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Gene Patents, Drug Prices, and Scientific Research: Unexpected Effects of Recently Proposed Patent Eligibility Legislation

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GENE PATENTS, DRUG PRICES, AND SCIENTIFIC RESEARCH: UNEXPECTED EFFECTS OF RECENTLY PROPOSED PATENT ELIGIBILITY LEGISLATION

CHARLES DUAN*

ABSTRACT

Recently, Congress has considered legislation to amend § 101, a section of the Patent Act that the Supreme Court has held to prohibit patenting of laws of nature, natural phenomena, and abstract ideas. This draft legislation would expand the realm of patent-eligible subject matter, overturning the Court's precedents along the way. The draft legislation, and movement to change this doctrine of patent law, made substantial headway with a subcommittee of the Senate holding numerous roundtables and hearings on the subject.

This article considers some less-discussed consequences of that draft legislative proposal. The legislation likely opens the door to patenting of subject matter such as human genes and scientific discoveries, given its broad language and abrogation of precedent. Allowing such patents would have consequential effects such as potentially raising drug prices, decreasing quality of health care, deterring scientific research, slowing the development of innovative technologies, and conflicting with scientific and ethical norms.

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Considerations such as these ought to be top-of-mind for legislators intending to change the law of patentable subject matter eligibility.

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I. INTRODUCTION

It was 1923, and Francesco Ruffini was going to rescue science. The Italian senator’s plan was simple: Give scientists an ownership stake in their discoveries—a sort of patent on the laws of nature they discovered. He had written a compelling and widely praised report and proposal, he had the backing of the newly formed League of Nations, and he had the support of prominent scientific and legal experts. But within a few years, Ruffini’s grand plan would fall apart. Scientists around the world rejected the plan, and lawmakers shelved it. Ruffini’s committee on the League of Nations, the Committee on Intellectual Cooperation, would come to be remembered by one member, Albert Einstein, as “the most ineffectual enterprise with which I have been associated.”¹

Now, Ruffini may have the last laugh. Despite decades—arguably centuries—of law prohibiting patents on “laws of nature, physical phenomena, and

1. Stanley W. Pycior, *Marie Skłodowska Curie and Albert Einstein: A Professional and Personal Relationship*, 44 POLISH REV. 131, 141 (1999). For references and authorities for this paragraph, see Section III.A *infra* notes 27–60.

abstract ideas,”² there has been recent interest in expanding the realm of patents in ways that may allow for patents on the scientific discoveries that Ruffini hoped to protect. In particular, in response to several recent Supreme Court decisions on patentable subject matter eligibility,³ there have been numerous calls for Congress to revise 35 U.S.C. § 101, the statutory basis for these limits on patent eligibility.⁴ Congress has listened: Across the first half of 2019, the Intellectual Property Subcommittee of the Senate Judiciary Committee first held a series of private roundtables to discuss potential legislation,⁵ then produced “draft bill text” to amend § 101,⁶ and then held three days of hearings in June with forty-five witnesses testifying on the state of patent eligibility law.⁷

By rendering an entire body of Supreme Court and other judicial precedent “hereby abrogated”⁸ among other things, the proposed legislation will undoubtedly have widespread and unexpected implications. This article identifies several, specifically directed to concerns about patents and scientific discoveries.

Section II reviews the draft legislation and considers its effects with respect to the perspectives of medicines and science.⁹ In particular, by abrogating precedent that conclusively rejected patenting of laws of nature and natural phenomena, the draft legislation reopens the door to patenting of scientific discoveries and human genes among other things. In other words, the legislation

2. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); see *O’Reilly v. Morse*, 56 U.S. 62, 119–20 (1853); Joshua D. Sarnoff, *Patent-Eligible Inventions After Bilski: History and Theory*, 63 HASTINGS L.J. 53, 63–69 (2011) (describing pre-*O’Reilly* doctrines of eligibility).

