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Patenting and Protecting Personalized Medicine Innovation Post-Mayo, Myriad, and Limelight

Leland L. Black

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**Patenting and Protecting Personalized Medicine Innovation
Post-*Mayo*, *Myriad*, and *Limelight****

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INTRODUCTION

The ultimate goal of personalized medicine is to provide a patient with the ideal treatment, optimized to the patient’s individual genome, to promote effective, efficient, and tailored care.¹ Developments in the sciences over the past seventy-five years have started making widespread personalized medicine a reality.² For example, breast cancers with high expression of human epidermal growth factor receptor 2 (“HER2”) were associated with poor patient

* © 2017 Leland L. Black, B.S., University of Florida, Microbiology, 2007; PhD, University of Alabama at Birmingham, Microbiology, 2014.

1. See Andrea D. Eckhart, Kirk Beebe & Mike Milburn, *Metabolomics as a Key Integrator for “Omic” Advancement of Personalized Medicine and Future Therapies*, 5 CLINICAL & TRANSLATIONAL SCI. 285, 285 (2012).

2. See *infra* Section I.A.

prognoses due to faster growth and spread.³ Throughout the 1990s, researchers developed monoclonal antibodies to target HER2, slowing the growth of HER2-positive breast cancers.⁴ Now there are drugs on the market, such as trastuzumab (Herceptin), given specifically to patients with HER2-positive breast cancer in combination with chemotherapy.⁵ This treatment regimen, personalized to the patient's genome, has nearly doubled the average time before a relapse and doubled the number of patients who have no evidence of tumor progression up to twelve months after treatment.⁶

However, the realities and difficulties associated with personalized drug development remain. Imagine that a pharmaceutical company would have to spend fifteen years and hundreds of millions, even billions, of dollars perfecting techniques for diagnosing and treating an aggressive cancer.⁷ What if a patent was no longer a viable option to protect and recoup the company's investment? What if, as a result, the lab across the street could reverse engineer the company's work with minimal time and effort? Would the company even start the work in the first place?

The drug development process begins in the laboratory, where researchers perform fundamental research to understand diseases, identify associated potential therapeutic targets, and find promising lead compounds that could be developed into new medicines.⁸ Following the U.S. Food and Drug Association (the "FDA") approval of a New Drug Application,⁹ Phase I clinical trials are conducted on a small number of healthy volunteers to assess the

3. *A Story of Discovery: HER2's Genetic Link to Breast Cancer Spurs Development of New Treatments*, NAT'L CANCER INST., <http://www.cancer.gov/research/progress/discovery/HER2> [<https://perma.cc/9LWY-QZKP>].

4. *Id.*

5. *Id.*

6. *See id.*

7. *See infra* note 1 and accompanying text.

8. PHARMA, BIOPHARMACEUTICAL RESEARCH AND DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 2–4 (2015), http://phrma.org/sites/default/files/pdf/rd_brochure.pdf [<https://perma.cc/S9CQ-7U7D>]. After the initial testing phase, researchers test the drugs utilizing various models to prioritize lead compounds and those "that survive the initial screening are then 'optimized,' or altered to make them more effective and safer." *Id.* at 7.

9. The New Drug Application "is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S." *New Drug Application (NDA)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/> [<https://perma.cc/W7J4-XHUU>].

safety, bioavailability, and metabolism of the candidate drug.¹⁰ Finally, Phase II and III clinical trials assess the safety and efficacy of the candidate drug in large cohorts of patients with the disease of interest.¹¹ When the development process concludes, a company could have invested upwards of \$2.6 billion and a minimum of ten years of labor to get a single successful drug to market.¹²

Intellectual property rights, particularly patents, are key in allowing pharmaceutical companies to get a return on their research and development investments. Patents grant patentees “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States,”¹³ typically for a period of twenty years from the date of filing.¹⁴ The idea that patent protection is a requirement is so ingrained in the industry that “pharmaceutical companies systematically screen their drug candidates to exclude the ones lacking strong patent protection, checking their patentability at least three different times during drug development.”¹⁵ The last check typically occurs before clinical trials, and if there are any major threats to patentability, the drug may be pulled.¹⁶ Additionally, now pharmaceutical companies must ensure that defensible patents protect their drugs, as the rise of generic manufacturer challenges since the mid-1990s has dramatically increased the amount of pharmaceutical patent litigation in the United States.¹⁷ After a brand name company brings an infringement suit, the generic company will invariably argue that the patent in question is invalid.¹⁸

In order to be eligible for patent protection, an invention must be useful,¹⁹ novel,²⁰ and non-obvious.²¹ While novelty and non-obviousness are needed for patentability, this Comment will focus on the statutory requirement of “usefulness” in 35 U.S.C. § 101, which states: “Whoever invents or discovers any new and *useful* process,

10. PHRMA, *supra* note 8, at 13.

11. *See id.*

12. *Id.* at 1.

13. 35 U.S.C. § 154(a)(1) (2015).

14. *Id.* § 154(a)(2). However, design patents run for fourteen years from the date of issue. *Id.* § 173 (stating that design patents run for a “term of fourteen years from the date of grant”).

15. Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545 (2009).

16. *See id.* at 546–47.

17. *See id.* at 550 & n.251.

18. *See id.*

19. *See* 35 U.S.C. § 101 (2012).

20. *See id.* § 102.

21. *See id.* § 103.

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.”²² Historically, an invention could be considered useful—directed to patent eligible subject matter—if it was “anything under the sun that [was] made by man.”²³ However, during the past four years, the scope of what is considered patent eligible subject matter has been shrinking.²⁴ Patent applications directed solely to natural phenomena and laws of nature have never been patent eligible,²⁵ but a recent shift in the Court’s interpretation of what is “directed to” natural phenomena and laws of nature,²⁶ and subsequent agency guidance, has been deemed a serious threat to biotech patents.²⁷ This shift can be seen in two recent Supreme Court opinions—*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*²⁸ and *Association for Molecular Pathology v. Myriad Genetics, Inc.*²⁹—and the United States Patent & Trademark Office’s (the “USPTO”) attempts to provide guidance and ensure compliance with said decisions.³⁰ Thus, the relationship between the usefulness standard and personalized medicine patents, which are typically directed in part to measuring something naturally present in the body, is ripe for discussion.

The developing restrictions on the patentability of biotech patents will unfortunately affect the progress of personalized medicine, if they have not already.³¹ Incentives for companies to spend time and effort developing advancements in personalized medicine, specifically a company’s ability to protect its research and development investments through patents, are sure to decline in the

22. *Id.* at § 101 (emphasis added).

23. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

24. *See infra* Section II.B.

25. 2014 *Interim Eligibility Guidance Quick Reference Sheet*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/law/exam/myriad-mayo_qrs.pdf [https://perma.cc/N456-G4PV].

26. *See infra* Part II.

27. *See generally* Gene Quinn, *Erosion of Patent Rights Will Harm US Economy*, IP WATCHDOG (Aug. 28, 2014), <http://www.ipwatchdog.com/2014/08/28/erosion-of-patent-rights-will-harm-us-economy/id=50136/> [https://perma.cc/Y4PK-C97J (staff-uploaded archive)] (predicting that “[b]y the time Congress figures it out things will have gotten worse, perhaps catastrophically bad”).

28. 132 S. Ct. 1289 (2012).

29. 133 S. Ct. 2107 (2013).

30. The USPTO issues guidance memos to assist patent examiners in the eligibility analysis of patent applications. *See, e.g.*, U.S. PATENT & TRADEMARK OFFICE, SUBJECT MATTER ELIGIBILITY EXAMPLES: LIFE SCIENCES, 1–28 (2016), <https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf> [https://perma.cc/YTK8-2PBG].

