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Promoting the Progress of Personalized Medicine: Redefining Infringement Liability for Divided Performance of Patented Methods

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NOTE

PROMOTING THE PROGRESS OF PERSONALIZED MEDICINE: REDEFINING INFRINGEMENT LIABILITY FOR DIVIDED PERFORMANCE OF PATENTED METHODS

I. INTRODUCTION

We've made so many achievements and come a long way in our understanding and application of genetics knowledge. And yet, we are just beginning to realize the full potential of this science to predict the onset of disease, diagnose earlier, and develop therapies that can treat or cure Americans from so many afflictions . . . [W]e stand at this new and expansive frontier of personalized medicine . . . that can protect and promote our health.

– Barack Obama¹

Suppose that there are present in your genetic make-up certain mutations or variants which increase your susceptibility to a specific disease.² If a diagnostic test can be used to detect such variants well before the manifestation of clinical symptoms, a physician can diagnose early and employ therapies that may delay or prevent the adverse effects of disease altogether.³ Further, detecting particular genetic variants following the onset of symptoms may allow a physician to more precisely identify your disease,⁴ and determine the safety and efficacy of specific pharmaceutical and other therapies, enabling the physician

1. 153 CONG. REC. 7528-29 (2007) (introducing the Genomics and Personalized Medicine Act of 2007 in the U.S. Senate).

2. See Geoffrey S. Ginsburg & Jeanette J. McCarthy, *Personalized Medicine: Revolutionizing Drug Discovery and Patient Care*, 19 TRENDS BIOTECHNOLOGY 491, 493 (2001) (“Genetic variants can be used to predict the predisposition of an individual for future disease development.”).

3. See *id.* (“The ultimate goal of personalized medicine is to define disease at the molecular level so that preventive resources and therapeutic agents can be directed at the right population of people while they are still well.”).

4. See *id.* (“[M]olecular diagnosis based on gene- or protein-expression fingerprints might differentiate diverse diseases with similar clinical phenotypes.”).

to tailor treatment in a manner best adapted to your individual disease characteristics.⁵

Now suppose that you are on the board of directors at a large clinical laboratory that develops and performs diagnostic testing. You are aware that conducting research to identify gene variants that will allow physicians to prescribe treatment in a way that is best adapted to an individual patient's needs could be a profitable undertaking for your company.⁶ However, such research will involve a substantial investment of capital, and thus holds considerable financial risk.⁷ If your company makes the necessary expenditures to discover these gene variants, and unauthorized physicians and diagnostic testing companies then use these discoveries to provide treatment options to their patients without compensating you, you may be unable to recoup your investment.⁸ In light of this concern, you may decide to forego research efforts to make discoveries of useful genetic markers, unless there exists some

5. See Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301, 302 (2010) (discussing how breast tumors that overexpress human epidermal growth factor receptor type 2 ("HER2"), caused by a mutation in the HER2 gene, despite indicating a less favorable prognosis, predict better responses in patients to the medication trastuzumab); S.H. Katsanis et al., *A Case Study of Personalized Medicine*, SCI., Apr. 4, 2008, at 53 (discussing the advantage of using a patient's genotypic variant profile to determine optimal pharmaceutical dosage over a traditional trial-and-error approach and the ability to predict interactions of a drug with a patient's other medications based on the presence of certain genetic markers). Increases in efficacy and safety resulting from diagnostic testing can also result in substantial cost reductions for healthcare consumers. See Jerel C. Davis et al., *The Microeconomics of Personalized Medicine: Today's Challenge and Tomorrow's Promise*, 8 NATURE REVIEWS DRUG DISCOVERY 279, 279 (2009) ("Although such tests cost from US\$100-3,000 per test, they save \$600-28,000 per patient."). An example of such a diagnostic test that is commercially available is Oncotype DX™, a reverse transcriptase polymerase chain reaction ("RT-PCR") assay that analyzes gene expression in twenty-one genes to predict tumor recurrence in breast cancer patients and allows for stratification of patients based upon the likelihood of benefit from chemotherapy. Melina B. Flanagan et al., *Histopathologic Variables Predict Oncotype DX™ Recurrence Score*, 21 MOD. PATHOLOGY 1255, 1255-56 (2008).

6. See Davis et al., *supra* note 5, at 282 ("Molecular diagnostics are often cited as a more attractive market segment than typical diagnostics, given the potential for higher prices . . . and higher gross margins . . .").

7. See *id.*

8. Joseph Scott Miller, *Building a Better Bounty: Litigation-Stage Rewards for Defeating Patents*, 19 BERKELEY TECH. L.J. 667, 680-85 (2004) (explaining that inventions are merely information that can be easily appropriated by competitors who do not bear the cost of development and that "[t]he public good characteristics of information make it more difficult to earn a good return on an investment in producing new information"). This is known in patent law as the "free-rider problem." *Id.*

protection against appropriation of your discovery by others,⁹ such as the exclusive rights granted by a patent.¹⁰

You cannot secure a valid patent over the physical sequence of DNA for which you have discovered a use, even if it is isolated from the surrounding genetic and cellular material.¹¹ Further, a diagnostic test to analyze a patient's DNA for the presence of a molecular variant using conventional DNA analysis techniques, without more, is not patent-eligible.¹² Still, you are likely to obtain a valid patent when you claim as your invention a specific application of this genetic information in a treatment method wherein a patient is tested for certain molecular markers by way of a diagnostic test, and a physician administers a prescribed treatment based upon that test.¹³ But, even supposing that you have obtained a patent that will withstand a challenge to its validity, your decision to invest in the discovery of useful genetic markers will turn more importantly on your ability to enforce your patent rights against competitors.¹⁴

A patent grant ostensibly gives an inventor the right to exclude others from practicing the patented method, exposing unauthorized users to liability for infringement.¹⁵ However, under the "single-entity rule,"¹⁶ there is no liability for direct infringement unless an individual party or parties, under an entity's "control or direction," performs each and every

9. See *id.* at 682 ("[I]f an inventor who is motivated by profit concludes that free riders will compete away her chance to cover her invention costs, the inventor will refuse to incur those costs at the outset. As a result, if we want the benefits offered by capital-intensive inventions and easily copied inventions, we must provide a fix that banishes the free riders.").

10. See *id.* at 683 ("We . . . target the free riders' use with a right to exclude, providing the inventor with a time-limited right to exclude others from using the invention The patent insulates the inventor from price competition and thus provides the inventor a chance to recoup her investment.").

11. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116-20 (2013).

12. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012); *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1334-35 (Fed. Cir. 2012).

13. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067-69 (Fed. Cir. 2011) (holding that a claim to a treatment method incorporating information derived from a diagnostic assay is eligible for patent protection); Holly J. Atkinson et al., *Personalized Medicine Patents at Risk: Tips for Battling Prometheus and Myriad to Obtain Claims to Diagnostics*, CIPA J., Mar. 2013, at 127.

14. See *McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S. App. LEXIS 7531, at *17 (Fed. Cir. Apr. 12, 2011) (Newman, J., dissenting) ("A patent that cannot be enforced on any theory of infringement, is not a statutory patent right."); Miller, *supra* note 8, at 680-85.

15. See 35 U.S.C. §§ 154, 271 (2006).

16. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1321 (Fed. Cir. 2012) (en banc) (Newman, J., dissenting).

step of the claimed method.¹⁷ Absent evidence of control or direction by a single party, the patent owner must rely on the “inducement-only” rule,¹⁸ where infringement liability exists only where one party either actively induced other parties to perform each and every step of the method or performed some of the steps of the method itself and actively induced the performance of the remainder of the steps.¹⁹

Since personalized medicine methods involving diagnostic testing and treatment administration steps are performed by two parties acting in concert, that is, a clinical laboratory performing diagnostic testing and a physician, neither party is performing all of the steps alone.²⁰ Further, it may be that neither the diagnostic testing party nor the physician is under the “control or direction” of the other party.²¹ Thus, while unauthorized users of patented diagnostic testing and treatment methods may be practicing each and every step of a claimed method when viewed in combination, the patent owner will be unable to enforce his exclusive rights absent evidence of active inducement, which will be difficult to show in the context of unauthorized use of diagnostic testing and treatment methods.²² Thus, these inventors are provided with a right to exclude that rings hollow, and which gives little incentive by way of the patent system to pursue research into beneficial biomarkers.²³

Although patent scholars generally agree that incentivizing innovation is the primary purpose of the patent system,²⁴ competing theories, arguing for alternative scopes of patent protection, have been forwarded describing how the patent system can best effectuate that aim.²⁵ However, these theories are not actually inconsistent with one

17. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380-81 (Fed. Cir. 2007).

18. *Akamai*, 692 F.3d at 1319.

19. *Id.* at 1305 (majority opinion).

20. See Press Release, Mayo Clinic & SV Bio, Mayo Clinic and SV Bio Enter Strategic Relationship on Genome Diagnostics and Interpretation (Jan. 21, 2013) [hereinafter Mayo Press Release], available at http://www.svbio.com/sites/default/files/fields/press-release-pdf/svbio-mayo_final.docx_pdf (“SV Bio’s turnkey genomics interpretation solutions query a patient’s genome at the point of care and distill the biological data into a concise, actionable report that physicians can use to make faster, more informed decisions.”); *Akamai/McKesson Decided—Implications for Personalized Medicine Patents*, STERNE, KESSLER, GOLDSTEIN & FOX PLLC (Sept. 5, 2012), <http://skgf.com/media/pnc/3/media.1763.pdf> [hereinafter *Akamai/McKesson Decided*].

21. See Mayo Press Release, *supra* note 20 (announcing an arms-length collaborative agreement, as opposed to an agency relationship, that would satisfy the control or direction standard).

22. See *Akamai*, 692 F.3d at 1306; *infra* Part III.C.

23. See *Akamai*, 692 F.3d at 1336 (Newman, J., dissenting) (“Today’s new rule of inducement-only liability serves no public interest, no innovation need. The consequences for the technology communities are uncertainty, disincentive, and new potential for abuse.”).

24. Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1597 (2003).

25. See *id.* at 1615-30 (discussing the different levels of protection implicated by prospect

another, but rather, the theory that best effectuates the utilitarian purposes of the patent system depends upon the structural realities of the industry in question.²⁶ Further, Professors Dan L. Burk and Mark A. Lemley have identified areas of the patent system where courts are left a considerable amount of discretion to adapt general requirements to particular circumstances, calling these areas “policy levers.”²⁷ Courts can use these policy levers to inject industry-specific patent policies that will allow the patent system to take into account the realities of innovation in different industries and utilize a theory of protection that best achieves the utilitarian purposes of the patent system.²⁸

This Note argues that, because a broad scope of patent protection is necessary to offset the high level of commercial risk involved in the research and development of innovative genetic inventions,²⁹ the current standard for divided infringement is insufficient to incentivize innovation in the personalized medicine industry.³⁰ Further, this Note suggests that infringement liability is a previously unrecognized patent policy lever.³¹ Finally, this Note proposes that, given the need for greater protection in the field of personalized medicine, courts should utilize their discretion under this newly recognized policy lever to implement a rule providing for the enforcement of diagnostic testing and treatment methods in cases of divided performance.³²

Part II of this Note explains why broad patent protection is needed to spur the development of personalized medicine by providing an overview of the personalized medicine industry,³³ and outlining theories of patent protection.³⁴ Part III describes the development of the current standard for patent infringement in cases involving the divided performance of patented methods.³⁵ Part III then discusses the implications that the current divided infringement standard has for the

theory, competitive innovation theory, cumulative innovation theory, anticommons theory, and the theory of patent thickets); Christopher A. Cotropia, *Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms*, 47 WM. & MARY L. REV. 49, 117-24 (2005) (discussing the broad scope of protection implicated by the prospect theory of patents and the narrow protection warranted under competitive innovation theory).

