

American University Washington College of Law
Digital Commons @ American University Washington College of Law

Articles in Law Reviews & Journals

Student Scholarship

1-1-2012

A Thousand Tiny Pieces: The Federal Circuit's Fractured 'Myriad' Ruling, Lessons to Be Learned, and the Way Forward

Jonathan Stroud

Follow this and additional works at: http://digitalcommons.wcl.american.edu/stusch_lawrev

 Part of the [Intellectual Property Commons](#), and the [Science and Technology Commons](#)

Recommended Citation

Stroud, Jonathan. "A Thousand Tiny Pieces: The Federal Circuit's Fractured 'Myriad' Ruling, Lessons to Be Learned, and the Way Forward." IP Theory (forthcoming 2012).

This Article is brought to you for free and open access by the Student Scholarship at Digital Commons @ American University Washington College of Law. It has been accepted for inclusion in Articles in Law Reviews & Journals by an authorized administrator of Digital Commons @ American University Washington College of Law. For more information, please contact fbrown@wcl.american.edu.

A THOUSAND TINY PIECES: THE FEDERAL CIRCUIT’S FRACTURED *MYRIAD* RULING, LESSONS TO BE LEARNED, AND THE WAY FORWARD

Jonathan Stroud*

- I. INTRODUCTION
- II. BACKGROUND
 - A. *Procedural Background*
 - B. *Personalized Medicine, Diagnostic Companies, and You*
 - C. *Myriad Possible Interpretations*
- III. THE FEDERAL CIRCUIT’S SPLIT DECISION
- III. PROMETHEUS-BOUND
- IV. INFERENCES AND ARGUMENTS
- V. CONCLUSION

The Supreme Court granted, vacated, and remanded the infamous Myriad gene isolation patentability case to the Court of Appeals for the Federal Circuit (CAFC) in light of the recent Prometheus decision, which held 9-0 that a certain diagnostic method was invalid subject matter because it was an abstract idea merely modified by other obvious steps. This Essay argues that Myriad should be affirmed again by the Federal Circuit, particularly in light of Prometheus, in order to inject certainty, clarity, and consistency into the § 101 patentable subject matter jurisprudence.

Then beneath the earth those hidden blessings for man, bronze, iron, silver and gold—who can claim to have discovered before me? No one, I am sure, who wants to speak to the purpose. In one short sentence understand it all: every art of mankind comes from Prometheus.
—Aeschylus (generally attributed)¹

I. INTRODUCTION

On July 29, 2011, the Court of Appeals for the Federal Circuit handed down the long-awaited decision in *Association of Molecular Pathology v. U.S. Patent and Trademark Office (AMP v. USPTO or Myriad I)*² upholding the patentability of claims on isolated human genes³ in

¹ AESCHYLUS, *PROMETHEUS BOUND* (GREEK TRAGEDY IN NEW TRANSLATIONS) II. 498–505 (James Scully & C. John Herington trans., University Oxford Press 1975) (c. 415 B.C.E.).

* Summer Associate, Finnegan, Henderson, Farabow, Garrett, & Dunner LLP, 2012 (expected); Patent Examiner, United States Patent and Trademark Office, 2007–2012. J.D., American University Washington College of Law (WCL), 2013 (expected); M.A., Print Journalism, University of Southern California, 2006; B.S.E., Biomedical Engineering, Tulane University, 2004. Mr. Stroud is the Senior Symposium Editor of the *Administrative Law Review*, the Senior Symposium Chair for the *Intellectual Property Brief (IP Brief)*, and the Executive Tournament Director of the *Moot Court Honor Society*. He is also a Dean’s Fellow to Professors Jonas Anderson and Andrew Popper and is the founder of the Court of Appeals for the Federal Circuit weekly beat, *The Short Circuit*, at the *IP Brief*. Thank you to the entire staff of IP Theory, and to

a 2–1 decision that has provoked a petition to rehear the case en banc,⁴ which was denied.⁵ Subsequently, a Supreme Court petition for certiorari was filed,⁶ which the high court recently granted, vacated, and remanded (GVRed) in *Association of Molecular Pathology v. U.S. Patent and Trademark Office (Myriad II)*⁷ in light of their recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc. (Prometheus)*.⁸

After the Federal Circuit’s initial decision, the genomic testing startup companies breathed a collective (if temporary) sigh of relief. That is, until the Supreme Court issued its

Michael Ruggiero and Corrine Parver, without whose teachings this would not have been written.

2. Ass’n of Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad I*), 653 F.3d 1329 (Fed. Cir. 2011), *cert. granted, vacated, and remanded sub nom.* Ass’n of Molecular Pathology v. Myriad Genetics, Inc. (*Myriad II*), No. 11–725, WL 986819 (U.S. Mar. 26, 2012)(remanding to the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012)).

