point, both addressed processes using mathematical formulas that, like laws of nature, are not themselves patentable. In *Diehr,* the overall process was patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. 450 U. S., at 187. These additional steps transformed the process into an inventive application of the formula. But in *Flook,* the additional steps of the process did not limit the claim to a particular application, and the particular chemical processes at issue were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. 437 U. S., at 594. Here, the claim presents a case for patentability that is weaker than *Diehr*'s patent-eligible claim and no stronger than *Flook*'s unpatentable one. The three steps add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. Pp. 11–13.

(2) Further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable is provided in *O'Reilly* v. *Morse*, 15 How. 62, 114–115; *Neilson* v. *Harford,* Webster's Patent Cases 295, 371; *Bilski, supra,* at ___–___; and *Benson*, *supra,* at 64, 65, 67. Pp. 14–16.

(3) This Court has repeatedly emphasized a concern that patent law not inhibit future discovery by improperly tying up the use of laws of nature and the like. See, *e.g., Benson,* 409 U. S., at 67, 68. Rewarding with patents those who discover laws of nature might encourage their discovery. But because those laws and principles are "the basic tools of scientific and technological work," *id.,* at 67, there is a danger that granting patents that tie up their use will inhibit future innovation, a danger that becomes acute when a patented process is no more than a general instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. The patent claims at issue implicate this concern. In telling a doctor to measure metabolite levels and to consider the resulting measurements in light of the correlations they describe, they tie up his subsequent treatment decision re-

gardless of whether he changes his dosage in the light of the inference he draws using the correlations. And they threaten to inhibit the development of more refined treatment recommendations that combine Prometheus' correlations with later discoveries. This reinforces the conclusion that the processes at issue are not patent eligible, while eliminating any temptation to depart from case law precedent. Pp. 16–19.

(c) Additional arguments supporting Prometheus' position—that the process is patent eligible because it passes the "machine or transformation test"; that, because the particular laws of nature that the claims embody are narrow and specific, the patents should be upheld; that the Court should not invalidate these patents under §101 because the Patent Act's other validity requirements will screen out overly broad patents; and that a principle of law denying patent coverage here will discourage investment in discoveries of new diagnostic laws of nature—do not lead to a different conclusion. Pp. 19–24.

628 F. 3d 1347, reversed.

BREYER, J., delivered the opinion for a unanimous Court.

SUPREME COURT OF THE UNITED STATES

No. 10–1150

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., PETITIONERS *v.* PROMETHEUS LABORATORIES, INC.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[March 20, 2012]

JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U. S. C. §101.

The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond* v. *Diehr*, 450 U. S. 175, 185 (1981); see also *Bilski* v. *Kappos*, 561 U. S. ___, ___ (2010) (slip op., at 5); *Diamond* v. *Chakrabarty*, 447 U. S. 303, 309 (1980); *Le Roy* v. *Tatham*, 14 How. 156, 175 (1853); *O'Reilly* v. *Morse*, 15 How. 62, 112–120 (1854); cf. *Neilson* v. *Harford*, Webster's Patent Cases 295, 371 (1841) (English case discussing same). Thus, the Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could

not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, *supra*, at 309 (quoting *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U. S. 127, 130 (1948)).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk* v. *Benson*, 409 U. S. 63, 67 (1972). And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in *Diehr* the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" 450 U. S., at 187 (quoting *Parker* v. *Flook*, 437 U. S. 584, 590 (1978)). It added that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, *supra,* at 187. And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph Co.* v. *Radio Corp. of America,* 306 U. S. 86 (1939):

> "'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'" 450 U. S., at 188 (quoting *Mackay Radio*, *supra*, at 94).

See also *Funk Brothers*, *supra*, at 130 ("If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new

and useful end").

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, *e.g.*, *Benson*, *supra*, at 71–72.

The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook*, *supra*, at 593. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. *Morse*, *supra*, at 112–120; *Benson*, *supra*, at 71–72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. *Flook*, *supra*, at 594; see also *Bilski*, *supra*, at ___ (slip op.,

at 14) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity'" (quoting *Diehr*, *supra*, at 191–192)).

We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

A

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6–TG) and 6-methyl-mercaptopurine (6–MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. See U. S. Patent No. 6,355,623, col. 8, ll. 37–40, 2 App. 10. ("Previ-

ous studies suggested that measurement of 6–MP metabolite levels can be used to predict clinical efficacy and tolerance to azathioprine or 6–MP" (citing Cuffari, Théorêt, Latour, & Seidman, 6-Mercaptopurine Metabolism in Crohn's Disease: Correlation with Efficacy and Toxicity, 39 Gut 401 (1996))). But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. The patent claims at issue here set forth processes embodying researchers' findings that identified these correlations with some precision.

More specifically, the patents—U. S. Patent No. 6,355,623 ('623 patent) and U. S. Patent No. 6,680,302 ('302 patent)—embody findings that concentrations in a patient's blood of 6–TG or of 6–MMP metabolite beyond a certain level (400 and 7000 picomoles per $8x10^8$ red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6–TG metabolite lower than a certain level (about 230 picomoles per $8x10^8$ red blood cells) indicate that the dosage is likely too low to be effective.

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

> "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
> "(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
> "(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
> "wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to

> increase the amount of said drug subsequently administered to said subject and
> "wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, ll. 10–20, 2 App. 16.

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

B

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the '623 and '302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per $8x10^8$ for 6–TG and 5700 pmol per $8x10^8$ for 6–MMP). Prometheus then brought this action claiming patent infringement.

The District Court found that Mayo's test infringed claim 7 of the '623 patent. App. to Pet. for Cert. 110a–115a. In interpreting the claim, the court accepted Prometheus' view that the toxicity-risk level numbers in Mayo's test and the claim were too similar to render the tests significantly different. The number Mayo used (450) was too close to the number the claim used (400) to matter given appropriate margins of error. *Id.,* at 98a–107a. The District Court also accepted Prometheus' view that a doctor using Mayo's test could violate the patent even if he did not actually alter his treatment decision in the light of the test. In doing so, the court construed the claim's language, "indicates a need to decrease" (or "to increase"), as

not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable. *Id.,* at 107a–109a; see also Brief for Respondent i (describing claimed processes as methods "for improving . . . treatment . . . by using individualized metabolite measurements *to inform* the calibration of . . . dosages of . . . thiopurines" (emphasis added)).

Nonetheless the District Court ultimately granted summary judgment in Mayo's favor. The court reasoned that the patents effectively claim natural laws or natural phenomena—namely the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages—and so are not patentable. App. to Pet. for Cert. 50a–83a.

On appeal, the Federal Circuit reversed. It pointed out that in addition to these natural correlations, the claimed processes specify the steps of (1) "administering a [thiopurine] drug" to a patient and (2) "determining the [resulting metabolite] level." These steps, it explained, involve the transformation of the human body or of blood taken from the body. Thus, the patents satisfied the Circuit's "machine or transformation test," which the court thought sufficient to "confine the patent monopoly within rather definite bounds," thereby bringing the claims into compliance with §101. 581 F. 3d 1336, 1345, 1346–1347 (2009) (internal quotation marks omitted).

Mayo filed a petition for certiorari. We granted the petition, vacated the judgment, and remanded the case for reconsideration in light of *Bilski*, 561 U. S. ___, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, but only an important and useful clue. *Id.,* at ___–___ (slip op., at 7–8). On remand the Federal Circuit reaffirmed its earlier conclusion. It thought that the "machine-or-transformation test," understood merely as an important and useful clue,

nonetheless led to the "clear and compelling conclusion . . . that the . . . claims . . . do not encompass laws of nature or preempt natural correlations." 628 F. 3d 1347, 1355 (2010). Mayo again filed a petition for certiorari, which we granted.

II

Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that *if* the levels of 6–TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per $8x10^8$ red blood cells, *then* the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no.

A

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to

monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Bilski*, *supra,* at ___ (slip op., at 14) (quoting *Diehr*, 450 U. S., at 191–192).

Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decisionmaking (rather like Einstein telling linear accelerator

operators about his basic law and then trusting them to use it where relevant).

Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12–65, 2 App. 11. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds. '623 patent, col. 8, ll. 37–40, *id.,* at 10. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. Purely "conventional or obvious" "[pre]-solution activity" is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Flook*, 437 U. S., at 590; see also *Bilski*, 561 U. S., at ___ (slip op., at 14) ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant post-solution activity'" (quoting *Diehr*, *supra*, at 191–192)).

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr*, *supra*, at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in

light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

B

1

A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are *Diehr* and *Flook,* two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. The *Diehr* process (held patent eligible) set forth a method for molding raw, uncured rubber into various cured, molded products. The process used a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. It consisted in effect of the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal "a device" to open the press. *Diehr*, 450 U. S., at 177–179.

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the

equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.,* at 187. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Ibid.* These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.

The process in *Flook* (held not patentable) provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons. Certain operating conditions (such as temperature, pressure, and flow rates), which are continuously monitored during the conversion process, signal inefficiency or danger when they exceed certain "alarm limits." The claimed process amounted to an improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, *e.g.,* the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm-limit values. 437 U. S., at 585–587.

The Court, as in *Diehr,* pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it characterized the claimed process as doing nothing other than "provid[ing] a[n unpatentable] formula for computing an updated alarm limit." *Flook*, *supra*, at 586. Unlike the process in *Diehr*, it did not "explain how the variables used in the formula were to be selected, nor

did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit." *Diehr*, *supra*, at 192, n. 14; see also *Flook*, 437 U. S., at 586. And so the other steps in the process did not limit the claim to a particular application. Moreover, "[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring-alarming'" were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. *Id.,* at 594. "[P]ost-solution activity" that is purely "conventional or obvious," the Court wrote, "can[not] transform an unpatentable principle into a patentable process." *Id.,* at 589, 590.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in *Diehr* was not so characterized; that in *Flook* was characterized in roughly this way.

2

Other cases offer further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable. This Court has previously discussed in detail an English case, *Neilson,* which involved a patent claim that posed a legal problem very similar to the problem now before us. The patent applicant there asserted a claim

> "for the improved application of air to produce heat in fires, forges, and furnaces, where a blowing apparatus is required. [The invention] was to be applied as follows: The blast or current of air produced by the blowing apparatus was to be passed from it into an air-vessel or receptacle made sufficiently strong to endure the blast; and through or from that vessel or receptacle by means of a tube, pipe, or aperture into the fire, the receptacle be kept artificially heated to a considerable temperature by heat externally applied." *Morse*, 15 How., at 114–115.

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an inventive way. Baron Parke wrote (for the court):

> "It is very difficult to distinguish [Neilson's claim] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first

> invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace." *Neilson* v. *Harford*, Webster's Patent Cases, at 371.

Thus, the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle.

In *Bilski* the Court considered claims covering a process for hedging risks of price changes by, for example, contracting to purchase commodities from sellers at a fixed price, reflecting the desire of sellers to hedge against a drop in prices, while selling commodities to consumers at a fixed price, reflecting the desire of consumers to hedge against a price increase. One claim described the process; another reduced the process to a mathematical formula. 561 U. S., at ___–___ (slip op., at 2–3). The Court held that the described "concept of hedging" was "an unpatentable abstract idea." *Id.,* at ___ (slip op., at 15). The fact that some of the claims limited hedging to use in commodities and energy markets and specified that "well-known random analysis techniques [could be used] to help establish some of the inputs into the equation" did not undermine this conclusion, for "*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." *Id.,* at ___, ___ (slip op., at 16, 15).

Finally, in *Benson* the Court considered the patentability of a mathematical process for converting binary-coded decimal numerals into pure binary numbers on a general purpose digital computer. The claims "purported to cover any use of the claimed method in a general-purpose digital computer of any type." 409 U. S., at 64, 65. The Court recognized that "'a novel and useful structure created with the aid of knowledge of scientific truth'" might be patentable. *Id.,* at 67 (quoting *Mackay Radio*, 306 U. S., at 94). But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. For the mathematical formula had "no substantial practical application except in connection with a digital computer." *Benson*, *supra*, at 71. Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said "apply the algorithm."

3

The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in *Morse* the Court set aside as unpatentable Samuel Morse's general claim for "'the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances,'" 15 How., at 86. The Court explained:

> "For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by

> this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee." *Id.*, at 113.

Similarly, in *Benson* the Court said that the claims before it were "so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]." 409 U. S., at 67, 68. In *Bilski* the Court pointed out that to allow "petitioners to patent risk hedging would preempt use of this approach in all fields." 561 U. S., at ___ (slip op., at 15). And in *Flook* the Court expressed concern that the claimed process was simply "a formula for computing an updated alarm limit," which might "cover a broad range of potential uses." 437 U. S., at 586.

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson*, *supra*, at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. See generally Lemley, Risch, Sichelman, & Wagner, Life After *Bilski,* 63 Stan. L. Rev. 1315 (2011) (hereinafter Lemley) (arguing that §101 reflects this kind of concern); see also C. Bohannan & H. Hovenkamp, Creation without Restraint: Promoting Liberty and Rivalry in Innovation 112 (2012) ("One problem with [process] patents is that the more abstractly their claims are stated, the more difficult it is to determine precisely what they cover. They risk being applied to a wide range of situations that were not anticipated by the patentee"); W. Landes & R. Posner, The Economic Struc-

ture of Intellectual Property Law 305–306 (2003) (The exclusion from patent law of basic truths reflects "both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in them and . . . the enormous transaction costs that would be imposed on would-be users [of those truths]").

The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The "determining" step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation

to depart from case law precedent.

III

We have considered several further arguments in support of Prometheus' position. But they do not lead us to adopt a different conclusion. First, the Federal Circuit, in upholding the patent eligibility of the claims before us, relied on this Court's determination that "[t]ransformation and reduction of an article 'to a different state or thing' is *the clue* to the patentability of a process claim that does not include particular machines." *Benson*, *supra*, at 70–71 (emphasis added); see also *Bilski*, *supra*, at ___ (slip op., at 6–7); *Diehr*, 450 U. S., at 184; *Flook*, *supra*, at 588, n. 9; *Cochrane* v. *Deener*, 94 U. S. 780, 788 (1877). It reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels. 628 F. 3d, at 1356–1357.

The first of these transformations, however, is irrelevant. As we have pointed out, the "administering" step simply helps to pick out the group of individuals who are likely interested in applying the law of nature. See *supra,* at 9. And the second step could be satisfied without transforming the blood, should science develop a totally different system for determining metabolite levels that did not involve such a transformation. See *supra,* at 18. Regardless, in stating that the "machine-or-transformation" test is an "*important and useful clue"* to patentability, we have neither said nor implied that the test trumps the "law of nature" exclusion. *Bilski*, *supra*, at ___ (slip op., at 6–7) (emphasis added). That being so, the test fails here.

Second, Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld. Thus, it encourages us to draw distinctions among laws of nature

based on whether or not they will interfere significantly with innovation in other fields now or in the future. Brief for Respondent 42–46; see also Lemley 1342–1344 (making similar argument).

But the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor. See *supra,* at 17. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research. See s*upra*, at 17–18.

In any event, our cases have not distinguished among different laws of nature according to whether or not the principles they embody are sufficiently narrow. See, *e.g., Flook*, 437 U. S. 584 (holding narrow mathematical formula unpatentable). And this is understandable. Courts and judges are not institutionally well suited to making the kinds of judgments needed to distinguish among different laws of nature. And so the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like, which serves as a somewhat more easily administered proxy for the underlying "building-block" concern.

Third, the Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. Brief for United States as *Amicus Curiae.* The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U. S. C. §102, that it not be

"obvious in light of prior art," §103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, §112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

This approach, however, would make the "law of nature" exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections. *Bilski*, 561 U. S. ___; *Diehr*, *supra*; *Flook*, *supra*; *Benson*, 409 U. S. 63. See also H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952) ("A person may have 'invented' a machine or a manufacture, which may include anything under the sun that is made by man, *but it is not necessarily patentable under section 101* unless the conditions of the title are fulfilled" (emphasis added)).

We recognize that, in evaluating the significance of additional steps, the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

What role would laws of nature, including newly discovered (and "novel") laws of nature, play in the Government's suggested "novelty" inquiry? Intuitively, one would suppose that a newly discovered law of nature is novel. The Government, however, suggests in effect that the novelty of a component law of nature may be disregarded when evaluating the novelty of the whole. See Brief for United States as *Amicus Curiae* 27. But §§102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. *Diehr,* 450 U. S., at 188 (patent claims "must be considered as a whole"). And studiously ignoring *all* laws of nature when evaluating a patent application under §§102

and 103 would "make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Id.*, at 189, n. 12. See also Eisenberg, Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After *In re Bilski,* 3 Case W. Res. J. L. Tech. & Internet 1, ___ (forthcoming, 2012) (manuscript, at 85–86, online at http://www.patentlyo.com/files/eisenberg.wisdomordeadhand.patentlyo.pdf (as visited Mar. 16, 2012, and available in Clerk of Court's case file)); 2 D. Chisum, Patents §5.03[3] (2005).

Section 112 requires only a "written description of the invention . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." It does not focus on the possibility that a law of nature (or its equivalent) that meets these conditions will nonetheless create the kind of risk that underlies the law of nature exception, namely the risk that a patent on the law would significantly impede future innovation. See Lemley 1329–1332 (outlining differences between §§101 and 112); Eisenberg, *supra,* at ___ (manuscript, at 92–96) (similar). Compare Risch, Everything is Patentable, 75 Tenn. L. Rev. 591 (2008) (defending a minimalist approach to §101) with Lemley (reflecting Risch's change of mind).

These considerations lead us to decline the Government's invitation to substitute §§102, 103, and 112 inquiries for the better established inquiry under §101.

Fourth, Prometheus, supported by several *amici,* argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Brief for

Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." Brief for American College of Medical Genetics et al. as *Amici Curiae* 7; see also App. to Brief for Association Internationale pour la Protection de la Propriété Intellectuelle et al. as *Amici Curiae* A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another. See Bohannan &

Hovenkamp, Creation without Restraint, at 98–100.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U. S. C. §§161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

* * *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered.

in the manner done by this patentee. Nothing in the record shows that the patentee's concurrent changes in width, depth, and pitch were simply "knowledge so basic that it certainly lies within the skill set of an ordinary artisan." *Mintz v. Dietz & Watson, Inc.,* 679 F.3d 1372, 1377 (Fed.Cir.2012). Yet the evidence is that the consumer has shown a clear preference for the patentee's product as compared with the prior art products. This is highly relevant to the question of obviousness, for the purchasing consumer is in the best position to evaluate technological changes that appear to judges to be minor, yet that are of significance to the product's properties, as measured in the marketplace. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.,* 776 F.2d 281, 306 (Fed.Cir. 1985) ("Secondary considerations may be the most pertinent, probabitve, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/nonobviousness issue.").

The Court observed in *Dickinson v. Zurko,* 527 U.S. 150, 162, 119 S.Ct. 1816, 144 L.Ed.2d 143 (1999), that "[t]he APA requires meaningful review," "not simply rubber-stamping agency factfinding." On the correct law, the polishing pad with the claimed parameters has not been shown to be obvious. From my colleagues' contrary holding, I respectfully dissent.

AKAMAI TECHNOLOGIES, INC., Plaintiff–Appellant,

and

The Massachusetts Institute of Technology, Plaintiff–Appellant,

v.

LIMELIGHT NETWORKS, INC., Defendant–Cross Appellant.

and

McKesson Technologies, Inc. (formerly McKesson Information Solutions, LLC), Plaintiff–Appellant,

v.

Epic Systems Corporation, Defendant–Appellee.

Nos. 2009–1372, 2009–1380, 2009–1416, 2009–1417, 2010–1291.

United States Court of Appeals, Federal Circuit.

Aug. 31, 2012.

Background: In two separate cases, the United States District Court for the District of Massachusetts, Rya W. Zobel, J., 614 F.Supp.2d 90, and the United States District Court for the Northern District of Georgia, Jack T. Camp, J., 2009 WL 2915778, entered judgment in favor of defendants on patent infringement claims, and patentees appealed.

Holding: On rehearing en banc, the Court of Appeals held that a defendant may be held liable for induced infringement of a method patent if the defendant has performed some of the steps of a claimed method and has induced other parties to commit the remaining steps, or if the defendant has induced other parties to collectively perform all the steps of the claimed method, but no single party has performed all of the steps itself; overruling *BMC*

Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373.

Reversed and remanded.

Newman, Circuit Judge, filed dissenting opinion.

Linn, Circuit Judge, filed dissenting opinion in which Dyk, Prost, and O'Malley, Circuit Judges, joined.

1. Patents ⚿226.6, 229

For a party to be liable for direct patent infringement, that party must commit all the acts necessary to infringe the patent, either personally or vicariously; in the context of a method claim, that means the accused infringer must perform all the steps of the claimed method, either personally or through another acting under his direction or control. 35 U.S.C.A. § 271(a).

2. Patents ⚿259(1)

Unlike direct patent infringement, induced infringement is not a strict liability tort; it requires that the accused inducer act with knowledge that the induced acts constitute patent infringement. 35 U.S.C.A. § 271(b).

3. Patents ⚿259(1)

Induced patent infringement does not require that the induced party be an agent of the inducer or be acting under the inducer's direction or control to such an extent that the act of the induced party can be attributed to the inducer as a direct infringer; it is enough that the inducer causes, urges, encourages, or aids the infringing conduct and that the induced conduct is carried out. 35 U.S.C.A. § 271(b).