26. See Burk & Lemley, *supra* note 24, at 1615-30.

27. See *id.* at 1638-68.

28. See *id.* at 1675-96.

29. See *infra* Part II.B.

30. See *infra* Part III.C.

31. See *infra* Part IV.B.

32. See *infra* Part IV.D.

33. See *infra* Part II.A.

34. See *infra* Part II.B.

35. See *infra* Part III.A-B.

enforceability of personalized medicine methods and the incentives to innovate in the personalized medicine industry.³⁶

Part IV of this Note argues that infringement liability is a policy lever that gives courts discretion to take into account industry-specific policy in formulating infringement standards.³⁷ Part IV also analyzes previously proposed divided infringement standards and describes why they are inadequate to achieve the requisite level of protection in the personalized medicine context.³⁸ Part IV then proposes a standard for courts to use when evaluating infringement of personalized medicine methods.³⁹ Part V concludes this Note.⁴⁰

II. INCENTIVIZING PERSONALIZED MEDICINE INNOVATIONS BY WAY OF THE PATENT SYSTEM

Discovering the molecular basis of disease involves difficult and costly research of genetic material.⁴¹ Meanwhile, patent eligibility requirements limit the ways in which inventors can protect the discovery of beneficial genetic information.⁴² Encouraging investment in the development of personalized medicine inventions requires construing these limited patent rights broadly in order to prevent the appropriation of these discoveries by competitors.⁴³

Subpart A provides an overview of personalized medicine and the inherent market risks that may deter investment in genetic research.⁴⁴ Further, Subpart A discusses the patentability of personalized medicine discoveries.⁴⁵ Finally, Subpart B describes theories of patent protection and how they indicate that broad protection is needed to incentivize the development of innovative personalized medicine inventions.⁴⁶

A. Personalizing Medicine

The core hypothesis of personalized medicine is that “diseases are heterogeneous, from their causes to rates of progression to their response

36. See *infra* Part III.C.

37. See *infra* Part IV.B.

38. See *infra* Part IV.C.

39. See *infra* Part IV.D.

40. See *infra* Part V.

41. See Davis et al., *supra* note 5, at 282; Ginsburg & McCarthy, *supra* note 2, at 494-95; *infra* notes 55-59 and accompanying text.

42. See *infra* notes 64-77 and accompanying text.

43. See *infra* Part II.B.

44. See *infra* Part II.A.

45. See *infra* Part II.A.

46. See *infra* Part II.B.

to drugs.”⁴⁷ Variations in individual patients occur at the molecular level in their genetic code, and minor variations explain such characteristics as height and hair color.⁴⁸ However, more significant variations, often involved in complex interactions with other genes as well as environmental factors, define the characteristics of disease, determining a patient’s predisposition to disease, disease prognosis, and safety and efficacy of treatment.⁴⁹

Personalized medicine seeks to identify these variations that will allow physicians to make more accurate diagnoses at an earlier stage, or even before disease manifests, as well as make more effective treatment decisions.⁵⁰ Once identified, a test can be developed to screen patients for the presence of molecular markers by comparing a patient’s DNA to a normal reference sequence, testing gene products that will indicate variations in DNA such as proteins or RNA, or using DNA probes which bind to sequences of DNA containing variants.⁵¹ Diagnostic testing companies can perform these analyses to detect variants and provide information on disease characteristics to physicians.⁵² Then, physicians may implement targeted preventative or therapeutic treatments best suited to the needs of individual patients based upon the molecular and environmental factors that determine the patient’s disease progression and drug response.⁵³ Further, pharmaceutical companies can utilize identified molecular markers to develop drugs that are the most effective for particular groups of patients.⁵⁴

However, discovering the molecular mechanism of disease is a complex endeavor, both because of the complexity of genomic material and the influence of the interactions between numerous genes and environmental factors on disease.⁵⁵ While nearly 99.9% of the genetic code of all humans is identical,⁵⁶ the remaining DNA consists of

47. See Ginsburg & McCarthy, *supra* note 2, at 492-93.

48. See Kristen L. Burge, *Personalized Medicine, Genetic Exceptionalism, and the Rule of Law: An Analysis of the Prevailing Justification for Invalidating BRCA 1/2 Patents in Association of Molecular Pathology v. USPTO*, 8 WASH. J. L. TECH. & ARTS 501, 509 (2013).

49. See Geoffrey S. Ginsburg & Huntington F. Willard, *Genomic and Personalized Medicine: Foundations and Applications*, 154 TRANSLATIONAL RES. 277, 281-83 (2009).

50. See Ginsburg & McCarthy, *supra* note 2, at 491.

51. See Burge, *supra* note 48, at 516-17.

52. See Ginsburg & Willard, *supra* note 49, at 280 (“[T]o support a clinician in his or her treatment of a patient with breast cancer, an [Electronic Health Records] system could consider the gene expression profile of the patient’s cancer biopsy and provide an individually tailored prediction of how the patient is likely to respond to various therapeutic options.”); Mayo Press Release, *supra* note 20.

53. See Ginsburg & McCarthy, *supra* note 2, at 493.

54. See Katsanis et al., *supra* note 5, at 53.

55. See Ginsburg & McCarthy, *supra* note 2, at 494-95.

56. Eric S. Lander, *Scientific Commentary: The Scientific Foundations and Medical and*

millions of individual nucleotides, mutation in any one of which can result in numerous diseases.⁵⁷ Further, since many diseases are not caused by single mutations, but rather by interactions between variations in a number of genes in addition to environmental factors, identifying precisely such mechanisms of disease is an even greater challenge.⁵⁸

This complexity necessitates large financial investments in research in order to develop diagnostic testing methods and targeted therapies.⁵⁹ The high costs and lengthy time period associated with development contribute to the significant business risk facing companies considering molecular diagnostics.⁶⁰ Additionally, delays in regulatory approval, coverage for genetic testing by insurance companies, and adoption of testing by healthcare providers increase the financial risk.⁶¹ Add to these inherent market risks the problem of appropriation of research efforts by competitors,⁶² and there exist major economic challenges and few incentives to invest in beneficial research of molecular disease markers.⁶³

Innovators in the field of personalized medicine have sought to protect their substantial investments in research and development by way of the patent system.⁶⁴ However, since molecular diagnostics involve naturally occurring genetic material and basic biochemical interactions, subject matter eligibility requirements have posed problems for securing patent protection.⁶⁵ One avenue of protection that

Social Prospects of the Human Genome Project, 26 J.L. MED. & ETHICS 184, 185 (1998).

57. See Burge, *supra* note 48, at 509.

58. See Ginsburg & McCarthy, *supra* note 2, at 494 ("To uncover DNA variants that predict common, complex diseases that result from a combination of genes and environmental factors will require cost-effective, high-throughput genotyping; large, well-characterized patient populations; sophisticated computational methodologies; and a detailed understanding of the biological pathways of disease.").

59. See Davis et al., *supra* note 5, at 282.

60. See *id.*

61. See *id.* (discussing that, based on benchmarks from several molecular diagnostics businesses, a one-year delay in the adoption of an average diagnostic test can reduce the 10-year net present value of such a test from \$15 million to \$10 million).

62. See Miller, *supra* note 8, at 680-85.

63. See Davis et al., *supra* note 5, at 279, 282 ("Although scientific challenges remain, it now seems that the economic challenges . . . present the most significant obstacles to the further development of personalized medicine.").

64. See Burge, *supra* note 48, at 510.

65. See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116-20 (2013) (holding claims to isolated DNA molecules ineligible for patent protection); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F. App'x. 65, 68-73 (Fed. Cir. 2012) (holding that a diagnostic testing method involving screening markers in a pregnant woman to determine the risk of Down syndrome in the fetus is not eligible for protection). The language of the statute governing subject matter eligibility is broad. See 35 U.S.C. § 101 (2006) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement

companies have sought consists of directing patent claims to the gene associated with the disease itself, when isolated and purified from the surrounding material.⁶⁶ However, in *Ass'n for Molecular Pathology v. Myriad Genetics*,⁶⁷ the Supreme Court determined that these claims are invalid because they assert ownership over products of nature, subject matter that is ineligible for protection.⁶⁸ Companies have also attempted to protect genetic discoveries by claiming the diagnostic method used to identify the presence of a molecular marker in a patient.⁶⁹ However, the Supreme Court in *Mayo v. Prometheus*⁷⁰ made claiming diagnostic tests generally more difficult when it held that a method claim directed to merely observing a natural correlation in a patient, without more, is not a patent-eligible application of a law of nature.⁷¹ This holding was subsequently applied to invalidate claims to diagnostic tests in which a patient is tested for the presence of a molecular marker to indicate disease susceptibility.⁷²

However, the use of the correlation between a molecular marker and disease in the making of treatment decisions is a specific application of a law of nature.⁷³ Thus, personalized medicine inventors can likely

thereof, may obtain a patent therefore . . ."); *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980) (discussing that the legislative history of the statute indicated that Congress intended for subject matter eligibility to be construed broadly). However, judicially created exclusions on patentability of laws of nature, products of nature, abstract ideas, or the "basic tools of scientific and technological work" exist because granting protection over such basic elements of scientific inquiry would "foreclose[] more future innovation than the underlying discovery could reasonably justify." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1301 (2012); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

66. See U.S. Patent No. 5,747,282 (filed June 7, 1995) (claiming an isolated DNA coding for a BRCA1 polypeptide, associated with the development of breast cancer).

67. 133 S. Ct. 2107 (2013).

68. See *id.* at 2117-20.

69. See *Burge*, *supra* note 48, at 516-17.

70. 132 S. Ct. 1289 (2012).

71. See *id.* at 1297-98. "[T]o transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" *Id.* at 1294. The Court held that the method for determining optimal therapeutic dosage of a pharmaceutical involving the steps of "administering" the drug and "determining" the level of drug metabolites in the patient's blood does not add enough to the non-patentable law of nature, namely the correlation between drug metabolites and optimal dosage, to make the method claim valid. *Id.* at 1297-98.

72. See *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1334-35 (Fed. Cir. 2012) (holding that claims directed to "comparing" or "analyzing" patients' DNA sequences are indistinguishable from claims held ineligible for protection in *Mayo*), *rev'd in part sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *PerkinElmer, Inc. v. Intema Ltd.*, 496 F.Appx. 65, 68-73 (Fed. Cir. 2012).

73. See *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011) (holding that the addition of an immunization step to a diagnostic test was a sufficiently "specific, tangible application" to "traverse[] the coarse eligibility filter of § 101").

still obtain valid claims, despite recent Supreme Court decisions, where they add a treatment administration step following the diagnostic testing step.⁷⁴ These claims may take the form of a two-step process that entails: “(1) Test[ing] for mutation X and, if present, (2) Administer[ing] drug Y.”⁷⁵ Given the manner in which genetic testing is carried out and treatment decisions are generally made in the healthcare industry, a diagnostic testing company will perform the testing step and a physician will perform the administration step.⁷⁶ While such patents are valid, their ability to encourage innovation in the personalized medicine industry depends upon the scope of protection they provide to their owners when they need to be enforced.⁷⁷ The discussion will now turn to an examination of the scope of protection needed to encourage innovation generally and in the personalized medicine industry specifically.⁷⁸

74. See *id.*; Atkinson et al., *supra* note 13, at 126; Elizabeth A. Doherty, *Biomarker and Personalized Medicine Patent Claims One Year After Mayo v. Prometheus*, FULL DISCLOSURE (June 2013), http://www.finnegan.com/files/upload/Newsletters/Full_Disclosure/2013/June/FullDisclosure_Jun13_5.html; see also Angela L. Morrison, *Mayo v. Prometheus: Patent Eligibility of Claims Covering Natural Laws*, COLO. LAW., July 2012, at 77, 82-83 (advising that claims should be “novel,” “active,” and “specific”). To be novel, claims can “include . . . a novel relationship between what is detected and a particular disease, a novel method of administration, or a novel means of detecting or determining the target.” Morrison, *supra*, at 83. Additionally, a claim may be active by avoiding mental steps in favor of steps where an actor physically does something. *Id.* Finally, a claim may be specific by describing exactly how to detect genetic markers and specific commercial embodiments. *Id.*

75. See *Akamai/McKesson Decided*, *supra* note 20. Claims involving a therapy administration step are perhaps not the only claims involving genetic testing that may be patentable following *Myriad* and *Mayo*. See Atkinson et al., *supra* note 13, at 128-29. For example, claims directed to a diagnostic method using a novel antibody or assay to detect a molecular marker, a method for detecting a novel or unexpected combination of markers, or a method reciting the use of a man-made DNA probe to detect a molecular marker may be patent eligible. See *id.* Of these methods, however, those involving an administration step have Federal Circuit precedent supporting their patentability. See *Classen*, 659 F.3d at 1067-69. Additionally, under *Myriad*, claims directed to complementary DNA (“cDNA”) remain patent eligible because the non-coding regions have been removed, and it is thus not a naturally occurring molecule. See *Myriad*, 133 S. Ct. at 2119.