3. Compare James J. Mullen, III & Mary Prendergast, *Federal Circuit Decision in Myriad Genetics Confirms that Isolated Human DNA Molecules Are Patentable*, MORRISON FOERSTER (Aug. 1, 2011), <http://www.mofo.com/files/Uploads/Images/110801-DNA-Molecules-Patentable.pdf> (highlighting the case as a win for diagnostic manufacturers interested in isolated human genome testing), with Recent Case, *Federal Circuit Invalidates Diagnostic Method Claims as Drawn to “Abstract Mental Processes.”*—Association for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (*Fed. Cir. 2011*), 125 HARV. L. REV. 658, 658 (2011) (arguing the case erroneously invalidated all diagnostic “method patents” under an unadvisable “abstract mental processes” standard), and Courtenay Brinckerhoff, *Federal Circuit Issues Mixed Decision on Myriad Claims*, PHARMAPATENTS (July 30, 2011), <http://www.pharmapatentsblog.com/federal-circuit-decisions/federal-circuit-decides-myriad-oks-isolated-dna-claims/> (calling the Federal Circuit’s *Myriad I* ruling a “mixed decision” and saying that “there is much to be analyzed before the full impact of this decision—and the contours of the holdings—will be understood”). See also Seth R. Ogden, Note, *The Federal Circuit’s Decision in Myriad: Isolated DNA Molecules Are Patentable Subject Matter*, 61 AM. U. L. REV. 443 (2011).

4. Petition for Rehearing En Banc, Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office, No. 2010-1406 (Fed. Cir. Aug. 31, 2011).

5. Denial of Petition for Rehearing En Banc, Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office, No. 2010-1406 (Fed. Cir. Sept. 13, 2011).

6. See Kevin E. Noonan, *AMP v. USPTO: Oral Argument at the Federal Circuit*, PATENT DOCS (Apr. 7, 2011, 12:00 PM), <http://www.patentdocs.org/2011/04/amp-v-uspto-oral-argument-at-the-federal-circuit.html> (“[The *Myriad I* case] is likely to be subject to *en banc* review, a petition for *certiorari* to the Supreme Court, or both. The case is far from over.”).

⁷ See Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office (*Myriad II*) No. 11–725, WL 986819 (U.S. March 26, 2012): “The petition for a writ of certiorari is granted. The judgment is vacated, and the case is remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 556 U.S. ____ (2012).”

8. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10–1150 (March 20, 2012) (slip op.) available at <http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>.

recent GVR, thus recreating the original uncertainty surrounding gene patents. The case is the latest chapter in the *AMP v. USPTO* saga, which has thrown the biotech world into turmoil over contentious genetic testing and threatened the future of personalized medicine in America. The Federal Circuit was right to rule definitively, and it is unfortunate that the dissenting judge divided the opinion and created uncertainty. The Supreme Court compounded that uncertainty when they chose to GVR the case and again create a swirl of confusion where clarity is sorely needed.

In the wake of the Supreme Court's recent unanimous invalidation of a diagnostic testing patent in *Prometheus* as unpatentable subject matter,⁹ however, commentators have suggested that the Federal Circuit may reverse the panel decision in light of the Supreme Court's unanimous precedent.¹⁰ *Prometheus* indicates that obvious subject matter, coupled with what the Court believes are laws of nature, is not patentable under § 101. Thus, the possibly obvious isolation of human genes could be held invalid, as isolation techniques have existed for some time.

Part II of this Article will give a brief synopsis of the procedural and historical background of the case and will discuss the importance of the patent claims to the genetic diagnostics industry and personalized medicine in general. Part III will analyze the Federal Circuit's divided opinion; Part IV will discuss *Prometheus*. Part IV will attempt to draw inferences about the possibilities surrounding *Myriad II*. Part V will conclude on a hopeful note.

II. BACKGROUND

The Patent and Trademark Clause of the U.S. Constitution grants the federal government the ability to grant patent rights,¹¹ and those laws have been codified for nearly as long as there has been a United States of America.¹² The statutory subject matter requirement is set forth in 35 U.S.C. § 101, and reads "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain

⁹ Id. at *8 (asking "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?" and stating "We believe that answer is no.").

¹⁰ Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLY-O.COM (May 20, 2012), <http://www.patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.html>:

Following *Mayo*, the court could logically find that the information in the DNA represents a law of nature, that the DNA itself is a natural phenomenon, that the isolation of the DNA simply employs an isolation process already well known and expected at the time of the invention, and ultimately that the isolated DNA is unpatentable because it effectively claims a law of nature or natural phenomenon.