4. Patents ⚿259(1)

Inducement gives rise to liability for induced patent infringement only if the inducement leads to actual infringement; there can be no indirect infringement without direct infringement. 35 U.S.C.A. § 271(b).

5. Patents ⚿259(1)

A defendant may be held liable for induced infringement of a method patent if the defendant has performed some of the steps of a claimed method and has induced other parties to commit the remaining steps, or if the defendant has induced other parties to collectively perform all the steps of the claimed method, but no single party has performed all of the steps itself; overruling *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373. 35 U.S.C.A. § 271(b).

Donald R. Dunner, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for plaintiffs-appellants on rehearing en banc in appeal nos. 2009–1372, –1380, –1416, and –1417 ("the Akamai appeals"). With him on the brief for Akamai Technologies, Inc. were Kara F. Stoll and Elizabeth D. Ferrill. Of counsel on the brief was Jennifer S. Swan, of Palo Alto, CA. On the brief for The Massachusetts Institute of Technology was Robert S. Frank, Jr., Choate, Hall & Stewart, LLP, of Boston, MA. Of counsel were G. Mark Edgarton and Carlos Perez–Albuerne.

Aaron M. Panner, Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C. of Washington, DC, argued for defendant-cross appellant on rehearing en banc in the Akamai appeals. With him on the brief was Michael E. Joffre. Of counsel on the brief were Dion Messer, Limelight Networks, Inc., of Tempe, AZ. Also on the brief were Alexander F. Mackinnon, Kirkland & Ellis, LLP, of Los Angeles, CA and Young J. Park, of New York, NY. On counsel was John C. Rozendaal, Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C., of Washington, DC.

Raymond P. Niro, Niro, Haller & Niro, of Chicago, IL, for amici curiae Cascades Ventures, Inc. and VNS Corporation on rehearing en banc in the Akamai appeals. With him on the brief was John C. Janka.

Meredith Martin Addy, Brinks Hofer Gilson & Lione, of Chicago, IL, for amici curiae Aristocrat Technologies Australia Pty Limited, et al. on rehearing en banc in the Akamai appeals. Of counsel on the brief was Anthony De Alcuaz, McDermott Will & Emery, LLP, of Menlo Park, CA.

Eric L. Abbott, Shuffle Master, Inc., of Las Vegas, NV, for amicus curiae Shuffle Master, Inc. on rehearing en banc in the Akamai appeals.

Jeffrey W. Francis, Pierce Atwood LLP, of Boston, MA, for amicus curiae Boston Patent Law Association on rehearing en banc in the Akamai appeals.

Benjamin G. Jackson, Myriad Genetics, Inc., of Salt Lake City, UT, for amicus curiae Myriad Genetics, Inc. on rehearing en banc in the Akamai appeals. With him on the brief was Jay M. Zhang.

William G. Barber, Pirkey Barber, LLP, of Austin, TX, for amicus curiae American Intellectual Property Law Association on rehearing en banc in the Akamai appeals.

John W. Ryan, Sullivan & Worcester, of Washington, DC, for amicus curiae Biotechnology Industry Organization on rehearing en banc in the Akamai appeals. With him on the brief was Thomas M. Haas. Of counsel on the brief was Hans Sauer, PH.D., Biotechnology Industry Organization, of Washington, DC.

Robert P. Taylor, Arnold & Porter, LLP, of San Francisco, CA, for amicus curiae Pharmaceutical Research and Manufacturers of America on rehearing en banc in the Akamai appeals. With him on the brief was Monty M. Agarwal. Of counsel on the brief were David R. Marsh and Lisa A. Adelson, of Washington, DC and David E. Korn, Senior Assistant General Counsel, Pharmaceutical Research and Manufacturers of America, of Washington, DC.

Steven C. Sereboff, SoCal IP Law Group, LLP, of Westlake, Village, CA, for amicus curiae Conejo Valley Bar Association on rehearing en banc in the Akamai appeals. With him on the brief were Mark A. Goldstein and M. Karla Sarvaiya.

Julie P. Samuels, Electronic Frontier Foundation, of San Francisco, CA, for amicus curiae Electronic Frontier Foundation on rehearing en banc in the Akamai appeals. Of counsel on the brief was Michael Barclay.

Michael K. Kirschner, Hillis Clark Martin & Peterson, P.S., of Seattle, Washington, for amicus curiae Washington State Patent Law Association on rehearing en banc in the Akamai appeals. With him on the brief was Alexander M. Wu.

Jerry R. Selinger, Patterson & Sheridan, LLP, of Houston, TX, for amicus curiae Altera Corporation, et al. on rehearing en banc in the Akamai appeals. With him on the brief were B. Todd Patterson; and Gero G. McClellan, of Greensboro, NC.

Charles A. Weiss, New York Intellectual Property Law Association, of New York, NY, for amicus curiae New York Intellectual Property Law Association on rehearing en banc in the Akamai appeals. With him on the brief was Theresa M. Gillis.

Calvin L. Litsey, Faegre & Benson, LLP, of Minneapolis, MN, for amicus curiae Thomson Reuters Corporation on rehearing en banc in the Akamai appeals. With him on the brief were Aaron D. Van Oort, Christopher J. Burrell, and Timothy M. Sullivan.

Peter J. Brann, Brann & Isaacson, of Lewiston, ME, for amici curiae Internet Retailers on rehearing en banc in the Akamai appeals. With him on the brief were

David Swetnam–Burland and Stacy O. Stitham.

Garreth A. Sarosi, MetroPSC Wireless, Inc. of Richardson, TX, for amicus curiae MetroPCS Wireless, Inc. on rehearing en banc in the Akamai appeals. With him on the brief was Mark A. Stachiw. On the brief for CTIA–The Wireless Association were Gregory P. Stone, Andrew W. Song and Heather E. Takahashi, Munger, Tolles & Olson, LLP, of Los Angeles, CA.

Timothy S. Teter, Cooley, LLP, of Palo Alto, CA, for amicus curiae Apple Inc. on rehearing en banc in the Akamai appeals. With him on the brief were Lori R. Mason and Benjamin G. Damstedt. Of counsel on the brief were Iain R. Cunningham and Patrick J. Murphy, Apple, Inc., of Cupertino, CA.

Vicki G. Norton, Duane Morris LLP, of San Diego, CA, for amici curiae San Diego Intellectual Property Law Association, et al. on rehearing en banc in the Akamai appeals.

Edward R. Reines, Weil, Gotshal & Manges, LLP, of Redwood Shores, CA, for amici curiae Cisco Systems, Inc., et al. on rehearing en banc in the Akamai appeals. With him on the brief was Nathan Greenblatt.

Matthew D. McGill, Gibson, Dunn & Crutcher LLP, of Washington, DC, for amici curiae for Facebook, Inc., et al. on rehearing en banc in the Akamai appeals. With him on the brief was William G. Jenks.

Steven Gardner, Kilpatrick Townsend & Stockton LLP, of Winston–Salem, NC, for amicus curiae The Financial Services Roundtable on rehearing en banc in the Akamai appeals. With him on the brief was Alton L. Absher III. Of counsel on the brief was Gia L. Cincone, of San Francisco, CA.

Daryl L. Joseffer, King & Spalding, LLP, of Washington, DC, argued for plaintiff-appellant on rehearing en banc in appeal no.2010–1291 ("the McKesson appeal"). With him on the brief were Timothy G. Barber and Adam M. Conrad, of Charlotte, NC. Of counsel was Paul D. Clement, King & Spalding, of Washington, DC.

Steven D. Moore, of Kilpatrick Stockton LLP, of Atlanta, GA, argued for defendant-appellee on rehearing en banc in the McKesson appeal. With him on the brief were William H. Boice, Russell A. Korn, D. Clay Holloway and Jason D. Gardner. Of counsel on the brief was Adam H. Charnes, of Winston–Salem, NC.

Meredith Martin Addy, Brinks Hofer Gilson & Lione, of Chicago, IL, for amici curiae Aristocrat Technologies Australia Pty Limited, et al. on rehearing en banc in the McKesson appeal. With her on the brief was Anthony De Alcuaz, McDermott Will & Emery LLP, of Menlo Park, CA.

Jay Z. Zhang, Myriad Genetics, Inc., of Salt Lake City, UT, for amicus curiae Myriad Genetics, Inc. on rehearing en banc in the McKesson appeal. With him on the brief was Benjamin G. Jackson.

Hans Sauer, Ph.D., Biotechnology Industry Organization, of Washington, DC, for amicus curiae Biotechnology Industry Organization on rehearing en banc in the McKesson appeal. Of counsel on the brief were John W. Ryan and Thomas M. Haas, Sullivan & Worcester, of Washington, DC.

Robert P. Taylor, Arnold & Porter LLP, of San Francisco, CA, for amicus curiae Pharmaceutical Research and Manufacturers of America on rehearing en banc in the McKesson appeal. With him on the brief was Monty M. Agarwal. Of counsel on the brief were David R. Marsh and Lisa A. Adelson, of Washington, DC; and David E. Korn, Senior Assistant General Counsel, Pharmaceutical Research and Manufacturers of America, of Washington, DC.

William G. Barber, Pirkey Barber LLP, of Austin, TX, for amicus curiae American Intellectual Property Law Association on rehearing en banc in the McKesson appeal.

Julie Samuels, Electronic Frontier Foundation, of San Francisco, CA, for amicus curiae Electronic Frontier Foundation on rehearing en banc in the McKesson appeal. With her on the brief was Michael Barclay.

Sanford E. Warren, Jr., Akin Gump Strauss Hauer & Feld LLP, of Dallas, TX, for amicus curiae Encore Wire Corporation on rehearing en banc in the McKesson appeal. With him on the brief was Rex S. Heinke, of Los Angeles, CA.

Jerry R. Selinger, Patterson & Sheridan LLP, of Houston, TX, for amicus curiae Altera Corporation, et al. on rehearing en banc in the McKesson appeal. With him on the brief were B. Todd Patterson; and Gero G. McClellan, of Greensboro, NC.

Garreth A. Sarosi, of MetroPCS Wireless, Inc. of Richardson, TX, for amicus curiae MetroPCS Wireless, Inc. on rehearing en banc in the McKesson appeal. With him on the brief was Mark A. Stachiw. On the brief for CTIA–The Wireless Association were Gregory P. Stone, Andrew W. Song and Heather E. Takahashi, Munger, Tolles & Olson, LLP, of Los Angeles, CA.

Edward R. Reines, Weil, Gotshal & Manges, LLP, of Redwood Shores, CA, for amici curiae Cisco Systems, Inc., et al. on rehearing en banc in the McKesson appeal. With him on the brief was Nathan Greenblatt.

Charles A. Weiss, New York Intellectual Property Law Association, of New York, NY, for amicus curiae New York Intellectual Property Law Association, on rehearing en banc in the McKesson appeal. With him on the brief were John M. Hintz and Theresa M. Gillis.

Eric L. Abbott, Shuffle Master, Inc. of Las Vegas, NV, for amicus curiae Shuffle Master, Inc. on rehearing en banc in the McKesson appeal.

Before RADER, Chief Judge, NEWMAN, LOURIE, BRYSON, LINN, DYK, PROST, MOORE, O'MALLEY, REYNA, and WALLACH, Circuit Judges.

Opinion of the court filed PER CURIAM. Dissenting opinion filed by Circuit Judge NEWMAN. Dissenting opinion filed by Circuit Judge LINN, in which Circuit Judges DYK, PROST, and O'MALLEY join.

PER CURIAM.

When a single actor commits all the elements of infringement, that actor is liable for direct infringement under 35 U.S.C. § 271(a). When a single actor induces another actor to commit all the elements of infringement, the first actor is liable for induced infringement under 35 U.S.C. § 271(b). But when the acts necessary to give rise to liability for direct infringement are shared between two or more actors, doctrinal problems arise. In the two cases before us, we address the question whether a defendant may be held liable for induced infringement if the defendant has performed some of the steps of a claimed method and has induced other parties to commit the remaining steps (as in the *Akamai* case), or if the defendant has induced other parties to collectively perform all the steps of the claimed method, but no single party has performed all of the steps itself (as in the *McKesson* case).

The problem of divided infringement in induced infringement cases typically arises only with respect to method patents. When claims are directed to a product or apparatus, direct infringement is always present, because the entity that installs the final part and thereby completes the

claimed invention is a direct infringer. But in the case of method patents, parties that jointly practice a patented invention can often arrange to share performance of the claimed steps between them. In fact, sometimes that is the natural way that a particular method will be practiced, as the cases before us today illustrate. Recent precedents of this court have interpreted section 271(b) to mean that unless the accused infringer directs or controls the actions of the party or parties that are performing the claimed steps, the patentee has no remedy, even though the patentee's rights are plainly being violated by the actors' joint conduct. We now conclude that this interpretation of section 271(b) is wrong as a matter of statutory construction, precedent, and sound patent policy.

Much of the briefing in these cases has been directed to the question whether direct infringement can be found when no single entity performs all of the claimed steps of the patent. It is not necessary for us to resolve that issue today because we find that these cases and cases like them can be resolved through an application of the doctrine of induced infringement. In doing so, we reconsider and overrule the 2007 decision of this court in which we held that in order for a party to be liable for induced infringement, some other single entity must be liable for direct infringement. *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed.Cir.2007). To be clear, we hold that all the steps of a claimed method must be performed in order to find induced infringement, but that it is not necessary to prove that all the steps were committed by a single entity.

I

The essential facts of the cases before us are as follows:

Akamai Technologies, Inc., owns a patent that covers a method for efficient delivery of web content. The claimed method consists of placing some of a content provider's content elements on a set of replicated servers and modifying the content provider's web page to instruct web browsers to retrieve that content from those servers. Akamai filed a complaint against Limelight Networks, Inc., alleging infringement of the patent. In its complaint, Akamai alleged both direct and induced infringement. Limelight maintains a network of servers and, as in the patented method, it allows for efficient content delivery by placing some content elements on its servers. Limelight, however, does not modify the content providers' web pages itself. Instead, Limelight instructs its customers on the steps needed to do that modification.

McKesson Information Solutions LLC owns a patent covering a method of electronic communication between healthcare providers and their patients. McKesson filed a complaint against Epic Systems Corp. alleging that Epic induced infringement of the patent. Epic is a software company that licenses its software to healthcare organizations. The licensed software includes an application called "MyChart," which permits healthcare providers to communicate electronically with patients. McKesson alleged that Epic induced Epic's customers to infringe McKesson's patent. Epic does not perform any steps of the patent. Instead, those steps are divided between patients, who initiate communications, and healthcare providers, who perform the remainder of the steps.

In the respective district court cases, Limelight and Epic were held not to infringe the patents asserted against them. In *Akamai*, because Limelight's customers (and not Limelight itself) performed one of the steps of the claimed method, the district court granted Limelight's motion for judgment as a matter of law based on this court's opinions in *BMC* and *Muniauction*,

Inc. v. Thomson Corp., 532 F.3d 1318 (Fed.Cir.2008). In *McKesson*, the district court relied on the same cases to grant summary judgment of noninfringement on the ground that the patients (and not Epic's direct customers) performed the step of initiating the communication.

II

A

[1] This court has held that for a party to be liable for direct patent infringement under 35 U.S.C. § 271(a), that party must commit all the acts necessary to infringe the patent, either personally or vicariously. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed.Cir.2005); *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1568 (Fed. Cir.1983). In the context of a method claim, that means the accused infringer must perform all the steps of the claimed method, either personally or through another acting under his direction or control. Direct infringement has not been extended to cases in which multiple independent parties perform the steps of the method claim. Because direct infringement is a strict liability tort, it has been thought that extending liability in that manner would ensnare actors who did not themselves commit all the acts necessary to constitute infringement and who had no way of knowing that others were acting in a way that rendered their collective conduct infringing. *See In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed.Cir.2007) (en banc) ("Because patent infringement is a strict liability offense, the nature of the offense is only relevant in determining whether enhanced damages are warranted."). For that reason, this court has rejected claims of liability for direct infringement of method claims in cases in which several parties have collectively committed the acts necessary to constitute direct infringement, but no single party has committed all of the required acts. *See BMC*, 498 F.3d at 1381 ("Direct infringement is a strict-liability offense, but it is limited to those who practice each and every element of the claimed invention."); *see also Muniauction*, 532 F.3d at 1329 (same).

To be sure, the court has recognized that direct infringement applies when the acts of infringement are committed by an agent of the accused infringer or a party acting pursuant to the accused infringer's direction or control. *See BMC*, 498 F.3d at 1380. Absent an agency relationship between the actors or some equivalent, however, a party that does not commit all the acts necessary to constitute infringement has not been held liable for direct infringement even if the parties have arranged to "divide" their acts of infringing conduct for the specific purpose of avoiding infringement liability. *See Cross Med. Prods.*, 424 F.3d at 1311 (no liability for direct infringement if the party that is directly infringing is not acting as an agent of, or at the direction of, the accused infringer).

Because the reasoning of our decision today is not predicated on the doctrine of direct infringement, we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement under 35 U.S.C. § 271(a).

B

The induced infringement provision of the Patent Act, 35 U.S.C. § 271(b), provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Because section 271(b) extends liability to a party who advises, encourages, or otherwise induces others to engage in infringing conduct, it is well suited to address the problem presented by the cases before us, i.e., whether liability should extend to a party who induces the

commission of infringing conduct when no single "induced" entity commits all of the infringing acts or steps but where the infringing conduct is split among more than one other entity.

[2, 3] Induced infringement is in some ways narrower than direct infringement and in some ways broader. Unlike direct infringement, induced infringement is not a strict liability tort; it requires that the accused inducer act with knowledge that the induced acts constitute patent infringement. *See Global–Tech Appliances, Inc. v. SEB S.A.,* —— U.S. ——, 131 S.Ct. 2060, 2068, 179 L.Ed.2d 1167 (2011). In fact, this court has described the required intent as follows: "[I]nducement requires that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.,* 471 F.3d 1293, 1306 (Fed.Cir.2006) (en banc) (internal quotation marks omitted).[1] On the other hand, inducement does not require that the induced party be an agent of the inducer or be acting under the inducer's direction or control to such an extent that the act of the induced party can be attributed to the inducer as a direct infringer. It is enough that the inducer "cause[s], urge[s], encourage[s], or aid[s]" the infringing conduct and that the induced conduct is carried out. *Arris Grp., Inc. v. British Telecomms. PLC,* 639 F.3d 1368, 1379 n. 13 (Fed.Cir.2011); *see also Tegal Corp. v. Tokyo Electron Co.,* 248 F.3d 1376, 1379 (Fed.Cir.2001); *Nat'l Presto Indus., Inc. v. West Bend Co.,* 76 F.3d 1185, 1196 (Fed.Cir.1996) (analogizing inducement to aiding and abetting violations of criminal laws).

[4] An important limitation on the scope of induced infringement is that inducement gives rise to liability only if the inducement leads to actual infringement. That principle, that there can be no indirect infringement without direct infringement, is well settled. *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518, 526, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972); *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 365 U.S. 336, 341, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961); *Henry v. A.B. Dick Co.,* 224 U.S. 1, 12, 32 S.Ct. 364, 56 L.Ed. 645 (1912). The reason for that rule is simple: There is no such thing as attempted patent infringement, so if there is no infringement, there can be no indirect liability for infringement.

[5] That much is uncontroversial. In *BMC,* however, this court extended that principle in an important respect that warrants reconsideration. In that case, the court ruled that in order to support a finding of induced infringement, not only must the inducement give rise to direct infringement, but in addition the direct infringement must be committed by a single actor. The court reached that conclusion based on the propositions that (1) liability for induced infringement requires proof of direct infringement and (2) liability for direct infringement requires that a single party commit all the acts necessary to constitute infringement. While those two propositions were well supported in this court's law, the conclusion that the court drew from them was not.

Requiring proof that there *has been* direct infringement as a predicate for induced infringement is not the same as requiring proof that a single party would

1. Because liability for inducement, unlike liability for direct infringement, requires specific intent to cause infringement, using inducement to reach joint infringement does not present the risk of extending liability to persons who may be unaware of the existence of a patent or even unaware that others are practicing some of the steps claimed in the patent.

be *liable* as a direct infringer. If a party has knowingly induced others to commit the acts necessary to infringe the plaintiff's patent and those others commit those acts, there is no reason to immunize the inducer from liability for indirect infringement simply because the parties have structured their conduct so that no single defendant has committed all the acts necessary to give rise to liability for direct infringement.

A party who knowingly induces others to engage in acts that collectively practice the steps of the patented method—and those others perform those acts—has had precisely the same impact on the patentee as a party who induces the same infringement by a single direct infringer; there is no reason, either in the text of the statute or in the policy underlying it, to treat the two inducers differently. In particular, there is no reason to hold that the second inducer is liable for infringement but the first is not.

Likewise, a party who performs some of the steps itself and induces another to perform the remaining steps that constitute infringement has precisely the same impact on the patentee as a party who induces a single person to carry out all of the steps. It would be a bizarre result to hold someone liable for inducing another to perform all of the steps of a method claim but to hold harmless one who goes further by actually performing some of the steps himself. The party who actually participates in performing the infringing method is, if anything, more culpable than one who does not perform any steps.