31. *See infra* Section I.A.

near future.³² It is worth noting that the decisions from the Supreme Court and Federal Circuit that will be discussed in this Comment are in direct conflict with current health care initiatives promoted by the other branches of the federal government.³³ As the American Bar Association's Section of Intellectual Property Law chair recently stated, "At the same time that the President and Congress are calling for incentives to personalized medicine innovators, the Interim Guidance and the Courts are placing burdens on these same innovators by broadly interpreting 35 U.S.C. § 101."³⁴

In order to avoid drafting a personalized medicine patent directed to non-eligible subject matter, drafters typically include an "active treatment" step.³⁵ Specifically, the first few steps of the patent will require screening for a biomarker,³⁶ while the subsequent steps will be directed to treating the patient based on the results of the screening.³⁷ In method patents³⁸ such as these, multiple people usually perform the steps of the patent: a technician runs the test, a doctor prescribes the treatment, and a patient takes the medicine. Thus, in a personalized medicine infringement case, the infringement is usually divided among the multiple actors. Prior to a recent line of cases, a

32. See, e.g., Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization, and Utilization of Innovative Genetic Diagnostic Tests*, CTR. FOR PROTECTION OF INTELL. PROP., July 2014, at 3, <http://cpip.gmu.edu/wp-content/uploads/2014/04/Holman-Critical-Role-of-Patents-in-Genetic-Diagnostic-Tests.pdf> [<https://perma.cc/MQ7H-6XT9>].

33. See Letter from Lisa A. Dunner, Section Chair, Am. Bar Ass'n, Section of Intellectual Prop. Law, to the Honorable Michelle Lee, Under Sec'y of Commerce for Intellectual Prop. and Dir. of the U.S. Patent and Trademark Office, 4–5 (March 12, 2015), https://www.uspto.gov/sites/default/files/documents/2014ig_a_aba_2015mar12.pdf [<https://perma.cc/62PV-7FLC>].

34. *Id.* at 4.

35. See Duane C. Marks, Patent Counsel, Roche Diagnostics Operations, Inc., *Diagnostic Method Patents: A Framework for Patent-Eligibility of Diagnostic Method Patents Post-Mayo*, Presentation at the Subject Matter Eligibility Forum 8 (May 9, 2014), http://www.uspto.gov/sites/default/files/patents/announce/may9forum_marks.pdf [<https://perma.cc/4MUG-22A6>]; see also *Bilski v. Kappos*, 561 U.S. 593, 601–11 (2010) (describing how courts have examined cases where the subject matter eligibility of a patent was in question).

36. *NCI Dictionary of Cancer Terms*, NAT'L CANCER INST., <http://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=45618> [<http://perma.cc/5VZK-CDQV>] (defining a biomarker as "[a] biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease").

37. *Classen Immunotherapies v. Biogen IDEC*, 659 F.3d 1057, 1084 (Fed. Cir. 2011).

38. Patentable subject matter includes processes, machines, articles of manufacture, and compositions of matter. 35 U.S.C. § 101 (2012). Process patents are also referred to as method patents. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1379 (Fed. Cir. 2007), *overruled by Akami Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc).

patent directed to multiple actors could only be infringed if there was proof of direct infringement and a single party had exercised control or discretion over every step of the claimed method.³⁹ Recently the Federal Circuit and the Supreme Court addressed situations of divided infringement—in *Limelight I*,⁴⁰ *Limelight II*,⁴¹ and *Limelight III*⁴²—and took a patentee’s ability to protect a typical personalized medicine patent directed to multiple actors on a roller coaster ride.⁴³

Following the changes to subject matter eligibility, and before *Limelight III*,⁴⁴ pharmaceutical companies were on the verge of having to choose between not protecting their advances in personalized medicine due to subject matter ineligibility or receiving patents that could not be infringed due to the loophole in the law. In *Limelight III*, the Federal Circuit clarified the requirements to bring an infringement claim in divided infringement cases,⁴⁵ resulting in a small victory for the field of personalized medicine.

This Comment argues that, despite the recent subject matter eligibility guidelines provided by the USPTO⁴⁶ and in light of the infringement analysis framework set forth in *Limelight III*, only careful patent drafting with respect to what, specifically, is claimed and how multiple actors interact will ensure that claims directed to personalized medicine innovations are both eligible and protected. This Comment proceeds in four Parts. Part I discusses the history of personalized medicine and the current expectations for the field’s

39. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008).

40. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc), *rev’d* 134 S. Ct. 2111 (2014) (*Limelight I*).

41. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014) (*Limelight II*).

42. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (en banc) (*Limelight III*).

43. *See infra* Section III.B.

44. *See generally Limelight Networks*, 797 F.3d at 1020, 1022 (holding that when multiple actors perform the method steps, a single entity may be liable for direct infringement if the actions of others are attributable to the single entity, which occurs “(1) where that entity directs or controls others’ performance, and (2) where the actors form a joint enterprise”).

45. *See id.* at 1022–23.

46. *See* 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618, 74618–33 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1); U.S. PATENT & TRADEMARK OFFICE, GUIDANCE FOR DETERMINING SUBJECT MATTER ELIGIBILITY OF CLAIMS RECITING OR INVOLVING LAWS OF NATURE, NATURAL PHENOMENA, & NATURAL PRODUCTS (Mar. 4, 2014) [hereinafter March 2014 Guidelines], https://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf [<https://perma.cc/6YTB-44ZL>]; *see also* U.S. PATENT & TRADEMARK OFFICE, *supra* note 30, at 1–28. These publications provide instructions and examples for patent examiners to follow during the patent examination process.

implementation and development. Part II reviews patent law basics and discusses personalized medicine patents with respect to patent subject matter eligibility. Part III reviews patent infringement, the treatment of divided infringement in the *Limelight* line of cases, and discusses the framework for analyzing divided infringement cases presented in *Limelight III*. Part IV suggests how to effectively draft attainable and enforceable patents directed to personalized medicine methods. A brief conclusion follows.

I. PERSONALIZED MEDICINE

Personalized medicine can generally be defined as “[t]he tailoring of medical treatment to the individual characteristics of each patient.”⁴⁷ More specifically, personalized medicine is “[a] form of medicine that uses information about a person’s genes, proteins, and environment to prevent, diagnose, and treat disease.”⁴⁸ Medical treatments should optimally benefit patients with minimal side effects and cost. Advancements in personalized medicine have already

allow[ed] health care providers to: shift the emphasis in medicine from reaction to prevention[,] predict susceptibility to disease[,] improve disease detection, preempt disease progression[,] . . . avoid prescribing drugs with predictable side effects, reduce the time, cost, and failure rate of pharmaceutical clinical trials[, and] eliminate trial-and-error inefficacies that inflate health care costs . . .⁴⁹

Unfortunately, most doctors currently only have the resources to make a decision about which treatment regimen to follow based on the patient’s symptoms, some basic test results, and the general efficacy of available treatment options.⁵⁰ If Plan A fails to help or even harms the patient, the doctor will move on to Plan B, and then

47. U.S. FOOD & DRUG ADMIN., PAVING THE WAY FOR PERSONALIZED MEDICINE: FDA’S ROLE IN A NEW ERA OF MEDICAL PRODUCT DEVELOPMENT 7 (2013) (quoting the President’s Council of Advisors on Science and Technology).

48. *NCI Dictionary of Cancer Terms, Personalized Medicine*, NATIONAL CANCER INSTITUTE, <https://www.cancer.gov/publications/dictionaries/cancer-terms/?CdrID=561717> [<https://perma.cc/J4NE-FFEU>]; see also U.S. FOOD & DRUG ADMIN., *supra* note 47.

49. *The Benefits of Personalized Medicine*, JACKSON LABORATORY, <https://www.jax.org/genetics-and-healthcare/personalized-medicine/benefits-of-personalized-medicine> [<https://perma.cc/PN7A-M2CL>].

50. In 2012, it was estimated “that only 20 percent of practicing physicians had received any training on how to administer genomically guided medicine.” Turna Ray, *Reality Check: Educating Physicians on Genomic Medicine*, GENOMEWEB (Oct. 1, 2012), <https://www.genomeweb.com/clinical-genomics/reality-check-educating-physicians-genomic-medicine> [<https://perma.cc/LUS7-AACB>].

Plan C if B fails. With advancements in the ability to tailor treatments based on a patient's genome and to develop pharmaceuticals that are effective for people with specific genetic markers, practitioners can begin treatment by initially implementing said Plan C, potentially saving patients time, money, and adverse reactions to ineffective or dangerous treatments.

Both the commissioner of the FDA and the director of the National Institutes of Health (the "NIH") have recognized the importance of devoting funding to the research, testing, and application of personalized medicine techniques.⁵¹ The Precision Medicine Initiative, a White House research initiative, was allocated \$215 million of the 2016 Presidential budget to further the development of personalized medicine.⁵² Tracing the development of personalized medicine will shed light on the promise of this emerging medical field.