11. "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. CONST. art. I, § 8, cl. 8.

12. See United States Patent Act, 35 U.S.C. §§ 100–105 (2006) (granting statutory authority to issue 20-year patents).

a patent therefor, subject to the conditions and requirements of this title.”¹³ The Courts have usually interpreted the clause broadly, subject to a few judicially created exemptions.¹⁴

A. Procedural Background

Since the Supreme Court ruled in 1980 in *Diamond v. Chakrabarty* that bioengineered living organisms are patentable subject matter,¹⁵ the USPTO has generally held that isolated human genes—segments of human genes that have been excised, with non-important parts spliced out, and then isolated in the laboratory—are patentable,¹⁶ to the tune of thousands of issued patents over the years.¹⁷ However, the lower district court in *AMP v. USPTO* invalidated patent claims to two controversial isolated genes, the BRCA 1 and 2 genes, which have been linked to a higher risk of female patients developing breast cancer.

The case was a surprise to many¹⁸ and threw the market for many start-up biotech companies into disarray, as a judicial cloud settled over their isolated gene patents.¹⁹ Complicating matters further, the Justice Department and the U.S. Solicitor General took an interest in the case, and although the Solicitor General of the USPTO generally argues cases in front of the Federal Circuit on behalf of the government, instead the Justice Department unprecedentedly stepped in with a largely contrary position from the one the USPTO had long held.²⁰

13. *Id.* § 101.

14. *See Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office (Myriad I)*, 653 F.3d 1329, 1348 (Fed. Cir. 2011) (discussing the “broad, [but] not unlimited” nature of § 101).

15. 447 U.S. 303, 310 (1980) (stating that the ability of man resulted in bacteria with “markedly different characteristics” and the “potential for significant utility”).

16. *See, e.g.*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001) (formally stating said longstanding policy).

17. *See Ass’n of Molecular Pathology*, 653 F.3d at 1355 (“It is estimated that the PTO has issued 2,645 patents claiming ‘isolated DNA’ over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome.” (internal citations omitted)); *id.* at 1367 (Moore, J., concurring) (“[T]here 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.”).

18. *See, e.g.*, Robert Carlson, *Surprise District Court Ruling Invalidates Myriad Genetics’ BRCA Patents, But Appeal Is Pending*, BIOTECH. HEALTHCARE (Summer 2010), at 8–9, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2899793/>.

19. *Id.* (saying that members of the bar were “surprised” and “dismayed” and that it was “contrary to . . . Federal Circuit precedent”).

20. *See* Jonathan Stroud, *Myriad Madness—How the Department of Justice is Working Counter to U.S. Interests*, INTELL. PROP. BRIEF (Feb. 22, 2011, 7:00 AM), <http://www.ipbrief.net/2011/02/22/myriad-madness-%E2%80%93-how-the-department-of-justice-is-working-counter-to-u-s-interests/> (“This highly unusual request by the Justice Department—preempting the Department of Commerce’s usual role in appellate-level arguments for all patent cases—only highlights the deep divisions between the two agency’s positions.”). The Federal Circuit referred to the infighting obliquely:

Although the PTO did not “sign” the brief 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

B. Personalized Medicine, Diagnostic Companies, and You

Personalized Medicine is the use of an individual's characteristics, in particular, their genetic information, to target medicines to the individual rather than administer traditional drugs in the same form and dose to all patients, in a one-size-fits-all model.²¹ It has been heralded by the heads of the FDA and the NIH as the future of medicine,²² and involves packaging genetic diagnostic testing and targeted medicines together, such as the recently FDA-approved cancer treatments crizotinib, and its genetic associated test.²³

In 2004, the Food and Drug Administration (FDA) approved a similar drug called erlotinib as a second-line defense for a subset of lung cancer patients.²⁴ In various clinical tests, the drug has produced uneven—but dramatic—results. Some patients had 30% shrinkage of their tumors; others had an amazing 99% shrinkage, nearly curing them entirely;²⁵ and some had almost no shrinkage at all.²⁶ This had some calling it a miracle drug,²⁷ while others questioned

Executive Branch, so it is fair to assume that the Executive Branch has modified its position from the one taken by the PTO in its 2001 guidelines and, informally, before that.

Ass'n of Molecular Pathology, 653 F.3d at 1380–81 (majority opinion).

21. See generally FRANCIS S. COLLINS, *THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALIZED MEDICINE* (2010) (discussing the future of genetics and the biotech industry).

22. See Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 *NEW ENG. J. MED.* 301, 301–04 (2010) (calling for greater collaboration between the Food and Drug Administration (FDA) and the National Institute of Health (NIH)).