3. See *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 212 (2014); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

4. See, e.g., David O. Taylor, *Amending Patent Eligibility*, 50 U.C. DAVIS L. REV. 2149, 2152 (2017); Jeffrey A. Lefstin, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 BERKELEY TECH. L.J. 551, 592–600 (2018); AIPLA, *AIPLA LEGISLATIVE PROPOSAL AND REPORT ON PATENT ELIGIBLE SUBJECT MATTER* (2017), <https://web.archive.org/web/20180305202953/https://www.aipla.org/resources2/reports/2017AIPLADirect/Documents/AIPLA%20Report%20on%20101%20Reform-5-19-17-Errata.pdf>; Letter from Donna P. Suchy, Am. Bar Ass’n Section of Intellectual Prop. Law, to Michelle K. Lee, Under Sec’y of Commerce for Intellectual Prop. & Dir. of the U.S. Patent & Trademark Office, *Request for Comments Related to Patent Subject Matter Eligibility* (Mar. 28, 2017), <https://www.uspto.gov/sites/default/files/documents/RT2%20Comments%20ABA-IPL.pdf>.

5. See Malathi Nayak, *Tillis, Coons Vet Patent Eligibility Bill Principles with Stakeholders*, BLOOMBERG L. (Mar. 26, 2019), <https://news.bloomberglaw.com/ip-law/tillis-coons-vet-patent-eligibility-bill-principles-with-stakeholders>.

6. Press Release, *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act* (May 22, 2019) [hereinafter Draft § 101 Text], <https://www.tillis.senate.gov/2019/5/sens-tillis-and-coons-and-reps-collins-johnson-and-stivers-release-draft-bill-text-to-reform-section-101-of-the-patent-act>.

7. See *id.* (announcing hearings).

8. *Id.* (additional legislative provisions, second bullet).

9. See *infra* Section II.

would reach much the same result that Ruffini's proposal in the 1920s had hoped to accomplish.

The remainder of the article considers the effects of opening up the possibility of patenting scientific discoveries, human genes, and other analogous laws and products of nature. Section III discusses how the draft legislation could inhibit scientific research by enabling patents that essentially cover those laws of nature that are the foundation of scientific progress.¹⁰ After reviewing the historical parallels between the present legislative proposal and Senator Ruffini's proposal of the 1920s, the section will consider contemporary perspectives of scientists in the genetic research and similar fields, who generally find that patents on scientific discoveries would interfere with downstream research while failing to provide any concomitant incentive to scientific research.

Section IV discusses the likelihood that the draft legislation will raise drug prices at a time when soaring costs of health care are a top priority for American voters.¹¹ More concerning, there is historical reason to believe that expanding patent eligibility in this way may reduce access to lifesaving medical treatments, thereby resulting in American health care being lower in quality and diminished in safety compared to that of other nations.

Section V extends the previous two arguments by considering the effect of draft legislation on innovation, particularly in the health care and life science industries.¹² An important lesson from the last few decades is that the inventors of genetic testing and medical diagnostic technologies have recognized that patents on laws and products of nature frequently stymie their work. Those same inventors have further said that patents are not a necessary incentive for their work, and economic data supports their claims. Indeed, several past experiences show that expansive patents on products of nature actually *discouraged* further innovation even by the patent owner, instead leading to destructive races that soured collaboration and progress in science.

Finally, Section VI discusses ways in which the draft legislation may clash with scientific norms, medical ethics, and human rights.¹³ Patents on scientific discoveries draw scientists away from contributing to the public store of knowledge. Patents on diagnostic test results force medical professionals to choose between infringing patents and giving their patients potentially lifesaving information. And patents on human genes distort notions of bodily integrity and rights of self-determination.

10. See *infra* Section III.

11. See *infra* Section IV.

12. See *infra* Section V.

13. See *infra* Section VI.

Though the draft legislation on the table exhibits the many issues discussed above, it is not the only possible alternative. Section VII reviews a number of other pathways forward with regard to legislative or policy solutions.¹⁴ Some involve amendment to § 101, while others involve changes to other aspects of the patent laws in tandem. These alternatives, drawn from academic research and recent case law, ought to inform any process for going forward with reconsideration of patent subject matter eligibility.

II. PATENT ELIGIBILITY OF HUMAN GENES, SCIENTIFIC DISCOVERIES, AND OTHER NATURAL LAWS AND PHENOMENA

The draft legislation leaves little room for doubt as to its effect: It will allow for the patenting of human genes, diagnostic test results, and a wide range of scientific discoveries of the laws of nature.¹⁵

The legislative proposal explicitly eliminates the three historic categories of ineligible subject matter for patenting, notably including laws of nature and natural phenomena.¹⁶ It further abrogates all existing judicial precedent pertaining thereto, including *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,¹⁷ which prohibited the patenting of human or other naturally occurring gene sequences; *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,¹⁸ which prohibited the patenting of natural correlations between diagnostic tests and treatment adjustments; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,¹⁹ which prohibited the patenting of naturally occurring bacteria; and *Diamond v. Chakrabarty*,²⁰ which recognized the “relevant distinction” for patent eligibility purposes “between products of nature, whether living or not, and human-made inventions.”²¹