76. See Mayo Press Release, *supra* note 20.

77. See *McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S. App. LEXIS 7531, at *17 (Fed. Cir. Apr. 12, 2011) (Newman, J., dissenting) (“A patent that cannot be enforced on any theory of infringement, is not a statutory patent right. It is a cynical, and expensive, delusion to encourage innovators to develop new interactive procedures, only to find that the courts will not recognize the patent . . .”); Miller, *supra* note 8, at 680-83 (discussing that an inventor’s decision to invest in innovation will depend upon his ability to exclude competitors and thus insulate himself from price competition and recoup investment).

78. See *infra* Part II.B.

B. Promoting Progress and Theories of Patent Protection

The U.S. Constitution authorizes Congress to grant exclusive patent rights to inventors.⁷⁹ The aim of this authority is set out in the Constitution itself: promoting progress.⁸⁰ This express authorization to hinder competition by vesting an exclusive right in inventors represents a departure from the Framers' general abhorrence of economic monopolies,⁸¹ and thus demonstrates their attentiveness to the collective interest in the creation of technology.⁸² Although theorists have sought to justify the patent system on grounds of moral right, reward, or redistributive justice, the central purpose of the patent system is widely viewed as a utilitarian one, providing the incentive of a limited monopoly to spur the research and development of socially beneficial technologies.⁸³

How to best effectuate the primary utilitarian goal of the patent system is an issue far more contentious than the underlying justification itself, with scholars in fundamental disagreement as to the level of protection needed to provide adequate incentives to invent without preventing innovation that will occur in the usual course of the competitive market.⁸⁴ According to prospect theory,⁸⁵ patents encourage

79. U.S. CONST. art. I, § 8, cl. 8. Congress has the power 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." *Id.*

80. *See id.*

81. *See* *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 7 (1966) ("[Thomas] Jefferson, like other Americans, had an instinctive aversion to monopolies. It was a monopoly on tea that sparked the Revolution and Jefferson certainly did not favor an equivalent form of monopoly under the new government.").

82. Stacie L. Greskowiak, Note, *Joint Infringement After BMC: The Demise of Process Patents*, 41 LOY. U. CHI. L.J. 351, 357 (2010); *see also* Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in *JEFFERSON: POLITICAL WRITINGS* 581, 581 (Joyce Appleby & Terence Ball eds., 2004) [hereinafter Letter from Thomas Jefferson] ("Considering the exclusive right to invention as given not of natural right, but for the benefit of society, I know well the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.").

83. *See* Burk & Lemley, *supra* note 24, at 1597 (discussing that other justifications for the patent system "are hard to take seriously as explanations for the actual scope of patent law," and that agreement amongst courts and commentators as to this basic utilitarian purpose of patent law occurs "[t]o a greater extent than any other area of intellectual property"); *see also* Letter from Thomas Jefferson, *supra* note 82, at 580 ("Society may give an exclusive right to the profits arising from [inventions], as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody."). *But see* David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMP. L. REV. 181, 192-97 (2009) (arguing that, absent a determination of whether protection is actually needed to incentivize innovation in a certain industry, there has been a proliferation of patent monopolies that actually serve to stifle innovation).

84. *See* Burk & Lemley, *supra* note 24, at 1599 ("The growing body of economic literature on

future innovation by way of ex post incentives.⁸⁶ When a patentee is granted protection, he is encouraged to invest in further developments and improvements of the invention that will maximize its value, just as a landowner is encouraged to develop and improve his land efficiently.⁸⁷ By way of licensing agreements, he can control the downstream development of the invention in an efficient manner that could not be achieved without exclusive rights, in which case the patentee would fear “that the fruits of the investment will produce unpatentable information that competitors can appropriate.”⁸⁸ According to this theory, then, patents should grant their owners a broad scope of protection early in the inventive process over not only the specific invention described, but also all of its commercial embodiments and potential improvements.⁸⁹

Conversely, under competitive innovation theory,⁹⁰ patent protection is needed only to provide ex ante incentives to innovate.⁹¹ Patent protection is important to overcome the “free rider” problem and enable an inventor to recoup his investment in research and development,⁹² but once an invention is created, competition provides such incentives ex post that the exclusivity of the patent grant is no longer necessary to encourage companies to innovate, as they will do so anyway out of a desire to improve their competitive market position.⁹³ Thus, under this theory, patents should grant very narrow protection, giving the patentee a limited monopoly over a manner of competing in the relevant market, but not complete market control.⁹⁴

Prospect theory and competitive innovation are two of many theories that exist to describe how the patent system can best achieve its primary utilitarian goal.⁹⁵ Inasmuch as these theories provide

patent theory has developed *at least* five distinct approaches to the proper scope and allocation of patent rights.” (emphasis added)).

85. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 265-71 (1977) (describing prospect theory as “reintegrat[ing] the patent institution with the general theory of property rights”).

86. See Cotropia, *supra* note 25, at 122.

87. See Burk & Lemley, *supra* note 24, at 1601.

88. See Cotropia, *supra* note 25, at 122 (quoting Kitch, *supra* note 85, at 276).

89. See Burk & Lemley, *supra* note 24, at 1615-16 (“[P]rospect theory suggests that patents should be broad, stand alone, and confer almost total control over subsequent uses of the product.”).

90. See *id.* at 1604.

91. See *id.* at 1605 (“Prospect theory is wrong, on this view, because the only reason we need intellectual property rights is to create ex ante incentives, not ex post control rights.”).

92. See Miller, *supra* note 8, at 680-85.

93. See Cotropia, *supra* note 25, at 118-19.

94. See *id.* at 119.

95. See Burk & Lemley, *supra* note 24, at 1600-07. Other theories Burk and Lemley discuss are cumulative innovation theory, anticommons theory, and patent thickets theory. *Id.* at 1607-15. For other property-based views of intellectual property, see generally Kenneth W. Dam, *Some*

justification for alternative scopes of patent protection, they seem fundamentally inconsistent with one another.⁹⁶ However, Burk and Lemley argue that this is not necessarily the case.⁹⁷ Rather, they argue that, “[t]he range of patent theories parallels the range of ways in which the patent system affects companies in different industries. Like the proverbial blind men with the elephant, every theorist has focused on one aspect of the patent system, appropriate for one industry but irrelevant to others.”⁹⁸ Thus, under this view, the patent theory that best predicts the optimal scope of patent protection will vary depending upon the industry context to which it is applied.⁹⁹

For example, the prospect theory of patent protection, which favors a broad scope of patent protection early in the inventive process in order to allow for control over future innovation by a single firm, could predict the optimization of innovation incentives in the pharmaceutical industry.¹⁰⁰ The cost to develop new pharmaceuticals is exorbitantly expensive in itself, and even following development, the drug must go through a drawn-out and costly approval process.¹⁰¹ Further, competitors who enter the market later with a similar drug do not bear the burden of an extensive approval process,¹⁰² exacerbating the “free-rider” problem.¹⁰³ Also, given the nature of chemical compounds, closely related molecules to those developed by the patentee may achieve the same physiological result, and thus pharmaceutical inventions face the risk of being easily designed around by competitors to avoid infringement.¹⁰⁴ Thus, the scope of the patentee’s rights should be construed broadly so as to cover related chemical products.¹⁰⁵

On the other hand, competitive innovation theory, which supports a very narrow scope of monopoly power, perhaps most accurately predicts appropriate innovation incentives in industries having an absence of large and long-term development costs, such as business methods and

Economic Considerations in the Intellectual Property Protection of Software, 24 J. LEGAL STUD. 321 (1995); Trotter Hardy, *Property (and Copyright) in Cyberspace*, 1996 U. CHI. LEGAL F. 217.

96. Burk & Lemley, *supra* note 24, at 1615.

97. *See id.*

98. *Id.*

99. *See id.* at 1615, 1674 (“These differences are so stark that it may not even be meaningful to speak of the ‘right rule’ in a particular area of patent law without reference to the characteristics of the industry or innovation in question. Ignoring such differences is counterproductive.”).

100. *See id.* at 1615-17.

101. *See id.* at 1616.

102. *See id.*

103. *See* Miller, *supra* note 8, at 680-85.

104. *See* Burk & Lemley, *supra* note 24, at 1617.

105. *See id.*

Internet software.¹⁰⁶ Business methods will arguably be developed despite a lack of, or only modest, patent protection since they provide a competitive advantage and involve little or no cost to develop.¹⁰⁷ Similarly, the rapid development of the Internet occurred using open protocols of a nonproprietary nature, supporting the conclusion that there were existing incentives to innovate without strong, or even any, patent protection.¹⁰⁸ Burk and Lemley urge that “[u]nder these conditions, patents should be rare and very modest in scope in order to allow market forces their fullest latitude.”¹⁰⁹

The personalized medicine industry would seem to map most appropriately onto the prospect theory of patent protection, given its similarities to the pharmaceutical industry.¹¹⁰ Like pharmaceuticals,¹¹¹ molecular diagnostics are extremely costly to develop,¹¹² given the difficulty of research into the complex nature of molecular interactions that drive the mechanisms of disease.¹¹³ Additionally, a lengthy approval process increases the costs associated with developing molecular diagnostics,¹¹⁴ just as in the case of pharmaceuticals,¹¹⁵ and thus, competitors subsequently providing the same diagnostic test will have the advantage of avoiding such costs.¹¹⁶ Further, since the same genetic information can be obtained by several different methods, and similar pharmaceutical compounds can achieve identical therapeutic results, diagnostic testing and treatment administration methods are subject to being easily designed around.¹¹⁷ Thus, competitors may benefit from the discovery, although the investors in the initial research will have endured the much higher costs of discovering the important genetic information itself.¹¹⁸ As a consequence, the personalized medicine market provides inventors with little incentive to invest in research and development,¹¹⁹ as is true for the pharmaceutical market.¹²⁰ The

106. *See id.* at 1617-19.

107. *See id.* at 1618.

108. *See id.* at 1619.

109. *Id.*

110. *See id.* at 1615-17; Davis et al., *supra* note 5, at 282.

111. *See* Burk & Lemley, *supra* note 24, at 1616.

112. *See* Davis et al., *supra* note 5, at 282.

113. *See* Ginsburg & McCarthy, *supra* note 2, at 494-95.

114. *See* Davis et al., *supra* note 5, at 282-83.

115. *See* Burk & Lemley, *supra* note 24, at 1616.

116. *See* Davis et al., *supra* note 5, at 282.

117. *See* Burge, *supra* note 48, at 516-17 (discussing different methods of obtaining diagnostic information from a patient's DNA); *supra* note 104 and accompanying text.

118. *See* Davis et al., *supra* note 5, at 282.

119. *See id.*

120. *See* Burk & Lemley, *supra* note 24, at 1615-17.

similarities that personalized medicine shares with pharmaceuticals indicate that patent rights in personalized medicine inventions should be construed broadly so as to give would-be inventors the incentives necessary to invest in genetic research.¹²¹ The discussion will now turn to how the scope of protection for personalized medicine methods is determined by the rules governing liability for divided infringement.¹²²

III. DIVIDED INFRINGEMENT: THE “SINGLE-ENTITY” AND “INDUCEMENT-ONLY” RULES

Patent holders can enforce their exclusive rights by bringing an action for patent infringement against unauthorized users of their claimed invention.¹²³ Unauthorized parties that use the invention themselves are liable for direct infringement,¹²⁴ while parties that actively induce others to directly infringe are liable for indirect infringement.¹²⁵ Since diagnostic testing and treatment methods involve the interaction between a clinical laboratory and a physician, the unauthorized use of methods covered by patents may similarly involve both unauthorized diagnostic testing companies and unauthorized physicians acting in concert.¹²⁶ Since direct infringement requires the accused to have performed all of the steps of a claimed method,¹²⁷ and a predicate direct infringement is necessary for a finding of inducement,¹²⁸ establishing infringement liability in the field of personalized medicine is problematic as there is no single party performing all of the steps of the claimed method.¹²⁹

121. See *id.* at 1617.

122. See *infra* Part III.

123. See 35 U.S.C. §§ 271, 281 (2006).

124. See *id.* § 271(a).

125. See *id.* § 271(b).

126. See *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1314-15 (Fed. Cir. 2012) (discussing attempts by Myriad Genetics to enforce its diagnostic testing claims against other clinical laboratories who were providing the results of diagnostic tests to physicians), *rev’d in part sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116-20 (2013); Mayo Press Release, *supra* note 20.