A. *Personalized Medicine: Then and Now*

While modern personalized medicine focuses on tailoring treatment to best suit a patient's genetic and molecular characteristics, its basic tenets can be traced back thousands of years. Around 400 BCE, Hippocrates stated, "It's far more important to know what person the disease has than what disease the person has."⁵³ At that time, physicians examined a patient's unique humor makeup—blood, phlegm, choler (yellow bile), and melancholia (black bile)—to best characterize a patient's state of health prior to and during treatment.⁵⁴ Physicians believed that ideally these four elements should be in perfect balance, which is known as *eucrasia*.⁵⁵ Under this theory, shifts away from this equilibrium, *dyscrasia*, resulted in disease.⁵⁶ Physicians sought to cure a sick patient through a treatment regimen designed to equilibrate the particular humor imbalance, or by personalizing his care.⁵⁷

51. Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 *NEW ENG. J. MED.* 301, 301 (2010).

52. *Fact Sheet: President Obama's Precision Medicine Initiative*, THE WHITE HOUSE (Jan. 30, 2015), <https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative> [<https://perma.cc/AL58-5YYJ>].

53. See, e.g., Edward Abrahams & Mike Silver, *The History of Personalized Medicine*, in *INTEGRATIVE NEUROSCIENCE AND PERSONALIZED MEDICINE 3* (Evian Gordon & Stephen Koslow eds., 2010).

54. *Id.* at 4.

55. *Id.*

56. *Id.*

57. *Id.*

In 1957, Arno Motulsky⁵⁸ “introduced the concept of tailoring medicine to an individual’s genetic makeup” in a paper entitled “Drug Reactions, Enzymes, and Biochemical Genetics,” effectively “launch[ing] a new field of research.”⁵⁹ In his paper, Motulsky lists numerous studies correlating drug hypersensitivity or hyposensitivity with specific genetic traits of the patients.⁶⁰ For example, one such study noted that some patients given the standard dose of an anti-malarial drug, primaquine, developed hemolytic anemia.⁶¹ The red blood cells of these patients “lack[ed] sufficient enzymatic protection against damage by the drug” due to a genetic abnormality that caused defective glucose-6-phosphate dehydrogenase activity.⁶² Another study discussed by Motulsky highlighted genetically related sensitivity to a type of muscle relaxant due to reduced activity of the enzyme pseudocholinesterase and the subsequent insufficient inactivation of the drug.⁶³ As more studies confirmed the link between genetic traits and responses to disease treatments, interest in the field grew among researchers and practitioners and advances in technology made such studies more feasible.⁶⁴

Some of the most significant advances in the field of genomics, and thus personalized medicine, have taken place during the past twenty-six years. The first occurred in 1990 with the approval of the three-billion-dollar Human Genome Project.⁶⁵ By 2003, the 23,000 genes making up the human genome had been sequenced and published online as a publicly available reference.⁶⁶ Beginning in 1999, research groups began to collaborate to identify upwards of ten million loci of variation within the human genome in an effort to link these changes with the “predispos[ition] to cancer, diabetes, Alzheimer’s disease, and cardiovascular and other diseases.”⁶⁷ The

58. Arno Motulsky is the founder of pharmacogenetics and is a Professor of Genome Sciences at the University of Washington. See *Arno Motulsky*, U. OF WASH., <http://www.gs.washington.edu/faculty/motulsky.htm> [<https://perma.cc/R57U-AQNY>].

59. Abrahams & Silver, *supra* note 53, at 7 (analyzing Arno G. Motulsky, *Drug Reactions, Enzymes, and Biochemical Genetics*, 165 J. AM. MED. ASS’N 835 (1957)).

60. Arno G. Motulsky, *Drug Reactions, Enzymes, and Biochemical Genetics*, 165 J. AM. MED. ASS’N 835, 835–36 (1957).

61. *Id.*

62. *Id.* at 836.

63. *Id.*

64. Abrahams & Silver, *supra* note 53, at 7–8.

65. *Id.*

66. *Id.* at 8; see also *GenBank Overview*, GENBANK, <http://www.ncbi.nlm.nih.gov/genbank> [<https://perma.cc/9QXL-GZGN>] (last updated Mar. 2016).

67. Abrahams & Silver, *supra* note 53, at 9; see also *DBSNP, Short Genetic Variations*, NAT’L CENTER FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/SNP> [<https://perma.cc/K4MN-XZNF>].

International HapMap Project followed in the early 2000s to begin sorting and collating the data into a format that would be more user-friendly for researchers.⁶⁸ Finally, within the last decade or so, massive research studies called genome-wide association studies (“GWAS”) have commenced in an effort to identify genetic patterns in people with specific diseases.⁶⁹

Since 2006, the federal government has been searching for ways to improve the “regulatory, industrial, and social . . . support” for personalized medicine initiatives in what has become “a priority issue at the highest levels of government.”⁷⁰ In 2010, FDA Commissioner, Margaret Hamburg, and NIH Director, Francis Collins, recognized that such groundbreaking progress had limitless potential for improving patient-specific, targeted therapies.⁷¹ They announced support for a “national highway system for personalized medicine” to help “accelerate the translation of research into medical products and therapies.”⁷² In a 2013 FDA report, Hamburg affirmed “the Agency’s ongoing commitment to this important and emerging area of medicine.”⁷³ The report begins by discussing one of the poster children for personalized medicine, the cystic fibrosis drug Kalydeco, which was designed to treat abnormal protein function resulting from a specific gene mutation seen in four percent of cystic fibrosis patients.⁷⁴ Expectations have remained high, as the federal government has continued to allocate significant resources to the field of personalized medicine as recently as 2016.⁷⁵

However, despite all the grand discoveries, optimistic announcements, and devotion of resources to various initiatives, a closer look at the developing landscape of patent law indicates that patenting innovations in this promising field has become much more difficult. These changes could have lasting and disastrous effects on the development of personalized medicine.

68. Abrahams & Silver, *supra* note 53, at 9.

69. *Id.*

70. *Id.* at 12.

71. Hamburg & Collins, *supra* note 51, at 301.

72. *Id.* at 304.

73. U.S. FOOD & DRUG ADMIN., *supra* note 47, at 2.

74. *Id.* at 3.

75. See *Fact Sheet: President Obama’s Precision Medicine Initiative*, *supra* note 52 (allocating \$215 million of the 2016 Presidential budget to the Precision Medicine Initiative).

II. SUBJECT MATTER ELIGIBILITY

Changes in what is fundamentally considered “patentable” by the USPTO have left many wondering whether biotechnology-directed patents will receive protection in the near future.⁷⁶ This Part analyzes key cases in the development of current eligible subject matter, focusing on the lasting effects on the ability to patent future personalized medicine methods.

A. *Patentable Matter, Pre-2012*

Title 35, Section 101 of the United States Code states that “[w]hoever 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.”⁷⁷ However, judicial exceptions to patent eligible subject matter include laws of nature, physical phenomena, and abstract ideas.⁷⁸ In 1980, the Supreme Court visited what subject matter was considered statutorily eligible for a patent under 35 U.S.C. § 101 in *Diamond v. Chakrabarty*.⁷⁹

At issue in *Chakrabarty* was whether a bacterium given the ability to break down crude oil through genetic engineering was eligible for patent protection.⁸⁰ In its decision, the Court noted that “[i]n choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”⁸¹ As the “[r]espondent’s micro-organism constitute[ed] a ‘manufacture’ or ‘composition of matter’ within” § 101, being a “product of human ingenuity[,]” the bacterium was indeed eligible for patent protection.⁸² Additionally, the Court dismissed arguments that living things were not patentable⁸³ and that protection of

76. See Joanna Brougher & Konstantin M. Linnik, *Patents or Patients: Who Loses?*, 32 NATURE BIOTECHNOLOGY 877, 877–79 (2014) (discussing “[h]igher hurdles to obtaining a patent”); Gene Quinn, *The Looming Patent Nightmare Facing the Pharmaceutical Industry*, IP WATCHDOG (July 18, 2015), <http://www.ipwatchdog.com/2015/07/08/the-looming-patent-nightmare-facing-the-pharmaceutical-industry/id=51428> [https://perma.cc/5ZEY-Y8G8] (lamenting that a “Supreme Court that obviously doesn’t know the first thing about technology is about to upend America’s high tech economy”).

77. 35 U.S.C. § 101 (2012).

78. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

79. 447 U.S. 303 (1980).

80. *Id.* at 305–06.