The text of the induced infringement statute is entirely consistent with this analysis. While the direct infringement statute, section 271(a), states that a person who performs the acts specified in the statute "infringes the patent," section 271(b) is structured differently. It provides that whoever "actively induces infringement of a patent shall be liable as an infringer." Nothing in the text indicates that the term "infringement" in section 271(b) is limited to "infringement" by a single entity. Rather, "infringement" in this context appears to refer most naturally to the acts necessary to infringe a patent, not to whether those acts are performed by one entity or several.

C

The legislative history of the 1952 Patent Act provides strong support for interpreting induced infringement not to require that a single entity—as opposed to multiple entities—commit all the acts necessary to constitute infringement. Prior to the 1952 Act, inducement and contributory infringement were both referred to under the rubric of contributory infringement. Giles S. Rich, *Infringement Under Section 271,* 21 Geo. Wash. L.Rev. 521, 537 (1953). The 1952 Act broke the two concepts out into separate subsections of section 271, covering induced infringement (in subsection (b)) and contributory infringement (in subsection (c)). Subsection (b), the new inducement provision, was broad in scope. The House Report on the 1952 Act explained that the new subsection (b) "recites in broad terms that one who aids and abets an infringement is likewise an infringer." H.R.Rep. No. 82–1923, at 9. *See also* P.J. Federico, *Commentary on the New Patent Act* reprinted in 75 J. Pat. & Trademark Off. Soc'y 161, 214 (1993) (section 271(b) "is a broad statement and enactment of the principle that one who actively induces infringement of a patent is likewise liable for infringement").[2] On the

2. Federico's commentary, first published in 1954, has been cited by this court as constituting "an invaluable insight into the intentions of the drafters of the Act." *Symbol Techs., Inc. v. Lemelson Med.,* 277 F.3d 1361, 1366 (Fed.Cir.2002).

other hand, subsection (c) represented a compromise between differing views as to the proper scope of the doctrine of contributory infringement. The portions of the legislative history addressing subsection (c) show that it was responding to the Supreme Court's decisions in several then-recent cases that had applied the doctrine of patent misuse in a way that substantially restricted the scope of contributory infringement.[3] The compromise that Congress adopted with respect to subsection (c) restored the doctrine of contributory infringement and confined the scope of the Supreme Court's patent misuse cases, but it did not go as far as some in the patent bar would have liked. *See Hearing on H.R. 3866 Before Subcomm. No. 4 of the H. Comm. on the Judiciary,* 81st Cong. 20 (1949) ("1949 Hearing") (statement of G. Rich) ("So we have made what we consider to be a fair compromise, and we have pushed back these misuse situations to cover only those cases where we think the patentee is entitled to honest protection and justice.").

Although less was said about induced infringement than about contributory infringement in the legislative history, what was said was significant. Giles Rich, one of the principal drafters of the statute, and a frequent witness at hearings on the legislation, made clear in the course of his statement during an early House hearing on contributory infringement that the revised provisions on infringement were intended to reach cases of divided infringement, even when no single entity would be liable for direct infringement. In the course of his statement commenting on the proposed version of what was to become section 271(b) of the 1952 Act, Judge (then Mr.) Rich addressed the problem of "combination patents" and stated the following:

> Improvements in such arts as radio communication, television, etc., sometimes involve the new combinations of elements which in use are normally owned by different persons. Thus, a new method of radio communication may involve a change in the transmitter and a corresponding change in the receiver. To describe such an invention in patent claims, it is necessary either to specify *a new method which involves both transmitting and receiving,* or a new combination of an element in the receiver and an element in the transmitter. There are patents with such claims covering television inventions of importance.
>
> The recent decisions of the Supreme Court [the cases targeted by the statutory changes] appear to make it impossible to enforce such patents in the usual case where a radio transmitter and a radio receiver are owned and operated by different persons, *for, while there is obvious infringement of the patent, there is no direct infringer of the patent but only two contributory infringers.*

Contributory Infringement of Patents: Hearings Before the Subcomm. on Patents, Trade-marks, and Copyrights of the H. Comm. on the Judiciary, 80th Cong. 5 (1948) ("1948 Hearing") (statement of G. Rich on behalf of the New York Patent Law Association) (emphasis added).

3. The cases to which the legislation was principally directed were *Mercoid Corp. v. Mid–Continent Investment Co.,* 320 U.S. 661, 64 S.Ct. 268, 88 L.Ed. 376 (1944), and *Mercoid Corp. v. Minneapolis–Honeywell Regulator Co.,* 320 U.S. 680, 64 S.Ct. 278, 88 L.Ed. 396 (1944), which extended the patent misuse doctrine of *Carbice Corp. of America v. American Patents Development Corp.,* 283 U.S. 27, 51 S.Ct. 334, 75 L.Ed. 819 (1931), and *Leitch Manufacturing Co. v. Barber Co.,* 302 U.S. 458, 58 S.Ct. 288, 82 L.Ed. 371 (1938). *See Contributory Infringement of Patents: Hearings Before the Subcomm. on Patents, Trademarks, and Copyrights of the H. Comm. on the Judiciary,* 80th Cong. 4 (1948) (statement of G. Rich on behalf of the New York Patent Law Association).

Judge Rich's statement makes clear that he saw no anomaly in finding liability for indirect infringement when there was "obvious infringement of the patent" even though there was "no direct infringer of the patent." In the hypothetical case that he described, involving a claim to a method in which changes would be made in both a transmitter and a receiver, he expressly stated that the "obvious infringement" should be remediable, even though "there is no direct infringer" of the patent, a description that perfectly fits the two cases before us.

As if to lay to rest any doubts as to his views of the proper scope of indirect infringement under the new statute, Judge Rich added, in response to questioning, that "contributory infringement [apparently referring to both contributory infringement and induced infringement] is a specific application to patent law of the law of joint tort feasor where two people somehow together create an infringement which neither one of them individually or independently commits." *Id.* at 12; *see also* 1949 Hearing 3 (remarks of G. Rich) ("When two people combine and infringe a patent in some way or other, they are joint tort feasors, and it so happens that patents are often infringed by people acting in concert, either specifically or by implication, where neither one of them is a direct infringer."). Again, Judge Rich's comments clearly indicate that he viewed indirect infringement as an available remedy even in the absence of any single direct infringer.

The principles of contributory and induced infringement set forth in the earlier bills were carried forward into the 1952 Act and continued to serve the purpose of restoring the principles of contributory infringement that had been cast into doubt by the then-recent patent misuse decisions. *See* H.R.Rep. No. 82–1923, at 9 (1952); *Patent Law Codification and Revision, Hearings Before Subcomm. No. 3 of the H. Comm. on the Judiciary,* 82d Cong. 151–52 (1951); Rich, *Infringement Under Section 271, supra,* at 535–36, 541 (substance of 271 was carried forward from previous bills).

D

A principal's liability for acts committed not only through an agent but also by an innocent intermediary who was induced by the principal is not an idiosyncrasy of patent law, but is found in other areas of the law as well. For example, the aiding and abetting provision in the Federal Criminal Code states, in language similar to the language of section 271(b) of the Patent Act, that "[w]hoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission is punishable as a principal," 18 U.S.C. § 2(a), and "[w]hoever willfully causes an act to be done which if directly performed by him or another would be an offense against the United States, is punishable as a principal," *id.* § 2(b). That statute has been construed to permit the conviction of an accessory who induces or causes a criminal offense even when the principal is found not liable for the unlawful conduct. *Standefer v. United States,* 447 U.S. 10, 19, 100 S.Ct. 1999, 64 L.Ed.2d 689 (1980). As long as the induced criminal conduct has occurred, the inducer's liability does not turn on whether the intermediary is factually guilty or even capable of committing the charged offense. *See United States v. Tobon–Builes,* 706 F.2d 1092, 1099 (11th Cir. 1983) (defendant is liable if he causes an intermediary to commit a criminal act, even though the intermediary who performed the act has no criminal intent and hence is innocent of the substantive crime charged); *United States v. Gleason,* 616 F.2d 2, 20 (2d Cir.1979) ("[A] person who causes an innocent party to commit an act

which, if done with the requisite intent, would constitute an offense may be found guilty as a principal even though he personally did not commit the criminal act."); *United States v. Rapoport*, 545 F.2d 802, 806 (2d Cir.1976) ("Section 2(b) ... 'removes all doubt that one who puts in motion or assists in the illegal enterprise or causes the commission of an indispensable element of the offense by an innocent agent or instrumentality, is guilty....'") (quoting Reviser's Note to section 2(b)).[4] Under that provision, a defendant cannot avoid criminal liability by arranging for another to perform some part of the proscribed conduct. *See United States v. Hornaday*, 392 F.3d 1306, 1313 (11th Cir. 2004) ("Section 2(b) ... is obviously designed for the situation in which ... the defendant supplies the intent and maybe another element or two while getting someone else to supply at least one additional element that is necessary to the commission of the crime."); *United States v. Pearson*, 667 F.2d 12, 13 (5th Cir.1982) (Section 2 "allows a jury to find a person guilty of a substantive crime even though that person did not commit all acts constituting the elements of the crime.").

Tort law also recognizes the doctrine of liability for inducing innocent actors to commit tortious acts. The Second Restatement of Torts provides that a person is liable for tortious conduct if he "orders or induces the conduct, if he knows or should know of circumstances that would make the conduct tortious if it were his own." *Restatement (Second) of Torts* § 877(a) (1979). That basis for liability is "independent of the existence of liability" based "on the ground that [the defendant] was principal or master." *Id.* § 877 cmt. a.

The analogy to tort law is particularly telling because for induced infringement under section 271(b) the courts look to the common law principles of joint tortfeasance. *Hewlett–Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed.Cir. 1990); *see also Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 500, 84 S.Ct. 1526, 12 L.Ed.2d 457 (1964). Prior to the enactment of the Patent Act in 1952, courts applied indirect infringement to anyone who "commands, directs, advises, encourages, procures, instigates, promotes, controls, aids, or abets" patent infringement. Rich, *Infringement Under Section 271, supra*, at 525. Section 271(b) was enacted to codify that doctrine, which in turn was based on "the old common law doctrine of joint tort feasors." *Id.* at 537. In that setting, liability requires proof that the defendant "knowingly induced infringement and possessed specific intent to encourage another's infringement." *DSU Med. Corp.*, 471 F.3d at 1306.

The First Restatement of Torts, which was in effect at the time the 1952 Patent Act was enacted, draws an even sharper line than the Second Restatement between vicarious liability for tortious conduct and liability for inducing tortious conduct by others. Section 877 of the First Restatement sets forth the rules of vicarious liability for "a person directing or permitting conduct of another." *Restatement of Torts* § 877 (1938). Section 876 sets forth the rules of liability for inducement of tortious

4. *Shuttlesworth v. City of Birmingham*, 373 U.S. 262, 83 S.Ct. 1130, 10 L.Ed.2d 335 (1963), cited in Judge Linn's dissent, is inapposite. In that case, the underlying act was innocent, not because of any lack of scienter or immunity on behalf of the principals, but because the act the petitioners were charged with aiding and abetting did not constitute a crime. *Id.* at 265, 83 S.Ct. 1130 ("There was no evidence that any of the demonstrations which resulted from the meeting were disorderly or otherwise in violation of law.") By analogy, in patent law a party would not be liable for inducing infringement by encouraging others to engage in conduct that is not within the claims of the patent in suit.

conduct, including the requirement of scienter. It states that a person is liable if he "orders or induces [tortious] conduct, knowing of the conditions under which the act is done or intending the consequences which ensue," or if he "knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself." *Id.* § 876.

Moreover, the First Restatement makes clear that the rule imposing liability for inducement of a tort applies even if the person being induced is unaware that his act is injurious and is not liable for that reason. *Id.* § 876 cmt. b; *see Hoyt v. Clancey,* 180 F.2d 152, 158 (8th Cir.1950) (defendant liable for false representations passed through an innocent intermediary; intermediary not liable); *Davis v. Louisville Trust Co.,* 181 F. 10, 15 (6th Cir.1910) (same); *Graham v. Ellmore,* 135 Cal.App. 129, 26 P.2d 696 (1933) (same); *Moyer v. Lederer,* 50 Ill.App. 94 (Ill.App.Ct.1893) (same); *Kuehl v. Parmenter,* 195 Iowa 497, 192 N.W. 429 (Iowa 1923) (same); *see also Restatement of Torts* § 880 cmt. a (one who induces a witness to make a defamatory remark on the witness stand is liable even though the witness enjoys immunity from liability); *Laun v. Union Elec. Co.,* 350 Mo. 572, 166 S.W.2d 1065, 1071 (1943) (same); *Midford v. Kann,* 32 A.D. 228, 52 N.Y.S. 995 (N.Y.App.Div.1898) (defendant liable for false imprisonment for directing police to arrest former employees as trespassers without regard to whether police were liable). The implication of that principle, as applied in the divided infringement context, is that a party may be liable for inducing infringement even if none of the individuals whose conduct constituted infringement would be liable, as direct infringers, for the act of infringement that was induced.[5]

Judge Linn's dissent argues that the cited cases based liability on "breach of a direct duty" and are therefore "direct liability cases." That misses the point being made. The cited cases all involved intermediate actors who directly caused the injury to the plaintiff, but were not liable for that injury, while the party who induced the action causing the injury was held liable. As in those cases, an inducer of infringement has a duty not to cause the acts that constitute infringement even if the parties who cause the direct injury are not liable. The law frequently imposes a duty (and liability upon breach of the duty) on parties who use innocent third parties to carry out harmful acts. *See Pelster v. Ray,* 987 F.2d 514, 523–24 (8th Cir.1993) (civil liability for rolling back odometer attaches to anyone in the chain of ownership who knew of fraudulent reading, but not to innocent intermediaries); *Learjet Corp. v. Spenlinhauer,* 901 F.2d 198, 203 (1st Cir.1990) (cause of action for fraudulent misrepresentation by aircraft owner against aircraft manufacturer was proper where manufacturer allegedly made false representations to FAA to obtain certification and owner relied on FAA certification when purchasing aircraft); *Hawkins v. Upjohn Co.,* 890 F.Supp. 609, 611–12 (E.D.Tex.1994) (indirect reliance by plaintiffs on misrepresentations by defendants to FDA in effort to secure approval of drugs was sufficient to state claim of fraud); *see also Restatement (Second) of Torts* § 533 (one who makes a fraudulent misrepresentation is subject to liability to

5. The same rule extending liability for "intentionally inducing or encouraging direct infringement" has been adopted in copyright law, *see Metro–Goldwyn–Mayer Studios Inc. v. Grokster, Ltd.,* 545 U.S. 913, 930, 936, 125 S.Ct. 2764, 162 L.Ed.2d 781 (2005), but the issue presented in this case—whether the induced acts of infringement must be performed by a single entity that would be liable for infringement—does not appear to have been addressed in copyright cases.

one who relies on it to his detriment, even though the misrepresentation was not made directly to the injured party).

E

Judge Linn's dissent argues that the approach we adopt today has the effect of "defin[ing] direct infringement differently for the purposes of establishing liability under § 271(a) and (b)." That is not so, and the structure of section 271 explains why. Section 271(a) does not define the term "infringement." Instead, it simply sets forth a type of conduct that qualifies as infringing, i.e., it provides that anyone who makes, uses, or sells, etc., any patented invention "infringes the patent." Section 271(b) sets forth another type of conduct that qualifies as infringing, i.e., it provides that anyone who induces infringement "shall be liable as an infringer." But nothing in the text of either subsection suggests that the act of "infringement" required for inducement under section 271(b) must qualify as an act that would make a person liable as an infringer under section 271(a).

An examination of other subsections of section 271 confirms that the statute uses the term "infringement" in a way that is not limited to the circumstances that give rise to liability under section 271(a). For example, section 271(e)(2) makes it an "act of infringement" to submit an application to the FDA for a drug, or the use of a drug, claimed in a patent; that use of the term "infringement" is not in any way tied to the use of the term "infringes" in section 271(a). Similarly, section 271(f) provides that a party shall be "liable as an infringer" if it supplies in the United States a substantial portion of the components of a patented invention in such manner as to induce the combination of those components outside the United States. Again, the statutory term "infringer" does not advert to the requirements of section 271(a); indeed, it is not even necessary that the components are ever actually assembled abroad after export. *See Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1367–68 (Fed.Cir.2001). Finally, section 271(g) provides that a person who imports into the United States a product made by a process patented in the United States "shall be liable as an infringer." That provision likewise does not require that the process used to make the imported product be "infringing" in a way that would satisfy section 271(a), such as being performed by a single entity.

Judge Linn's dissent also relies on another provision of the Patent Act, 35 U.S.C. § 281, which states, "A patentee shall have remedy by civil action for infringement of his patent." Section 281, however, was designed to serve as a "preamble" for the sections on remedies and to ensure that an action for infringement (a "civil action") would be triable to a jury. *See* H.R.Rep. No. 82–1923, at 10, 29 (1952). It also serves to ensure that only "[a] patentee" may bring a civil action for infringement. *See Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 240 F.3d 1016, 1017 (Fed.Cir.2001). It cannot also be read to mean that any act of infringement will necessarily be remediable through a civil action; it does not, for example, give a patentee a "remedy by civil action" (i.e., in district court, *see* Fed.R.Civ.P. 2) against state or federal officers who are protected from suit and liability by sovereign immunity or (in the case of federal officers) who are suable only in a nonjury proceeding in the Court of Federal Claims.

The origin of section 281 is enlightening in this regard. When the bill that ultimately became the 1952 Act was first introduced in 1950 (as H.R. 9133), the subsection that would become section 271 read as follows: "Any person who makes, uses or sells any patented machine, manufacture, composition of matter or improve-

ment, or uses any patented process or improvement, within the territory of the United States and its Territories during the term of the patent therefor without authority, infringes the patent *and shall be liable to a civil action for infringement,* except as otherwise provided in this title." (emphasis added). That version of section 271 stated only that one who directly infringes a patent shall be liable. It did not declare that any practicing of a patented invention necessarily brought with it the right of the patent owner to recover in a civil action for infringement. The emphasized language was later moved and turned into a separate section—section 281—but with no indication that a change in meaning was intended. There is certainly no suggestion in the legislative history (or in subsequent caselaw) that section 281 was meant to restrict the scope of liability for induced infringement under section 271(b) to cases in which a single entity would be liable for direct infringement.

Looking to case law, Judge Linn's dissent relies heavily on prior decisions of this court and on the Supreme Court's decision in *Aro,* contending that those authorities compel us to hold that liability for induced infringement of a method claim depends on showing that a single induced entity would be liable for direct infringement of the claim. While the *BMC* case stands for that proposition, our earlier precedents, and the Supreme Court's decision in *Aro,* do not so hold.

In reciting the rule that indirect infringement requires a single entity to commit all the acts necessary to constitute direct infringement, the court in *BMC* cited this court's earlier opinion in *Dynacore Holdings Corp. v. U.S. Philips Corp.,* 363 F.3d 1263, 1272 (Fed.Cir.2004). The cited portion of the *Dynacore* case stands for the proposition that indirect infringement "can only arise in the presence of direct infringement." 363 F.3d at 1272. That proposition, however, is different in an important respect from the proposition articulated in *BMC. Dynacore* required that there be infringement in order for there to be inducement of infringement. As noted above, that is a sound and uncontroversial proposition. *BMC,* however, extended that proposition to require that a single party commit the entire act of direct infringement, an extension that is not supported by the decision in *Dynacore.*[6] That broader proposition invites evasion of the principles of patent infringement and serves no policy-based purpose. If an entity has induced conduct that infringes a patent, there is no justification for immunizing the inducer from liability simply because no single party commits all of the components of the appropriative act.

Both Limelight and Epic (like Judge Linn's dissent) rely on the Supreme Court's decision in *Aro* in support of their contention that liability for inducement requires that a single party be liable for direct infringement, but *Aro* does not stand for that proposition. *Aro* dealt with a patent for automobile convertible tops, including the fabric and supporting structures. 365 U.S. at 337, 81 S.Ct. 599. The accused product was fabric that was intended to replace the original fabric in the convertible top when it wore out. The

6. The *Dynacore* case dealt with a patent on a type of local area network. 363 F.3d at 1266. The issue in the case was whether manufacturers of networking equipment that was capable of being used to form an infringing network were liable for indirect infringement. *Id.* at 1272. Dynacore alleged only a "hypothetical direct infringement" and did not show that any specific infringing network was ever created. The court held that liability for indirect infringement required proof that actual infringement occurred, but the court did not hold that Dynacore could meet its burden of showing direct infringement only by proving that a single entity created the infringing network.

specific question addressed by the Court was "does the car owner [directly] infringe (and the supplier contributorily infringe) the combination patent when he replaces the spent fabric without the patentee's consent?" *Id.* at 339, 81 S.Ct. 599. Because the Court concluded that replacing the fabric was not an infringing "reconstruction," but instead was a permissible "repair," the Court held that the car owner did not infringe the patent. And because there was no direct infringement, there was no contributory infringement. As the Court explained: "In a word, if there is no infringement of a patent there can be no contributory infringer[.]" *Id.* at 345, 81 S.Ct. 599. Importantly, it was because the purchaser of the fabric was engaged in repair rather than reconstruction—and thus was not guilty of infringement at all—that the Court found there could be no contributory infringement. That case therefore does not stand, expressly or implicitly, for the proposition that there can be no induced infringement if there is actual infringing conduct but the acts necessary to constitute the infringement are committed by more than one party.