127. See *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005).

128. See *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004) (“A defendant’s liability for indirect infringement must relate to the identified instances of direct infringement.”).

129. See, e.g., *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305 (Fed. Cir. 2012) (en banc) (addressing the problem of liability for inducement arising in two consolidated cases where “the defendant has performed some of the steps of a claimed method and has induced other parties to commit the remaining steps (as in the *Akamai* case),” and where “the defendant has induced other parties to collectively perform all the steps of the claimed method, but no single party has performed all of the steps itself (as in the *McKesson* case)”; see also *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007) (“With other parties performing some

This Part will discuss the rules that have developed in Internet software and business methods cases governing liability in the divided performance context,¹³⁰ and the implications of these rules for personalized medicine.¹³¹ Subpart A will discuss the “single-entity rule” that governs direct infringement in cases of divided performance.¹³² Subpart B will discuss the “inducement-only” rule that governs liability for indirect infringement in the divided performance context.¹³³ Finally, Subpart C will discuss how these rules affect the enforceability of patented personalized medicine methods and how the scope of protection they afford personalized medicine inventors is insufficient to achieve the utilitarian aim of the patent system in this industry.¹³⁴

A. Direct Infringement Liability for Divided Performance of Method Claims

As provided by 35 U.S.C. § 271(a),¹³⁵ “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor” is liable for direct infringement.¹³⁶ The first step for courts in an action for infringement is to construe the claims of the patent in order to determine the limitations of the owner’s proprietary interest.¹³⁷ The purpose of the claims, which are required to “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention,”¹³⁸ is to notify the public, including potential competitors, of the precise scope of the patentee’s right to exclude.¹³⁹ The claims are construed according to the meaning they would have to a person of ordinary skill in the art, in light of the description of specific embodiments of the invention in the remainder of

claimed method steps, this court must determine if Paymentech may nonetheless be liable for direct infringement under 35 U.S.C. § 271(a) (2000).”).

130. See *infra* Part III.A–B.

131. See *infra* Part III.C.

132. See *infra* Part III.A.

133. See *infra* Part III.B.

134. See *infra* Part III.C.

135. 35 U.S.C. § 271(a) (2006).

136. *Id.*; see *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (en banc) (discussing that § 271(a) governs direct infringement).

137. See *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309, 1315 (Fed. Cir. 1998).

138. 35 U.S.C. § 112 (2006).

139. See *American Hoist & Derrick Co. v. Manitowoc Co.*, 448 F. Supp. 1372, 1386 (E.D. Wis. 1978), *aff’d*, 603 F.2d 629 (7th Cir. 1979) (“The purpose for [claims] is to ‘distinguish what is claimed from what went before in the art and clearly circumscribe what is foreclosed from future enterprise.’” (quoting *United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 236 (1942))).

the patent document, and the history of the patent's prosecution in the Patent and Trademark Office.¹⁴⁰

Following claim construction, courts compare the claim so construed to the allegedly infringing use.¹⁴¹ Direct infringement is a strict liability offense,¹⁴² and thus, the lack of intent to infringe or a lack of knowledge of the patent on the part of the accused is irrelevant to a determination of liability.¹⁴³ Likewise, independent creation, that is, a claim by the defendant that it did not copy, but rather, independently developed the invention, is not a defense to patent infringement.¹⁴⁴ However, under the well-settled "all limitations" rule, there is no infringing "use" within the meaning of the Patent Act unless each and every limitation of the claim has been practiced.¹⁴⁵ For a method claim, this means that each and every step of the claim must be performed in the manner set forth.¹⁴⁶ Thus, while it is clear that a single party

140. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005).

141. See *Ethicon Endo-Surgery*, 149 F.3d at 1315.

142. See *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007).

143. See *id.* ("[T]he nature of the offense is only relevant in determining whether enhanced damages are warranted.").

144. See Chris Falkowski, *Protecting Software: The Case for Software Patents*, MICH. B.J., June 2007, at 24, 27 (discussing that, while trade secret cases will often involve a claim that the defendant independently thought of the invention, which is a valid affirmative defense, this defense cannot be raised in the patent context). Several commentators have argued that the law should provide for an independent creation affirmative defense to patent infringement. See generally Michelle Armond, Comment, *Introducing the Defense of Independent Invention to Motions for Preliminary Injunctions in Patent Infringement Lawsuits*, 91 CAL. L. REV. 117 (2003) (arguing for an affirmative defense of independent creation to a motion for a preliminary injunction in order to avoid abuse of preliminary injunctions); Samson Vermont, *Independent Invention as a Defense to Patent Infringement*, 90 J. PAT. & TRADEMARK OFF. SOC'Y 268 (2008). The lack of a defense for independent creation is a divergence from other areas of intellectual property. See Falkowski, *supra*, at 27 (discussing how copyright or trade secret protection for software may be frustrated by independent creation by competitors). At least one commentator has discussed the perplexity of the availability of the independent creation defense for copyright infringement, but not patent infringement, given that "[t]rue independent creation of any but the simplest of artistic works, with perhaps the exception of popular music, is statistically highly unlikely," while conversely, "nearly identical or overlapping inventions are frequently developed, often contemporaneously, in patent law." Clarisa Long, *Information Costs in Patent and Copyright*, 90 VA. L. REV. 465, 526 (2004).

145. *Herman Miller, Inc. v. Teknion Corp.*, 504 F. Supp. 2d 360, 365 (N.D. Ill. 2007); see *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("Each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole."); *Prouty v. Ruggles*, 41 U.S. 336, 341 (1842) (holding that in a patent that is a combination of three elements, "[t]he use of any two of these parts only, or of two combined with a third, which is substantially different . . . is . . . not the thing patented" and that "[c]onsequently the use of either alone, by the defendants, would not . . . infringe the patent of the plaintiffs"). For the purposes of this Note, "Patent Act" refers to all patent provisions contained in Title 35 of the U.S. Code.

146. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("A method or process consists of one or more operative steps, and, accordingly, '[i]t is well established that a patent for a method or process is not infringed unless all steps or stages of the claimed process are

performing all of the steps of a claimed method is liable for direct infringement, “when the acts necessary to give rise to liability for direct infringement are shared between two or more actors, doctrinal problems arise.”¹⁴⁷

The Federal Circuit addressed divided performance in 2007 in *BMC Resources, Inc. v. Paymentech, L.P.*¹⁴⁸ The patent holder BMC Resources, Inc. (“BMC”) claimed a method for processing payment transactions over a telecommunications line using the payee’s account number or debit card number.¹⁴⁹ The payee would be prompted to enter his number using a telephone keypad, and then a remote financial network would be accessed to determine whether sufficient funds were available and either approve or deny the transaction.¹⁵⁰ The alleged infringement of Paymentech, L.P. (“Paymentech”) consisted of the receipt of the payee’s payment information from a merchant, the routing of said information to a debit network that then forwarded it to an affiliated financial institution for authorization or denial of the transaction, and the informing of the merchant of the status of the transaction.¹⁵¹

Since the debit network, the financial institution, and the merchant each performed some of the steps of the claimed method, Paymentech did not perform the entire claimed method itself.¹⁵² Nonetheless, BMC argued that under Federal Circuit precedent, a party could be liable for direct infringement, even though it did not perform all of the steps of the claimed method, if infringement resulted from the “participation and combined action(s) of more than one person or entity.”¹⁵³ However, the

utilized.” (quoting *Roberts Dairy Co. v. United States*, 530 F.2d 1342, 1354 (Ct. Cl. 1976))). Furthermore, all of the steps of the claimed method must have been practiced in the United States. *Id.*

147. See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1305 (Fed. Cir. 2012) (en banc).

148. 498 F.3d 1373 (Fed. Cir. 2007).

149. *Id.* at 1375-77.

150. *Id.* at 1376-77.

151. *Id.* at 1375-77.

152. *Id.* at 1375.

153. *Id.* at 1379-80 (quoting *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1344 (Fed. Cir. 2006)). In *On Demand*, the claimed invention was a method for selling a single copy of a book, wherein a party took an order from a customer for a copy of a book and then printed and bound a single copy for sale to the customer. *On Demand*, 442 F.3d at 1335-36. The alleged infringer took orders for a single book copy from customers, but another party did the printing and binding. *Id.* at 1335. The Federal Circuit stated on appeal that it “discern[ed] no flaw . . . as a statement of law” in the district court’s jury instruction that “[w]hen infringement results from the participation and combined action(s) of more than one person or entity, they are all joint infringers and jointly liable for patent infringement.” *Id.* at 1344-45. However, an issue of claim construction governed the outcome of the case and the court’s statement with regard to joint infringement was not essential to its holding. *Id.* at 1334.

court declined to endorse this rule as the proper standard for joint infringement, instead holding that a defendant who performed fewer than all of the steps of a claimed method may only be liable for direct infringement if the parties performing the remaining steps were under the defendant's "control or direction."¹⁵⁴ Since BMC had not proffered sufficient evidence to show that Paymentech had controlled or directed the other parties, Paymentech could not be liable for direct infringement.¹⁵⁵

The court was convinced that the "single-entity rule"¹⁵⁶ "derives from the statute itself," requiring that *a party* practice the *entire* invention to be liable for infringement.¹⁵⁷ Thus, except where the conduct of the other parties can be attributed to a single infringer, the statute requires a finding of non-infringement.¹⁵⁸ Though the court acknowledged that the "control or direction" standard could be easily subverted by two parties entering into an arms-length agreement,¹⁵⁹ it nonetheless determined that expanding direct infringement to cover actions by entirely independent entities would "subvert the statutory scheme for indirect infringement," reasoning that a patent owner would likely never need to bring an action for indirect infringement if direct infringement covered conduct by independent parties.¹⁶⁰ Further, the court believed that the problem of divided performance through arms-

154. *BMC Res. Inc.*, 498 F.3d at 1380-81. In a subsequent case, the court determined that the "control or direction" standard is satisfied "where the law would traditionally hold the accused direct infringer vicariously liable for the acts committed by another party that are required to complete performance of a claimed method," that is, where the accused would be liable for the acts of the other party under common law principles of agency. *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1330 (Fed. Cir. 2008).

155. *BMC Res., Inc.*, 498 F.3d at 1381-82.

156. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1321-22 (Fed. Cir. 2012) (en banc) (Newman, J., dissenting).

157. *BMC Res., Inc.*, 498 F.3d at 1380.

158. *See id.*

159. *Id.* at 1381.

160. *Id.*; *see also* Mark A. Lemley et al., *Divided Infringement Claims*, 33 AIPLA Q.J. 255, 262 (2005). Lemley and his coauthors note:

Construing the patent laws to permit the individual, non-infringing acts of unrelated parties together to add up to infringement would render both § 271(b) and § 271(c) meaningless. Section 271(b) provides that a party is liable if it knowingly induces another to infringe. But on a theory of joint infringement, no one need ever sue for inducement. All they need allege is that a party performed one of many steps of a method, and that someone else performed another step. No intent would be required.