23. Molly Peterson, *Pfizer Wins U.S. Approval for Lung Cancer Drug Seen as Filling Lipitor Gap*, *BLOOMBERG NEWS* (Aug. 27, 2011), <http://www.bloomberg.com/news/2011-08-26/pfizer-wins-u-s-approval-for-tumor-fighting-medicine-to-treat-lung-cancer.html> (reporting that Pfizer won approval of the drug, which is targeted to a specific form of lung cancer caused by a gene defect, along with the related genetic test approved by Abbott Labs); see also *Abbott Says FDA Clears Leukemia Genetic Test*, *YAHOO! NEWS* (Aug. 22, 2011), <http://news.yahoo.com/abbott-says-fda-clears-leukemia-genetic-test-154708318.html> (citing approval of a similar genetic test for leukemia).

24. *Tarceva® Erlotinib Tablets*, GENENTECH, <http://www.gene.com/gene/products/information/oncology/tarceva/> (last visited Mar. 19, 2012) (“Tarceva® (erlotinib) is a small molecule human epidermal growth factor type 1/epidermal growth factor receptor (HER1/EGFR) inhibitor which demonstrated, in a Phase III clinical trial, an increased survival in advanced non-small cell lung cancer (NSCLC) patients.”).

25. HOWARD HUGHES MED. INST., *GENETIC ACCOMPLICE HELPS SOME LUNG TUMORS EVADE TREATMENT* (March 23, 2011), available at <http://www.hhmi.org/news/pdf/sawyers20110323.pdf> (“Within weeks, [erlotinib] can shrink tumors with a particular mutation to near vanishing. But the drug does not work equally well in all patients. For others with the same mutation, the results can be disappointing. Tumors may only shrink by 30 percent.”).

26. Heidi Ledford, *Mutations Block Lung-Cancer Treatment*, *NATURE* (Mar. 23, 2011), <http://www.nature.com/news/2011/110323/full/news.2011.178.html> (“These drugs help most patients: about three quarters of those with EGFR-activating mutations respond well to gefitinib

the wisdom of approving a costly drug treatment that conveyed to many the false hope of a dramatic cure.²⁸ Nonetheless, the U.S. manufacturer Genentech has encouraged clinical research, and recent results have shown that clinicians can identify smaller and smaller subsets of lung cancer patients who will benefit through genetic testing.²⁹

Recently, the National Comprehensive Cancer Network and the American Society of Clinical Oncology (ASCO) recommended lung cancer patients be screened for a specific genetic mutation—EGFR—to identify patients most likely to benefit from the drug.³⁰ By combining the expensive drug with the genetic test, researchers believe patient outcomes can be improved,³¹ while others who might respond poorly to the medication can be screened out.³² It would also justify the high cost to the small subset of users who would benefit. Yet it has taken more than five years to make even this modest suggestion that targeted testing can improve outcomes. So this and similar drugs' future effectiveness seems to be pegged to the successful implementation of a very specific genetic test.³³

[a related EGFR-inhibitor], for example. But the rest respond poorly, if at all, and no one knows why.”).

27. *Id.* (“For some patients with lung cancer, the drug erlotinib is a near miracle.”); *see also Some of Our Survivors Call It the “Miracle Drug,”* BONNIE J. ADDARIO LUNG CANCER FOUND., <http://www.lungcancerfoundation.org/2009/03/19/some-of-our-survivors-call-it-the-%E2%80%9Cmiracle-drug%E2%80%9D/> (last visited Mar. 19, 2012).

28. Goran Mijuk & Sten Stovall, *Roche's UK Drug Appeal Failure Underscores Problems*, DOW JONES DEUTSCHLAND (June 29, 2011), <http://www.dowjones.de/site/2011/06/roches-uk-drug-appeal-failure-underscores-problems.html> (discussing the manufacturer’s “increasing problems with government bodies that view its medicines as too expensive” and pegging the cost of treatment at “between \$30,000 to \$60,000 per year”).

29. Trever G. Bivona et al., *FAS and NF-κB Signalling Modulate Dependence of Lung Cancers on Mutant EGFR*, 471 NATURE 523, 523–26 (2011) (finding that with Tarceva “the magnitude of tumour regression is variable and transient” and that “this . . . could result from genetic modifiers that regulate the degree to which tumour cells are dependent on mutant EGFR”).

30. Patrice Wendling, *Mutation Testing Guided Erlotinib Prescribing in Lung Cancer*, INTERNAL MED. NEWS DIGITAL NETWORK (July 11, 2011), <http://www.internalmedicineneeds.com/views/observation-unit/blog/mutation-testing-guided-erlotinib-prescribing-in-lung-cancer/31b54c31e5.html>.