81. *Id.* at 308.

82. *Id.* at 304.

83. *Id.* at 315 (stating that the relevant distinction is “between products of nature, whether living or not, and human-made inventions”).

microorganisms requires express authorization from Congress.⁸⁴ In sum, the Court at this point interpreted § 101 to be a broad filter with respect to patent eligible subject matter in the absence of a judicial exception.

Even as recently as 2011, the Federal Circuit still referred to the “coarse eligibility filter” of § 101 with respect to the eligibility of method patents directed to evaluating and improving the safety of immunization schedules.⁸⁵ In *Classen Immunotherapies v. Biogen IDEC*,⁸⁶ one of the claims in question was directed to “[a] method of immunizing a mammalian subject while reducing the risk of said subject thereby developing at least one chronic immune-mediated disorder, which comprises: (I) screening a plurality of immunization schedules . . . and (II) immunizing said subject according to a subject immunization schedule . . . associated with a lower risk of [disorder] development.”⁸⁷ Petitioners claimed that the “screening” process mentioned in the patent was a mental process, and thus the claims were not patent eligible because they were directed to an abstract idea.⁸⁸ However, when the court considered the invention as a whole, it noted that Step II was directed at an actual immunization, which was enough for the claim to not be considered directed to an abstract idea.⁸⁹ Thus, because personalized medicine patents are directed to screening and subsequent treatment, it is likely that these patents would have readily survived the requirements of § 101 as interpreted at this point in time.

B. Refining the “Coarse Filter,” 2012–Present

Two important Supreme Court cases have drastically changed the outlook for biotechnology and medical patents, specifically those directed to personalized treatment methods: *Mayo Collaborative Services v. Prometheus Labs*⁹⁰ and *Association for Molecular Pathology v. Myriad Genetics*.⁹¹ These cases illuminate the specific

84. *Id.* (noting that “Congress has performed its constitutional role in defining patentable subject matter . . . [and] we perform ours in construing the language Congress has employed”).

85. *Classen Immunotherapies v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011) (stating that “the statutory role of § 101 [is] as a ‘coarse eligibility filter,’ not [as] the final arbiter of patentability”).

86. 659 F.3d 1057 (Fed. Cir. 2011).

87. U.S. Patent No. 6,420,139 (filed July 16, 2002).

88. *See Classen*, 659 F.3d at 1062–63.

89. *Id.* at 1068.

90. 132 S. Ct. 1289 (2012).

91. 133 S. Ct. 2107 (2013).

repercussions that narrowing the previously coarse § 101 filter has had on life-saving innovation.

1. *Mayo* and Something More

At issue in *Mayo* was whether the patent claims contained “something more” than a natural law, making them patent eligible.⁹² In *Mayo*, the claims in question were directed to a method of calibrating drug dosage based on the concentration of drug metabolites present in a patient’s blood.⁹³ Specifically, the claim called for the administration of a thiopurine drug to a patient, determination of the level of a specific metabolite, 6-thioguanine, in the patient’s blood, and subsequent alteration of drug dosage based on the test results.⁹⁴ Invalidating the claim as non-patentable subject matter, the Court held that attempting to transform an unpatentable law of nature—blood metabolite concentration—into patent eligible subject matter requires “more than simply stat[ing] the law of nature while adding the words ‘apply it.’”⁹⁵ Thus, the inquiry into a patent centered around a law of nature became whether “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.”⁹⁶

Biotech patent drafters reacted negatively to the decision. Some interpreted the opinion to shift the burden to the patent drafter to ensure claims have enough additional features to confirm they are an application of a law of nature, not simply a claim to it.⁹⁷ Others felt *Mayo* could be interpreted as invalidating patents on diagnostic methods, as those methods are usually directed to laws of nature.⁹⁸ More dramatically, the founder of the blog IPWatchdog.com stated that “[t]hose in biotech, medical diagnostics and pharmaceutical industries have just been taken out behind the woodshed and

92. See *Mayo*, 132 S. Ct. at 1297 (deciding “whether the claims do significantly more than simply describe these natural relations”).

93. *Id.* at 1290.

94. *Id.* at 1295.

95. *Id.* at 1294.

96. *Id.* at 1297.

97. Dennis Crouch, *Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent*, PATENTLYO (Mar. 20, 2012), <http://patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.html> [<https://perma.cc/E5GY-PA6A>].

98. See Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 266–68 (2015) (exemplifying how the Court’s analysis in *Mayo* places the fundamentals of diagnostics in the “realm of natural laws,” and thus makes them unpatentable).

summarily executed by the Supreme Court this morning[.]” as the decision could be interpreted to imply that even an application of a law of nature was no longer patent eligible.⁹⁹ Overall, the *Mayo* decision resulted in a great deal of confusion, as the Court failed to explain what exactly would be “enough” to move something beyond a mere statement of a law of nature.¹⁰⁰

2. *Myriad* and Splitting Strands

In *Myriad*, the Supreme Court specifically addressed how much “more” a patent claim directed to a product of nature, specifically DNA, was required to include to be patent eligible;¹⁰¹ this was significant, as historically, a substance isolated from nature was patent eligible.¹⁰² Two different claims were at issue in *Myriad*: one directed to an isolated DNA sequence associated with a specific gene,¹⁰³ and one directed to the stable, lab-generated cDNA of the same gene.¹⁰⁴ The Court came to the conclusion that, unlike the bacterium in *Chakrabarty*,¹⁰⁵ the subject of Myriad Genetics’s patent was simply an excised gene that previously existed in nature.¹⁰⁶ Additionally, the Court noted that “[l]aws of nature . . . ‘are the basic tools of scientific and technological work,’ ” and “[p]atent protection strikes a delicate balance between” incentivization and impeding innovation.¹⁰⁷ With respect to the second claim, the Court quickly concluded that a “lab technician unquestionably creates something new when cDNA is made As a result, . . . [cDNA] is patent eligible under § 101.”¹⁰⁸

99. Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IP WATCHDOG (Mar. 20, 2012), <http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/> [<https://perma.cc/6MHW-FAG2> (staff-uploaded archive)].

100. See *Mayo*, 132 S. Ct. at 1297; Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. 423, 424–25 (2012).

101. See *Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107, 2116 (2013) (deciding “whether Myriad’s patents claim any ‘new and useful . . . composition of matter,’ . . . or instead claim naturally occurring phenomena”).

102. See, e.g., *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911) (holding that “mak[ing adrenaline] available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the [adrenaline], it became for every practical purpose a new thing . . .”), *aff’d in part, rev’d in part*, 196 F. 496 (2d Cir. 1911).

103. See *Myriad Genetics*, 133 S.Ct. at 2113 (giving the example of a claim “assert[ing] a patent on ‘[a]n isolated DNA coding for a BRCA1 polypeptide’ ”).

104. See *id.* (indicating claim two of the U.S. Patent No. 5,747,282 is for “the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1”).

105. See *supra* Section II.A (discussing the Court’s decision in *Chakrabarty*).

106. See *Myriad Genetics*, 133 S. Ct. at 2117–18.

107. See *id.* at 2116.

108. See *id.* at 2119.

While some anticipated the result in *Myriad*, the Court's holding has still changed the tenet that naturally occurring substances were patent-eligible if isolated from nature.¹⁰⁹ Specifically, *Myriad* foreclosed the possibility of obtaining patents on human genes.¹¹⁰ Under a broader interpretation, *Myriad* effectively rendered naturally-occurring biomarkers patent ineligible.¹¹¹ It is important to note, however, that “[m]ethod claims generally play a much more important role than isolated DNA claims in the patenting of innovations in [diagnostics and personalized medicine.]”¹¹² as the patents are generally directed to the personalized diagnostic and treatment process.¹¹³ Yet, even if *Myriad* did not cripple the field of personalized medicine, the lack of guidance as to subject matter eligibility required clarification from the USPTO to aid in both the drafting and prosecution of biotech patents.