Lemley et al., *supra*. But *see McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S. App. LEXIS 7531, at *2-3 (Fed. Cir. Apr. 12, 2011) (involving the owner of a method patent relying on the theory of inducement against a software provider, where the software provider performed none of the steps of the claimed method itself, but rather healthcare providers and patients acting in concert performed the entire method).

length agreements reflected poor claim drafting on the part of the patent owner, and that the patentee should bear the burden of drafting claims during the application stage to capture performance by a single party.¹⁶¹

A further justification for the “single-entity rule” is that a broader standard would entangle innocent parties.¹⁶² Since direct infringement is a strict liability offense, a broader rule would make parties that neither performed all of the necessary acts to constitute infringement, nor had any way of being aware that others were performing the remaining steps, liable for infringement.¹⁶³ Under this view, “[b]ecause virtually all modern patents are combinations of existing elements, permitting enforcement of distributed patent claims against anyone who produces or performs any single element, with or without an intent to infringe, would sweep a large number of innocent actors within the ambit of patent infringement.”¹⁶⁴ Indeed, in some circumstances, a broader direct infringement standard could open up parties to liability “who contributed only staple items of commerce—computers, telecommunications networks, routers, and the like,” or innocent consumers that performed only one step in a claimed method where, for example, some proprietary software performs the remainder of the steps.¹⁶⁵ Because a remedy for direct infringement is unavailable to patent owners in the case of divided

161. See *BMC Res., Inc.*, 498 F.3d at 1381 (“A patentee can usually structure a claim to capture infringement by a single party . . . [T]his court will not unilaterally restructure the claim or the standards for joint infringement to remedy these ill-conceived claims.”). In this case, the court was convinced that BMC could have drafted its claims to reach infringement by a single party, rather than multiple distinct entities. *Id.* (“The steps of the claim might have featured references to a single party’s supplying or receiving each element of the claimed process.”). Many patentees, of course, had already obtained patents prior to *BMC* that were subject to divided performance. See Ken Hobday, Comment, *The Incredibly Ever-Shrinking Theory of Joint Infringement: Multi-Actor Method Claims*, 38 CAP. U. L. REV. 137, 150-51, 163-67, 186 (2009) (“[M]any important and perhaps seminal patents filed during the early days of e-commerce in the 1990s may as a practical matter be unenforceable.”). A patentee could perhaps remedy such deficiencies after patent issuance by way of a reissue application to amend claims to capture infringement by a single actor. See 35 U.S.C. § 251 (2006). But see Damon Gupta, *Virtually Uninfringeable: Valid Patents Lacking Protection Under the Single Entity Rule*, 94 J. PAT. & TRADEMARK OFF. SOC’Y 61, 68-69 (2012) (“Presumably, there are many patents, largely for internet based applications, that include a divided claim . . . Considering how overtaxed the USPTO is presently, having as many afflicted patents come back for reissues would be excruciatingly overwhelming.”).

162. See Lemley et al., *supra* note 160, at 282-83; see also *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (en banc).

163. See *Akamai*, 692 F.3d at 1307.

164. Lemley et al., *supra* note 160, at 282.

165. *Id.*; see also *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1330 (Fed. Cir. 2008) (involving an online auction process where a consumer served as a bidder and performed one of the steps of the claimed method).

performance, patent owners may attempt to rely on an inducement theory in order to reach unauthorized divided performance.¹⁶⁶

B. Liability for Inducing Divided Performance of Method Claims

Under 35 U.S.C. § 271(b),¹⁶⁷ “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”¹⁶⁸ Inducement liability extends to a party who “cause[s], urge[s], encourage[s], or aid[s]” direct infringement by another party and the induced conduct is actually carried out.¹⁶⁹ Unlike liability for direct infringement, inducement liability requires an inquiry into the mental culpability of the accused.¹⁷⁰ Although the statute does not expressly require specific intent,¹⁷¹ courts have reasoned that implicit in the language that the infringement be “actively” induced is the requirement that the accused not only knowingly induce the acts that constitute infringement, but also know that the induced acts constitute infringement of an existing patent.¹⁷² Finally, since “[t]here is no such thing as attempted patent infringement,”¹⁷³ the alleged inducing party cannot be held liable for encouraging or causing the commission of acts by another party that ultimately do not constitute direct infringement of the patent.¹⁷⁴

After deciding the direct infringement issue, the *BMC* court addressed liability for inducing infringement in the context of divided

166. See *infra* Part III.B.

167. 35 U.S.C. § 271(b) (2006).

168. *Id.*

169. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1308 (Fed. Cir. 2012) (en banc) (quoting *Arris Grp., Inc. v. British Telecomms., PLC*, 639 F.3d 1368, 1379 n.13 (Fed. Cir. 2011)) (internal quotation marks omitted).

170. See Andrew Ward, *Inducing Infringement: Specific Intent and Damages Calculation*, 94 J. PAT. & TRADEMARK OFF. SOC’Y 1, 3 (2012) (citing *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)).

171. See 35 U.S.C. § 271(b).

172. See *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (citing *Water Techs. Corp.*, 850 F.2d at 668).

173. *Akamai*, 692 F.3d at 1308.

174. See *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 526 (1972) (“[I]t is established that there can be no contributory infringement without the fact or intention of a direct infringement. ‘In a word, if there is no [direct] infringement of a patent there can be no contributory infringer.’” (quoting *Mercoid Corp. v. Mid-Continent Co.*, 320 U.S. 661, 677 (1944) (Frankfurter, J., dissenting on other grounds))); *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1272 (Fed. Cir. 2004) (“Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement, though the direct infringer is typically someone other than the defendant accused of indirect infringement.”); *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.*, 803 F.2d 684, 687 (Fed. Cir. 1986) (holding that there was no inducement liability because there was no direct infringement where the supposed direct infringer practiced the invention, but had an implied license to do so).

performance.¹⁷⁵ The court relied upon the general rule for indirect infringement that there can be no liability for inducing infringement or contributory infringement in the absence of a direct infringer,¹⁷⁶ and held that Paymentech was not liable for inducing infringement of BMC's claimed method because there was no party liable for direct infringement under the "control or direction" standard.¹⁷⁷ Thus, following *BMC*, where independent parties divided performance of a claimed method, and there was no "single-entity" performing the claimed method, a patentee had no remedy for either inducement or direct infringement.¹⁷⁸

In *Akamai Technologies, Inc. v. Limelight Networks*,¹⁷⁹ the court recognized that this rule left patent owners with no remedy where parties intentionally divide performance of a claimed method for the purpose of circumventing the owner's rights.¹⁸⁰ However, the court declined to disturb the holding from *BMC* concerning direct infringement.¹⁸¹ Instead, the court overruled *BMC* regarding inducement, holding that a party could be liable for inducing infringement even absent the performance of all of the steps of the claimed method by a single entity.¹⁸²

The court reasoned that "[r]equiring proof that there *has been* direct infringement as a predicate for induced infringement is not the same as requiring proof that a single party would be *liable* as a direct

175. See *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380-81 (Fed. Cir. 2007).

176. See *id.*; *Dynacore Holdings Corp.*, 363 F.3d at 1272.

177. *BMC Res., Inc.*, 498 F.3d at 1381.

178. See *Akamai*, 692 F.3d at 1306 (discussing that recent decisions of the Federal Circuit "have interpreted section 271(b) to mean that unless the accused infringer directs or controls the actions of the party or parties that are performing the claimed steps, the patentee has no remedy, even though the patentee's rights are plainly being violated by the actors' joint conduct").

179. 692 F.3d 1301 (Fed. Cir. 2012).

180. See *id.* at 1306.

181. *Id.* at 1307 ("Because the reasoning of our decision today is not predicated on the doctrine of direct infringement, we have no occasion at this time to revisit any of those principles regarding the law of divided infringement as it applies to liability for direct infringement under 35 U.S.C. § 271(a)."). As Judge Pauline Newman notes in dissent, the only issue for which en banc review in *Akamai* was granted was to rule on the issue of direct infringement, and thus the "single-entity rule," in the divided infringement context. *Id.* at 1321 (Newman, J., dissenting). More than three-dozen organizations, representing a wide array of technological industries, including biotechnology organizations, social media companies, and financial services companies, filed briefs as amici curiae on the issue of direct infringement, but the issue was ultimately not addressed. *Id.* at 1303-05 (majority opinion); see also Timothy R. Holbrook, *The Potential Extraterritorial Consequences of Akamai*, 26 EMORY INT'L L. REV. 499, 507 (2012) ("Although most observers believed the court would address the 'single entity' rule of direct infringement, and then necessarily the law of inducement given its contingency on direct infringement, the court did no such thing Instead, the court's decision was specific to active inducement under § 271(b).").

182. See *Akamai*, 692 F.3d at 1306.

infringer.”¹⁸³ Because § 271(a) uses the term “whoever,” it requires a *person* to perform the acts necessary to constitute infringement in order to be liable for direct infringement.¹⁸⁴ Section 271(b), on the other hand, contains no limiting language requiring the performance of the underlying infringement by a single party.¹⁸⁵

The patent claims involved in the two consolidated cases on appeal in *Akamai* were directed to a method for electronic communication between patients and healthcare providers and a method for efficient delivery of web content.¹⁸⁶ The accused infringer of the electronic communication method, Epic Systems Corp. (“Epic”), licensed a software program that facilitated communication between healthcare providers and patients.¹⁸⁷ The accused infringer of the web content delivery method, Limelight Networks Inc. (“Limelight”), performed some of the steps of the method and provided instructions to customers for performing the remaining steps.¹⁸⁸ The court held that Epic could be liable for inducing infringement if the lower court found on remand that Epic’s software induced healthcare providers and patients to collectively perform the claimed method.¹⁸⁹ Further, the court held that Limelight could be liable for inducement if the lower court determined that it performed all but one of the steps of the claimed method itself and induced the performance of the remaining step by its customers.¹⁹⁰

Thus, this “inducement-only” rule¹⁹¹ provides patent owners with a remedy against parties who intentionally divide performance of claimed methods for the purpose of avoiding infringement.¹⁹² Further, it avoids subjecting innocent parties that perform fewer than all of the steps of the claimed method to liability because they will lack the requisite intent.¹⁹³ However, whatever benefit the extra protection of the “inducement-

183. *Id.* at 1308-09.

184. 35 U.S.C. § 271(a) (2006); *Akamai*, 692 F.3d at 1309.

185. *See* 35 U.S.C. § 271(b); *Akamai*, 692 F.3d at 1309. The Court found further support for this rule in the legislative history of the Patent Act, *see Akamai*, 692 F.3d at 1309-11, accomplice liability in criminal law, *see id.* at 1311-12, and liability for inducing tortious acts, *see id.* at 1312-13. As one commentator notes, since § 271(b) does not contain the territorial limitation requiring that the infringement occur within the United States that is found in § 271(a), divorcing inducement liability under § 271(b) from the conditions of direct infringement in § 271(a) could result in findings of inducement liability for infringement occurring wholly outside of the United States by an inducing party located outside of the United States. *See Holbrook, supra* note 181, at 508-12.

186. *See Akamai*, 692 F.3d at 1306.

187. *See id.*

188. *See id.*

189. *See id.* at 1318-19.

190. *See id.*

191. *Id.* at 1326 (Newman, J., dissenting).

192. *See id.* at 1309 (majority opinion).

193. *See id.* at 1308 n.1.

only” rule provides to the industries involved in *Akamai*, diagnostic testing and treatment methods in the personalized medicine industry may remain unenforceable despite this extra layer of protection.¹⁹⁴

C. Implications of the Divided Infringement Standard for Personalized Medicine

For personalized medicine methods that contain an administration step in addition to a diagnostic testing step,¹⁹⁵ the “single-entity” rule requires that either the physician or diagnostic testing company, performing some of the steps of a claimed method, control or direct the performance of the remainder of the steps by the other party in order for direct infringement liability to arise.¹⁹⁶ However, the relationship between diagnostic testing companies and physicians may be in the nature of an arms-length agreement or collaboration, rather than the principal-agent type of relationship required to satisfy the control or direction standard.¹⁹⁷ Thus, where unauthorized physicians and diagnostic testing companies divide performance of a patented method, neither party is likely to be liable for direct infringement.¹⁹⁸

As a consequence, the owners of personalized medicine method claims must rely upon a theory of inducement in order to enforce their exclusive patent rights.¹⁹⁹ This requires that the patentee meet the burden of proving that the unauthorized physician or diagnostic testing company performing some of the steps of the claimed method had knowledge of the patent and encouraged the performance of the remaining steps by the other party.²⁰⁰ However, concerning the physicians, it is unlikely that they will be aware of the existing patent that covers the method.²⁰¹ Further, even where a patent owner can establish that a physician had the requisite knowledge of the patent, the remedies available against physicians are limited by statute.²⁰² Concerning diagnostic testing companies, while it may be easier to prove knowledge of the patent at

194. See *supra* Part III.C.

195. See *supra* notes 75-76 and accompanying text.

196. See *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380-81 (Fed. Cir. 2007); Doherty, *supra* note 74 (“[I]t might be difficult to ultimately prove infringement of such a claim given that a single actor may not perform both the patient treatment and the diagnostic assay steps.”).