31. Fred Hirsch, *The Role of Genetic Testing in the Prediction of Response to EGFR Inhibitors in NSCLC*, 28 ONCOGENE S1, S1–S3 (2009) (releasing clinical findings that “pretreatment detection of such markers could facilitate a more personalized and specific approach to therapy, whereby the most appropriate and efficacious treatment is selected for a specific subset of patients”).

32. *See id.* (“EGFR mutation testing is ready for routine clinical use and [more targeted] testing will soon be ready.”); *cf.* Peggy Peck, *Tarceva Improves Survival in Subset of Patients with Refractory Non-Small Cell Lung Cancer*, MEDPAGE TODAY (July 13, 2005), <http://www.medpagetoday.com/Pulmonology/LungCancer/1353> (“While supporters of Tarceva . . . hailed [positive clinical trial results] as a major advance in ‘personalized medicine,’ the absolute numbers were less than overwhelming.”).

33. *Accord* FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF: IN VITRO COMPANION DIAGNOSTIC DEVICES 5 n.2 (2011) [hereinafter DRAFT GUIDANCE], *available at*

Indeed, the NIH recently announced it would, and now has, published a Genetic Testing Registry by early 2012, highlighting commercial genetic testing's growing importance.³⁴ However, the registry is voluntary,³⁵ and there is still a vast need for patent protection, especially in light of the FDA's confused treatment of genetic tests.

Over the past fifteen years, the FDA had begun to assert jurisdiction over laboratory diagnostic tests (LDTs) and end their long-practiced enforcement discretion.³⁶ In July of 2010, the FDA held a public meeting announcing its intent to regulate LDTs based on the risks that they posed, and stated that guidance would follow.³⁷ Then on July 11, 2011 the FDA issued draft guidance on what they termed "in vitro companion diagnostic devices" (IVCDDs).³⁸

In it, the FDA would require that the innovator seek FDA approval for new medical products (drugs and biologics) under either § 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) (drugs)³⁹ or § 351 of the Public Health Service Act (PHSA) (biologics),⁴⁰ while the innovator must seek contemporaneous approval for the IVCDD under § 510(k) of the Medical Device Amendments⁴¹ to the FDCA.⁴² Effectively, it would assert jurisdiction over any new laboratory tests that it are "essential for the safe and effective use of a corresponding therapeutic product."⁴³ It also seems to require FDA approval for such tests as full IVCDDs, subject to

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM262327.pdf> (using Herceptin and the associated test as another example of a treatment combination which is only useful for metastatic breast cancer and gastric cancer if the patient has the HER-2 genetic marker, which the test reveals).

34. *Genetic Testing Registry*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/gtr/> (last visited Jan. 20, 2012) ("Once operational, GTR will provide access to information about genetic tests for inherited and somatic genetic variations, including newer types of tests such as arrays and multiplex panels.").

35. *Id.* ("GTR information about tests primarily will be based on voluntary data submissions by test developers and manufacturers.").

36. *See, e.g.*, In Vitro Diagnostic Products For Human Use, 21 C.F.R. pt. 809 (2012); SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y (SACGHS), U.S. SYSTEM OF OVERSIGHT OF GENETIC TESTING: A RESPONSE TO THE CHARGE OF THE SECRETARY OF HEALTH AND HUMAN SERVICES (2008), http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf (recommending greater FDA oversight of laboratory diagnostic tests (LDTs) consistent with in vitro diagnostics (IVDs)).

37. FDA/CDRH Public Meeting, Oversight of Laboratory Developed Tests (LDTs) (July 19–20, 2010), *available at*

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm>.

38. DRAFT GUIDANCE, *supra* note 33, at 3, 7.

39. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, ch. 675, § 505, 52 Stat. 1040, 1055 (codified as amended in scattered sections of 21 U.S.C.).

40. Public Health Service Act, Pub. L. No. 78-410, ch. 373, 58 Stat. 682 (codified as amended at 42 U.S.C. §§ 262–300jj, 351 (2006 & Supp. II 2006)).

41. Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.).

42. DRAFT GUIDANCE, *supra* note 33, at 7.

43. *See id.* at 6.

exceptions for products that threaten serious or life-threatening conditions or already-approved products.⁴⁴

This would ostensibly prevent drug companies from seeking approval for drugs like crizotinib or erlotinib without also approving and commercializing the much-needed test and relying instead on variable LDTs nationwide. It also serves to expand the FDA's authority over such devices and would affect drug approvals: For instance, an expensive medicine with a small targeted population could possibly fail approval as not being "effective" enough to be generally prescribed, unless it was also coupled with the test, which the FDA would, under this guidance, require. Lastly, it begins the slow transition to a regulatory framework that considers IVDs an essential part of medical treatment. There is also a companion legislative push to regulate by statute the devices under a separate pathway at the FDA.⁴⁵ This would lower the cost of premarket approval and allow smaller companies to get their commercialized diagnostic tests to market.