In the course of its analysis, the *Aro* Court quoted from a dissenting opinion in an earlier case, which stated that "if the purchaser and user [of a product] could not be amerced as an infringer certainly one who sold to him ... cannot be amerced for contributing to a non-existent infringement." *Id.* (quoting *Mercoid Corp. v. Mid–Continent Inv. Co.,* 320 U.S. 661, 674, 64 S.Ct. 268, 88 L.Ed. 376 (1944) (Roberts, J., dissenting)). Although the reference to a direct infringer being "amerced" as an infringer could suggest that the Court considered liability for direct infringement as a predicate for indirect infringement, the Court in both cases was addressing direct infringement involving only a single party.

Unlike the present case, which deals with method claims, *Aro* dealt with product claims. In the case of a product claim, the party that adds the final element to the combination "makes" the infringing product and thus is liable for direct infringement even if others make portions of the product. *See Cross Med. Prods.,* 424 F.3d at 1312 (holding there was a genuine issue of fact as to whether surgeons infringe by "making" the claimed product when they complete the last limitation (contacting the anchor seat of the device with bone)). For product claims, whenever the product is made, used, or sold, there is always a direct infringer. Hence, the *Aro* Court, dealing only with product claims, was not presented with the divided infringement question we address today. For that reason, the Court's allusion to the potential liability of a direct infringer cannot reasonably be treated as suggesting that, as a predicate for indirect infringement, all of the steps necessary to constitute direct infringement of a method claim must be committed by a single party.

In cases prior to *BMC,* this court on numerous occasions recited the familiar and uncontroversial proposition that one of the elements of induced infringement is proof that there has been direct infringement. *See, e.g., Micro Chem., Inc. v. Great Plains Chem. Co.,* 103 F.3d 1538, 1549 (Fed.Cir.1997); *Joy Techs., Inc. v. Flakt, Inc.,* 6 F.3d 770, 774 (Fed.Cir.1993); *Met–Coil Sys. Corp. v. Korners Unlimited, Inc.,* 803 F.2d 684, 687 (Fed.Cir.1986). On occasion, the court described that principle by reference to direct infringement by "some party" or the party accused of direct infringement in the case. *See, e.g., Moba, B.V. v. Diamond Automation, Inc.,* 325 F.3d 1306, 1318 (Fed.Cir.2003); *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.,* 279 F.3d 1022, 1033 (Fed.Cir.2002); *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.,* 246 F.3d 1336, 1351

(Fed.Cir.2001); *Kendall Co. v. Progressive Med. Tech., Inc.*, 85 F.3d 1570, 1573 (Fed. Cir.1996); *C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc.*, 911 F.2d 670, 673 (Fed.Cir.1990). But in none of those cases did the court hold that, as a predicate for a finding of indirect infringement, all the steps of a method claim must be performed by the same entity. Those cases trace the rule that direct infringement is a prerequisite for induced indirect infringement back to the Supreme Court's opinion in *Aro* and its predecessors which, as discussed above, did not require that all the infringing steps be performed by a single actor.

The cases that predated *Aro* likewise did not apply the "single direct infringer" requirement as a predicate for induced infringement; instead, they emphasized that what was induced was the fact of infringement, not liability for direct infringement by a single actor. In one of the leading early cases, Judge (later Chief Justice) Taft wrote for the Sixth Circuit that it was "well settled that where one makes and sells one element of a combination covered by a patent with the intention and for the purpose of bringing about its use in such a combination he is guilty of contributory infringement." *Thomson–Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 721 (6th Cir.1897). Most of the early cases involved product claims, not process claims, and therefore the ultimate purchaser or user of the patented invention was a direct infringer, so the problem of divided infringement did not arise. Where it did arise, however, courts continued to look to the doctrine of induced (or contributory) infringement as a basis for liability of parties who had induced the infringing conduct.

For example, in *Solva Waterproof Glue Co. v. Perkins Glue Co.*, 251 F. 64 (7th Cir.1918), the defendants performed one step of a two-step process claim and relied upon their customers to perform the second step of the process. The court held the defendant to be a contributory infringer. It explained that the "rule of law in such case is that one who makes and sells one element of a patented combination with the intention and for the purpose of bringing about its use in such a combination is guilty of contributory infringement." 251 F. at 73–74.

Similarly, in *Peerless Equipment Co. v. W.H. Miner, Inc.*, 93 F.2d 98 (7th Cir. 1937), the Seventh Circuit dealt with a case closely analogous to the cases at bar. In that case, which involved a patent containing process claims, the defendant performed all the steps of the claimed process except the last. The purchaser would perform the last step after delivery of the products. The court observed that the defendant knew that the purchasers would perform that step. Accordingly, the court held that the defendant was "guilty of contributory infringement of each of the process claims." 93 F.2d at 105.

This court reached the same result in *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed.Cir.1983). The patent in that case involved both product and process claims. As in the *Peerless* case, the defendant performed all but the last step of the recited process; the last step was performed by the defendant's customers. Because no single party performed all the steps, the court stated that the defendant "cannot be liable for direct infringement." *Id.* at 1568. However, it added, the defendant "could be liable for contributory infringement." *Id.* at 1567–68. That case thus provides direct support for the two key propositions at issue in this case: (1) that liability for direct infringement requires that some actor perform all of the limitations (including the steps of a process claim), either personally or vicariously; and (2) that induced infringement can be

found even if there is no single party who would be liable for direct infringement.

In summing up its objections to this court's ruling, Judge Linn's dissent argues that the court today is making a "sweeping change to the nation's patent policy" that goes beyond the proper scope of the court's authority and that a step such as the one taken by the en banc court today should be left to Congress. Of course, the question whether the majority's position constitutes a change in the law, or whether the dissent's position would constitute a change, depends on what one thinks the prior rule was. Based on the legislative history, general tort principles, and prior case law, including this court's decision in *Fromson*, we believe that *BMC* and the cases that have followed it changed the pre-existing regime with respect to induced infringement of method claims, although admittedly at that time there were relatively few cases in which that issue had arisen. In either event, the court's task is to attempt to determine what Congress had in mind when it enacted the induced infringement statute in 1952. At the end of the day, we are persuaded that Congress did not intend to create a regime in which parties could knowingly sidestep infringement liability simply by arranging to divide the steps of a method claim between them. And we have found no evidence to suggest that Congress intended to create different rules for method claims than for other types of claims. While we believe that our interpretation of section 271(b) represents sound policy, that does not mean that we have adopted that position as a matter of policy preference. In the process of statutory interpretation, it is relevant to ask what policy Congress was attempting to promote and to test each party's proposed interpretation by asking whether it comports with that policy. In these cases, we conclude that it is unlikely that Congress intended to endorse the "single entity rule," at least for the purpose of induced infringement, advocated by Epic and Limelight, which would permit ready evasion of valid method claims with no apparent countervailing benefits.

III

In the *McKesson* case, Epic can be held liable for inducing infringement if it can be shown that (1) it knew of McKesson's patent, (2) it induced the performance of the steps of the method claimed in the patent, and (3) those steps were performed. McKesson preserved its claim of induced infringement, even though this court's decisions in *BMC* and *Muniauction* made the inducement claim difficult to maintain. McKesson is entitled to litigate that issue on remand to the district court.

In the *Akamai* case, although the jury found that the content providers acted under Limelight's direction and control, the trial court correctly held that Limelight did not direct and control the actions of the content providers as those terms have been used in this court's direct infringement cases. Notwithstanding that ruling, under the principles of inducement laid out above, Limelight would be liable for inducing infringement if the patentee could show that (1) Limelight knew of Akamai's patent, (2) it performed all but one of the steps of the method claimed in the patent, (3) it induced the content providers to perform the final step of the claimed method, and (4) the content providers in fact performed that final step.

Although the patentee in *Akamai* did not press its claim of induced infringement at trial, it argues this court should overrule "the mistaken view that only a single entity can infringe a method claim." That argument, while focused on direct infringement, is critical to the conclusion that divided infringement can give rise to liability, whether under a theory of direct infringement or induced infringement.

While we do not hold that Akamai is entitled to prevail on its theory of direct infringement, the evidence could support a judgment in its favor on a theory of induced infringement. For that reason, we conclude that Akamai should be given the benefit of this court's ruling disapproving the line of divided infringement cases that the district court felt compelled to follow. We therefore reverse the judgment in both cases and remand in both cases for further proceedings on the theory of induced infringement.

REVERSED and REMANDED

NEWMAN, Circuit Judge, dissenting.

This *en banc* court has split into two factions, neither of which resolves the issues of divided infringement. A scant majority of the court adopts a new theory of patent infringement, based on criminal law, whereby any entity that "advises, encourages, or otherwise induces," maj. op. 1307, or "causes, urges, encourages, or aids the infringing conduct," *id.* at 1308, is liable for the infringing conduct. The majority further holds that only the "inducer" is liable for divided infringement, and that the direct infringers are not liable although the patent rights are "plainly being violated by the actors' joint conduct." *Id.* at 1306. These are dramatic changes in the law of infringement.

On this new "inducement-only rule," the inducing entity is liable on greatly enlarged grounds, such as merely advising or encouraging acts that may constitute direct infringement. This new rule is not in accordance with statute, precedent, and sound policy. It raises new issues unrecognized by the majority, and contains vast potential for abuse. In turn, the two cases here on appeal can readily be resolved under existing law, as the majority opinion almost acknowledges in its remand instructions. Maj. op. 1318–19.

In contrast, a significant minority of the *en banc* court continues to favor the "single-entity rule," whereby divided infringement is not actionable at all unless all of the participants are in a contract or agency relationship that is directed or controlled by a single "mastermind." Although review of the singe-entity rule was the sole reason for this rehearing *en banc,* and the sole question briefed by the parties and the *amici curiae,* this aspect is not resolved by the majority, which simply states that it will not review the law of direct infringement, apparently on the theory that the inducement-only rule renders irrelevant whether there is a single mastermind of the direct infringement.

Neither faction provides a reasonable answer to the *en banc* questions concerning divided infringement. However, the issues of liability and remedy arising from interactive methods and collaborative performance are readily resolved by application of existing law. Issues of induced infringement are not new, but this aspect is ill served by the majority's distortion of the inducement statute, 35 U.S.C. § 271(b), and has no support in theory or practice. This new rule simply imposes disruption, uncertainty, and disincentive upon the innovation communities. I respectfully dissent.

DISCUSSION

This *en banc* court was convened in order to resolve inconsistencies in past panel rulings for situations in which different entities perform separate parts of a patented method. In the two earlier decisions whose rulings were the announced focus of this *en banc* review, *BMC Resources, Inc. v. Paymentech, L.P.,* 498 F.3d 1373 (Fed.Cir.2007) and *Muniauction, Inc. v. Thomson Corp.,* 532 F.3d 1318 (Fed.Cir.2008), panels of this court held that when separate entities perform the

steps of a patented method, there cannot be direct infringement unless a single mastermind directs or controls the performance of all of the steps. These decisions held that since there cannot be direct infringement without such direction or control, there cannot be indirect infringement by inducement or contributory infringement. Thus, the court held that there can be no liability for infringement, although all of the claim steps are performed. *BMC Resources*, 498 F.3d at 1379; *Muniauction*, 532 F.3d at 1329. This single-entity rule was applied by the district courts in the *Akamai* and *McKesson* decisions that are here on appeal, to deny all liability for infringement. We took these appeals *en banc* in order to resolve the conflicts within precedent.

The *en banc* court has been unable to reach consensus. The dissenting opinion authored by Judge Linn adheres to the single-entity rule, and the majority opinion presents the new position that when more than one entity performs the steps of a patented invention, the only liable entity is the inducer, not those who directly infringe the claim. Such an inducement-only rule has never been held, in any case. It has no foundation in statute, or in two centuries of precedent. The *en banc* majority, embracing this new rule, does not acknowledge the new problems of enforcement and compensation and defense that are also created, the new opportunities for gamesmanship and abuse and inequity. For example, if the direct infringers are not liable for infringement, one wonders whether they are subject to damages or injunction. These and other critical issues should be considered before a new law of inducement-only infringement is adopted.

The majority holds that there is "a duty not to cause the acts that constitute infringement even if the parties who cause the direct injury are not liable." Maj. op. 1313. I agree that we all have a duty to respect the law, but in the complexities of technology and commerce, one must wonder at the imposition of liability solely for "urg[ing]" or "encourag[ing]," *id.* at 1308, while exonerating direct infringers from liability when the patented method is "collectively practice[d]." *Id.* at 1309.

The prior laws of infringement effectively handled interactive and collaborative forms of infringement, before either the single-entity rule or the inducement-only rule. Before the law is changed so that only an inducer can be liable for divided infringement, on loose criteria for inducement, this court should at least obtain the advice of those who understand the consequences of this change in infringement law. This unannounced *en banc* ruling is made without briefing by the parties or notice to the *amici curiae*.[1]

1. Briefs *amicus curiae* were filed by Altera Corp., HTC Corp., HTC America, Inc., and Weatherford International; American Intellectual Property Law Association; Aristocrat Technologies Australia Pty Ltd. and Aristocrat Technologies, Inc.; Apple Inc.; Biotechnology Industry Organization; Boston Patent Law Association; CTIA—The Wireless Association and MetroPCS Wireless, Inc.; Cascades Ventures, Inc. and VNS Corp.; Cisco Systems, Inc., Dell, Inc., eBay Inc., Google Inc., Hewlett–Packard Co., Intel Corp., Intuit, Inc., Micron Technology, Inc., NetApp, Inc., RingCentral, Inc., SAP America, Inc., Symantec Corp., Yahoo, Inc., and Zynga Inc.; Conejo Vally Bar Association; Electronic Frontier Foundation; Encore Wire Corp.; Facebook, Inc. and LinkedIn Corp.; Internet Retailers; Myriad Genetics, Inc.; New York Intellectual Property Law Association; Pharmaceutical Research and Manufacturers of America; Shuffle Master, Inc.; The Financial Services Roundtable; San Diego Intellectual Property Law Association, The Foundry Group, First Round Capital, and Kedrosky Capital; Thomson Reuters Corp.; and Washington State Patent Law Association.

I

THE *EN BANC* ISSUE

The only issue for which these cases were taken *en banc*, the only issue on which briefing was solicited from the parties and *amici curiae*, was the conflict in precedent arising from the single-entity rule of *BMC Resources* and *Muniauction*. The concerned communities had expressed concern with this conflict, but the *en banc* majority now declines its responsibility, and states that "we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement." Maj. op. 1307. The majority rejects the single-entity rule only "as a predicate for a finding of indirect infringement." *Id.* at 1317. The majority explains that it overrules *BMC Resources* "in which we held that in order for a party to be liable for induced infringement, some other single entity must be liable for direct infringement." *Id.* at 1306.

Instead, the majority holds that when more than one entity is involved, only the inducer is liable for infringement, although the patent rights are "plainly being violated by the actors' joint conduct," and the inducer acts to "encourage[ ]" the infringement. *Id.* at 1306, 1307–08. The court thus avoids the *en banc* issue, even as it creates a new liability; yet the court gives no attention to the accompanying new issues such as the measure of damages, or the availability of remedy against direct infringement. While the majority states that it "overrule[s]" *BMC Resources*, *id.* at 1306, it is far from clear, for the majority also cites *BMC Resources* and *Muniauction* as precedent, *id.* at 1307 ("[T]his court has rejected claims of liability for direct infringement of method claims in cases in which several parties have collectively committed the acts necessary to constitute direct infringement, but no single party has committed all of the required acts."), and *id.* ("To be sure, the court has recognized that direct infringement applies when the acts of infringement are committed by an agent of the accused infringer or a party acting pursuant to the accused infringer's direction or control."). The majority appears to overrule only a single sentence of *BMC Resources*, at 498 F.3d at 1379: "Indirect infringement requires, as a predicate, a finding that some party amongst the accused actors has committed the entire act of direct infringement." The majority also defines "inducement" as not "direction or control to such an extent that the act of the induced party can be attributed to the inducer as a direct infringer," maj. op. 1308, and preserves the rulings of *Muniauction* and *Golden Hour Data Systems, Inc. v. emsCharts, Inc.*, 614 F.3d 1367 (Fed.Cir.2010), and holds that interactive and collaborative infringement is not actionable. The majority's theory is a spontaneous judicial creation. And it is wrong.

It is apparent that this jurisprudence is in need of correction, clarification, and consistency, for neither the single-entity rule nor the majority's newly minted inducement-only rule is in accord with the infringement statute, or with any reasonable infringement policy. In contrast, the established law and precedent of 35 U.S.C. § 271 can readily reach and remedy every infringement situation that has been presented.

Cases of divided infringement have not caused past turmoil, as the majority announces. However, turmoil will surely be created, to the detriment of technological advance and its industrial development, for stability and clarity of the law are essential to innovative commerce.

II

THE SINGLE-ENTITY RULE

Questions of divided infringement are not new, but resolution by way of the

single-entity rule is plainly inadequate. The district court remarked in the *McKesson* case, after applying this court's rulings in *BMC Resources* and *Muniauction*, that the single-entity rule leaves a meritorious patentee without redress:

> [T]he single entity rule and *BMC*'s interpretation thereof severely limits the protection provided for patents which would otherwise be valid and enforceable. . . . As long as the sale of a product constitutes an arms length transaction between the customer and the infringing company, which is insufficient to create vicarious liability, the patent holder would likely have no redress against the infringer. This result weakens the policy of providing protection to those who devote the time and resources to develop otherwise novel and patentable methods.

McKesson Info. Solutions LLC v. Epic Sys. Corp., 2009 WL 2915778, at *7 (N.D.Ga. Sept. 8, 2009).

In *McKesson* the first step of the multi-step claim to an interactive health-care method requires the patient to enter the system—a step held not directed or controlled by contract or agency, whereby the district court stated that it was required to hold that there was not direct infringement, and thus that McKesson's claim for induced infringement must fail. Had the district court not been constrained by the single-entity rule, the case could easily have been decided on long-standing infringement law.

Direct infringement may be by more than one entity

The court in *BMC Resources* held that the single-entity rule "derives from the statute itself," 498 F.3d at 1380, and the defendants herein press this argument. The statute at § 271(a) states the fundamental requirements of patent infringement, and is sometimes called the "direct infringement" provision:

> § 271(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

The word "whoever" in § 271(a) does not support the single-entity rule. By statutory canon the word "whoever" embraces the singular and plural. The first statute in the United States Code, 1 U.S.C. § 1, states that:

> § 1. In determining the meaning of any Act of Congress, unless the context indicates otherwise—
>
> words importing the singular include and apply to several persons, parties, or things; . . . the words 'person' and 'whoever' include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals. . . .

This principle was cited in *United States v. Oregon & C.R. Co.*, 164 U.S. 526, 541, 17 S.Ct. 165, 41 L.Ed. 541 (1896) and *Barr v. United States*, 324 U.S. 83, 91, 65 S.Ct. 522, 89 L.Ed. 765 (1945). The usage "whoever" appears not only in § 271 of Title 35, but in §§ 101, 161, and 171 in referring to inventors without distinguishing between singular and plural. *See In re Henriksen*, 55 CCPA 1384, 399 F.2d 253, 258 (1968) (1 U.S.C. § 1 applies to Title 35). Neither the defendants nor any *amicus* has offered any reason to view "whoever" differently in § 271, the patent infringement statute.

Direct infringement requires that every claimed step of a patented method or system is performed in accordance with the limitations stated in the claim. Thus, when more than one entity performs all of the steps, the claim is directly infringed. Until the rulings in *BMC Resources* and *Muniauction*, it was not disputed that

when a claimed method is performed without authorization, the claim is infringed. *See, e.g., Graver Tank & Mfg. Co. v. Linde Air Products Co.,* 339 U.S. 605, 607, 70 S.Ct. 854, 94 L.Ed. 1097 (1950) ("If accused matter falls clearly within the claim, infringement is made out and that is the end of it."); *Warner–Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997) (for infringement, every element of the claim must be performed, literally or by an equivalent).

Infringement is not a question of how many people it takes to perform a patented method. The Court observed in *Aro Manufacturing Co. v. Convertible Top Replacement Co.,* 365 U.S. 336, 342, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961) that "§ 271(a) of the new Patent Code, which defines 'infringement,' left intact the entire body of case law on direct infringement." As applied to the steps of a claimed process, the law before and after the 1952 Act has been stable. *E.g., Joy Techs., Inc. v. Flakt, Inc.,* 6 F.3d 770, 773 (Fed.Cir.1993) (to infringe a process claim, every claimed step of the process must be performed); *Mowry v. Whitney,* 81 U.S. 620, 652, 14 Wall. 620, 20 L.Ed. 860 (1871):

> The exclusive use of them singly is not secured to him. What is secured is their use when arranged in the process. Unless one of them is employed in making up the process, and as an element of it, the patentee cannot prevent others from using it.

The Court stated in *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518, 522, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972) that "Infringement is defined by 35 U.S.C. § 271 in terms that follow those of § 154." Section 154, "the keystone provision of the patent code," *id.,* codifies every patentee's right to exclude "others" from practicing the patented invention:

> § 154(a)(1) Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention....

The legislative history of the 1952 Patent Act reflects the linkage between § 154 and § 271, the House Committee Report explaining that § 271(a) was "not actually necessary":

> Section 271, paragraph (a), is a declaration of what constitutes infringement. There is no declaration of what constitutes infringement in the present statute. It is not actually necessary because the granting clause [35 U.S.C. § 154] creates certain exclusive rights and infringement would be any violation of those rights.