3. The Aftermath

Following the *Myriad* and *Mayo* decisions, the USPTO, in March 2014, released a procedure for determining subject matter eligibility for all things natural.¹¹⁴ The guidelines set forth a three-question framework for determining if a claim passes the § 101 threshold:

- Step 1: Is the claim to a process, machine, manufacture, or composition of matter? If yes, move to Step 2A; if no, claim is not subject matter eligible.
- Step 2A: Does the claim recite or involve a law of nature, natural phenomenon, or abstract idea? If no, claim is subject matter eligible under § 101; if yes, proceed to Step 2B.
- Step 2B: Does the claim recite additional elements that amount to significantly more than the judicial exception? If

109. See *Parke-Davis & Co. v. H. K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911).

110. See, e.g., Courtenay C. Brinckerhoff, *Supreme Court Decides Myriad Gene Patents Case, Holds Isolated Human Genes May Not Be Patented*, PHARMAPATENTS (June 13, 2013), <https://www.pharmapatentsblog.com/2013/06/13/supreme-court-decides-myriad-gene-patents-case/> [<https://perma.cc/KD93-FDN9>].

111. See Eisenberg, *supra* note 98, at 277.

112. Christopher M. Holman, *Mayo, Myriad, and the Future of Molecular Diagnostics and Personalized Medicine*, 15 N.C. J.L. & TECH. 639, 639 (2014).

113. Christopher M. Holman, *Patent Eligibility as a Policy Lever to Regulate the Patenting of Personalized Medicine*, in PERSPECTIVES ON PATENTABLE SUBJECT MATTER 114, 117 (Michael B. Abramowicz et al. eds., 2015).

114. See March 2014 Guidelines, *supra* note 46, at 1–10.

yes, claim qualifies as eligible subject matter under § 101; if no, claim is not subject matter eligible.¹¹⁵

Furthermore, the USPTO clarified how to determine whether a claim has elements that amount to “significantly more” than the judicial exception by setting forth a non-exhaustive list of various factors.¹¹⁶ Limitations which can weigh in favor of “significantly more” include the following: methods limiting the scope of a claim from encompassing a judicial exception; additional steps that are not added essentially for show; steps in addition to the judicial exception that go beyond saying “apply it”; and steps that go beyond conventional techniques in a particular field.¹¹⁷

However, in the examples that apply this test, the USPTO said that if gunpowder had been invented today, it would not be eligible for patent protection because it involves a mixture of natural products without “something significantly different.”¹¹⁸ Following an outcry from the chemistry and life sciences patent community, the USPTO opted to revise their test language from “reciting or involving” a judicial exception, which all life sciences patents do, to asking if the claims are “directed to” a judicial exception, and, if so, whether they contain “something more.”¹¹⁹ Additional guidance regarding life science patent claims continues to confuse, rather than clarify, the issue.¹²⁰

Unfortunately, the Supreme Court’s precedent and the USPTO’s subject matter eligibility guidelines have already failed to protect more than one life-changing discovery. For example, in 2015, a researcher reported discovering a bacterium that, when cultured, produced compounds that killed “a wide variety of pathogens without detectable resistance.”¹²¹ In a Office action, the patent application’s

115. *Id.* at 2 (paraphrasing steps for determining subject matter eligibility).

116. *See id.* at 3.

117. *Id.* at 3–5.

118. *See id.* at 9–10.

119. *See, e.g.*, Jonathan Singer & Rebecca Shult, *USPTO Guidance on Natural Product Development*, PHARMACEUTICAL COMPLIANCE MONITOR (Dec. 5, 2014), <http://www.pharmacompliance.com/uspto-guidance-natural-product-development/8057/> [<https://perma.cc/H2XW-UB58>].

120. *See generally* U.S. PATENT & TRADEMARK OFFICE, *supra* note 30 (discussing several examples of life sciences patents claims while also cautioning that these examples are not to be considered too closely since eligibility is analyzed on a case-by-case basis).

121. Warren D. Woessner, “Isolated” Natural Products Still in Purgatory Post-PTO Guidance?, PATENTS4LIFE (Apr. 2015), <http://www.patents4life.com/2015/04/isolated-natural-products-still-in-purgatory-post-pto-guidance/> [<https://perma.cc/4TXH-YQ5A>]. *See generally* Losee L. Ling et al., *A New Antibiotic Kills Pathogens Without Detectable*

examiner deemed the isolated antibiotic patent ineligible under the § 101 statutory bar because it failed to “includ[e] any elements in addition to the natural product.”¹²² To fully understand the implications of such a ruling by the USPTO, it is worth noting that “[n]early 80% of our current antibiotics were originally derived from natural sources.”¹²³ Surely the USPTO did not intend to exclude novel, broad-spectrum antibiotics from patent protection. However, until the USPTO further clarifies the § 101 eligibility analysis,¹²⁴ patentees will likely need to claim “non-natural” forms of isolated natural products, such as a synthetic variant of said natural product, in order to maintain patent eligibility.¹²⁵

While there is little case law following the USPTO’s latest subject matter eligibility guidelines, the Federal Circuit indicated its discomfort with the current standards in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*¹²⁶ and its subsequent en banc rehearing denial.¹²⁷

The patent in *Ariosa Diagnostics* claimed a method for detecting cell-free fetal DNA (“cffDNA”) in a mother’s blood that could then be used for non-invasive genetic testing of a fetus.¹²⁸ Despite Sequenom’s argument that the method was a narrow and specific patent eligible application involving a newly discovered natural

Resistance, 517 NATURE BIOTECHNOLOGY 455 (2015) (describing the research that produced the bacterium that “kills pathogens without detectable resistance”).

122. Non-Final Rejection, U.S. Patent Application Serial No. 14/095,415, at 2 (filed Dec. 3, 2013) <http://portal.uspto.gov/pair/PublicPair> [<https://perma.cc/SA6A-8SCR>].

123. Teresa Griffiths & Helen Bellchambers, *Breakthrough Antibiotic Not Patentable in the US*, LEXOLOGY (Feb. 11, 2015), <http://www.lexology.com/library/detail.aspx?g=9e39370a-57d5-4fc-b223-07ce0cd0519d> [<https://perma.cc/377C-7FHU>].

124. The issuance of the updated December 2014 Guidelines revising the language of the test indicates that the USPTO is willing to continue clarifying its test to stay consistent with Supreme Court rulings. See 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618, 74618–33 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

125. See generally Woessner, *supra* note 121 (discussing the patent eligibility of naturally and non-naturally occurring crystalline forms of products isolated from nature).

126. 788 F.3d 1371 (Fed. Cir. 2015), *reh’g denied*, 809 F.3d 1282 (Fed. Cir. 2015) (en banc).

127. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282 (Fed. Cir. 2015).

128. *Ariosa Diagnostics, Inc.*, 788 F.3d at 1373. The patent claim was directed to

[a] method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

Id. at 1373–74.

phenomenon, cffDNA, the *Ariosa* court held that the claim was directed to patent ineligible subject matter.¹²⁹

However, in his concurrence, Judge Linn stated that he “join[ed] the court’s opinion invalidating the claims . . . only because [he was] bound by the sweeping language of the test set out in *Mayo*.”¹³⁰ He found that Sequenom’s patent was distinguishable from the case in *Mayo*, as the claims were directed to non-conventional activities (non-invasive fetal DNA testing) while the patent at issue in *Mayo* was directed to routine testing of blood metabolite concentrations.¹³¹ During the en banc rehearing, Judges Lourie and Moore expanded on Judge Linn’s concurrence stating that “the claims here are directed to an actual use of the natural material of cffDNA . . . [b]ut applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.”¹³² Thus, while these rumblings in the Federal Circuit are promising, personalized medicine patents directed to natural laws and phenomena will still require methods claims directed to non-conventional “something more” steps.

As discussed in Part IV, these guidelines can be implemented to carefully draft a narrow personalized medicine patent. However, drafting a patent requires preemptively addressing the above-mentioned questions posed by the USPTO. One of the most effective ways to do so involves adding the aforementioned method steps.¹³³ However, in doing so the drafter will need to take precautions to ensure the patent holder can protect her rights should another party infringe. The additional “something more” application steps, which the USPTO currently requires, result in personalized medicine patents having attributes that, until recently, made successful infringement suits exceedingly difficult.¹³⁴

III. THE DIVIDED INFRINGEMENT LOOPHOLE

Typically, a patentee can have a cause of action against both direct and indirect infringers under 35 U.S.C. § 271.¹³⁵ Direct infringement occurs when a party “without authority, makes, uses,

129. *See id.* at 1378–79.

130. *Id.* at 1380 (Linn, J., concurring).

131. *See id.* at 1380–81.

132. *Ariosa Diagnostics, Inc.*, 809 F.3d at 1286.

133. *See* March 2014 Guidelines, *supra* note 46, at 4.