However, until the Congress or the FDA acts to streamline the approval process, currently the only readily available path to commercialization for small companies is the patent process. Companies seeking to commercialize research and development—particularly university spinouts and start-up companies—need a fast and effective way to protect their research and commercialize their genetic tests, and isolated gene patents have been the primary vehicle to do so, particularly for companies like Myriad that do not have the resources of a Pfizer or an Abbott Labs to undergo the expensive and time-consuming FDA approval process (as it now stands). Thus, the importance of the *USPTO v. AMP* decision for that industry cannot be overstated: In this context, it is an all-or-nothing affair. These companies need these patents to survive and continue to innovate, unless and until Congress or the FDA reform to the point where these products can be approved cheaply.

C. Myriad Possible Interpretations

44. *See id.* at 8–9.

45. Advocates of FDA enforcement authority over LDTs and industry representatives seeking a clear pathway to approval for more targeted medicines in the development pipeline have begun to lobby Congress to expand the regulatory authority of the FDA to include all commercially available laboratory tests of any targeted therapeutic significance. *See* Scott Gottlieb, *Will Regulation Thwart the Personalization of Medicine?*, HEALTH POL'Y OUTLOOK 3 (Am. Enter. Inst. for Pub. Policy Research, Wash., D.C.), Oct. 2010, at 7, <http://www.aei.org/files/2010/10/22/2010-10-No-3-g.pdf> (advocating for a legislative solution to the regulatory problem). The easiest vehicle to amend the law would be the reauthorization bill of the Prescription Drug User Fee Act, a widely popular bill that is up for reauthorization in 2012. *See id.* at 7 ("The way to change LDT regulation may be the reauthorization of the Medical Device User Fee and Modernization Act next year, rather than the FDA's internal policy process. Legislation is likely to get coupled to the act that would give the FDA new authority over LDTs."). The draft legislation getting the most attention—that is under development by Senator Orrin Hatch's office—is the Better Evaluation and Treatment Through Essential Regulatory Reform for Patient Care (BETTER Patient Care) Act of 2011. SENATE LEGISLATIVE COUNCIL (2011) (draft legislation) (on file with author).

The instant cases, *Myriad I & II*, pits concerned doctors and women’s health groups against the company that isolated the gene and developed and patented the genetic test.⁴⁶ They rests largely on two very distinct ways of seeing the science behind isolating the human genome. The first could be called the “informational” view, and is the argument that won the day in the lower court—that the human genome represents information and sequences that occur naturally, and thus cannot be patented. The second can be called the “chemical” or “mechanical” view, and it posits that the isolated molecules—which have been chemically cleaved, separated, and do not occur in this chemically differing state in nature—are “markedly different” under the *Chakabarty* test and have distinct utility (as primers and test pieces).⁴⁷

III. THE FEDERAL CIRCUIT’S SPLIT DECISION

The Attorney General’s office argued for the former in this case, positing a “magic microscope” test in oral argument, where if one were to magnify the human genome, one could see the sequence as claimed in the patent.⁴⁸

In the majority opinion, Judge Lourie flatly rejected that test,⁴⁹ and adopted the “chemical” view outlined above.⁵⁰ The majority found that the chemical cleaving of the bonds that connect all human genomes produced a markedly different chemical structure than the one found in nature, and thus the resulting invention was patentable.⁵¹ Arguing against the dissent, the majority clearly found the informational view lacking, making a clear distinction between claims over structure and claims over function.⁵² Further, the majority stressed the “utility” of the invention, and the “markedly different” or “distinctive” characteristics.⁵³

In a remarkably well-written concurring opinion, Judge Moore said that, at least with regards to a certain set of broad claims, it was a much closer question, but that the economic reliance interests and the long-settled expectations of the biotechnology industry tipped the

46. *Ass’n of Molecular Pathology v. U.S. Patent and Trademark Office (Myriad I)*, 653 F.3d 1329, 1329 (Fed. Cir. 2011).

47. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

48. *See Ass’n of Molecular Pathology*, 653 F.3d at 1350.

49. *Id.* at 1368–70 (stating the magic microscope test “has curb appeal” in its “child-like simplicity” but that ultimately it is not a “limited position” as the government asserted, and the government is “wrong”).

50. *Id.* at 1353 (“Visualization does not cleave and isolate the particular DNA; that is the act of human invention.”).

51. *Id.* (“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 ever exists as a separate molecule in the body or anywhere else in nature, and may have an entirely different utility. That would discourage innovation.”).

52. *Id.* (“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 their functions.”).