14. See *infra* Section VII.

15. The Senate proponents and the supporters of the legislative text repeatedly disputed this claim during the hearings, arguing that the “proposal would not change the law to allow a company to patent a gene as it exists in the human body.” Kelly Servick, *Controversial U.S. Bill Would Lift Supreme Court Ban on Patenting Human Genes*, SCIENCE (June 4, 2019), <https://www.sciencemag.org/news/2019/06/controversial-us-bill-would-lift-supreme-court-ban-patenting-human-genes> (quoting Sen. Coons). Yet, as discussed below, the controversy over patenting of genes has consistently been whether *isolation* outside the body is sufficient to confer patent eligibility, see *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 580 (2013); the careful wording “as it exists in the human body” cleverly sidesteps the question of whether the draft legislation undoes the prohibition on patenting isolated genes.

16. See Draft § 101 Text, *supra* note 6 (additional legislative provisions, second bullet).

17. *Ass'n for Molecular Pathology*, 569 U.S. at 580.

18. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012).

19. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

20. *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980).

21. *Id.*

Furthermore, the draft legislation enshrines into law the primary argument that the Supreme Court considered and rejected in *Myriad* when considering the patent eligibility of human gene sequences. *Myriad Genetics*, the patent owner, contended that the BRCA1 and BRCA2 genes at issue in the case were not products of nature because they had been isolated from the rest of the genome, and thus were the product of human intervention rather than nature; the Supreme Court rejected this argument.²² By contrast, the draft legislation provides that patent eligibility inheres in any “invention or discovery” that arises “through human intervention.”²³ The draft legislation thus, by its plain language, undoes the exact argument that the Supreme Court relied on to reject the patenting of human genes.

The draft legislation further eliminates barriers to patenting scientific discoveries of principles of nature. Besides explicitly abrogating the “laws of nature” exception to patent eligibility, the draft provides that patent eligibility is to be determined “without discounting or disregarding any claim limitation.”²⁴ Any competent patent attorney can include a conventional step of receiving information or a test sample prior to reciting a natural law to which the information or test sample is to be applied.²⁵ That would apparently render the natural law patent-eligible, despite the fact that there would be no practical change to who would infringe the patent.

Accordingly, the draft legislation evinces no limits that would prevent the patenting of human genes or scientific discoveries. If this legislation were enacted, it must be assumed that such patents would issue in due course.

III. EFFECTS FOR SCIENTIFIC RESEARCH

It has long been recognized that patents on the laws and products of nature can stifle important scientific research. As the Supreme Court explained in *Funk Bros.*, natural laws and phenomena, “like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge” and as such are “free to all men [and women] and reserved exclusively to none.”²⁶ By abrogating this decision among others, the draft legislation is thus to the detriment of the storehouse of knowledge and to the detriment of the progress of science that the storehouse of knowledge may beget.

22. *Ass'n for Molecular Pathology*, 569 U.S. at 593.

23. Draft § 101 Text, *supra* note 6, § 100(k).

24. *Id.* § 101(b).

25. *Cf. Parker v. Flook*, 437 U.S. 584, 590 (1978) (“A competent draftsman could attach some form of post-solution activity to almost any mathematical formula . . .”).

26. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

History and experience prove what theory suggests: Patents on human genes—products of nature—have forestalled research into genetics, and patents on diagnostics—laws of nature—have forestalled research in other fields. Insofar as basic research has been foundational to innumerable advances in science and technology, the possibility that the patent system could interfere with that foundation should be of great concern.

A. Early-1900s “Scientific Property” Proposals

The draft legislation on § 101 is remarkably similar to a proposal for a right of “scientific property” discussed in the early twentieth century. Review of the history of that proposal and its ultimate failure provides helpful context for understanding the present-day proposal.