134. *See infra* Section IV.B.2.

135. 35 U.S.C. § 271(a)–(d) (2012).

offers to sell, or sells any patented invention, within the United States.”¹³⁶ For methods patents, “a party [must] perform or use each and every step or element of a claimed method” to constitute direct infringement.¹³⁷ Additionally, one can be liable for indirect infringement by either inducing or contributing to infringement.¹³⁸ A party induces infringement if he “actively induces infringement of a patent.”¹³⁹

However, plaintiffs may not have a cause of action when different parties carry out the steps of a method patent. Divided infringement, sometimes called joint infringement, of method patents occurs when multiple parties perform each and every step of a claimed process.¹⁴⁰ However, according to the single entity rule, in situations “where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises ‘control or direction’ over the entire process such that every step is attributable to the controlling party, i.e., the ‘mastermind.’”¹⁴¹ Additionally, “indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement.”¹⁴² Thus, as the Federal Circuit noted in *BMC Resources, Inc. v. Paymentech, L.P.*,¹⁴³ a loophole exists wherein “the standard requiring control or discretion for a finding of joint infringement may in some circumstances allow parties to enter into arms-length agreements to avoid infringement . . . [, but] this concern does not outweigh concerns over expanding the rules governing direct infringement.”¹⁴⁴ This Part examines the Federal Circuit’s attempts to close the divided infringement loophole, and how the resulting guidelines presented in *Limelight III* will favorably impact the protection of personalized medicine patents necessarily directed to multiple actors.

136. *Id.* § 271(a).

137. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007).

138. Mark A. Lemley et al., *Divided Infringement Claims*, 33 *AIPLA Q. J.* 255, 257 (2005).

139. 35 U.S.C. § 271(b) (2012).

140. *See Akami Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305–06 (Fed. Cir. 2012) (en banc) (noting that “[t]he problem of divided infringement in induced infringement cases typically only arises with respect to method patents”), *rev’d*, 134 S. Ct. 2111 (2014).

141. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008) (quoting *BMC Res.*, 498 F.3d at 1380–81).

142. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004).

143. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373 (Fed. Cir. 2007).

144. *Id.* at 1381.

A. *An Attempt to Overrule BMC Resources and Muniauction*

In *Limelight I*,¹⁴⁵ Akamai Technologies held a patent that claimed a method for creating an “infrastructure designed to serve Web content efficiently, effectively, and reliably to end users.”¹⁴⁶ In this method, a content provider can tag content supported on a set of hosting servers, which will then be served, in embedded form, from the content provider’s site.¹⁴⁷ *Limelight*, the alleged infringer, was executing the patented method, except instead of using the content provider, *Limelight* tagged external content for service, and its customers received instructions on how to tag the content themselves.¹⁴⁸ Thus, *Limelight* itself was not actually practicing each and every step of the allegedly infringed patent. Consistent with the single entity rule set forth in *BMC Resources*, the district court issued *Limelight* a judgment as a matter of law.¹⁴⁹ Akamai appealed the Federal Circuit and again “address[ed] the question [of] 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.”¹⁵⁰

In revisiting the court’s holding in *BMC Resources*, affirmed in *Muniauction, Inc. v. Thomson Corp.*,¹⁵¹ the *Limelight I* court noted that the decisions in those cases resulted from “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.”¹⁵² The Federal Circuit then decided it should find a way to ensure that those who induce infringement are held liable even when the acts of infringement are committed by multiple parties, resulting in no direct infringement.¹⁵³ In its conclusion, the Federal Circuit held that although “Akamai [was not] entitled to prevail on its theory of direct infringement, the evidence could support a judgment

145. *Akami Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc), *rev’d*, 134 S. Ct. 2111 (2014).

146. *Id.* at 1306; U.S. Patent No. 6,108,703 (filed May 19, 1999).

147. ‘703 Patent.

148. *See Limelight Networks, Inc.*, 692 F.3d at 1306.

149. *Id.* at 1307; *see also BMC Res., Inc.*, 498 F.3d at 1375, 1380.

150. *Limelight Networks, Inc.*, 692 F.3d at 1305.

151. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1329 (Fed. Cir. 2008).

152. *Limelight Networks, Inc.*, 692 F.3d at 1308.

153. *Id.* at 1308–09 (“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.”).

in its favor on a theory of induced infringement,”¹⁵⁴ which effectively ignored the established precedent requiring there be a case of direct infringement before a cause of action for indirect infringement exists.¹⁵⁵ The decision closed a frustrating loophole in patent law and was met with cautious optimism.¹⁵⁶ However, at least one scholar predicted that the Supreme Court would grant certiorari and hear an appeal of such a radical decision.¹⁵⁷

After granting certiorari, the Supreme Court unanimously and succinctly held that “liability for infringement must be predicated on direct infringement.”¹⁵⁸ Before remanding the case to the Federal Circuit to properly apply § 271(b) and potentially revisit the appropriateness of the application of the single entity rule under § 271(a),¹⁵⁹ the Court stated that “[a] desire to avoid *Muniauction*’s natural consequences does not justify fundamentally altering the rules of inducement liability.”¹⁶⁰

Unlike the 2012 Federal Circuit decision, the Supreme Court reversal was met with concern because of the broad interdisciplinary implications.¹⁶¹ With respect to personalized medicine, it was noted that “[a]s personalized medicines often consist of screening a patient for a biomarker and then administering a therapy based on the results, if the two steps are performed by two independent entities, infringement liability can thus be avoided.”¹⁶² Thankfully, the Federal

154. *Id.* at 1319.

155. *See id.* at 1319–20 (Newman, J., dissenting) (noting that in *BMC Resources* and *Muniauction*, the court applied the single entity rule and “held there can be no liability for infringement, although all of the claim steps are performed” when there is not a “single mastermind”).

156. *See, e.g.*, Dennis Crouch, *Joint Infringement: Federal Circuit Changes the Law of Inducement*, PATENTLYO (Aug. 31, 2012), <http://patentlyo.com/patent/2012/08/joint-infringement-federal-circuit-changes-the-law-of-inducement.html> [<https://perma.cc/SM6V-74NY>].

157. *See, e.g.*, “*Joint Infringement and the Federal Circuit’s Akamai and McKesson En Banc Opinion*,” GOODWIN PROCTOR LLP: IP ADVISOR 2–3 (Nov. 28, 2012), http://1npdf9.cloudapp.net/pdfrenderer.svc/v1/ABCpdf9/GetRenderedPdfByUrl/IP_Advisor__November_2012.pdf?url=http://www.goodwinlaw.com:80%2fviepoints%2f2012%2f11%2f20121128%3fpdf%3dtrue&attachment=false [<https://perma.cc/22T6-CHVS>].

158. *Limelight Networks, Inc. v. Akami Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014).

159. *Id.* at 2120.

160. *Id.*

161. *See generally* Jingyuan Luo, *Shining the Limelight on Divided Infringement: Emerging Technologies and the Liability Loophole*, 30 BERKELEY TECH. L.J. 675, 676–77 (2015) (positing that the decision would extend from infringement claims in internet and computer technology to “other contexts involving interactive technologies,” including biotechnology).

162. Brougher & Linnik, *supra* note 76, at 879.

Circuit took the Supreme Court's veiled suggestion that it should revisit § 271(a) upon remand.

B. Divided Infringement Revisited

In 2015, after rehearing *Akamai v. Limelight* on remand, the Federal Circuit updated and clarified the framework for determining divided infringement under 35 U.S.C. § 271(a) in *Limelight III*.¹⁶³ First, a single entity must be responsible for the performance of all the steps of a claimed method for a valid infringement claim, thus satisfying the direct infringement requirement.¹⁶⁴ Second, if more than one entity is involved, the “court must determine whether the acts of one are attributable to the other such that a single entity is responsible for the infringement.”¹⁶⁵ Third, there are two situations in which one party can be held responsible for another's performance of steps in a method patent: “(1) where that entity directs or controls others' performance, and (2) where the actors form a joint enterprise.”¹⁶⁶ Direction or control can be evidenced by agency relationships and the existence of contracts, similar to vicarious liability in tort law.¹⁶⁷

The addition of a “joint enterprise” category effectively expanded the circumstances under which a party can be liable for direct infringement under § 271(a).¹⁶⁸ Here, if “two or more actors form a joint enterprise, all can be charged with the acts of the other, rendering each liable for the steps performed by the other as if each is a single actor.”¹⁶⁹ The Federal Circuit held that

[a] joint enterprise requires proof of four elements: (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

163. See *Akami Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1022–23 (Fed. Cir. 2015) (en banc).

164. *Id.* at 1022.