53. *Id.* at 1351 (“Applying this test to the isolated DNA in this case, we conclude that the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different—have a distinctive chemical identity and nature—from molecules that exist in nature.”).

scales in favor of allowing patentability on isolated genes (as the USPTO and the Federal Circuit always have).⁵⁴

This is a pragmatic argument that takes into account the large number of property rights that the Court would be strip from inventors and former applicants, many of whom have been relying on their isolated gene patents for decades. Yet the bulk of both opinions rest on the hard science—the chemistry of chemical bonds—complete with charts and diagrams, and resists devolving into sentimental policy judgments. At the end of the day, § 101 is not the avenue to invalidate these patents; Congress is.

In one of the more memorable lines of the case, the majority seemed to rebuke the lower court’s lengthy opinion, urging deference to Congress and endorsing judicial minimalism: “[C]ourts decide cases, they do not draft legal treatises.”⁵⁵

IV. PROMETHEUS-BOUND

On March 20, 2012, the Supreme Court complicated matters when it unanimously held in *Prometheus* that a diagnostic method patent was invalid under § 101 because it “set forth mere laws of nature”—relationships between blood-borne metabolites and the appropriate dosage of a dangerous drug—rather than a patentable diagnostic process.⁵⁶ It held that diagnostic patents that *apply* so-called natural laws using known processes are invalid, and it held that the underlying mathematical relationship between metabolite levels of the blood and the drug thiopurine was an immutable law of nature.⁵⁷

Thus, the Supreme Court endorsed a “law-of-nature-plus-obviousness” methodology for analyzing unpatentable subject matter under § 101, whereby any mathematical equation or natural relationship that is applied using an already-known methodology is invalid under § 101.⁵⁸

The Court noted that many argued in the case that “a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to make valuable

54. *Id.* at 1367–73 (Moore, J., concurring-in-part). I argued this back in November 2010:

Because it will fuel scientific progress, give a reasonable financial incentive to companies interested in genomics, and lead to further research in this rapidly expanding field, not to mention the fact that it is consistent with prevailing Federal Circuit precedent, the court should overturn this dangerous ruling. The government should not support the ruling, which in effect would invalidate over 2,000 genomic patents.

Jonathan Stroud, *The Government is Wrong: The Case for Human Gene Patents and the Genomics Revolution*, INTELL. PROP. BRIEF (Nov. 2, 2010, 10:30 AM)

<http://www.ipbrief.net/2010/11/02/the-government-is-wrong-the-case-for-human-gene-patents-and-the-genomics-revolution/>.

55. *Ass’n of Molecular Pathology*, 653 F.3d at 1354 (majority opinion).

⁵⁶ . *Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10–1150 at *8 (March 20, 2012) (slip op.) *available at* <http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>.

⁵⁷ *Id.*

⁵⁸ *Id.*; *Accord* Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLY-O.COM (May 20, 2012) <http://www.patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.htm> (suggesting that the new test invalidates any natural process coupled with known elements).

discoveries, particularly in the area of diagnostic research,⁵⁹ but found equally compelling the counter-argument brought by, among others, the Association of Molecular Pathology, the petitioner in *Myriad I & II*.⁶⁰ They argued is that if patent protection is allowed over the body's natural response to drugs, then "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."⁶¹

Justice Breyer was seemingly nervous about ruling in such a way as to protect the medical diagnostic industry that might have produced unforeseen results in other fields of technology,⁶² for instance, in internet patents. Frustratingly, the Court sidestepped the issue, stating, "we must recognize the role of Congress in crafting more finely tailored rules where necessary" and "we need not determine here whether, from a policy perspective, increased protection from discoveries of diagnostic laws of nature is desirable."⁶³ Indeed, the Court chose not to address the issue at all, much to the chagrin of the Author and the entire diagnostic testing community.

Thus, it is an open question whether human genomic sequences might rise to the level of natural laws isolated via a known means of isolation, or whether the Federal Circuit may hold that the isolation of specific genes is a non-obvious means of harnessing and testing for the gene and uphold *Myriad II* based on the analysis put forth in *Prometheus*.

V. INFERENCES AND ARGUMENTS

The Federal Circuit's majority opinion in *Myriad I* argued persuasively, adopted the chemical view, and was the correct position, and Judge Moore's concurrence eloquently bolstered the Court's position, while both the majority and the concurring opinion weakened the dissent's reasoning, and both make a persuasive case based on sound scientific and economic principles. The validity and strength of the ruling, however, has been cast into doubt by the binding precedent of *Prometheus*. Yet to understand the lingering doubts, the emotional resonance of the dissent, and the uncertainty cast on the case by the Supreme Court's GVR, one must look to the underlying issue in the case.