The scientific property proposal was a product of the League of Nations’ Committee on Intellectual Cooperation, the predecessor to today’s U.N. Educational, Scientific and Cultural Organization, commonly known as UNESCO.²⁷ The committee—a star-studded affair with members including Albert Einstein, Marie Curie, H.A. Lorentz, and Robert Millikan—had a mission of improving the state of science in the wake of the European economic devastation of the First World War.²⁸ The committee would contemplate a variety of international topics during its tenure, such as creation of an international university, academic exchange programs, and even the adoption of Esperanto as a universal language.²⁹

Francesco Ruffini, an Italian senator who was a member of the committee, had another idea for how to increase scientific research.³⁰ His *Report on Scientific Property* of 1923 contended that a scientist who made a breakthrough

27. See *Inventory of the Archives of the International Institute of Intellectual Co-operation (IICI) 1925–1946*, 8–9, UNESCO Doc. UIS.90/WS/1 (June 1990), <https://unesdoc.unesco.org/ark:/48223/pf0000086288> (“*La première Conférence générale de l’Unesco en novembre-décembre 1946, tenue à Paris, approuva un accord avec l’IICI, dont l’objet étoit d’assurer, sous la responsabilité de l’Unesco, la continuité de l’oeuvre menée depuis 1925 par l’institut. . . . L’Unesco hérite des biens de l’Institut comprenant ses archives et publications, qui furent transférées au siège de l’Unesco, Avenue Kléber à Paris.*” [“The first General Conference of Unesco in November–December 1946, held in Paris, approved an agreement with the IICI, the object of which was to ensure, under the responsibility of Unesco, the continuity of the work carried out since 1925 by the institute. . . . Unesco inherits the property of the Institute including its archives and publications, which were transferred to Unesco headquarters, Avenue Kléber in Paris.”]). The IICI, or International Institute of Intellectual Cooperation, was a successor to the Committee on Intellectual Cooperation. See *id.* at 7–8. See generally Jan Stöckmann, *90 Years of Intellectual Cooperation: The Forgotten History of UNESCO’s Predecessor*, J. HIST. IDEAS BLOG (Oct. 12, 2016), <https://jhiblog.org/2016/10/12/90-years-of-intellectual-cooperation-the-forgotten-history-of-unescos-predecessor/>.

28. See Robert A. Millikan, *The Interchange of Men of Science*, 91 PROC. AM. PHIL. SOC’Y 129, 129 (1947).

29. See *id.* at 129–32.

30. See *id.* at 130.

discovery should own the discovery, receiving “scientific property” in the same way that artists hold copyrights in their art and inventors get patents on their inventions.³¹ He recognized that this would be an extraordinary reform to intellectual property laws worldwide, which at the time uniformly rejected rights in scientific discoveries.³² Nevertheless, he found the inability of scientists to obtain exclusivities in their discoveries to be an “injustice” that his proposal would “eliminate.”³³

The Committee on Intellectual Cooperation approved Ruffini’s report and proposal, and the full League of Nations Assembly distributed the report to member countries for comment.³⁴ Soon thereafter it received substantial praise in the United States. Professor John Henry Wigmore of Northwestern University coauthored an article with Ruffini, praising Ruffini’s report as “an admirably comprehensive and practical survey of the problem.”³⁵ The article notes a \$1000 prize (more than \$14,500 today) for an essay on a “speedy solution to the problem,” offered by the Charles J. Linthicum Foundation of Northwestern University.³⁶ The prize went to C.J. Hamson, whose 1930 book *Patent Rights for Scientific Discoveries* argued that property rights in scientific discoveries would “remedy the injustice under which scientists labor,” “secure to science the independence which it may properly claim,” and “attract to the study of pure science a type of person whose ability is undoubted but who is at present deterred by the position of scientists.”³⁷

Patent lawyers, too, were intrigued by the concept of scientific property.³⁸ The American Patent Law Association formed a Committee of Scientific Property, choosing prominent Chicago lawyer Edward S. Rogers as the committee

31. Comm. on Intellectual Cooperation, League of Nations, *Report on Scientific Property*, § 2, at 2, League of Nations Doc. A.38.1923.XII A (Sept. 1, 1923) (prepared by F. Ruffini), <https://www.scribd.com/document/400469172/Ruffini-Report>; see *id.* § 14, art. 1, at 24 (providing “for the protection of the rights of authors to their scientific discoveries”).

32. See *id.* § 3, at 4–5 (noting “duality of systems” for intellectual property, namely patents and copyrights, which leave unprotected a “neutral zone . . . in which scientific work, properly so called, is developed”).

33. *Id.* § 2, at 4.