165. *Id.*

166. *Id.*

167. *Id.* at 1022–23. This rule is not a change from pre-*Limelight* cases, including *BMC Resources*. See *BMC Resources, Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380–81 (Fed. Cir. 2007) (describing the single-entity rule).

168. Robert Schaffer & Joseph Robinson, *Akamai v. Limelight: Defendant May Directly Infringe Where Steps Performed by a Third Party*, IP WATCHDOG (Aug. 20, 2015), <http://www.ipwatchdog.com/2015/08/20/akamai-v-limelight-infringe-where-steps-are-performed-by-a-third-party-in-the-absence-of-a-principal-agent-or-joint-venture-relationship/id=60822/> [<https://perma.cc/Y8W7-9ADJ>] (staff-uploaded archive)].

169. *Limelight Networks, Inc.*, 797 F.3d at 1023 (noting that the definition is consistent with RESTATEMENT (SECOND) OF TORTS § 491 (AM. L. INST. 1965)).

the members; and (4) an equal right to a voice in the direction of the enterprise, which gives an equal right of control.¹⁷⁰

Furthermore, the question of whether there is a single entity in charge of the infringing actions or a joint enterprise among multiple actors is a question of fact for a jury.¹⁷¹

The framework presented in *Limelight III* to evaluate the existence of a joint enterprise has already been applied—albeit in a non-binding district court—in an infringement suit brought to defend a patent directed to a treatment regimen¹⁷² associated with reducing the toxicity of a specific mesothelioma therapeutic in *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*¹⁷³ The patent at issue, No. 7,772,209 (the “‘209 patent”), was directed to

an improved method for administering pemetrexed disodium [to a patient in need of chemotherapeutic treatment] comprising “a) administration of between 3500 μ and about 1000 μ of folic acid prior to the first administration of pemetrexed disodium; b) administration of about 500 μ to about 1500 μ of vitamin B12, prior to the first administration of pemetrexed disodium; and c) administration of pemetrexed disodium.”¹⁷⁴

In this case, defendant Teva, makers of a generic version of plaintiff Eli Lilly’s drug, were distributing instructions to physicians to follow the treatment regimen described in the above claim of Eli Lilly’s ‘209 patent.¹⁷⁵ The evidence presented included packaging information passed from the doctor to the patient that clearly stated that “it is very important to take folic acid during your treatment with ALITMA [the drug in question] to lower your chances of harmful side effects.”¹⁷⁶ Thus, because the physicians administered the B12 injections and the drug itself, while the patients were responsible for taking the folic acid, the question arose as to whether all the steps of the claimed method could be attributable to the defendant, allowing Eli Lilly to bring a direct infringement claim under § 271(a) and an induced or contributory infringement claim under § 271(b).¹⁷⁷ The *Eli Lilly* court found that “[t]he evidence showed that physicians specify

170. *Id.*

171. *Id.*

172. U.S. Patent No. 7,772,209 (filed July 11, 2007).

173. 126 F. Supp. 3d. 1037, 1041–43 (S.D. Ind. 2015).

174. *Id.* at 1039 (quoting ‘209 Patent).

175. *Id.* at 1039.

176. *Id.*

177. *Id.* at 1041–42.

both the ‘manner and timing’ [of folic acid administration] in detail,” and that was enough to conclude that the performance of all of the steps of the ‘209 patent could be attributed to a single actor.¹⁷⁸

While this case is only a single example of a company being able to protect a method patent requiring performance of multiple actors, it is still promising and informative. First, it shows that it is not impossible to win an infringement suit when a patent is directed at multiple actors. Second, it provides some guidance with respect to counseling clients during and after the drafting process to ensure they act in a way that a jury could find, at minimum, the existence of a joint enterprise when the method is implemented. Finally, *Eli Lilly* sets a promising, though non-binding, example for future divided infringement cases involving patents directed to personalized medicine methods, especially in combination with navigating subject matter eligibility.

IV. DRAFTING PERSONALIZED MEDICINE PATENTS

The following Part first discusses personalized method patents. Then, this Part suggests some patent drafting and implementation techniques for optimizing personalized medicine directed patents in light of *Mayo*, *Myriad*, and *Limelight III*. As discussed above, following the Supreme Court’s decision in *Limelight II* to uphold the divided infringement loophole,¹⁷⁹ the general consensus was that personalized medicine would quickly become a thing of the past, despite multiple government initiatives to advance personalized medicine.¹⁸⁰ Thankfully, the Federal Circuit recently relaxed the definition of what constitutes a single party being in control of a third party and provided a framework from which one can draft protectable, directly infringeable patents.¹⁸¹

A. *Personalized Medicine Patents in General*

Typically, “useful processes” are patent eligible.¹⁸² While this framework is “subject to the conditions and requirements of” 35 U.S.C. § 101¹⁸³ and other patent statutes,¹⁸⁴ it is important for the purpose of this Comment to note that a “useful process” is defined as

178. *Id.* at 1043.

179. *See supra* Section III.A.

180. *See supra* Section IV.A.

181. *See supra* Section III.B.

182. 35 U.S.C. § 101 (2012).

183. *Id.*

184. *See supra* Section II.A.

a “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”¹⁸⁵ A useful process could include: (1) identification of a genetic or biochemical marker through diagnostic testing and (2) the direction of treatment based upon the significance of that marker.¹⁸⁶ These two steps form the core of a personalized medicine patent.¹⁸⁷

Take, for example, the following patent claim deemed subject matter eligible by the Federal Circuit in *Classen Immunotherapies v. Biogen IDEC*:

A method of immunizing a mammalian subject which comprises:

- (I) *screening* a plurality of immunization schedules, by
 - (a) *identifying* a first group of mammals and at least a second group of mammals, . . . the first group of mammals having been immunized with one or more [vaccine] doses . . . according to a first screened immunization schedule, and the second group of mammals having been immunized with one or more [vaccine] . . . according to a second screened immunization schedule . . .
 - (b) *comparing* the effectiveness of said first and second screened immunization schedules in protecting against or inducing a chronic immune-mediated disorder in said first and second groups [and] . . .
- (II) *immunizing* [a] subject according to a subject immunization schedule, . . . in accordance with said lower risk screened immunization schedule . . .¹⁸⁸

In this claim, the “identification” step takes place when the immunization schedule is screened to determine which schedule is the lowest risk for the subject—step (I)(a)–(b) of the above claim. The “direction of treatment” step takes place when the subject is immunized according to the more appropriate immunization schedule. However, take note of the divided infringement issues that could occur. One entity could easily conduct the screening step and another could conduct the immunization step. The patent could therefore be vulnerable to infringement with no recourse if the company did not take steps to ensure the implementation of their methods fit within the *Limelight III* framework.

185. 35 U.S.C. § 100(b) (2012).

186. Holman, *supra* note 113, at 114, 117.

187. *Id.*

188. *Classen Immunotherapies Inc. v. Biogen IDEC*, 659 F.3d 1057, 1060–61 (Fed. Cir. 2011) (emphasis added).

B. Suggested Approaches to Drafting Personalized Medicine Claims

Theoretically, a personalized medicine claim would be patent eligible as long as there is an active treatment step included during drafting.¹⁸⁹ The claims deemed patent eligible in *Classen*,¹⁹⁰ including a method of optimizing an immunization schedule and subsequent treatment of a patient, serve as examples of this concept.¹⁹¹ In comparison, “a claim drafted so broadly as to encompass the mere mental recognition of the existence of the biomarker correlated with a medically relevant physiological state will be found patent ineligible.”¹⁹² The claim deemed patent ineligible in *Mayo*—a method of determining the amount of a drug metabolite in the blood—serves as a cautionary tale of this concept.¹⁹³

When seeking to protect the many facets of a personalized medicine invention some argue that one should draft claims directed to any diagnostic assays, the optimized compound(s), and the method(s) of treatment.¹⁹⁴ Assuming the client is a pharmaceutical company with near-limitless funds, this could be an acceptable approach. However, following the series of cases discussed in this Comment, some of these types of claims are far more likely than others to succeed. The difficulty associated with securing patents for diagnostic testing has discouraged researchers like Professor Rebecca Eisenberg who stated recently that “most important advances in [diagnostic testing] lie outside the boundaries of patent-eligible subject matter.”¹⁹⁵ Nonetheless, *Limelight III* should have quelled similar concerns¹⁹⁶—that directing claims to multiple actors by claiming diagnosis and treatment steps would lead to unenforceable patents—by relaxing the divided infringement standard.¹⁹⁷ Therefore, because multi-step processes are more protectable under *Limelight III*, the following suggestions are directed primarily to the standard two-step personalized medicine patents with one initial exception.