H.R.Rep. No. 82–1923, at 9 (1952). The same guidance appears in the Senate Committee Report, S.Rep. No. 82–1979, at 8 (1952), 1952 U.S.C.C.A.N. 2394. Giles S. Rich, a principal contributor to the 1952 Patent Act, summarized that "Paragraph (a) defines direct infringement and is present only for the sake of completeness. We got along without it for 162 years and we could again. Its omission would change nothing." G.S. Rich, *Infringement Under Section 271 of the Patent Act of 1952,* 21 Geo. Wash. L.Rev. 521, 537 (1953).

The linkage between § 154 and § 271 finds its mooring in the law as summarized in Professor Robinson's classic *The Law of Useful Inventions* (1890) at Section 897:

> The nature of the act of infringement is indicated by that of the exclusive right which it invades. Hence an infringement may be committed either by making, using, or selling the patented invention. These words, however, are interpreted as comprehending every method by which the invention can be made available for the benefit of the

> infringer, and any person who participates in any wrongful appropriation of the invention becomes thereby a violator of the rights protected by the patent.

(footnote omitted). This court has lost sight of this statutory foundation, although, as the Court explained in *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10, 33 S.Ct. 616, 57 L.Ed. 1041 (1913), "Congress did not use technical or occult phrases" in "defining the extent of the rights and privileges secured to a patentee."

The conflicts in precedent should be resolved

Although the word "whoever" in the infringement statute is not limited to a single-entity, this does not resolve the questions of joint or collaborative or interactive infringement that are raised by this court's rulings in *BMC Resources* and *Muniauction*, and relied on by the district courts in *Akamai* and *McKesson*. In *BMC Resources* this court held that the claims could not be directly infringed, on facts whereby the defendant Paymentech, who provided a computerized system for verifying and paying debit transactions, did not direct or control the performance of separate process steps by the debit networks that routed the transactions to the financial institutions who paid the amounts verified. Although Paymentech administered the system and provided transaction information to the debit networks, the panel observed that it was not shown that "Paymentech also provides instructions or directions regarding the use of those data," and that there was "no evidence even of a contractual relationship between Paymentech and the financial institutions." *BMC Resources*, 498 F.3d at 1381–82. The panel held that because Paymentech did not direct or control the actions of these participating entities, the claims were not directly infringed, and that without direct infringement there could not be induced or contributory infringement by the provider of the claimed method.

In *Muniauction* this court elaborated on *BMC Resources*, and explained that direction or control requires more than controlling access to a system or the issuance of instructions for performance of a claim step. The claimed invention was a method of conducting bond auctions over an electronic network, and the patentee Muniauction had argued that direct infringement was met because the defendant Thomson controlled access to the auction system and instructed bidders on participating in the system. At the trial the district court instructed the jury on the law of direct infringement, as follows:

> Consider whether the parties are acting jointly or together in relation to the electronic auction process. Are they aware of each other's existence and interacting with each other in relation to the electronic auction process? Is there one party teaching, instructing, or facilitating the other party's participation in the electronic auction process? These are the types of questions that you should ask in making your decision on this issue. If you find that there is a sufficient connection between Thomson and the bidders and the issuers that used Thomson's process, then you could find Thomson liable for direct infringement.

Jury instruction, quoted in *Muniauction*, 532 F.3d at 1329. The jury found that the claims were infringed, and the district court denied JMOL. On appeal this court criticized the jury instruction, stating that "none of the questions identified by the jury instruction are relevant to whether Thomson satisfies the 'control or direction' standard of *BMC Resources*." *Id.* at 1330. The court held that although Thomson controlled access to its electronic auction system and instructed bidders on its use,

the claimed method could not be directly infringed because Thomson did not direct or control the actions of the bidders.

Applying these principles, the Federal Circuit panel in *Akamai* elaborated that the requirements of direction or control are not satisfied unless any separate entity involved in direct infringement is acting as the agent of, or by contract with, the mastermind of the entire performance. 629 F.3d 1311 (Fed.Cir.2010). This holding has no support in precedent. In *On Demand Machine Corp. v. Ingram Industries, Inc.*, 442 F.3d 1331, 1344–45 (Fed. Cir.2006), this court approved a jury instruction that summarized precedent as it then existed, as follows:

> It is not necessary for the acts that constitute infringement to be performed by one person or entity. When infringement results from the participation and combined action(s) of more than one person or entity, they are all joint infringers and jointly liable for patent infringement. Infringement of a patented process or method cannot be avoided by having another perform one step of the process or method. Where the infringement is the result of the participation and combined action(s) of one or more persons or entities, they are joint infringers and are jointly liable for the infringement.

To add to the confusion, some cases declined to follow the single-entity rule, or carved new exceptions. For example, in *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1309 (Fed.Cir.2011) a panel of this court held: "That other parties are necessary to complete the environment in which the claimed element functions does not necessarily divide the infringement between the necessary parties." In *Centillion Data Systems, LLC v. Qwest Communications International, Inc.*, 631 F.3d 1279, 1285 (Fed.Cir.2011) a panel of this court held that a claim to a multi-step system could be directly infringed, although the infringer did not perform or direct or control "the back-end processing" of the accused system. In contrast, in *Golden Hour*, 614 F.3d at 1371, a panel of this court held that there could be no direct infringement, although all of the claim steps were performed by two entities that "formed a strategic partnership, enabled their two programs to work together, and collaborated to sell the two programs as a unit."

I take note of the Linn cadre's argument that ingenious patent claim drafting can avoid single-entity problems, and undoubtedly it would help in some situations. I do not discourage ingenuity, but the presence or absence of infringement should not depend on cleverness or luck to satisfy a malleable single-entity rule. The Court in *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188, 100 S.Ct. 2601, 65 L.Ed.2d 696 (1980), discussing the law of contributory infringement, cautioned lest "the technicalities of patent law" enable persons "to profit from another's invention" by performing "acts designed to facilitate infringement by others."

Lessons from copyright law

Useful guidance has evolved in connection with copyright law, for copyright and patent law are in "close[ ] analogy." *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 439, 104 S.Ct. 774, 78 L.Ed.2d 574 (1984). The Court stated in *Metro–Goldwyn–Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 930, 125 S.Ct. 2764, 162 L.Ed.2d 781 (2005) that one "infringes vicariously by profiting from direct infringement while declining to exercise a right to stop or limit it," citing *Shapiro, Bernstein & Co. v. H.L. Green Co.*, 316 F.2d 304, 307 (2d Cir.1963).

Defendants Limelight and Epic Systems state that vicarious infringement is inapposite in the cases before us, for no one entity performs all steps of the claimed

invention. That theory is incorrect. Both of the defendants agree that agency is a form of attribution, which includes *respondeat superior.* Restatement (Third) of Agency § 7.07(1) (2006). However, as explained in *A & M Records, Inc. v. Napster, Inc.,* 239 F.3d 1004, 1022 (9th Cir.2001), "Vicarious copyright liability is an 'outgrowth' of respondeat superior," quoting *Fonovisa, Inc. v. Cherry Auction, Inc.,* 76 F.3d 259, 262 (9th Cir.1996). Given "the historic kinship between patent law and copyright law," *Sony,* 464 U.S. at 439, 104 S.Ct. 774, there is no reason why agency theory attributes the performance of claim steps but the principle of vicarious infringement does not.

The court should simply acknowledge that a broad, all-purpose single-entity requirement is flawed, and restore infringement to its status as occurring when all of the claimed steps are performed, whether by a single entity or more than one entity, whether by direction or control, or jointly, or in collaboration or interaction.

III

The Inducement-Only Rule

The majority opinion states that "Direct infringement has not been extended to cases in which multiple independent parties perform the steps of the method claim." Maj. op. 1307. That is of course incorrect. Despite this challenged statement, the court's opinion never reaches the issue, although it was extensively briefed by the parties and the many *amici curiae.* Instead, the majority holds that "[i]t is not necessary for us to resolve that issue today" of "the question whether direct infringement can be found when no single entity performs all of the claimed steps of the patent." *Id.* at 1306. The authority cited for "reject[ing] claims of liability for direct infringement of method claims in cases in which several parties have collectively committed the acts necessary to constitute direct infringement" is *BMC Resources* and *Muniauction. Id.* at 1307. These are the cases that led to convening this *en banc* court. Thus the majority discards decades of precedent, refuses our *en banc* responsibility, and states that "we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement." *Id.* The apparent justification is the new inducement-only rule of liability.

The court holds that only inducement to infringe is actionable when the claim is practiced by two or more entities, and that there can be no liability for direct infringement. The court holds that "the acts necessary to constitute direct infringement" are different from "the acts specified in the statute [§ 271(a)]," *id.* at 1307, 1309, and other new theories. The majority relies on the criminal law principles codified at 18 U.S.C. § 2. However, "[t]he analogy between accomplice liability and contributory infringement fails given careful consideration of the reasons behind imposing criminal sanctions on indirect actors." M. Bartholomew, *Cops, Robbers, and Search Engines: The Questionable Role of Criminal Law in Contributory Infringement Doctrine,* 2009 BYU L.Rev. 783, 786. Bartholomew points out at page 807 the differences between accomplice liability and contributory infringement:

> As it stands currently, contributory infringement law does not require the strong showings of intent required for accomplice liability in criminal law.... [W]hile both contributory liability doctrines [*e.g.,* induced and contributory infringement] allow the defendant's mental state to be inferred through circumstantial evidence, infringement law takes a comparatively generous approach in determining what evidence is probative of knowledge of the underlying illegal act. Most importantly, ac-

> complice liability places little stock in the *actus reus* requirement while contributory infringement decisions often hinge on whether the defendant's actions were 'material' enough to justify liability.

The LaFave treatise reiterates that "[c]onsiderable confusion exists as to what the accomplice's mental state must be in order to hold him accountable for an offense committed by another." *Criminal Law* § 13.2, at 712 (5th ed.2010).[2]

The majority opinion states that "the problem presented by the cases before us [is] whether liability should extend to a party who induces the commission of infringing conduct." *Id.* at 1307. That is not the problem presented. Liability for inducement is established by statute. The problem before the court is not whether an inducer, properly defined, is liable for infringement; the problem is whether a method patent is infringed when more than one entity performs the claimed steps of the method. Until the *BMC* line of cases held that the answer is "no" unless there is an agency or contractual relationship among all of the performing entities, this question was resolved by application of the existing laws of infringement, whether direct, induced, or contributory infringement.

In accordance with § 271(c) the entity that provides the system that is used to perform the claimed method, or steps thereof, for which there is no substantial noninfringing use, is liable for contributory infringement—it is noteworthy that the court's opinion does not distinguish between induced and contributory infringement, misciting precedent accordingly. The rules of contributory infringement, in which the court seeks support for its elimination of liability for direct infringement, were established to provide liability in situations in which the contributory infringer knows that "the combination for which his component was especially designed was both patented and infringing," as the Court explained in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488, 84 S.Ct. 1526, 12 L.Ed.2d 457 (1964). In *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565 (Fed.Cir.1983) this court ruled that there could be contributory infringement by the provider of the printing plate, when the final step of coating of the plate is performed by the customer.

As summarized in *Aro*, 377 U.S. at 512, 84 S.Ct. 1526, contributory infringement is "designed for cases where enforcement against direct infringers is impracticable." (quotation omitted). *See also Dawson*, 448 U.S. at 188, 100 S.Ct. 2601 ("This protection [of contributory infringement] is of particular importance in situations, like the oil lamp case itself [*Wallace v. Holmes*, 29 F. Cas. 74 (No. 17,100) (C.C.D.Conn. 1871)], where enforcement against direct infringers would be difficult, and where the technicalities of patent law make it relatively easy to profit from another's invention without risking a charge of direct infringement."). The court's opinion incorrectly treats these cases as "inducement" cases. Inducement is a different concept, and the new breadth with which the court infuses the concept is an unwarranted and unsupported enlargement of the law.

2. The majority also defends its adventure into uncharted infringement law, by reciting other assorted special statutes, such as the Hatch–Waxman Act's artificial infringement provision for challenge to a patent when there is no case or controversy because there is no infringement, in order to enable generic drug producers to test the patent while prohibited from making or selling the patented product. § 271(e)(2). This special expedient does not justify this court's creation of a new law of infringement.

Liability for inducement requires direct infringement

Precedent establishes the circumstances in which the purveyor of less than the entire claimed invention can be liable for infringement. For all forms of indirect infringement liability, it is necessary to establish that the claimed invention is directly infringed. My colleagues hedge, and while acknowledging that "there can be no indirect infringement without direct infringement," maj. op. 1308, the court holds that there need not be direct infringers. I need not belabor the quandary of how there can be direct infringement but no direct infringers.

Judge Rich, in *Hewlett–Packard Co. v. Bausch & Lomb, Inc.,* 909 F.2d 1464, 1469 (Fed.Cir.1990), explained that under common law "[contributory infringement] liability was under a theory of joint tortfeasence, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor." The requirement of a "primary tortfeasor" applies to inducement, as has long been understood: "Liability under 35 U.S.C. 271(b) requires the existence of direct infringement by another party which is actionable under 35 U.S.C. 271(a)." C. Miller, *Some Views on the Law of Patent Infringement by Inducement,* 53 J. Pat. Off. Soc'y 86, 102 (1971). I take note of the majority's statement that an inducer is not liable for inducing "others to engage in conduct that is not within the claims of the patent in suit." Maj. op. 1312 n. 4 (citing *Shuttlesworth v. City of Birmingham,* 373 U.S. 262, 83 S.Ct. 1130, 10 L.Ed.2d 335 (1963)). That statement is incomplete, for when the direct infringer is not liable, for whatever reason, the performance of claim steps is not prohibited by law. When the performance of the claim steps is not unlawful, the inducer cannot be liable for inducing infringement, on any theory of tort or criminal or patent law. *See Shuttlesworth,* 373 U.S. at 265, 83 S.Ct. 1130 ("It is generally recognized that there can be no conviction for aiding and abetting someone to do an innocent act.").

Precedent routinely reflects that liability for inducement depends on liability for direct infringement. In *Met–Coil Systems Corp. v. Korners Unlimited, Inc.,* 803 F.2d 684, 687 (Fed.Cir.1986) the court held that there was no liability for induced infringement by sale of equipment for use in the patentee's machine, because the "customers enjoyed an implied license to practice the inventions claimed." That is, although the customers "practice[d]" the claimed invention, maj. op. 1309, they did not directly infringe, so there could be no inducement of infringement. *Cf. Giese v. Pierce Chem. Co.,* 29 F.Supp.2d 33, 36 (D.Mass.1998) ("If the end users are not infringers due to the protection of the experimental use doctrine, then the defendants Vector and Pierce cannot be liable for contributory infringement or inducement.").

In *NTP, Inc. v. Research in Motion, Ltd.,* 418 F.3d 1282, 1318 (Fed.Cir.2005) the court held that there was no liability for inducement by sale of a system that had a component located in Canada, because the customers did not perform all the steps of the claimed method in the United States. That is, although "all the steps of a claimed method [were] performed," maj. op. 1306, the customers did not directly infringe, so there could be no inducement. *Cf. Everpure, Inc. v. Cuno, Inc.,* 875 F.2d 300, 302 (Fed.Cir.1989) ("[T]here can be neither contributory nor induced infringement when, because of the permissible repair doctrine, there has been no direct infringement.").

In *National Presto Industries, Inc. v. West Bend Co.,* 76 F.3d 1185 (Fed.Cir. 1996) the court held that there was no liability for inducing infringement before

the patent issued, because there is no direct infringement before issuance. The court stated that "if the thing that was abetted was not illegal at the time of abetment, but depended on some future event that might not occur (such as issuance of the patent) liability can not be retroactively imposed." *Id.* at 1196; *cf. Joy Techs.*, 6 F.3d at 775 ("If the plant sold by Flakt cannot be used by the purchaser to infringe directly because it will not be operational within the term of the patent, Flakt cannot be guilty on a theory of contributory infringement with respect to that plate.").

Discarding precedent, the majority holds that there is liability for inducement when the inducer breaches the "duty not to cause the acts that constitute infringement even if the parties who cause the direct injury are not liable." Maj. op. 1313. Duty, breach, and causation apply in the tort of negligence, not patent infringement. Prosser & Keeton explain that "in negligence cases, the duty is always the same—to conform to the legal standard of reasonable conduct in the light of the apparent risk." *Prosser & Keeton on the Law of Torts,* § 53, at 356 (5th ed.1984). In addition to its incorrect treatment of the foundational requirement of direct infringement, the majority creates a new, ill defined, and open-ended theory of liability for patent infringement, simply by "caus[ing], urg[ing], encourag[ing], or aid[ing]" someone to perform separate steps of a patented method. Maj. op. 1308.

To support its unprecedented ruling of induced infringement without direct infringers, the court also misconstrues the 1952 Patent Act and its history. In 1948 then attorney Giles S. Rich testified that "obvious infringement" should be subject to remedy, and that judicial decisions "appear to make it impossible to enforce [combination] patents in the usual case." *Contributory Infringement in Patents: Hearings Before the Subcomm. on Patents, Trade–Marks, and Copyrights of the House Comm. on the Judiciary,* 80th Cong. 5 (1948) (statement of G.S. Rich on behalf of the New York Patent Law Association) ("1948 Hearings"). Mr. Rich gave an example of two equal participants in a radio system, sending and receiving, and described: "there is no direct infringer of the patent but only two contributory infringers." *Id.* The court today places great weight on this statement. However, a year later Mr. Rich testified again, stating that: "The law always has been that, to hold anyone for contributory infringement, there must have been somewhere a direct infringement which was contributed to." *Contributory Infringement: Hearings on H.R. 3866 Before Subcomm. No. 4 of the House Comm. on the Judiciary,* 81st Cong. 67 (1949) (statement of G.S. Rich) ("1949 Hearings"); *id.* at 5 ("Somewhere along the line there must be a direct infringement. . . .").

In the 1951 hearings Mr. Rich again testified, stating that "wherever there is contributory infringement there is somewhere something called direct infringement, and to that direct infringement someone has contributed." *Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the House Comm. on the Judiciary,* 82nd Cong. 151 (1951) (statement of G.S. Rich). Mr. Rich never proposed the conditions of induced infringement that the court now propounds. Mr. Rich summarized, when the statute was enacted, that "[a]ctive inducement implies that there is not a *direct* infringement by the one doing the inducing and that the direct infringement was by another." G.S. Rich, *Infringement Under Section 271 of the Patent Act of 1952, supra* at 537.

The court's opinion quotes other testimony, none of which proposes or suggests the court's creative ruling. At the 1948 hearing Representative Kenneth Keating asked "[t]he law of torts is the basic part of patent law, is it not?," and Mr. Rich answered that: "Infringement is considered to be a tort and contributory infringement is a specific application to patent law of the law of joint tort feasor where two people somehow together create an infringement which neither one of them individually or independently commits." *1948 Hearings,* at 12. At the 1949 hearing Mr. Rich again explained:

> When two people combine and infringe a patent in some way or other, they are joint tort feasors, and it so happens that patents are often infringed by people acting in concert, either specifically or by implication, where neither one of them is a direct infringer. The only way you can protect your right is to proceed against someone who is not a direct infringer. That person who does something less than the direct infringement is called a contributory infringer.

1949 Hearings, at 3. The statements and testimony for the 1948 and 1949 hearings, quoted out of context in the court's opinion, do not state, or hint, that the proposed legislation would accommodate indirect infringement without direct infringers. Nowhere in the entire legislative effort did any supporter or sponsor of the codification of indirect infringement in § 271(b) and (c) refer to "practicing" the claimed invention or "the acts necessary to constitute direct infringement" as liberated from the requirement of proving direct infringement, as the majority does today. Maj. op. 1314–15, 1307.

What about remedies?

According to the court's new ruling, it appears that the patentee cannot sue the direct infringers of the patent, when more than one entity participates in the infringement. The only remedial path is by way of "inducement." We are not told how compensation is measured. The only thing that is clear, is that remedy is subject to new uncertainties. Since the direct infringers cannot be liable for infringement, they do not appear to be subject to the court's jurisdiction. Perhaps the inducer can be enjoined—but will that affect the direct infringers? Since the inducer is liable when he breaches the "duty" not to induce, is the inducer subject to multiplication of damages? This return to the "duty to exercise due care to determine whether or not he is infringing" of *Underwater Devices Inc. v. Morrison–Knudsen Co., Inc.,* 717 F.2d 1380, 1389 (Fed.Cir.1983) raises tension with the ruling of the *en banc* court in *In re Seagate Technology LLC,* 497 F.3d 1360 (Fed.Cir.2007) that overruled the standard of *Underwater Devices.*

Nor has the court ascertained the views of the communities affected by this change in law. The many *amici curiae* explained how the single-entity rule affects their activities; none has had an opportunity to consider the effect of the inducement-only change now adopted *en banc.*

It is not necessary to change the law in order to design a fair infringement law. The court misconstrues "strict liability" as requiring that every participant in an interactive or collaborative method is fully responsible for the entire harm caused by the infringement. *Global–Tech Appliances, Inc. v. SEB S.A.,* 563 U.S. ——, 131 S.Ct. 2060, 2065 n. 2, 179 L.Ed.2d 1167 (2011), does not so hold. The tort principle of "strict liability" applies when injury results from inherently hazardous or dangerous activity, not from patent infringement. Black's Law Dictionary 998 (9th ed.2009) sums up the law:

> Liability that does not depend on actual negligence or intent to harm, but that is

based on the breach of an absolute duty to make something safe. Strict liability most often applies either to ultrahazardous activities or in products-liability cases.