197. See Mayo Press Release, *supra* note 20.

198. See Atkinson et al., *supra* note 13, at 129; Doherty, *supra* note 74.

199. See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1318-19 (Fed. Cir. 2012) (en banc).

200. See *id.*; *Akamai/McKesson Decided*, *supra* note 20.

201. See *Akamai/McKesson Decided*, *supra* note 20.

202. See 35 U.S.C. § 287(c)(1) (2006).

issue, it is unlikely that patent owners will be able to prove that the diagnostic testing company encouraged the physician to administer a treatment based upon the results of the diagnostic test that the company provided.²⁰³ Thus, the divided infringement standard articulated by the Federal Circuit potentially allows competitors to utilize claimed personalized medicine methods while escaping liability for infringement.²⁰⁴

As discussed above, companies are unlikely to invest in the development of useful diagnostic testing and treatment administration methods when the patent system does not provide strong patent rights, given the absence of incentives to innovate provided by the market.²⁰⁵ Personalized medicine inventors are currently not provided strong patent rights due to a divided infringement standard that requires patent owners to prove knowledge of the patent in issue absent a single infringer and allows competitors to use claimed methods without facing liability.²⁰⁶ Further, strict subject matter eligibility requirements have rendered many personalized medicine claims invalid.²⁰⁷ The patent system is thus unlikely to achieve its utilitarian aim in the personalized medicine industry, since broad protection is needed to encourage investment in these research intensive technologies.²⁰⁸ However, by viewing infringement liability as an area where Congress has granted courts discretion to implement industry-specific patent policy, courts may limit the holdings of the previous divided infringement cases to the types of industries there involved, and fashion a new, broader rule for divided infringement in the personalized medicine context.²⁰⁹

203. See Mayo Press Release, *supra* note 20 (discussing that the role of the clinical laboratory is to provide genetic information to physicians who can thereafter use that information to benefit patients); *Akamai/McKesson Decided*, *supra* note 20.

204. See *supra* notes 195-203 and accompanying text.

205. See *supra* Part II.A.

206. See *supra* text accompanying notes 195-204.

207. See *supra* Part II.A.

208. See *supra* notes 110-21 and accompanying text.

209. See *infra* Part IV.

IV. USING A POLICY LEVER TO STRENGTHEN ENFORCEABILITY OF PERSONALIZED MEDICINE METHOD PATENTS

The court should simply acknowledge that a broad, all-purpose single-entity requirement is flawed.

– Judge Pauline Newman, United States Court of Appeals for the Federal Circuit²¹⁰

The cases in which the divided infringement standard was developed involved different technologies and different policy concerns than those involved in the personalized medicine industry.²¹¹ Namely, a greater scope of protection is needed to encourage the development of personalized medicine methods than is necessary for the types of inventions involved in *BMC* or *Akamai*.²¹² This Part argues that Congress has given courts the discretion to take these differences in policy into account to develop industry-specific rules for infringement.²¹³ Further, courts should use this discretion to fashion an infringement rule for diagnostic testing and treatment methods that provides for liability in cases where one party provides the results of the diagnostic testing step to a physician, who thereafter uses those results in the performance of the administration step.²¹⁴

Subpart A discusses “policy levers,” areas of the patent system where Congress has delegated the authority to courts to formulate industry-specific patent rules.²¹⁵ Subpart B argues that infringement liability is a policy lever that gives courts discretion to formulate industry-specific infringement standards and discusses the relevant policy differences in the personalized medicine context that warrant a broader infringement standard.²¹⁶ Subpart C considers previously proposed tests for divided infringement liability that could be applied to personalized medicine inventions, and concludes that these tests would be insufficient to provide the broad scope of protection needed to encourage the creation of personalized medicine methods.²¹⁷ Finally,

210. *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1326 (Fed. Cir. 2012) (en banc) (Newman, J., dissenting).

211. *See infra* text accompanying notes 253-76.

212. *See Akamai*, 692 F.3d at 1306 (majority opinion) (involving Internet software); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1375 (Fed. Cir. 2007) (involving a payment method); *supra* Part II.B (discussing the difference between the protection needed for, on one hand, Internet software and business methods, and, on the other hand, personalized medicine).

213. *See infra* Part IV.B.

214. *See infra* Part IV.D.

215. *See infra* Part IV.A.

216. *See infra* Part IV.B.

217. *See infra* Part IV.C.

Subpart D discusses how infringement liability in cases of divided performance of diagnostic testing and treatment methods should be determined to provide the necessary scope of protection in the personalized medicine industry.²¹⁸

A. Patent Policy Levers

Since the optimal scope of patent protection varies in light of relevant differences in the way innovation occurs in particular industries,²¹⁹ it follows that these differences should be taken into account when formulating the rules of the patent system.²²⁰ Congress could perform this function itself when enacting patent legislation.²²¹ However, this would create a number of difficulties,²²² and as Professors Burk and Lemley argue, Congress has chosen instead to delegate the authority to formulate industry-specific patent rules to the courts.²²³

The Patent Act, according to Burk and Lemley, exists, as all statutes do, “on a continuum between detailed rules such as the tax code capable of rote application on one end, and rules like antitrust law delegating broad authority to judges to make correct decisions on the other.”²²⁴ With general, industry-neutral standards concerning patent validity and scope that must be applied in idiosyncratic technological industries, the patent system falls on this continuum somewhere near the broad judicial authority present in antitrust law.²²⁵ Judges hearing patent cases are thus given wide discretion to consider industry-specific policy in applying general patent rules, making these areas of discretion “doctrinal policy levers” that can be used by judges to adjust the scope of protection in order to achieve the utilitarian purpose of patent law in the industry at issue.²²⁶

218. See *infra* Part IV.D.

219. See *supra* Part II.B.

220. See Burk & Lemley, *supra* note 24, at 1630-31.

221. See *id.*

222. *Id.* at 1634. Among the primary issues with relying upon industry-specific patent legislation is that such a route “would involve substantial administrative costs and uncertainties” as Congress attempted to draft statutes tailored to the vast number of technical categories into which inventions could fit. *Id.* at 1635-47. Even should Congress be able to meet the burden of such a task, it would still leave the issue of accommodating new technology that was not, and could not, be considered when the statutes were adopted. See *id.*

223. See *id.* at 1638.

224. *Id.*

225. *Id.*

226. *Id.* at 1638-40.

Burk and Lemley identify a number of existing policy levers.²²⁷ The prohibition on protection for abstract ideas, the utility requirement, and the disclosure requirement are just a few.²²⁸ Courts use the prohibition on patenting of abstract ideas, which is ostensibly a restriction on subject matter eligibility, to deny patent protection for entire concepts, which could stifle downstream innovation in some industries.²²⁹ Similarly, courts apply a heightened utility requirement in the field of life sciences, requiring that a claimed product have an identified or “specific” use in order to prevent the preclusion of research on the product that could result in further innovation downstream.²³⁰ The disclosure requirements, both enablement and the written description requirement, are policy levers similarly applied in the chemical and pharmaceutical context to limit protection, so as to not deter research that could result in downstream innovation.²³¹

However, Burk and Lemley argue of this latter example that, given the manner in which prospect theory maps these industries,²³² the disclosure requirements, properly used as policy levers, would be relaxed so as to give patentees the broad scope of protection necessary to allow them to overcome the high research and development costs that are associated with such innovation.²³³ In other instances, courts have replaced their discretion in adjusting these policy levers with rigid rules that largely confine their discretion.²³⁴ If courts endeavor to set the legal rules in these areas without considering industry-specific policy, they are nonetheless setting patent policy, but they are doing so inadvertently rather than intelligibly.²³⁵ A benefit of recognizing these policy levers,

227. *Id.* at 1641-68 (identifying a number of areas of judicial discretion fit for treatment as policy levers in addition to those described here, such as experimental use, secondary considerations for nonobviousness, reasonable interchangeability, pioneering patents, reverse doctrine of equivalents, presumption of validity, new secondary considerations, patent misuse, and injunctions); *see also* Cotropia, *supra* note 25, at 127-33 (arguing that claim interpretation methodology is a patent policy lever).

228. *See* Burk & Lemley, *supra* note 24, at 1642-51.

229. *See id.* at 1642-44.

230. *See id.* at 1644-46.

231. *See id.* at 1648-54.

232. *See id.* at 1615-17.

233. *See id.* at 1686-87.

234. *See id.* at 1672-73.

235. *See id.* at 1674. Whether or not courts openly acknowledge and discuss their policy determinations, their decisions in areas that can be identified as policy levers will necessarily require them to make substantive rules, since there is indeed no clear statutory guidance on these issues. *See* Cotropia, *supra* note 25, at 129-30 (“No statutes exist that dictate how claims are interpreted, and claim interpretation methodologies include claim scope paradigms that embed patent theory in the resulting claim definitions. When courts are faced with choices between methodologies, they are also facing patent policy choices.”). Thus, the objection that Congress is better equipped to consider policy concerns is misplaced, since Congress has failed to provide

then, and considering industry-specific policy explicitly, is that the setting of these rules becomes transparent as courts and observers can clearly discern the policies that inform decisions made in the context of particular industries.²³⁶ The discussion will now turn to the discretion that courts are given to develop industry-specific rules governing patent infringement.²³⁷

B. Infringement Liability as a Policy Lever

Despite Chief Judge Randall Rader's announcement in *BMC* that the "single-entity" rule "derives from the statute itself,"²³⁸ the language of 35 U.S.C. § 271(a) does not compel a reading that all of the steps of a claimed method must be performed by a single party in order for direct infringement liability to arise.²³⁹ First, while it is settled that infringement liability requires performance of each and every element of the claimed invention,²⁴⁰ the use of "whoever" in the statute²⁴¹ does not require that all elements be performed by a single party.²⁴² The rules of statutory construction laid out in 1 U.S.C. § 1 provide that, "unless the context indicates otherwise . . . words importing the singular include and apply to several persons, parties, or things."²⁴³ Further, the term "whoever" appears elsewhere in the Patent Act, such as in the provision governing who may obtain patent protection.²⁴⁴ This use of "whoever" cannot be construed to mean that a single inventor must create the entire invention in order for it to qualify for protection, as evidenced by the provision providing for joint inventors, and there is no reason to believe "whoever" should have a different interpretation in § 271(a).²⁴⁵ As the

guidance, while courts are required to formulate substantive rules. *See id.* In addition, such determinations are appropriately delegated to the Federal Circuit, given its "institutional competence" in regard to patents, which is a result of both its handling of nearly all patent cases filed in the United States and the technical and patent law backgrounds of some of its members. *See id.* at 131.

236. *See* Cotropia, *supra* note 25, at 130.

237. *See infra* Part IV.B.

238. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380 (Fed. Cir. 2007).

239. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1322-23 (Fed. Cir. 2012) (en banc) (Newman, J., dissenting) ("Infringement is not a question of how many people it takes to perform a patented method.").

240. *See supra* note 145 and accompanying text.

241. 35 U.S.C. § 271(a) (2006).

242. *See Akamai*, 692 F.3d at 1322.

243. 1 U.S.C. § 1 (2012); *Akamai*, 692 F.3d at 1322 ("By statutory canon the word 'whoever' embraces the singular and plural.").

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

245. *See* 35 U.S.C. § 116 (2006); *Akamai*, 692 F.3d at 1322.