189. Holman, *supra* note 113, at 118 (“[T]he inventor’s ability to obtain an adequate return on investment will likely hinge on the availability of effective patent protection directed towards the diagnostic method used . . .”).

190. See, e.g., U.S. Patent No. 6,638,739 (filed Apr. 18, 2002).

191. See *supra* Section IV.A.

192. Holman, *supra* note 112, at 148.

193. See *supra* Section II.B.1.

194. See generally Robert C. Millonig, Marsha Rose Gillentine & Rebecca Hammond, *The Best Offense Is a Good Defense: Patent Prosecution Strategies During Personalized Medicine Drug Development*, 34 BIOTECHNOLOGY L. REP. 39 (2015) (identifying various patent prosecution strategies).

195. See Eisenberg, *supra* note 98, at 256.

196. See Millonig et al., *supra* note 194, at 42.

197. See *supra* Section III.B.

1. Start with Composition of Matter Patents

First and foremost, patent drafters should not forget claims directed to the treatment itself. A composition of matter patent can be directed to a “composition of two or more substances and all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gasses, fluids, powders or solids.”¹⁹⁸ In the case of pharmaceutical patents, the key “composition of matter” is the active ingredient of the drug. Additionally, in the case of diagnostic methods, “claims to diagnostic assay reagents themselves may be [an] appropriate alternative way[] to protect the assay.”¹⁹⁹ If the personalized medicine patent involves treatment with a new therapeutic, drafters should make sure to claim the drug itself separately. For example, the company that owns the cystic fibrosis drug Kalydeco,²⁰⁰ Vertex Pharmaceuticals, has patent applications filed for both the composition itself as well as methods of treatment using the composition.²⁰¹

However, one will need to be wary that said composition is not simply isolated from nature in its naturally occurring form. As discussed above with respect to a naturally occurring antibiotic, the current subject matter eligibility guidelines no longer allow the patenting of such substances without a significant change from its natural state.²⁰²

2. Strive for “Something More”

As the differences between the Federal Circuit’s reasoning in *Classen* and *Mayo* are subtle,²⁰³ it is apparently necessary that drafters blatantly include the required “something more” in the patent claim.²⁰⁴ Thus, when drafting a method claim, drafters should consult the subject matter eligibility guidelines²⁰⁵ that include relevant factors that weigh toward and against eligibility. First and foremost, if drafters claim a process involving a judicial exception, drafters should ensure that the claim is not simply directed to the judicial exception,

198. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

199. *See* Millonig et al., *supra* note 194, at 43.

200. *See supra* notes 70–75 and accompanying notes.

201. *See, e.g.*, U.S. Patent No. 9,192,606 (filed Mar. 19, 2014); U.S. Patent No. 8,614,325 (filed Sept. 20, 2011).

202. *See supra* Section II.B.3.

203. *See supra* Section IV.B.

204. *See Mayo Collaborative Servs. v. Prometheus Labs.*, 132 S. Ct. 1289, 1297 (2012).

205. March 2014 Guidelines, *supra* note 46, at 2.

so as to avoid foreclosing it from use by others.²⁰⁶ Ideally, drafters should try to ensure that the examiner will consider the steps mentioned in addition to the judicial exception to be “something more.”²⁰⁷

Specifically, the examiner’s analysis will look to see if the claim recites limitations that qualify as “something more” or not. Factors that weigh in favor of eligibility include claims that are

improvements to another technology or technical field; . . . effecting a transformation or reduction of a particular article to a different state or thing; adding a specific limitation other than what is well-understood, routine and conventional in the field, or adding unconventional steps that confine the claim to a particularly useful application; or other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment.²⁰⁸

Factors that weigh against eligibility include

adding the words ‘apply it’ . . . with the judicial exception . . . ; simply appending well-understood and conventional activities previously known to the industry, specified at a high level of generality . . . ; adding insignificant extrasolution activity to the judicial exception . . . ; generally linking the use of the judicial exception to a particular . . . field of use.²⁰⁹

However, including relevant factors that weigh in favor of eligibility may prove more easily said than done, as what the USPTO has considered “something more” has remained unclear. Although Sequenom petitioned the Supreme Court for certiorari,²¹⁰ essentially in hopes of clarifying or overruling *Mayo*’s overly broad test,²¹¹ the

206. *Id.* at 2–3. The claims set forth in *Diamond v. Diehr*, 450 U.S. 175, 178–84 (1981), are some of the only eligible examples provided by the USPTO. The Court noted that because the claims were directed at a process of molding rubber and not the mathematical formula used in the process, the claims were patent eligible under 35 U.S.C. § 101. *Id.* at 191.

207. March 2014 Guidelines *supra* note 46, at 3–4.

208. 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618, 74,624 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1).

209. *Id.*

210. Petition for a Writ of Certiorari, *Sequenom v. Ariosa Diagnostics, Inc.*, No. 15-1182 (U.S. Mar. 21, 2016), 2016 WL 1105544, *cert. denied*, 136 S. Ct. 2511 (2016).

211. *Id.* at *i.

The question presented is: Whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that

petition was denied.²¹² Thus, patent drafters will need to continue erring on the side of caution. They will need to discuss with their clients if narrower patent claims, directed to more specific subject matter, are an acceptable solution to ensure that an indisputable “something more” has been added to the judicial exception. If not, the potential patent holder will either have these claims denied by the USPTO or risk having these patent invalidated during future infringement litigation.

3. Engage All of the Actors

Personalized medicine is, by necessity, conducted among multiple actors. Technicians run the diagnostic tests. A doctor examines the patient and prescribes the drugs. The patients themselves may administer the drugs. Following the pro-patentee opinion in *Limelight III*,²¹³ drafters must pay close attention to how the Federal Circuit defines both what constitutes direction and control of another’s performance and what is required to establish a joint enterprise.²¹⁴

Patent prosecutors need to carefully discuss with their clients how they plan to implement the patented method, using *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*²¹⁵ as an example. If the method will not be conducted in-house, or if a contractual or agency relationship does not exist with those implementing the method,²¹⁶ the company will need make sure any use of the method will fall within the joint enterprise framework set forth in *Limelight III*. Thus, the patentee will need to establish one of the four elements of a joint enterprise:

- (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; or
- (4) an equal right to a voice in the

discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

Id.

212. See *Sequenom v. Ariosa Diagnostics*, 136 S. Ct. 2511 (2016).

213. See *supra* Section III.B.

214. See *Akami Techs., Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020, 1023 (Fed. Cir. 2015) (en banc).

215. 126 F. Supp. 3d 1037, 1041–43 (S.D. Ind. 2015).

216. See *Limelight Networks, Inc.*, 797 F.3d at 1023.

direction of the enterprise, which gives an equal right of control.²¹⁷

In sum, now that the standards for what constitutes direct infringement have been relaxed, patentees need to know of and exercise their right to protect their intellectual property.

CONCLUSION

Following the Supreme Court's opinion in *Limelight II*, a multitude of commentators lamented the evisceration of medical treatment method patents. Decision after decision narrowing the so-called "coarse filter" of patent eligible subject matter necessitating patents directed to unprotectable, complicated methods conducted by multiple actors was a recipe for disaster. While biotech patent eligibility under § 101 is still somewhat hit or miss, recent subject matter eligibility guidelines, publicly available Office actions, and case law provide some patent drafting help. One of the most likely means of overcoming an examiner's declaration that a personalized medicine patent is directed to a judicial exception is to include an active treatment step, thus creating patent claims directed to a method of treatment. The Federal Circuit's opinion in *Limelight III* allows for exactly that style of drafting without handing the technology off to the closest generic company, forgoing any available recourse. Thus, there is hope that the exciting field of personalized medicine will continue to evolve, spurred by advances in technology, hefty federal funding, and the promise that pharma investors can recoup the billions required for effective research and development.

LELAND L. BLACK**

217. *Id.*

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