Although the term "strict liability" has crept into patentese, it does not have the consequences given by my colleagues. Proper analysis is illustrated by Blair & Cotter, who point out the inapplicability to patent infringement. *Strict Liability and its Alternatives in Patent Law,* 17 Berkeley Tech. L.J. 799 (2002). For example, they explain at page 808 that under a true strict liability standard, damages would be recoverable even before the accused infringer has "knowledge or notice that the conduct infringes." *See* 35 U.S.C. § 287 (notice requirements).

As stated in *Carbice Corp. of America v. American Patents Development Corp.,* 283 U.S. 27, 33, 51 S.Ct. 334, 75 L.Ed. 819 (1931), "Infringement, whether direct or contributory, is essentially a tort, and implies invasion of some right of the patentee." When the patent is infringed through the cooperation or interaction of more than one entity, assessment of remedy is appropriately allocated in accordance with traditional tort principles. The Court stated in *Burlington Northern & Santa Fe Railway Co. v. United States,* 556 U.S. 599, 614, 129 S.Ct. 1870, 173 L.Ed.2d 812 (2009) that "apportionment is proper when there is a reasonable basis for determining the contribution of each cause to a single harm" (quotation omitted). These fundamentals apply here, and resolve all of the issues for which both factions of the court disrupt law and precedent.

Remedy for infringement may be apportioned on such traditional tort factors as the relative contribution to the injury to the patentee, the economic benefit received by the tortfeasor, and the knowledge and culpability of the actor. Applicable considerations are summarized in the Restatement of the Law Torts: Apportionment of Liability (2000), as follows:

§ 8. Factors for Assigning Shares of Responsibility

Factors for assigning percentages of responsibility to each person whose legal responsibility has been established include

(a) the nature of the person's risk-creating conduct, including any awareness or indifference with respect to the risks created by the conduct and any intent with respect to the harm created by the conduct; and

(b) the strength of the causal connection between the person's risk-creating conduct and the harm.

Comment c to § 8 of the Restatement further elaborates on the factors for assigning shares of responsibility:

c. Factors in assigning shares of responsibility . . . . The nature of each person's risk-creating conduct includes such things as how unreasonable the conduct was under the circumstances, the extent to which the conduct failed to meet the applicable legal standard, the circumstances surrounding the conduct, each person's abilities and disabilities, and each person's awareness, intent, or indifference with respect to risks. The comparative strength of the causal connection between the conduct and the harm depends on how attenuated the causal connection is, the timing of each person's conduct in causing the harm, and a comparison of the risks created by the conduct and the actual harm suffered by the plaintiff.

One or more of these factors may be relevant for assigning percentages of responsibility, even though they may not be a necessary element proving a particular claim or defense. However, these factors are irrelevant even to apportionment if there is no causal connection

> between the referenced conduct and the plaintiff's injuries. See Comment *b.* It should be noted that the mental-state factors in this Section may be considered for apportioning responsibility even if they are not themselves causally connected to the plaintiff's injury, as long as the risk-creating conduct to which they refer is causally connected to the injury.

Apportionment of remedy for shared infringement permits consideration of the actual situation, and is particularly suitable in cases of divided infringement. *See Birdsell v. Shaliol,* 112 U.S. 485, 488, 5 S.Ct. 244, 28 L.Ed. 768 (1884) ("In the case of infringement, the liability of infringers arises out of their own wrongful invasion of his rights."); *Aro,* 377 U.S. at 500, 84 S.Ct. 1526 ("[A] contributory infringer is a species of joint-tortfeasor, who is held liable because he has contributed with another to the causing of a single harm to the plaintiff.").

Whether the infringement is direct or indirect, the allocation of remedy is a case-specific determination. In *Grokster,* 545 U.S. at 930 n. 9, 125 S.Ct. 2764, the Court observed that "the lines between direct infringement, contributory infringement and vicarious liability are not clearly drawn," quoting *Sony,* 464 U.S. at 435 n. 17, 104 S.Ct. 774. *Grokster* accommodates the realities of today's technology without departing from the principles of precedent, by identifying when "it is just to hold one individual accountable for the actions of another." *Sony,* 464 U.S. at 435, 104 S.Ct. 774. When the several steps of a process claim are performed by more than one entity, whether the entities operate under common direction or control, or jointly or independently or interactively, remedy for infringement is appropriately allocated based on established criteria of culpability, benefit, and the like.

The law has always permitted allocation of remedy when multiple parties are responsible for civil wrongs. The example in Judge Linn's dissent at pages 1314–15, that the person who provides the nuts, bolts, or gears that hold together an infringing machine would be responsible for full damages for infringement by the machine, does not pass the chuckle test. I must also remark that according to the dissenters' thesis the manufacturer of the infringing machine would not be liable at all unless the purveyor of the nuts, bolts, or gears is in an agency relationship with a mastermind.

Although *Grokster* is mentioned in the majority's opinion, it is undercut by the majority's insistence that there is no need to establish direct infringement "[b]ecause the reasoning of our decision today is not predicated on the doctrine of direct infringement." Maj. op. 1307. However, in *Grokster* it was not disputed that the users of the defendants' systems were liable for direct infringement, and the Court held that the defendants could be liable for inducing the infringement.

When there is combined participation in direct infringement, there is a fair concern for imposing damages on minor participants. Law and precedent do not so require, and experience makes clear that the target is the deep-pocket commercial participant, not the occasional customer. For example, in the *McKesson* case neither the patient who accesses his medical records, nor the healthcare provider who assembles and provides the records, was sued. Only the licensor of the system software was sued, for the injury to the patentee was in the commercial profit from the license of the software. Neither the single-entity rule nor the inducement-only rule is needed to protect the innocent patient who turns on his computer to access the system containing his medical records.

Potential for abuse

The majority states that "nothing in the text of either subsection [§ 271(a) or (b)] suggests that the act of 'infringement' required for inducement under section 271(b) must qualify as an act that would make a person liable as an infringer under section 271(a)," maj. op. 1314, and holds that liability for inducement arises simply on "advis[ing]." *Id.* at 1307. Now that this untenable theory is the law of this *en banc* court, potential for abuse looms large, for the majority does not require proof of direct infringement, but holds that the entity that advises or enables or recommends the divided infringement is fully responsible for the consequences of the direct infringement.

Many of the *amici curiae* pointed to ongoing abuses of the system of patents, and the ensuing disincentive to innovative commerce. The majority ignores these cautions, as it creates new potential problems. And while many innovative industries explained how they may be affected by possible rulings on divided infringement, not one of the many *amici* suspected the inducement-only theory that is here adopted.

IV

The Two Cases on Appeal

The majority remands for application of the inducement-only rule to the now-vacated panel decisions of *Akamai* and *McKesson.* In its remand instructions the majority declines guidance on direct infringement, instead stating at maj. op. 1318: "While we do not hold that Akamai is entitled to prevail on its theory of direct infringement, the evidence could support a judgment in its favor on a theory of induced infringement." The panels had held that without direct infringement there cannot be induced infringement. That simple rule was confirmed over and over at the hearings leading to the 1952 Patent Act, for the legislative history plainly states the understanding that there must be direct infringement before there can be liability for inducement to infringe.

Brief review of the facts of the cases on appeal demonstrates that these cases are readily decided under the present law, with no need for creative revision of history.

Akamai Technologies, Inc. v. Limelight Networks, Inc., Appeal No.2009–1372, –1380, –1416, –1417

The district court in *Akamai* held a full trial, on jury instructions that included the single-entity rule as established in *BMC Resources.* The jury found infringement, the district court granted JMOL after *Muniauction* was decided, and a panel of this court affirmed that there could be no infringement, based on failure to meet the single-entity rule. The court today holds that there can be liability, but only for inducement.

The patent at issue, assigned to the Massachusetts Institute of Technology and licensed to Akamai, is entitled "Global Hosting System," a system for providing content delivery of website information. In brief, the text of a web page is stored on and served from the content provider's server, and other content such as images, video, and sound, called embedded objects, are stored on the hosting servers of a content delivery network. The defendant Limelight Networks provides such a content delivery system. Claims 19 and 34 of U.S. Patent No. 6,108,703 are representative of the claims asserted at trial, with Limelight providing the service but with the customer conducting the step of tagging of embedded objects (the boldface step):

19. A content delivery service, comprising:

replicating a set of page objects across a wide area network of content servers managed by a domain other than a content provider domain;

for a given page normally served from the content provider domain, **tagging the embedded objects** of the page so that requests for the page objects resolve to the domain instead of the content provider domain;

responsive to a request for the given page received at the content provider domain, serving the given page from the content provider domain; and

serving at least one embedded object of the given page from a given content server in the domain instead of from the content provider domain.

34. A content delivery method, comprising:

distributing a set of page objects across a network of content servers managed by a domain other than a content provider domain, wherein the network of content servers are organized into a set of regions;

for a given page normally served from the content provider domain, **tagging at least some of the embedded objects** of the page so that requests for the objects resolve to the domain instead of the content provider domain;

in response to a client request for an embedded object of the page:

resolving the client request as a function of a location of the client machine making the request and current Internet traffic conditions to identify a given region; and

returning to the client an IP address of a given one of the content servers within the given region that is likely to host the embedded object and that is not overloaded.

The single-entity issue turned on the tagging step performed by the customer. Akamai pursued the charge of direct infringement, recognizing precedent and thus arguing that the single-entity rule is satisfied because the customer tags the embedded objects in accordance with instructions provided by Limelight, within the context of a contractual relationship. The issue of "direction or control" was extensively explored at trial, and the jury was instructed in accordance with *BMC Resources:*

> If Limelight did not direct and control this action, then this substitution cannot be attributed to Limelight. And Limelight cannot, therefore, infringe. . . .
>
> Again, the first [question] again is whether this method of getting to the Defendant content delivery network infringes any claim, and the second question, again, is whether the content provider acted under the direction and control of Limelight. And again, if Limelight directed and controlled this action, it was effectively the action of Limelight, and then it may be found responsible. But if Limelight did not direct and control, both are necessary, the modification at the content provider, then it cannot be deemed to infringe.
>
> . . .
>
> So, you should review the evidence, decide how the Limelight systems work, how does the interaction with the content provider work, and, specifically, does Limelight direct and control the modifications or does the content provider carry out these tasks entirely independently. Then compare each of the mechanisms with what is claimed in the certain claims and, specifically, does either of the Defendant's content delivery methods practice each element of whichever claim you are considering.

Trial Tr. 20:20 to 22:4 (Feb. 28, 2008), J.A. 818–19. The district court further instructed the jury, after discussion with

counsel, that "[i]t is either direct or control, control or direct; it doesn't have to be both." *Id.* at 53:3–5, J.A. 826.

The jury found that Limelight infringed the claims. Limelight moved for judgment as a matter of law, and the district court denied the motion, explaining that "unlike in *BMC Resources*, here there was evidence that not only was there a contractual relationship between Limelight and its customers, but that it provided those customers with instructions explaining how to utilize its content delivery service." *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 614 F.Supp.2d 90, 119 (D.Mass.2009).

Two weeks later this court decided *Muniauction*, and the district court received Limelight's request for reconsideration on the ground that *Muniauction* established the additional requirement that direct infringement "requires a showing that the accused direct infringer is vicariously liable for the acts committed by any others required to complete performance of the claimed method," a more rigorous standard than had been presented to the jury based on *BMC Resources*. Dkt. No. 377, at 2 (July 25, 2008). The district court found that there was "no material difference between Limelight's interaction with its customers and that of Thompson [sic] in *Muniauction*." *Akamai*, 614 F.Supp.2d at 122. The district court held that on the law established in *Muniauction*, the jury verdict of infringement could not be sustained.

The majority now remands for application of its inducement-only rule. However, on the jury instruction that was given, the majority's criteria for infringement are met. And this endless litigation is further prolonged, for the majority gives no appellate review to the other issues on appeal, including claim construction, the measure of damages, and other decisions of the district court presented for appellate review. They are ignored.

McKesson Technologies Inc. v. Epic Systems Corp., Appeal No.2010–1291

McKesson's action was for inducement of infringement by Epic Systems, who licenses a software system that is designed for interactive use by healthcare providers and their patients. The patent, entitled "Electronic Provider—Patient Interface System," is for "a communication system for providing automated, electronic communications between at least one healthcare provider and a plurality of users of the health-care provider." U.S. Patent No. 6,757,898, abstract. The patent states that "once the patient has logged into his/her own Web page," the patient can access a variety of healthcare records and services including "appointment requests and updates, prescription refills, online triage, health search information and the like." *Id.* at col.4 ll.52–56. Epic has a system called MyChart, and licenses the system software to health-care providers.

The district court applied *Muniauction*, and granted summary judgment that the patent cannot be directly infringed, and thus that there cannot be inducement to infringe. The district court held that because the patient performs some steps of the claim, direct infringement is precluded because neither the healthcare provider nor the provider of the overall system directs or controls the actions of the patient. Application of the majority's theory of inducement could help to clarify today's rulings, with their uncertainties and contradictions.

As claimed in the '898 patent, the patient initiates a communication as the first step of the method, which includes interactive steps:

> 1. A method of automatically and electronically communicating between at least one health-care provider and a plurality of users serviced by the health-

care provider, said method comprising the steps of:

initiating a communication by one of the plurality of users to the provider for information, wherein the provider has established a preexisting medical record for each user;

enabling communication by transporting the communication through a provider/patient interface over an electronic communication network to a Web site which is unique to the provider, whereupon the communication is automatically reformatted and processed or stored on a central server, said Web site supported by or in communication with the central server through a provider-patient interface service center;

electronically comparing content of the communication with mapped content, which has been previously provided by the provider to the central server, to formulate a response as a static or dynamic object, or a combined static and dynamic object; and

returning the response to the communication automatically to the user's computer, whereupon the response is read by the user or stored on the user's computers

said provider/patient interface providing a fully automated mechanism for generating a personalized page or area within the provider's Web site for each user serviced by the provider; and

said patient-provider interface service center for dynamically assembling and delivering custom content to said user.

McKesson charged Epic with inducing infringement of the '898 patent. Epic argued in defense that in accordance with *BMC Resources* the claims cannot be directly infringed because no single entity performs or directs or controls every step of the claimed method. McKesson responded that the requirements of *BMC Resources* are met, in that the healthcare provider controls the patient's access to the MyChart system, for the healthcare provider requires the user to accept a "cookie" in order to use the system and the system requires login information to restrict the user's access to information.

The district court at first denied summary judgment, finding genuine issues of material fact as to the question of direction or control. This court then decided *Muniauction*, and the district court concluded that summary judgment of noninfringement was "compel[ed]." *McKesson*, 2009 WL 2915778, at *5. The district court drew analogy to the facts and result in Muniauction to conclude that there could not be direct infringement as a matter of law. The majority is silent on the provisions embodied in *Muniauction*, although the district court held them to be controlling.

Conclusion

The issues that were presented for *en banc* review can be simply resolved on the present law. The court should acknowledge that an all-purpose single-entity requirement is flawed, and restore direct infringement to its status as occurring when all of the claimed steps are conducted, whether by a single entity or in interaction or collaboration. Remedy is then allocated as appropriate to the particular case, whether for direct or induced or contributory infringement, in accordance with statute and the experience of precedent.

The court has fractured into two flawed positions, each a departure from established precedent, each poorly suited to the issues and technologies that dominate today's commerce. Today's new rule of inducement-only liability serves no public interest, no innovation need. The consequences for the technology communities are uncertainty, disincentive, and new potential for abuse.

LINN, Circuit Judge, dissenting, with whom Circuit Judges DYK, PROST, and O'MALLEY join.

I. Introduction

In its opinion today, this court assumes the mantle of policy maker. It has decided that the plain text of § 271(a) and (b) fails to accord patentees certain extended rights that a majority of this court's judges would prefer that the statute covered. To correct this situation, the majority effectively rewrites these sections, telling us that the term "infringement" was not, as was previously thought, defined by Congress in § 271(a), but instead can mean different things in different contexts.

The majority's approach is contrary to both the Patent Act and to the Supreme Court's longstanding precedent that "if there is no direct infringement of a patent there can be no contributory infringement." *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 365 U.S. 336, 341, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961); *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518, 526, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972) (quoting *Mercoid Corp. v. Mid–Continent Co.* (*Mercoid I*), 320 U.S. 661, 677, 64 S.Ct. 268, 88 L.Ed. 376 (1944) (Frankfurter, J., dissenting on other grounds)); *see also Joy Techs., Inc. v. Flakt, Inc.,* 6 F.3d 770, 774 (Fed.Cir.1993) ("Liability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement."); *C.R. Bard v. Advanced Cardiovascular Sys., Inc.,* 911 F.2d 670, 673 (Fed.Cir.1990) (same). In 1952, Congress removed joint-actor patent infringement liability from the discretion of the courts, defining "infringement" in § 271(a) and expressly defining the *only* situations in which a party could be liable for something less than an infringement in § 271(b) and (c)—clearing away the morass of multi-actor infringement theories that were the unpredictable creature of common law. Since that time, Congress has on three occasions made policy choices to treat certain special circumstances as tantamount to "infringement." *See* 35 U.S.C. § 271(e)(2), (f), and (g). In doing so, Congress did not give the courts blanket authority to take it upon themselves to make further policy choices or define "infringement."

The majority opinion is rooted in its conception of what Congress ought to have done rather than what it did. It is also an abdication of this court's obligation to interpret Congressional policy rather than alter it. When this court convenes en banc, it frees itself of the obligation to follow its own prior precedential decisions. But it is beyond our power to rewrite Congress's laws. Similarly, we are obliged to follow the pronouncements of the Supreme Court concerning the proper interpretation of those acts. *Rivers v. Roadway Express, Inc.,* 511 U.S. 298, 312–313, 114 S.Ct. 1510, 128 L.Ed.2d 274 (1994); *Rodriguez de Quijas v. Shearson/Am. Express, Inc.,* 490 U.S. 477, 484, 109 S.Ct. 1917, 104 L.Ed.2d 526 (1989).

On this unsound foundation, the majority holds that in the present appeals there has been predicate "infringement" even though § 271(a)'s requirements are not satisfied. On that basis, the majority vacates the contrary judgments of the district courts and remands for further proceedings concerning liability under § 271(b). In my view, the plain language of the statute and the unambiguous holdings of the Supreme Court militate for adoption en banc of the prior decisions of the court in *BMC Resources, Inc. v. Paymentech, L.P.,* 498 F.3d 1373, 1378–79 (Fed.Cir.2007) and *Muniauction, Inc. v. Thomson Corp.,* 532 F.3d 1318, 1329 (Fed. Cir.2008), which hold that liability under § 271(b) requires the existence of an act of direct infringement under § 271(a), mean-

ing that all steps of a claimed method be practiced, alone or vicariously, by a single entity or joint enterprise. For these reasons, I respectfully dissent.

II. Discussion

A. Direct Infringement Liability is a *Sine Qua Non* of Indirect Infringement Liability

The majority essentially skirts the en banc question in the *Akamai* case by holding that "[b]ecause the reasoning of our decision today is not predicated on the doctrine of direct infringement, we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement under 35 U.S.C. § 271(a)." Maj. Op. 1307. With all due respect to my colleagues in the majority, the question of "joint infringement" liability under § 271(a) is essential to the resolution of these appeals. Divorcing liability under § 271(a) from liability under § 271(b) is unsupported by the statute, subverts the statutory scheme, and ignores binding Supreme Court precedent.

1. The Statutory Scheme

Patent infringement is not a creation of common law. It is a statutorily-defined tort. *See 3D Sys., Inc. v. Aarotech Labs., Inc.,* 160 F.3d 1373, 1379 (Fed.Cir.1998) ("[T]he tort of infringement ... exists solely by virtue of federal statute."); *N. Am. Philips Corp. v. Am. Vending Sales, Inc.,* 35 F.3d 1576, 1579 (Fed.Cir.1994). "Defining the contours of the tort of infringement ... [thus] entails the construction of the federal statute." *3D Sys.,* 160 F.3d at 1379.

35 U.S.C. § 271(a) provides that:

> Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

Section 271(a) defines infringement. H.R.Rep. No. 82–1923, at 9 (1952) ("Section 271, paragraph (a), is a *declaration of what constitutes infringement.*") (emphasis added). 35 U.S.C. § 271(b) and (c), in turn, codify the doctrines of inducement and contributory infringement respectively:

> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.
>
> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Congress carefully crafted subsections (b) and (c) to expressly define the *only* ways in which individuals not completing an infringing act under § 271(a) could nevertheless be liable, rejecting myriad other possibilities that existed in the common law at the time, such as, for example, *Peerless Equipment Co. v. W.H. Miner, Inc.,* 93 F.2d 98, 105 (7th Cir.1938) and *Solva Waterproof Glue Co. v. Perkins Glue Co.,* 251 F. 64, 73–74 (7th Cir.1918). In creating § 271(b) and (c), Congress intended to codify "contributory" infringement liability in a limited manner:

> The doctrine of contributory infringement has been a part of our law for about 80 years.... *Considerable doubt and confusion as to the scope of contributory infringement has resulted from a*

> *number of decisions of the courts in recent years. The purpose of* [*section 271*] *is to codify in statutory form principles of contributory infringement and at the same time eliminate this doubt and confusion.* Paragraph (b) recites in broad terms that one who aids and abets an infringement is likewise an infringer. The principle of contributory infringement is set forth in . . . paragraph [(c)] which is concerned with the usual situation in which contributory infringement arises. [Paragraph (c)] is much more restricted than many proponents of contributory infringement believe should be the case.