Supreme Court has emphasized, “Congress did not use technical or occult phrases in defining the extent of the rights and privileges secured to a patentee.”²⁴⁶

Further, 35 U.S.C. § 154(a)(1) provides that a patent grants its owner the right to exclude “others” from practicing his claimed invention.²⁴⁷ The Supreme Court has determined that “[i]nfringement is defined by § 271(a) in terms that follow those of § 154.”²⁴⁸ Thus, since the exclusive rights of a patent owner granted under § 154 are violated by “any person who participates in any wrongful appropriation of the invention,” which could include a party that participates in divided performance of method claims, by any “method by which the invention can be made available for the benefit of the infringer,” such person may be liable for patent infringement under § 271(a).²⁴⁹

If the statute indeed does not require that every step be performed by a single defendant in order for liability to arise, then it is within the discretion of courts to establish a standard by which a party can perform fewer than all of the steps of a claimed method and still be liable for infringement.²⁵⁰ This broad discretion will necessarily require courts to make substantive determinations when adapting the general requirements of infringement to the particular circumstances involved in the wide array of industries that make use of the patent system.²⁵¹ Courts should thus explicitly consider relevant differences amongst industries to develop industry-specific rules concerning infringement, using infringement liability as a “doctrinal policy lever.”²⁵²

A proper exercise of courts’ discretion to utilize infringement liability as a policy lever would include considering the relative measure of incentives to innovate and other relevant differences in the various

246. *Akamai*, 692 F.3d at 1324 (quoting *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 10 (1913)) (internal quotation marks omitted).

247. See 35 U.S.C. § 154(a)(1) (2006).

248. *Akamai*, 692 F.3d at 1323 (quoting *DeepSouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 522 (1972)); see also H.R. REP. NO. 82-1923, at 9 (1952) (“Section 271, paragraph (a), is a declaration of what constitutes infringement It is not actually necessary because the granting clause [35 U.S.C. § 154] creates certain exclusive rights and infringement would be any violation of those rights.”); Giles S. Rich, *Infringement Under Section 271 of the Patent Act of 1952*, 21 GEO. WASH. L. REV. 521, 537 (1953) (“Paragraph (a) defines direct infringement and is present only for the sake of completeness. We got along without it for 162 years and we could again. Its omission would change nothing.”).

249. See *Akamai*, 692 F.3d at 1323-24 (quoting WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 897 (1890)); see also *id.* at 1306 (noting that in the case of divided performance “the patentee’s rights are plainly being violated by the actors’ joint conduct”).

250. See *supra* text accompanying notes 224-26.

251. See *supra* note 235 and accompanying text.

252. See *Burk & Lemley*, *supra* note 24, at 1640-41.

industries in which the problem of divided infringement arises.²⁵³ *Akamai* and *BMC*—two cases in which the current divided infringement standard was developed—involved industries where incentives to innovate exist even in the absence of protection provided by the patent system, such as business methods and Internet software.²⁵⁴ With low research and development costs, these industries do not require strong patent rights in order for innovation to occur.²⁵⁵ In fact, strong patent protection in these industries may inhibit the competitive market forces that would spur innovation in the absence of exclusive rights.²⁵⁶ Further, the concern that truly innocent parties performing only some of the steps of a patented method would be swept up in liability for infringement may be valid in these industries, especially in cases where the party performing the final step is a consumer.²⁵⁷ Thus, construing the patent right narrowly in *Akamai* and *BMC*—by requiring the patent owner to show either an agency relationship between the parties or active inducement—may have been appropriate for the industries involved in those cases.²⁵⁸

However, the policy concerns that warrant a narrow rule for infringement liability in the Internet software and business methods industries are not present in the personalized medicine context.²⁵⁹ First of all, unlike Internet software and business methods, the market for personalized medicine inventions lacks sufficient incentives to invest in innovation absent strong protection from the patent system.²⁶⁰ Rather, the manner in which innovation occurs in the personalized medicine industry favors the broad scope of protection that is consistent with the prospect theory of patents.²⁶¹

Aside from the greater relative need for protection in the personalized medicine industry, the concern that a broad divided

253. See *id.* at 1641.

254. See *Akamai*, 692 F.3d at 1306 (involving a patent that covers a method for delivering web content); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1375 (Fed. Cir. 2007) (involving patent protection for a method for processing a payment transaction); *supra* text accompanying notes 106-09. As pointed out above, Internet technology developed in a widely nonproprietary setting with no ownership rights, and thus incentives could be said to exist absent patent protection, which would call for a narrow scope of patent rights. See *supra* notes 106-09.

255. See *supra* notes 106-09.

256. See Burk & Lemley, *supra* note 24, at 1619.

257. See, e.g., *Muniauction, Inc. v. Thomson Corp.*, 32 F.3d 1318, 1330 (Fed. Cir. 2008); Lemley et al., *supra* note 160, at 282-83.

258. See *Akamai*, 692 F.3d at 1306; *BMC Res., Inc.*, 498 F.3d at 1381-82; Burk & Lemley, *supra* note 24, at 1619.

259. See *infra* text accompanying notes 260-76.

260. See *supra* notes 113-20 and accompanying text.

261. See *supra* notes 110-21 and accompanying text.

infringement rule will entangle innocent parties in infringement liability does not apply to personalized medicine methods.²⁶² Claims to Internet software or business methods may involve steps performed by unassuming merchants processing their customers' transactions,²⁶³ consumers performing only the final step in an Internet-based method,²⁶⁴ or patients and healthcare providers using a proprietary software program.²⁶⁵ Conversely, the personalized medicine methods discussed here only involve clinical laboratories and physicians, rather than innocent consumers or even parties "who contributed only staple items of commerce."²⁶⁶ Diagnostic testing companies—even performing fewer than all of the steps of the claim—can hardly be considered innocent parties in the same sense as the customers involved in Internet software and business methods, as they are likely the competitors of the inventor.²⁶⁷ To the extent that the physicians performing the administration step are innocent parties, the Patent Act limits the remedies against them for infringement.²⁶⁸

Further, the concern that finding liability in cases of divided performance would "subvert the statutory scheme for indirect infringement"—which the court in *BMC* used to justify the "single-entity" requirement²⁶⁹—does not apply in the personalized medicine context, since there may be at least one situation involving personalized medicine methods where a party could perform none of the steps of a claimed method and yet still be liable for inducing infringement.²⁷⁰ For example, suppose a pharmaceutical company were to market a drug with instructions on how to perform a diagnostic test for determining the

262. See *infra* text accompanying notes 263–68.

263. See *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1375–76, 1380–81 (Fed. Cir. 2007).

264. See *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1323, 1328–30 (Fed. Cir. 2008).

265. See *McKesson Techs. Inc. v. Epic Sys. Corp.*, No. 2010-1291, 2011 U.S. App. LEXIS 7531, at *2 (Fed. Cir. Apr. 12, 2011).

266. Lemley et al., *supra* note 160, at 282; see *supra* text accompanying notes 75–76.

267. See, e.g., *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297–98 (2012) (involving a dispute over a diagnostic test between two competing diagnostic testing companies); *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1314–15 (Fed. Cir. 2012) (discussing enforcement actions taken by the owner of a diagnostic testing patent to prevent unauthorized use by other clinical laboratories).

268. See 35 U.S.C. § 287(c)(1) (2006).

269. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380–81 (Fed. Cir. 2007).

270. See *infra* text accompanying notes 271–72. The extent to which this is even a relevant concern weighing against a broader divided infringement rule in the software context is questionable, as shown by the facts of the *McKesson* case. See *Akamai Techs. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1306 (Fed. Cir. 2012) (en banc). In that case, the alleged inducer performed none of the steps of the claimed method itself, and thus the patentee would not have been able to reach the defendant under any theory of direct infringement, having to rely instead on a claim of inducement. See *id.*

presence of a particular molecular marker, and then described the administration of a certain drug dosage based upon the presence of that marker.²⁷¹ In this situation, the pharmaceutical company could be liable for inducement without having performed any of the claimed method itself if a physician and diagnostic testing company did in fact follow the instructions and perform the patented method.²⁷²

Finally, the sentiment expressed by the *BMC* court—that the burden should fall on patentees since they can address the issue of divided infringement at the claim drafting stage by writing claims to capture infringement by a single party—does not allow owners of diagnostic testing and treatment methods to protect their inventions.²⁷³ A valid claim could probably be drafted to make the conduct of the physician alone infringing by adding a step wherein the physician requests the results of a diagnostic test from a diagnostic testing company.²⁷⁴ Again, however, since the Patent Act limits the remedies available against physicians,²⁷⁵ requiring patent owners to enforce their exclusive rights against physicians rather than diagnostic testing companies, who are likely to be their competitors, is inadequate in view of the broad protection needed to encourage the development of personalized medicine inventions.²⁷⁶

Thus, while the “single-entity” and “inducement-only” rules may properly balance competing policy concerns in the Internet software and business methods context,²⁷⁷ the same policy concerns weighing against protection are not present in the personalized medicine industry.²⁷⁸ In fact, good patent policy weighs in favor of granting greater protection to personalized medicine inventions than that provided by the current divided infringement standard.²⁷⁹ What the court has done, instead of exercising its discretion to implement these industry-specific policy concerns, is to “confine” a policy lever, creating a strict rule applicable

271. See *Akamai/McKesson Decided*, *supra* note 20.

272. See *id.*

273. See *BMC Res., Inc.*, 498 F.3d at 1381; *infra* text accompanying notes 274–76.

274. See *Atkinson et al.*, *supra* note 13, at 129 (“A method for treating X in a patient comprising: requesting a test providing the results of an analysis to determine whether the patient expresses protein A and administering treatment Y to the patient if the patient expresses A.”).

275. See 35 U.S.C. § 287(c)(1) (2006).

276. See *supra* text accompanying notes 110–21.

277. See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1306–07 (Fed. Cir. 2012) (en banc) (adding protection for inducement in divided infringement of web content delivery technology, but not doing so in consideration of specific characteristics of the industry in question); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380–81 (Fed. Cir. 2007) (applying the “single-entity rule” to divided infringement of payment processing technology).

278. See *supra* text accompanying notes 259–76.

279. See *supra* text accompanying notes 259–76.

to all industries, “in effect cabining its own discretion.”²⁸⁰ Courts facing the issue of divided infringement in the personalized medicine context should limit the “single-entity” and “inducement-only” rules to Internet software and business methods and utilize their discretion to develop an infringement standard that takes into account the relevant differences in the personalized medicine industry that weigh in favor of broad protection.²⁸¹

C. Previously Proposed Tests for Divided Infringement

Commentators have proposed a number of divided infringement tests since the Federal Circuit took up the issue in *BMC*.²⁸² While not proposed in an industry-specific manner, to the extent they allow for greater protection than the current standard, they could be appropriate for courts to utilize when confronted with divided performance of personalized medicine inventions.²⁸³ These proposed standards involve expansion of the “control or direction” definition itself, by way of a multi-pronged test,²⁸⁴ or by applying a standard lower than common law agency;²⁸⁵ using principles of civil conspiracy to reach divided infringers;²⁸⁶ applying a willful blindness test to cases of divided

280. Burk & Lemley, *supra* note 24, at 1673.

281. See *infra* Part IV.C–D.

282. See, e.g., Keith Jaasma, *Finding the Patent Infringement “Mastermind”: The “Control or Direction” Standard for “Joint” Infringement*, 26 SANTA CLARA COMPUTER & HIGH TECH. L.J. 411, 453–56 (2010); Joshua P. Larsen, *Liability for Divided Performance of Process Claims After BMC Resources, Inc. v. Paymentech, L.P.*, 19 DEPAUL J. ART TECH. & INTELL. PROP. L. 41, 63–64 (2008); Alice Juwon Ahn, Note, *Finding Vicarious Liability in U.S. Patent Law: The “Control or Direction” Standard for Joint Infringement*, 24 BERKELEY TECH. L.J. 149, 174 (2009); Reza Dokhanchy, Note, *Cooperative Infringement: I Get By (Infringement Laws) with a Little Help from My Friends*, 26 BERKELEY TECH. L.J. 135, 159–60 (2011); Long Truong, Note, *After BMC Resources, Inc. v. Paymentech, L.P.: Conspiratorial Infringement as a Means of Holding Joint Infringers Liable*, 103 NW. U. L. REV. 1897, 1924–26 (2009).

283. See *supra* text accompanying notes 259–77.

284. Jaasma, *supra* note 282, at 453. Under this approach, whether a defendant is liable as a direct infringer in a divided infringement case depends upon the following two factors: “Does the defendant’s alleged ‘control or direction’ relate to the specific technology accused of infringement? If so, did the defendant require the third party to perform the relevant limitations of the claim in the manner provided for in those limitations?” *Id.*

285. Dokhanchy, *supra* note 282, at 159–60 (arguing that cooperation, rather than agency, should be sufficient to find joint infringement); Ahn, *supra* note 282, at 172–74 (arguing that courts should borrow from the copyright test for vicarious liability and determine whether the defendant: (1) taught or instructed the other party or parties, and (2) derived a commercial benefit).