The unspoken view at the heart of the conflict, one that does not appeal to the scientist or even to legal reason but rather to baser emotions, is the basic "my body, my property" view. This view essentially conflates the genetic information that is common to most human beings—and hence the potential unlocked when its sequence is discovered—with a person's own individual DNA. The logic is simple—the DNA is mine. No one else can own it. It conjures up images of human organ trafficking and reminds us of dystopian science fiction plotlines about commoditized body parts, and it ostensibly raises issues about personal privacy and bodily autonomy. Like the magic microscope test or the dissent's leaf test, it has "curb appeal" and "a

⁵⁹ *Prometheus*, No. 10–1150 at *23.

⁶⁰ *Id.*

⁶¹ *Id.* (quotation and citation omitted).

⁶² *Id.* at *24 ("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.").

⁶³ *Id.* (citation omitted).

childlike simplicity,”⁶⁴ but it ultimately oversimplifies and perhaps misunderstands the issues in the case in a play to emotions.

It would be intellectually disingenuous to say that the true issue is over personal autonomy. The problem is that Myriad did not seek to buy or sell any individual’s particular genome, or genetic material, or even to prevent them from analyzing it—they sought to exclude others from making or using only the test for analyzing it that they innovated. Beyond the emotional appeal, we must understand the pragmatic effects of such a limited ruling. Without allowing such patents to stand, the court would doom the nascent personalized medicine movement that has given us erlotinib and crizotinib, and it would render targeted care more difficult to innovate and thus provide. Complex companion tests, IVCDDs, and LDTs would not be commercially viable at all without such patent protection and a strong FDA approval pipeline, and companies would be forced to abandon promising treatments to seek greener pastures, so to speak.

The true underlying issue we must keep in mind is not the existence of the test Myriad developed—it is the cost. All agree that the test itself is highly beneficial and may save lives; why else would so many people and groups be interested in the test in the first place? The question is whether the patent system is the appropriate vehicle for protecting genetic diagnostic testing.

In response, you do not throw the baby out with the bathwater. One may not always like the cost of prescription medicines, but sick patients are still better off when beneficial drugs and companion tests exist and are generally available. Patent protection may be too long,⁶⁵ too exclusive,⁶⁶ or too over-enforced,⁶⁷ but allowing the Courts to alter precedent and simply invalidate the patents entirely in one broad stroke is not the solution.

Nor should the *Prometheus* decision alter this ruling. The Myriad company invested a large amount of time and money locating, identifying, and isolating the genes in question, and then recreating the unique methodology required to isolate these particular genes on a commercial scale. Thus, even if isolating other genes is a known method of testing for them, the isolation of each specific gene requires a unique chemical methodology that is not generally known at the time of patent filing. I believe the Federal Circuit understands the unique nature of this chemical process, and will uphold their initial ruling after applying the *Prometheus* framework by determining that the isolation method patented was, in fact, as non-obvious as the underlying genes it isolates. At the worst, they should limit the scope of the independent claims in light of the specific embodiments outlined in the specification.

Ultimately, however, the true solution to this problem, as Justice Breyer suggested, is through effective legislative and administrative regulation of commercialized diagnostic genetic tests, and strong patent protection for isolated gene patents targeting specified genomes. Only

64. See *supra* note 45 and accompanying text.

65. Cf. Gideon Parchomovsky & Michael Mattioli, *Partial Patents*, 111 COLUM. L. REV. 207, 208–09 (2011) (introducing the idea of partial patents and semi-patents which offer variable protection over the current one-size-fits-all model, in order to increase use and access to technologies while reducing the cost of innovation).

66. Cf. *id.* at 208 (arguing partial patents that allow enforcement only against rival commercial entities would help spur innovation and limit deleterious exclusion).

67. Cf. *id.*

then can personalized medicine truly flourish, while still generating jobs, innovation, and economic growth. *Myriad II* should be again upheld by the Federal Circuit.

VI. CONCLUSION

In conclusion, the majority and concurring opinions in *Myriad I* provide strong positions from which to defend the longstanding practice of allowing patents on chemically isolated human genomes, but it remains to be seen whether the Supreme Court's *Prometheus* ruling has significantly altered the analysis to the point where they must reverse their ruling. Until then, the genomic and diagnostic start-up market will suffer the consequences of that uncertainty. Hopefully, the Federal Circuit will quickly issue an opinion reaffirming their previous ruling in light of the *Prometheus* framework, and thus re-inject certainty into a market that is one of America's brighter spots in terms of innovation, job creation, and economic growth. At the least, they can reinforce thousands of preexisting property rights, uphold *stare decisis*, and leave it to Congress to legislate the difficult policy questions.