H.R.Rep. No. 82–1923, at 9 (1952) (emphasis added). While subsections (b) and (c) are not mutually exclusive, they each address a particular type of multi-party conduct.

Reading subsection (b) in light of subsection (a) is a straightforward exercise. Section 271(a) defines infringement, and, in turn, § 271(b) and (c) establish indirect infringement liability for one who "actively induces *infringement*" or sells a component part "especially adapted for use in an *infringement*" (emphases added). A person who practices the entire invention is an infringer, liable under subsection (a); a person who actively induces such practice is an inducer, liable under subsection (b) ("positive articulation"). The negative inference is equally straightforward: A person who does not practice the entire invention is not liable under subsection (a); a person who actively induces such partial practice is not liable under subsection (b) ("negative articulation"). Such has been the consistent reasoning of this court (and of the Supreme Court, *see infra*) for years. *Joy Techs.*, 6 F.3d at 774 (citing Supreme Court and Federal Circuit precedent).

The majority rejects this reasoning. It is satisfied with the positive articulation but not the negative articulation because the latter means that some claims (e.g., the claims on appeal) are unenforceable in the absence of a direct infringer. The majority attempts to avoid the result of some patentees having technically valid but valueless claims by essentially rewriting subsection (b) so that it reads: "Whoever actively induces infringement of [*or induces two or more separate parties to take actions that, had they been performed by one person, would infringe*] a patent shall be liable as an infringer."

2. It is Impermissible to Redefine "Infringement" for the Purposes of Establishing Liability Under § 271(b)

To support its tenuous position, the majority impermissibly bends the statute to define direct infringement differently for the purposes of establishing liability under § 271(a) and (b). The majority asserts that "[s]ection 271(a) *does not define* the term 'infringement.' Instead, it simply sets forth a type of conduct that qualifies as infringing." Maj. Op. 1314. Contrary to the majority's statement, however, both the House and Senate reports from the statute's adoption confirm that § 271(a) is, in fact, "*a declaration of what constitutes infringement in the present statute.*" S.Rep. No. 82–1979, at 8 (1952), 1952 U.S.C.C.A.N. 2394, 2402 (emphasis added); *accord* H.R.Rep. No. 82–1923, at 9 (1952). In *Aro,* the Supreme Court unequivocally stated the same: "And § 271(a) of the new Patent Code, *which defines 'infringement,'* left in tact the entire body of case law on direct infringement." 365 U.S. at 342, 81 S.Ct. 599 (emphasis added).

The idea of defining infringement separately in the context of § 271(a) and (b) is simply unsupported by the text itself. *See* 35 U.S.C. § 271(a) and (b). The majority essentially asserts that the word "infringement" in § 271(b)—and presumptively

§ 271(c) as well—can be defined however this court wants without reference to *any* statutory provision. Such a bold move from settled principles is unsupported and unwarranted. Congress is presumed to have intended the word "infringement" in § 271(b) and (c) to target the same conduct as "infringes" in § 271(a); it is the same word, simply used as a verb in paragraph (a) to define the act. *See Taniguchi v. Kan Pac. Saipan, Ltd.*, —— U.S. ——, 132 S.Ct. 1997, 2004–05, 182 L.Ed.2d 903 (2012) ("[I]t is a normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.") (internal quotations omitted); *Hall v. United States*, —— U.S. ——, 132 S.Ct. 1882, 1891, 182 L.Ed.2d 840 (2012) ("At bottom, identical words and phrases within the same statute should normally be given the same meaning.... Absent any indication that Congress intended a conflict between two closely related chapters, we decline to create one." (internal quotation omitted)). As the Supreme Court has held, when the relevant language "was inserted into [the statutory provisions] *at the same time*," as is the case with § 271(a)-(c), "[t]hat maxim is doubly appropriate." *Powerex Corp. v. Reliant Energy Servs., Inc.*, 551 U.S. 224, 232, 127 S.Ct. 2411, 168 L.Ed.2d 112 (2007) (emphasis added). "The interrelationship and close proximity of these provisions of the statute presents a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning." *Comm'r v. Lundy*, 516 U.S. 235, 250, 116 S.Ct. 647, 133 L.Ed.2d 611 (1996) (internal quotations omitted).

The limited doctrines of indirect infringement are explicitly premised on an underlying "infringement." *See* 35 U.S.C. § 271(a)-(c); *Aro*, 365 U.S. at 341, 81 S.Ct. 599. The Supreme Court has expressly rejected interpreting the 1952 Act to divorce indirect infringement from direct infringement. In *Aro*, the Supreme Court unequivocally held: "[I]t is settled that if there is no direct infringement of a patent there can be no contributory infringement." *Aro*, 365 U.S. at 341, 81 S.Ct. 599. The majority argues that *Aro* does not stand for the proposition that "liability for inducement requires that a single party be liable for direct infringement" because the issue in *Aro* was limited to whether there was *any* underlying act of direct infringement based on the defense of permissible repair. Maj. Op. 1315–16. The majority's attempt to distance *Aro* from this case is unconvincing. There is no indication in the Supreme Court's statement in *Aro* that it was intended to have such a limited meaning. The question of whether or not there was *liability* for an underlying act of direct infringement was squarely at issue in *Aro*, and the Court held that without "direct infringement *under § 271(a)*," i.e., *liability*, there can be no indirect infringement. 365 U.S. at 341, 81 S.Ct. 599 ("[Defendant's] manufacture and sale [of a component part] with ... knowledge might well constitute contributory infringement under § 271(c), *if, but only if, such a replacement by the purchaser himself would in itself constitute a direct infringement under § 271(a)*." (emphasis added)). Not being liable under § 271(a) based on the doctrine of permissible repair is indistinguishable from not being liable under § 271(a) based on the fact that no one has made, used, offered for sale, or sold the patented invention, i.e., no one has performed a complete act of direct infringement. In *Aro*, the Supreme Court meant exactly what it said: " 'In a word, if there is no infringement of a patent there can be no contributory infringer,' ... and ... 'if the purchaser and user could not be amerced as an infringer certainly one who sold to him ... cannot be amerced for contributing to a non-existent infringe-

ment.' " *Id.* (quoting *Mercoid I,* 320 U.S. at 674, 677, 64 S.Ct. 268). The word "amerced" is directly tied to *liability.* The Supreme Court was not just talking about underlying conduct, but liability. Unless someone is liable as a direct infringer, no one is liable for indirect infringement.

The majority cites portions of congressional testimony by Giles S. Rich (later "Judge Rich") to support its interpretation of the statute. But Judge Rich's testimony is inconclusive and raises as many questions as it answers. First, it is not at all apparent that the statement relied on by the majority at pages 1310–11 of its opinion is actually directed to inducement and not contributory infringement. As the majority itself recognizes, "[p]rior to the 1952 Act, inducement and contributory infringement were both referred to under the rubric of contributory infringement." Maj. Op. 1309 (citing Giles S. Rich, *Infringement Under Section 271,* 21 Geo. Wash. L.Rev. 521, 537 (1953)). Moreover, Judge Rich later took a seemingly different position before Congress at the 1951 hearings, stating: "I should state at the outset that wherever there is contributory infringement there is somewhere something called direct infringement, and to that direct infringement someone has contributed. It is a very different thing from a concept like contributory negligence." *Aro,* 365 U.S. at 347 n. 1, 81 S.Ct. 599 (quoting *Hearings before Subcomm. of House Judiciary Comm. On H.R. 3760,* 82d Cong. 151 (1951)).

However the testimony may be read, the Supreme Court has repeatedly admonished that Congressional hearing testimony, not from a member of Congress, is not entitled to any weight or significance in statutory interpretation. *See, e.g., Kelly v. Robinson,* 479 U.S. 36, 51 n. 13, 107 S.Ct. 353, 93 L.Ed.2d 216 (1986) (Even when "comments in the hearings ... may suggest that the language bears the interpretation [in question b]ut none of those statements was made by a Member of Congress, nor were they included in the official Senate and House Reports[, w]e decline to accord any significance to these statements."); *McCaughn v. Hershey Chocolate Co.,* 283 U.S. 488, 493, 51 S.Ct. 510, 75 L.Ed. 1183 (1931) (The same principle applies to "statements ... made to committees of Congress or in discussions on the floor of the Senate by senators who were not in charge of the bill."). "For reasons which need not be restated, such individual expressions are with out weight in the interpretation of a statute." *McCaughn,* 283 U.S. at 494, 51 S.Ct. 510 (citations omitted). With the upmost respect for Judge Rich, his testimony at the Congressional hearings does not and cannot justify extending by judicial fiat the scope of § 271 beyond the words chosen by Congress to reflect *its* intent.

Under the majority's approach, if two or more parties independently practice the elements of a claim, an act of "infringement" to support a charge of induced infringement under § 271(b) has occurred. *See* Maj. Op. 1308–09. The problem with that approach is that there is no statutory basis for concluding that such independent acts constitute infringement and no basis for asserting a cause of action for infringement against any of those independent parties. This runs directly afoul of 35 U.S.C. § 281, which provides that when there is an "infringement," "[a] patentee *shall* have remedy by civil action...." § 281 (emphasis added). As the majority points out, "[s]ection 281 ... was designed to serve as a 'preamble' for the sections on remedies and to ensure that an action for infringement (a 'civil action') would be triable to a jury." Maj. Op. 1314 (citing H.R.Rep. No. 82–1923, at 10, 29 (1952) ("[T]he modern term civil action is used, [so] there would be, of course, a right to a jury trial.")). While the majority looks to

the legislative history as evincing that § 281 does "not declare that any practicing of a patented invention necessarily brought with it the right of the patent owner to *recover* in a civil action for infringement," Maj. Op. 1314 (emphasis added), whether there is a recovery or not is beside the point. The fact remains that, under § 281, where patent "infringement" exists, a patentee has a right to plead a cause of action in civil court, i.e., the patentee has a right *not* to have his claim dismissed under Fed. Rule of Civ. P. 12(b)(6) for "failure to state a claim upon which relief *can* be granted" (emphasis added).

The Majority's reliance on *Fromson v. Advance Offset Plate, Inc.*, 720 F.2d 1565, 1567 (Fed.Cir.1983), is misplaced and misleading. First, *Fromson* merely vacates an incorrect claim construction. *Id.* at 1571. Contrary to the majority's reading, there was no holding in *Fromson* that a party could contributorily infringe a method claim by performing some but not all of the steps thereof. Second, *Fromson* never identified the claims that were potentially contributorily infringed. As the Majority notes, the case involved both product and process claims. Maj. Op. 1317–18. A *product* claim is directly infringed by *making the product.* Thus, the statement in *Fromson* can be read to relate only to the product claims. Third, in the sentences immediately after the portion quoted by the Majority, the court in *Fromson* explained that even though some products were not completed by the accused infringer (but by the customer), other products were. Thus, the claim construction issue actually decided in that case did not depend on the resolution of the doctrinal question at issue here. Finally, *Fromson* contains no doctrinal analysis on this issue. Rather it contains little more than a recitation of hornbook law in explaining the background of the appeal.

Broadening the doctrine of inducement, such that no predicate act of direct infringement is required, is a sweeping change to the nation's patent policy that is not for this court to make. *See Mayo Collaborative Servs. v. Prometheus*, —— U.S. ——, 132 S.Ct. 1289, 1305, 182 L.Ed.2d 321 (2012) ("[W]e must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary."). This is not a case where Congress has given us a statute of unclear meaning and it falls to the court to interpret the statute. This is the opposite case, where the meaning of Congress's enactments is clear. That a majority of this court dislikes the policy that results from the statute as Congress wrote it is not a valid foundation for the action taken today. *See id.* (declining to determine "whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable").

3. Congress's Addition of § 271(e)(2), (f), and (g) Exemplify that Defining Infringement is not the Province of This Court

The majority points to the more recent additions of 35 U.S.C. § 271(e)(2), (f), and (g) as evidence that "the statute uses the term 'infringement' in a way that is not limited to the circumstances that give rise to liability under section 271(a)." Maj. Op. 1314. From this, the majority justifies its new definition of "infringement" under § 271(b). Maj. Op. 1308 (defining "infringement" for the purposes of inducement liability as "acts that collectively practice the steps of the patented method"). But these newer additions do not support the majority; indeed they contradict it. Section 271(b) does not define infringement *at all.* Section 271(a) does.

Aro, 365 U.S. at 342, 81 S.Ct. 599. Section 271(b) was added with knowledge of the definition of infringement in § 271(a). *See id.*

Congress enacted § 271(e) and (f) in 1984 and § 271(g) in 1987 to satisfy specific policy goals. The fact that § 271(e), (f), and (g) identify acts not falling under § 271(a) that are to be treated as infringement confirms that, when Congress intended to cover acts not encompassed within the traditional definition of infringement, it knew how to create an alternative definition thereof. For example, Congress enacted § 271(e)(2) to create "an act of patent infringement [when a party] submit[s] an ANDA for a drug (1) which is claimed in a valid product patent, or (2) a use of which is claimed in a valid use patent. . . ." H.R.Rep. No. 98–857, at 26 (1984), 1984 U.S.C.C.A.N. 2647, 2678. Section 271(e)(2), is "a highly artificial act of infringement," *Eli Lilly & Co. v. Medtronic, Inc.,* 496 U.S. 661, 678, 110 S.Ct. 2683, 110 L.Ed.2d 605 (1990), which Congress created to satisfy "a very limited and technical purpose that relates only to certain drug applications," *id.* at 676, 110 S.Ct. 2683. Similarly, Congress enacted § 271(f) to create "an [act of] infringement [when an entity] suppl[ies] components of a patented invention . . . that are to be combined *outside the United States.*" H.R.Rep. No. 1984 U.S.C.C.A.N. 5827, 5828 (emphasis added). In passing that section, Congress responded to the Supreme Court's decision in *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518, 92 S.Ct. 1700, 32 L.Ed.2d 273 (1972), interpreting § 271(a) to exclude such extraterritorial acts. This was "*a legislative solution to close a loophole in patent law.*" H.R.Rep. No. 1984 U.S.C.C.A.N. 5827, 5828 (emphasis added); *see also* S.Rep. No. 98–663, at 3 (1984) (explaining the policy goal of preventing entities from "circumvent[ing] a patent" by supplying components for assembly abroad). Finally, Congress enacted § 271(g) to create an act of infringement when an entity "without authority imports in the United States or sells or uses within the United States a product which is made by a process patented in the United States." S.Rep. No. 100–83, at 48 (1987). The House Report explains that "[t]here [wa]s no policy justification for encouraging such overseas production and concurrent violation of United States intellectual property rights. *The courts cannot solve this defect. The Congress can. The compelling nature of this policy deficiency has been evident to leaders in both the legislative and executive branches.*" H.R.Rep. No. 100–60, at 6 (1987) (emphasis added).

Congress knows how to create alternative forms of infringement. Congress, however, apparently does not take issue with this court's interpretation of § 271(a), (b), and (c) in *BMC* and *Muniauction.* If it did, Congress recently had the chance to amend the statute in the Leahy–Smith America Invents Act, Pub.L. No. 112–29, 125 Stat. 284 (2011), signed into law on September 16, 2011. The fact that Congress was aware of *BMC* and *Muniauction* when it reformed the 1952 Patent Act indicates that Congress did not intend to abrogate the single entity rule for direct infringement, or broaden indirect infringement liability beyond its intentionally limited scope.

4. The Majority's Analogies to Criminal and Tort Law are Flawed

In an attempt to justify its statutory revision, the majority overstates and improperly analogizes to fundamental principles of criminal and tort law. The majority asserts that 18 U.S.C. § 2 "has been construed to permit the conviction of an accessory who induces or causes a criminal offense even when the principal is found not liable for the unlawful conduct." Maj.

Op. 1311 (citing *Standefer v. United States*, 447 U.S. 10, 19, 100 S.Ct. 1999, 64 L.Ed.2d 689 (1980)). This proposition is unremarkable, however, as illustrated by *Standefer*. In *Standefer*, while the principal was acquitted on the relevant charges in a *separate trial*, the Supreme Court found that, in the trial at bar, the "petitioner received a fair trial at which the Government ... prov[ed] beyond reasonable doubt that [the principal] violated [the statute] and that petitioner aided and abetted him in that venture." 447 U.S. at 26, 100 S.Ct. 1999. The Supreme Court held: "In denying preclusive effect to the [principal's] acquittal [in the previous trial], ... [t]his case does no more than manifest the simple, if discomforting reality that different juries may reach different results under any criminal statute." *Id.* at 25, 100 S.Ct. 1999 (internal quotations omitted). In *Standefer*, the Supreme Court required proof of the *underlying statutory violation*, the Government met its burden to prove the *underlying statutory violation* in the case at bar, and thus the case does not stand for the broad proposition that the majority has quoted it for.

Moreover, the Majority's statutory analogy to 18 U.S.C. § 2 is facially incorrect. Each of the cases upon which the majority relies to assert that "the inducer's liability does not turn on whether the intermediary is factually guilty or even capable of committing the charged offense," Maj. Op. 1311, was decided under 18 U.S.C. § 2(b), which imposes liability on a defendant who causes an "act," which "*would be an offense*," to be done through an intermediary (who may be innocent). 18 U.S.C. § 2(b) ("Whoever willfully causes an act to be done which, if directly performed by him or another would be an offense against the United States, is punishable as a principal."); Maj. Op. 1311 (citing *United States v. Tobon–Builes*, 706 F.2d 1092, 1099 (11th Cir.1983), *United States v. Gleason*, 616 F.2d 2, 20 (2d Cir.1979), and *United States v. Rapoport*, 545 F.2d 802, 806 (2d Cir. 1976)). The appropriate analogy, however, is between 35 U.S.C. § 271(b) and 18 U.S.C. § 2(a), *not* § 2(b). Section 2(a) provides that anyone who "*aids, abets, counsels, commands, induces or procures* [the] commission [of a crime], is punishable as a principal." *Compare with* 35 U.S.C. § 271(b) ("Whoever *actively induces* infringement of a patent shall be liable as an infringer."). In *United States v. Concepcion*, 983 F.2d 369 (2d Cir.1992), the second circuit explained:

> The requirements of § 2(a) [Federal criminal aiding and abetting or "inducement"], however, are somewhat *different* [than § 2(b)]. Whereas § 2(a) speaks in terms of procuring or aiding and abetting the commission of an "offense," *and hence requires proof that the primary actor had criminal intent*, § 2(b) speaks in terms of causing the actor to perform only an "act."

Id. at 383. When a defendant is charged with aiding and abetting under § 2(a)—unlike for a defendant who is a cause in fact of a "would be" offense under § 2(b)—*the guilt of the principal must be proven. Id.* at 383–84. "It is hornbook law that a defendant charged with aiding and abetting the commission of a crime by another [under § 2(a)] cannot be convicted in the absence of proof that the crime was actually committed" (although the principal need not be prosecuted or may have been acquitted by a separate jury in a different trial, been granted immunity from liability, or pleaded to a lesser offense). *United States v. Ruffin*, 613 F.2d 408, 412–13 (2d Cir.1979) (holding that "the acquittal of [the principal] by the same jury which convicted [the appellant] precludes a finding under 18 U.S.C. § 2(a) that [the appellant] aided and abetted ... the alleged crime"); *accord Standefer*, 447 U.S. at 25–26, 100 S.Ct. 1999 (1980).

Like 18 U.S.C. § 2(a), which requires an actual "offense," 35 U.S.C. § 271(b) requires an actual "infringement." Congress's specific addition of subsection (b) to 18 U.S.C. § 2 in 1948 to capture situations that did *not* qualify as aiding and abetting in the criminal context discredits the majority's position that we can reach an analogous result in the context of inducement under 35 U.S.C. § 271, absent a similar statutory revision by Congress. *See Concepcion*, 983 F.2d at 383–84 (explaining that Congress added subsection 2(b) in 1948 to reach situations where the primary actor did not "have . . . the 'essential criminal intent' " to "secure a conviction on a theory of aiding and abetting in violation of subsection (a)" (citations omitted)). The majority does not even attempt to explain its reliance on 18 U.S.C. § 2(b) despite the fact that the operative language of 18 U.S.C. § 2(b)—"would be an offense"—is not found in 35 U.S.C. § 271(b). If Congress wished for inducement under 35 U.S.C. § 271(b) to reach the inducement of acts that "would be" an infringement, Congress would have had to use similar language to that in 18 U.S.C. § 2(b), such as it did in 35 U.S.C. § 271(f), which says "would infringe." The majority's "liability-free direct infringement to support inducement" theory is, thus, contrary to the "generally recognized" principle that "there can be no conviction for aiding and abetting someone to do an innocent act." *Shuttlesworth v. City of Birmingham*, 373 U.S. 262, 265, 83 S.Ct. 1130, 10 L.Ed.2d 335 (1963).