286. Truong, *supra* note 282, at 1924–25. Liability under this proposal would require: (1) an association of multiple parties; (2) the intent to circumvent the method claim; (3) an agreement to circumvent the claim and the means of carrying it out; and (4) the actual performance by all of the parties of the claimed method. *Id.*

performance;²⁸⁷ holding intentional divided infringers liable under a “prima facie tort” theory;²⁸⁸ or utilizing a “combined nuisance” theory.²⁸⁹

All of these proposed tests vary to the extent in which the relationship between divided infringers or the intent of the various infringers to violate the patentee’s rights is relevant, and thus they vary also in the burden placed on the patentee to prove infringement.²⁹⁰ Tests that rely upon theories of civil conspiracy, willful blindness, prima facie tort, or combined nuisance, by requiring an inquiry into the intent of the party, protect patent owners from deliberate divided performance for the purpose of circumventing the method patent.²⁹¹ However, this is already achieved by the current “inducement-only” rule,²⁹² and these tests would provide inadequate protection to personalized medicine inventors by placing on them the burden of proving a specific intent to infringe on the part of diagnostic testing companies.²⁹³

Two of the proposed tests that expand the “control or direction” standard similarly miss the mark of adequate protection in the personalized medicine context.²⁹⁴ First, requiring the owner of a personalized medicine patent to show that a diagnostic testing company required a physician to perform the administration step in the manner set

287. Gupta, *supra* note 161, at 71 (arguing for direct infringement liability where a defendant “subjectively believe[s] that there is a high probability that the collaborative action will constitute unauthorized practice of a patented process” and “take[s] deliberate actions to collaborate,” which must be shown by evidence that the defendant: (1) “agreed to a collaboration,” and (2) “knew the collaboration would result in unauthorized practice of the patented process”). This willful blindness test is adapted from that used by the Supreme Court to determine inducement liability. *Id.* at 70; see *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2070-71 (2011).

288. Larsen, *supra* note 282, at 63-64. Under the “prima facie tort” theory, an intentional infliction of harm may be actionable, even though the actions taken are in themselves lawful. *Id.* In the patent context, a similar theory could justify liability for parties who intentionally divide up performance of a claimed method. See *id.* at 64.

289. *Id.* at 68-70. Similarly to combined nuisance in property—where “a single defendant’s conduct alone would not have interfered with the plaintiff’s property,” but “the combined effect of multiple defendants’ actions harmed the plaintiff and gave rise to joint liability against each defendant who possessed knowledge of the other defendant’s conduct”—divided infringers “who knowingly participate in a scheme to appropriate the commercial benefit of a patented process” could be liable for infringement. *Id.*

290. See Gupta, *supra* note 161, at 71 (requiring both an agreement between parties as well as knowledge of infringement); Dokhanchy, *supra* note 282, at 159-60 (requiring that some connection, as opposed to an agency relationship, is sufficient for divided infringement liability); Truong, *supra* note 282, at 1924-25 (requiring an agreement between parties in addition to intent to violate patent rights).

291. See Gupta, *supra* note 161, at 71; Larsen, *supra* note 282, at 63-66, 68-70; Truong, *supra* note 282, at 1924-25.

292. See *supra* Part III.B.

293. See *supra* Part III.C.

294. See *infra* text accompanying notes 295-98.

forth in the claim²⁹⁵ is likely inadequate because there may be no contract between the two parties requiring the physician to administer any particular treatment.²⁹⁶ Second, requiring that the diagnostic testing company teach or instruct the physician on how to perform the therapy administration²⁹⁷ could allow companies to avoid liability if they provide diagnostic test results but do not instruct the physician to use the particular treatment administration step provided for in the claimed method.²⁹⁸

The previously proposed test that probably comes closest to providing sufficiently broad protection to personalized methods would find liability where there is merely “some connection” between the diagnostic company and the physician, who have both performed the claimed method in concert.²⁹⁹ This standard seems to require less of a connection than either the “control or direction” standard as currently envisioned or the other expanded versions previously proposed.³⁰⁰ However, to the extent the connection is sufficient to give rise to liability under this standard remains undefined, courts may differ in the types of connections deemed sufficient in the personalized medicine context, and a more specific rule for diagnostic testing and treatment methods should be provided to guide courts’ determination of infringement.³⁰¹

D. A New Divided Infringement Standard for Personalized Medicine

Courts should implement a broad infringement rule for cases involving divided performance of diagnostic testing and treatment methods that will provide personalized medicine inventors with the appropriate level of protection.³⁰² Since the current standard for divided infringement and most of the standards proposed by academics provide relatively narrow protection to personalized medicine inventors,³⁰³ they are unlikely to encourage innovation in the personalized medicine

295. See Jaasma, *supra* note 282, at 443-45, 453.

296. See Ginsburg & Willard, *supra* note 49, at 280 (discussing electronic systems that could provide a patient’s genetic information and dosing recommendations or predictions on how a patient is likely to respond to certain therapies, but does not direct the physician to choose a particular one); Mayo Press Release, *supra* note 20 (discussing that the clinical laboratory will provide a report to physicians but no requirement that physicians follow any particular course of action or instructions on any course of action to take based upon such a report).

297. See Ahn, *supra* note 282, at 167-68.

298. See *supra* note 296.

299. See Dokhanchy, *supra* note 282, at 159-63.

300. See *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380-81 (Fed. Cir. 2007); Ahn, *supra* note 282, at 172-74; Jaasma, *supra* note 282, at 453.

301. See *infra* Part IV.D.

302. See *supra* Part IV.B.

303. See *supra* Parts III.C, IV.C.

industry by any appreciable measure.³⁰⁴ As urged above, courts have the discretion to employ a different rule in the personalized medicine context, as they are given wide latitude to take into account industry-specific policy concerns when deciding cases of infringement.³⁰⁵

Liability for direct infringement of diagnostic testing and treatment administration methods should arise where a party provides the results from the diagnostic testing step of a claimed method to a physician who thereafter performs the treatment administration step based upon the results of the test.³⁰⁶ The patent owner would thus be relieved of the burden of proving that the diagnostic testing company had knowledge of the patent.³⁰⁷ Further, the patent owner would no longer need to show that the company encouraged the physician to perform the treatment administration step.³⁰⁸

The relationship between the physician and diagnostic testing company need not be examined under this standard except insofar as the court must be satisfied that the company provided test results to the physician who actually administered the requisite treatment.³⁰⁹ This standard thus provides a clearer definition of the connection between the parties that is sufficient to give rise to liability than the “some connection” standard previously proposed.³¹⁰ In this situation, the requirement of such a minimum connection between the two parties

304. See *supra* notes 195-208 and accompanying text.

305. See *supra* Part IV.B.

306. Cf. *Akamai Techs., Inc. v. Limelight Networks Inc.*, 692 F.3d 1301, 1326 (Fed. Cir. 2012) (en banc) (Newman, J., dissenting) (“The court should . . . restore infringement to its status as occurring when all of the claimed steps are performed, whether by a single entity or more than one entity, whether by direction or control, or jointly, or in collaboration or interaction.”).

307. *Akamai/McKesson Decided*, *supra* note 20 (“[M]ost physicians will not have the requisite knowledge of the patents involved to establish an intent to induce.”); see *supra* note 306 and accompanying text. Compare *Akamai*, 692 F.3d at 1301 (majority opinion) (holding that, where independent parties divide performance of a claimed method, one party must induce infringement in order for liability to arise), and *DSU Medical Corp. v. JMS Co.*, 471 F.3d 1293, 1305 (Fed. Cir. 2006) (discussing that, for inducement liability to arise, an accused party must have knowledge of the patent at issue), with *In re Seagate Tech., LLC*, 497 F.3d 1360, 1368 (Fed. Cir. 2007) (noting that direct infringement is a strict liability offense).

308. See *Akamai*, 692 F.3d at 1308 (holding that a party who has performed fewer than all of the steps of the claimed method must have encouraged performance of the remaining steps by another party in order to be liable for inducement); *Akamai/McKesson Decided*, *supra* note 20 (discussing that liability of clinical laboratories under the standard in *Akamai* is unlikely in this context, since patent owners will probably not be able to meet the burden of showing that the laboratory encouraged the physician to administer any particular treatment). But see *supra* note 306 and accompanying text.

309. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1380-81 (Fed. Cir. 2007) (holding that the relationship necessary to give rise to liability requires one party to be under the control or direction of the other party). But see *supra* note 306 and accompanying text.

310. *Dokhanchy*, *supra* note 282, at 159-63. But see *supra* note 306 and accompanying text.

relieves the patent owner of the burden of proving that the physician was under the control or direction of the diagnostic testing company.³¹¹ This would allow patentees to enforce their exclusive rights in the claimed method against diagnostic testing companies in the types of relationships that exist between companies and physicians in the personalized medicine industry.³¹²

Courts should explicitly adopt this standard in future cases involving diagnostic testing and treatment methods, recognizing the industry-specific policy concerns that inform their decisions, so as to set policy intelligibly rather than inadvertently, and provide transparency in their establishment of legal rules.³¹³ Such a broad rule would give personalized medicine inventors a greater scope of protection in an industry where there may otherwise be few incentives to innovate.³¹⁴ It is, of course, a prohibitively difficult task to determine the precise scope of the protection necessary to incentivize innovation in a given industry without hampering the innovation that would occur in the absence of patent rights.³¹⁵ However, a rule that provides personalized medicine inventors with a clearly enforceable right to exclude competitors from misappropriating their discoveries is more appropriately aligned with the needs of the industry and may do much to encourage the growth of an industry that promises to revolutionize healthcare.³¹⁶

V. CONCLUSION

This Note posits that courts should adopt a broad standard for infringement liability in cases involving divided performance of personalized medicine methods, allowing for liability where a company provides the genetic information derived from a diagnostic test to a physician who thereafter uses that information in administering treatment.³¹⁷ Strong patent rights are necessary to encourage the development of personalized medicine because of the large expenditure of capital necessary for the development of genetic inventions.³¹⁸ However, the current standard governing liability for divided

311. See *supra* notes 195-98 and accompanying text.

312. Compare *supra* Part III.C, with *supra* notes 306-11.

313. See Burk & Lemley, *supra* note 24, at 1674; Cotropia, *supra* note 25, at 130; *supra* text accompanying notes 306-12.

314. See *supra* Part II.A-B; see also text accompanying notes 306-08.

315. See Burk & Lemley, *supra* note 24, at 1596-615 (discussing the proliferation of theories of optimal patent scope).

316. See *supra* notes 110-21, 306-12 and accompanying text.

317. See discussion *supra* Part IV.D.

318. See discussion *supra* Part II.B.

infringement, requiring a “single-entity” to perform the entire invention or evidence of active inducement, prevents the owners of personalized medicine methods from enforcing their exclusive patent rights against unauthorized users.³¹⁹

The cases in which the current standard for divided infringement developed involved claims directed to Internet software and business methods.³²⁰ These industries do not suffer from such an absence of incentives to innovate as is evident in the personalized medicine industry, which requires broad protection to incentivize investment in genetic research.³²¹ Further, concerns of imparting liability upon innocent parties and subverting the statutory scheme for indirect infringement liability—that weighed in favor of a narrow infringement rule for Internet software and business methods—do not apply to the personalized medicine industry.³²² Meanwhile, the patent system gives courts discretion to consider industry-specific patent policy when deciding cases of infringement.³²³ Accordingly, courts should take into account the relevant differences in the personalized medicine industry when deciding cases involving divided performance of diagnostic testing and treatment methods, and should adopt a standard for infringement that places liability on diagnostic testing companies that participate in the performance of the method, regardless of “control or direction” or active inducement of physicians.³²⁴

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319. See discussion *supra* Part III.C.

320. See *Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1306 (Fed. Cir. 2012) (en banc); *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1375 (Fed. Cir. 2007); discussion *supra* Part III.A–B.

321. See discussion *supra* Part II.B.

322. See discussion *supra* Part IV.B.

323. See discussion *supra* Part IV.A–B.

324. See discussion *supra* Part IV.

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