Even if 18 U.S.C. § 2(b) "causation" liability could be compared to inducement under 35 U.S.C. § 271(b)—which as explained *supra*, it cannot—to be liable under § 2(b) the actor must nevertheless cause "*prohibited conduct.*" *Ruffin*, 613 F.2d at 413; *accord Tobon–Builes*, 706 F.2d 1092, 1099 ("[I]t is well established that § 2(b) was designed to impose criminal liability on one who causes an intermediary to commit *a criminal act* . . . ." (emphasis added)); *Gleason*, 616 F.2d at 20 ("Under 18 U.S.C. § 2(b) a person who causes an innocent party to commit an act which, if done with the requisite intent, *would constitute an offense* may be found guilty as a principal . . . ." (emphasis added)); *Rapoport*, 545 F.2d at 806 (same). In contrast here, the tort of patent infringement is statutorily defined in § 271(a) as the unauthorized "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any *patented invention.*" § 271(a) (emphasis added). Practicing less than all elements of a claim is *not* patent infringement under § 271(a). *Warner–Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997); *Aro*, 365 U.S. at 340, 81 S.Ct. 599 ("The patent is for a combination only. Since none of the separate elements of the combination is claimed as the invention, none of them when dealt with separately is protected by the patent monopoly." (quoting *Mercoid I*, 320 U.S. at 667, 64 S.Ct. 268)). When a person induces one or more entities to perform acts that do not constitute the statutorily defined act of *patent infringement*—i.e., induces some form of partial or "contributory" action—that person does not induce any prohibited conduct under the statute, and thus cannot be said to aid and abet any prohibited conduct. *See Shuttlesworth*, 373 U.S. at 265, 83 S.Ct. 1130.

The majority also errs in stating that "liability for inducement of a tort applies even if the person being induced is unaware that his act is injurious and *is not liable for that reason.*" Maj. Op. 1313 (emphasis added). The majority cites the Restatement of Torts ("1st Restatement") § 876 cmt. b (1938), but that comment merely states that a defendant may be liable for assisting or encouraging the tortious conduct of another "whether or not the other knows his act to be tortious."

The premise of the 1st Restatement is that an encouraged person *is* liable for "tortious conduct." The 1st Restatement does *not* suggest that the "encouraged party" would not be liable. *See* 1st Restatement § 876 cmt. b, illus. 4–5. Nor do the cited cases support the majority's proposition that inducement can be based upon liability-free acts. In each of these cases, the alleged liability is based on the defendant's breach of a direct duty to the plaintiffs; the cases are thus *direct liability* cases—analogous to direct or vicarious liability situations in the patent law context under § 271(a)—and are not dependent upon the commission of a separate statutorily defined tortious act by some innocent or otherwise immune party. *Pelster v. Ray,* 987 F.2d 514, 523–24 (8th Cir.1993) (rejecting a directed verdict for defendants where defendants allegedly sold the plaintiff a car knowing that the vendor had rolled back the odometer); *Hoyt v. Clancey,* 180 F.2d 152, 158 (8th Cir.1950) (not reaching liability, but rather remanding because "the court's ruling on evidence were [sic] unreasonably restrictive"); *Learjet Corp. v. Spenlinhauer,* 901 F.2d 198, 203 (1st Cir.1990) (plaintiff stated a claim for fraudulent misrepresentation based on defendant's intentional false misrepresentations to the FAA); *Davis v. Louisville Trust Co.,* 181 F. 10, 20 (6th Cir.1910) (fraudulent misrepresentation based on false representations to a publishing agency "with knowledge ... that their substance would be published to all who might wish to deal with the companies...."); *Hawkins v. Upjohn Co.,* 890 F.Supp. 609, 611 (E.D.Tex.1994) (plaintiff stated a claim for conspiracy to commit fraud based on "defendants' repeated and concerted efforts to manufacture and withhold evidence regarding the drugs at issue from the Food and Drug Administration"); *Graham v. Ellmore,* 135 Cal.App. 129, 26 P.2d 696, 697 (1933) (salesman not liable for fraudulent inducement of a real estate transaction where he made a false statement to purchasers which he "believed ... to have been true" based on the landowner's misrepresentation; and not addressing the liability of the landowner on appeal); *Moyer v. Lederer,* 50 Ill.App. 94, 94–96 (Ill.App.Ct.1893) (upholding a jury instruction that "if a merchant furnishes to a mercantile agency ... a willfully false statement ... with intent to obtain a standing and credit to which he knows that he is not justly entitled, and thus to defraud whoever may refer to the agency, ... his liability to any party defrauded by these means is the same as if he had made the false representation *directly to the party injured*" (emphasis added)); *Kuehl v. Parmenter,* 195 Iowa 497, 192 N.W. 429, 431 (1923) (affirming a directed verdict for defendants in a fraud case in which the plaintiff failed to prove damages); *Laun v. Union Elec. Co. of Mo.,* 350 Mo. 572, 583, 166 S.W.2d 1065 (1943) ("The perjured witness and the one who suborns him are joint tortfeasors, acting in conspiracy or combination to injure the party defamed. The fact that one of them is protected from a civil suit by a personal privilege does not exempt the other joint tortfeasor from such suit." (quotation omitted)); *Midford v. Kann,* 32 A.D. 228, 52 N.Y.S. 995 (1989) (upholding a trial judge's charge of false imprisonment against defendant where the defendant caused police officers to illegally arrest the plaintiffs on his property; and not addressing the officers' liability). As shown, in each cited case, although intermediate actors may have directly caused an injury, the party held liable also was held to have *directly* caused an injury.

The 1st Restatement only provides for inducement liability in the presence of an underlying wrongful or "tortious" act or "breach of duty." 1st Restatement § 876; *see also* Maj. Op. 1313. The "tortious conduct" or "breach of duty" in this case is

the act *statutorily defined* in § 271(a). There is no tort for inducing an act that is something less than an infringement, and thus *not* itself wrongful, tortious, or a breach of duty. *See* First Restatement § 876.

B. The Single Entity Rule for Direct Infringement Liability under § 271(a)

Direct infringement liability requires that one actor performs each and every element or step of a claim. *See Aro,* 365 U.S. at 340, 81 S.Ct. 599 ("The patent is for a combination only. Since none of the separate elements of the combination is claimed as the invention, none of them when dealt with separately is protected by the patent monopoly." (quoting *Mercoid I,* 320 U.S. at 667, 64 S.Ct. 268)). Unlike indirect infringement under § 271(b) and (c), which both require a certain mens rea, *Global–Tech Appliances, Inc. v. SEB S.A.,* —— U.S. ——, 131 S.Ct. 2060, 2068, 179 L.Ed.2d 1167 (2011), under § 271(a), direct infringement is a strict-liability offense, *id.* at 2065 n. 2 ("Direct infringement has long been understood to require no more than the unauthorized use of a patented invention.... [A] direct infringer's *knowledge or intent is irrelevant.*" (emphasis added)). Because of the strict-liability nature of direct infringement, this court has limited direct infringement liability "to those who practice each and every element of the claimed invention," *BMC,* 498 F.3d at 1381, i.e., the "single entity rule." *See Cross Med. Prods. v. Medtronic Sofamor Danek,* 424 F.3d 1293, 1311–12 (Fed.Cir.2005) (applying the single entity rule). The single entity rule, consistent with the statute, protects an actor who practices less than all elements of a claim—i.e., does not practice the "patented invention"—from direct patent infringement liability.

The legislative history supports the single entity rule for direct infringement. Congress enacted § 271 to clarify the scope of *indirect infringement,* and in so doing, "left in tact the entire body of case law on direct infringement." *Aro,* 365 U.S. at 342, 81 S.Ct. 599. When the Supreme Court held in *Aro* that § 271(a) did not change the law of *direct* infringement, the Court was referring to the single entity, all elements rule of direct infringement that was "well settled" in 1952. *See Wallace v. Holmes,* 29 F. Cas. 74, 80 (C.C.D.Conn.1871) ("The rule of law invoked by the defendants is this—that, where a patent is for a combination merely, it is not infringed by one who uses one or more of the parts, but not all, to produce the same results.... *This rule is well settled, and is not questioned on this trial.*" (emphasis added)).

Today, just as in 1952, where a single entity does not perform each and every claim limitation, that entity may not be characterized as or held liable as a direct infringer. *See Aro,* 365 U.S. at 340, 81 S.Ct. 599; *Cross Med.,* 424 F.3d at 1311–14 (Fed.Cir.2005) (holding that there can be no direct infringement of a product claim where surgeons, and not the defendant, made the claimed apparatus in the operating room, and remanding to determine whether the surgeons directly infringed such that Medtronic could be held liable for indirect infringement). Contributory actions—such as the performance of some, but not all, steps of a method claim—do not meet the all elements test, and thus must be analyzed exclusively under the doctrines of indirect infringement. *BMC,* 498 F.3d at 1381 ("[E]xpanding the rules governing direct infringement to reach independent conduct of multiple actors would subvert the statutory scheme for indirect infringement.").

Limelight and many *amici* argue that the word "whoever" in § 271(a) ("whoever ... uses ... any patented invention") undermines the single entity rule. *See* 1

U.S.C. § 1 ("In determining the meaning of any Act of Congress, *unless the context indicates otherwise*—words importing the singular include and apply to several persons, parties, or things . . . ." (emphasis added)). This argument fails for two reasons. First, if one interprets "whoever" to include the plural, the statute simply states the obvious: More than one entity can be independently liable for direct patent infringement if each entity practices every element of the claim. Second, the statutory context, with § 271(b) and (c) extending liability to actors who do not independently infringe in limited, specifically defined circumstances, indicates that § 271(a) excludes joint liability. *See City of Columbus v. Ours Garage & Wrecker Serv., Inc.,* 536 U.S. 424, 445, 122 S.Ct. 2226, 153 L.Ed.2d 430 (2002) ("It is a well-established principle of statutory construction (and of common sense) that when . . . 'two words or expressions are coupled together, one of which generally includes the other, it is obvious that the more general term is used in a meaning excluding the specific one.' ") (quoting J. Sutherland, Statutes and Statutory Construction § 266 p. 349 (1891)).

C. Traditional Principles of Vicarious Liability Still Apply to § 271(a)

Our "divided infringement" case law is rooted in traditional principles of vicarious liability. *BMC* held that, where the actions of one party can be legally imputed to another such that a single entity can be said to have performed each and every element of the claim, that single entity is liable as a direct infringer. 498 F.3d at 1380–81. Before *BMC,* the judiciary and the patent law community generally recognized that multiple actors could together infringe a patent only if one somehow controlled the other(s). *See Mobil Oil Corp. v. Filtrol Corp.,* 501 F.2d 282, 291–92 (9th Cir.1974) ("Mobil contends that Filtrol and Texaco split between them the performance of the four steps of the claim . . . . *We question whether a method claim can be infringed when two separate entities perform different operations and neither has control of the other's activities.* No case in point has been cited." (emphasis added)); Mark Lemley et al., *Divided Infringement Claims,* 33 AIPLA Q.J. 255, 258 (2005) ("[C]ourts have imposed liability for direct infringement *where another person acts as an agent of the alleged infringer.*" (emphasis added)). Applying traditional principles of vicarious liability to direct infringement under § 271(a) protects patentees from a situation where a party attempts to "avoid infringement . . . simply by contracting out steps of a patented process to another entity . . . . It would be unfair indeed for the mastermind in such situations to escape liability." *BMC,* 498 F.3d at 1381.

BMC's holding that direct infringement liability under § 271(a)—in the context of joint actors—exists only where one party was shown to "control or direct each step of the patented process," 498 F.3d at 1380, is properly rooted in the doctrine of vicarious liability. *See also Muniauction,* 532 F.3d at 1329. Both tort and agency law guide BMC's test. *See* Restatement (Second) of Torts § 877 (1979) ("For harm resulting to a third person from the tortious conduct of another, *one is subject to liability if he . . . orders or induces the conduct . . ., [or] controls, or has a duty to use care to control, the conduct of the other . . .* and fails to exercise care in the control . . . ." (emphases added)); Restatement (Third) of Agency § 1.01 (2006) ("Agency is the fiduciary relationship that arises when one person (a 'principal') manifests assent to another person (an 'agent') that the agent shall act on the principal's behalf and subject to the principal's control, and the agent manifests assent or otherwise consents so to act."); Restatement (Second) of Torts § 315 (1965)

("There is no duty so to control to the conduct of a third person as to prevent him from causing physical harm to another unless ... *a special relation exists between the actor and the third person which imposes a duty upon the actor to control the third person's conduct*...." (emphasis added)).

The vicarious liability test also reaches joint enterprises acting together to infringe a patent. The acts of each participant in a joint enterprise are, by definition, imputed to every member.

> All members of a joint venture may be jointly and severally liable to third persons for wrongful acts committed in furtherance of the joint enterprise. Thus, the negligence of one participant in the enterprise or venture, while acting within the scope of agency created by the enterprise, may be imputed to another participant so as to render the latter liable for the injuries sustained by third persons as a result of the negligence.

48A C.J.S. Joint Ventures § 60; *see also* Restatement (Second) of Torts § 491 (1965) ("Any one of several persons engaged in a joint enterprise, such as to make each member of the group responsible for physical harm to other persons caused by the negligence of any member, is barred from recovery against such other persons by the negligence of any member of the group.").

A joint enterprise exists for the purposes of imposing vicarious liability when there is:

> (1) an agreement, express or implied, among the members of the group; (2) a common purpose to be carried out by the group; (3) a community of pecuniary interest in that purpose, among the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control. Whether these elements exist is frequently a question for the jury, under proper direction from the court.

Restatement (Second) Torts § 491 cmt. *c.; see also* 57B Am.Jur.2d Negligence § 1138. In *Golden Hour Data Sys., Inc. v. emsCharts, Inc.,* 614 F.3d 1367 (Fed.Cir. 2010), this court, relying on *BMC* and *Muniauction,* affirmed the district court's grant of JMOL that there could be no direct infringement because there was insufficient evidence of direction or control, *id.* at 1380–81, even though the two accused entities "formed a strategic partnership, enabled their programs to work together, and collaborated to sell the two programs as a unit," *id.* at 1371. Because the parties in that case would have satisfied the test for joint enterprise based on common purpose and an equal right of mutual control, *see id.,* the en banc court should expressly overrule the holding in that case. This case, as well as the other "joint infringement" cases decided under § 271(a), however, cannot be addressed under the majority's analysis, which purports to limit itself to § 271(b).

The well established doctrine of vicarious liability is the proper test for establishing direct infringement liability in the multi-actor context. Absent direct infringement, the patentee has not suffered a compensable harm. *See, e.g., BMC,* 498 F.3d at 1379. In patent law, unlike in other areas of tort law—where the victim has no ability to define the injurious conduct upfront—the patentee specifically defines the boundaries of his or her exclusive rights in the claims appended to the patent and provides notice thereby to the public to permit avoidance of infringement. As this court correctly recognized in *BMC,* "[t]he concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting. A patentee can usually structure a claim to capture infringement by single party." 498 F.3d at 1381. As many *amici* have

pointed out, the claim drafter is the least cost avoider of the problem of unenforceable patents due to joint infringement, and this court is unwise to overrule decades of precedent in an attempt to enforce poorly-drafted patents.

Accordingly, I would hold that direct infringement is required to support infringement under § 271(b) or § 271(c) and properly exists only where one party performs each and every claim limitation or is vicariously liable for the acts of others in completing any steps of a method claim, such as when one party directs or controls another in a principal-agent relationship or like contractual relationship, or participates in a joint enterprise to practice each and every limitation of the claim.

D. Judge Newman's Dissent Errs by Resuscitating the Common Law of Joint Tortfeasor

Judge Newman's opinion, which would permit joint actor infringement liability whenever independent parties collectively infringe a patent, is no more satisfactory as a matter of either statutory interpretation or legal analysis. Judge Newman attempts to justify this loose approach to direct infringement liability under § 271(a) by asserting that § 271(a) is not a strict liability provision after all, with the apparent consequence that innocent participants are in fact not liable. This assertion is fallacious. In *Global–Tech*, the Supreme Court held that "[d]irect infringement has long been understood to require no more than the unauthorized use of a patented invention.... [A] direct infringer's *knowledge or intent is irrelevant.*" 131 S.Ct. at 2065 n. 2 (emphasis added). The fact that the statutory tort of infringement has no mental state requirement, actual or constructive, *by definition*, renders it a strict liability offense. *See Black's Law Dictionary* 998 (9th ed.2009) (defining "strict liability" as "[l]iability that does not depend on actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe"); XVI *Oxford English Dictionary* 899 (2d ed.1989) (defining "strict liability" as "a liability which does not depend upon intent to commit an offence"). Judge Newman's reliance on § 287's notice provisions for damages as evidence of a requisite mental state conflates *preconditions of suit* with *elements of the tort*, treating the marking requirement as tantamount to a "knew or should have known" element of infringement proper.

Judge Newman's joint actor liability approach under § 271(a) would also disrupt well-settled law with respect to system and apparatus claims by permitting multi-party infringement liability in the context of an apparatus or system claim—an absurd and unworkable result. For example, if a patentee, P, has an apparatus claim to a new and improved machine; and parties N, B, and G are manufactures who make the nuts, bolts, and gears that comprise the machine; and N, B, and G sell to party A, who assembles and sells or uses the machine; under Judge Newman's test, all are now joint infringers of P's patent. Under such an approach, the need for contributory infringement and inducement, as Congress envisioned, is essentially eviscerated.

III. Application to the Cases on Appeal

A. *Akamai*

In the *Akamai* case, the asserted claims were drafted so as to require the activities of both Limelight and its customers for a finding of infringement. Thus, Akamai put itself in a position of having to show that the allegedly infringing activities of Limelight's customers were attributable to Limelight. Akamai did not meet this burden because it did not show that Limelight's customers were acting as agents of or otherwise contractually obligated to Limelight or that they were acting in a

joint enterprise when performing the tagging and serving steps. Accordingly, I would affirm the district court's grant of Limelight's motion for JMOL of non-infringement under § 271(a).

I would also reinstate the portion of the panel's opinion addressing Limelight's alternative ground for affirmance and conditional cross-appeal of the damages award, as well as the portion dealing with the '645 and '413 Patents.

B. *McKesson*

In the *McKesson* case, the doctor-client relationships of the MyChart health care providers and their patients do not by themselves give rise to an agency relationship or impose on patients a contractual obligation such that the voluntary actions of the patients can be said to represent the vicarious actions of their doctors. Nor is there anything to indicate that the MyChart health care providers act in any joint enterprise with their patients. Accordingly, I would affirm the district court's grant of Epic's renewed motion for summary judgment of noninfringement.

MIRROR WORLDS, LLC, Plaintiff–Appellant,

v.

APPLE INC., Defendant–Appellee.

No. 2011–1392.

United States Court of Appeals, Federal Circuit.

Sept. 4, 2012.

Background: Owner of patents disclosing a document stream operating system and method brought action against competitor alleging infringement. Following entry of judgment as a matter of law on indirect infringement, jury found patents valid and infringed and listed damages of $208.5 million for each patent. Competitor filed renewed motion for judgment as a matter of law, motion for new trial and motion for remittitur. Patent owner moved for entry of judgment, interest, damages, fees and costs. The United States District Court for the Eastern District of Texas, Leonard Davis, J., 784 F.Supp.2d 703, granted competitor's motion and denied patent owner's motion. Patent owner appealed.

Holdings: The Court of Appeals, Lourie, Circuit Judge, held that:

(1) patents were not infringed under doctrine of equivalents;

(2) patent was not directly infringed; and

(3) competitor did not induce infringement.

Affirmed.

Prost, Circuit Judge, filed opinion dissenting in part.

1. Courts ⚿96(7)

Court of Appeals reviews the grant or denial of a motion for judgment as a matter of law under the law of the regional circuit.

2. Federal Courts ⚿776

Court of Appeals reviews the grant or denial of judgment as a matter of law de novo.

3. Federal Civil Procedure ⚿2142.1, 2608.1

If there is substantial evidence opposed to judgment as a matter of law it should be denied.

4. Patents ⚿324.55(5)

Jury's determination of patent infringement is a question of fact, which Court of Appeals reviews for substantial evidence.

Arnold & Porter LLP
Patent Law CLE
January 30, 2013

Selected Cases on Implied Patent Licensing via Legal Estoppel

***AMP v. United States*, 389 F.2d 448 (Ct. Cl. 1968)**

A license to practice certain identified inventions, rather than particular patents, covers, via legal estoppel, an earlier filed, dominant patent (i.e., one that was necessarily infringed by the practice of such inventions) later acquired by the licensor.

***TransCore v. Electronic Transaction Consultants Corp.*, 563 F.3d 1271 (Fed. Cir. 2009)**

Notwithstanding a statement in a settlement agreement that a covenant not to sue on specified patents did NOT apply to any later-issuing patents, the covenant not to sue did apply, via legal estoppel, to a later-issued patent that was related to the specified patents and was pending at the time the settlement agreement was executed.

***General Protecht Group, Inc. v. Leviton Manufacturing Co.*, 651 F.3d 1355 (Fed. Cir. 2011)**

A covenant not to sue in a settlement agreement to two patents covering certain products also applies, via legal estoppel, to any continuations of those patents, whether or not pending at the time the settlement agreement was executed, and even if those continuations are narrower than the specified patents (i.e., it was possible to infringe the specified patents without infringing the continuations), absent a clear indication of mutual intent to the contrary.

***Intel Corp. v. Negotiated Data Solutions, Inc.*, 2012 WL 6554690 (Fed. Cir. 2012)**

As a matter of California law, a patent license agreement applies not only to the literally described patents and applications but also to their reissue progeny.

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