34. See David Philip Miller, *Intellectual Property and Narratives of Discovery/Invention: The League of Nations’ Draft Convention on “Scientific Property” and its Fate*, 46 HIST. SCI. 299, 306 (2008); Thomas R. Ilosvay, *Scientific Property*, 2 AM. J. COMP. L. 178, 183 (1953).

35. John H. Wigmore & Francesco Ruffini, *Scientific Property*, 22 ILL. L. REV. 355, 359 (1927). Wigmore was a participant at the Committee on Intellectual Cooperation; a memorandum by Wigmore was attached as an annex to Ruffini’s report. See *id.* at 358; League of Nations Doc. A.38.1923.XII A, *supra* note 31, at 26–28.

36. Wigmore & Ruffini, *supra* note 35, at 378.

37. C.J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES 16 (1930).

38. See generally Miller, *supra* note 34, at 314–19; Ilosvay, *supra* note 34, at 190–92.

head in 1924.³⁹ Rogers was optimistic about the idea, writing that an intellectual property right to “protect discoveries in science is, after all, no more than the extension into a broader and somewhat more abstract, but not a different field, of the principle of protection already accorded to other inventions.”⁴⁰ The American Bar Association’s Patent, Trademark, and Copyright Section in 1932 initiated an effort to investigate the subject, convinced the effort would succeed to the great benefit of scientists: “When the interest of so many is at stake, the protection of that interest is generally capable of accomplishment.”⁴¹

The present-day draft legislation from the Intellectual Property Subcommittee has much in common with Ruffini’s 1920s idea. Like the modern draft legislation that responds to Supreme Court precedent limiting patent eligibility,⁴² Ruffini and Wigmore viewed the scientific property proposal as a legislative response to judicial decisions such as *Morton v. New York Eye Infirmary* that prohibited patenting the discovery of ether’s anesthetic properties.⁴³ Both limit any exclusive right to practical applications of scientific discoveries rather than exclusivity in the discovery itself.⁴⁴ And two of the key organizations who have promoted § 101 reform today, the American Intellectual Property Law Association⁴⁵ and the Patent Section of the American Bar Association,⁴⁶ are remarkably the same two patent organizations that supported Ruffini’s proposal above, with subsequent name changes to replace “Patent” with “Intellectual Property.”⁴⁷

Those similarities suggest that there may be important lessons for the present legislative proposal to be learned from Ruffini’s 1923 effort—particularly lessons about how that earlier effort failed. Despite initial optimism about Ruffini’s idea, discontent quickly arose.⁴⁸ Rogers, who praised the idea in 1925,

39. See Miller, *supra* note 34, at 315.

40. Edward S. Rogers, *The Proposal for Scientific Copyright, with the Literary Parallel*, 7 J. COMP. LEGIS. & INT’L L. 69, 85 (1925).

41. Richard Spencer, *Scientific Property*, 18 A.B.A. J. 79, 82 (1932); see also Miller, *supra* note 34, at 316.

42. See Draft § 101 Text, *supra* note 6 (additional legislative provisions, second bullet).

43. See *Morton v. N.Y. Eye Infirmary*, 17 F.Cas. 879, 882 (C.C.S.D.N.Y. 1802) (No. 9,865); Wigmore & Ruffini, *supra* note 35, at 356.

44. Compare Draft § 101 Text, *supra* note 6, § 100(k) (requiring “human intervention” for patentability), with League of Nations Doc. A.38.1923.XII A, *supra* note 31, § 14, art. 5 (limiting scientific property right to “economic advantages” of “industrial or commercial exploitation of new applications of [scientists’] discoveries and inventions”).

45. See AM. INTELLECTUAL PROP. LAW ASS’N, *supra* note 4.

46. Suchy, *supra* note 4.

47. See Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1033 n.4 (2005).

48. See Miller, *supra* note 34, at 317 (noting how “legal efforts to protect scientific property ran out of steam in the U.S. in the 1930s”).

ended up advising against it in 1931, saying in a letter to the Department of Commerce that the plan “sounds awfully good” but ultimately “the whole scheme seems impractical.”⁴⁹ The Patent Section of the American Bar Association would also shelve its plan, after receiving a strongly negative report from the American Association for the Advancement of Science.⁵⁰ The member nation replies to the League of Nations were mixed but included disapprovals from the United Kingdom, the United States, France, Germany, India, Czechoslovakia, Yugoslavia, South Africa, and Thailand.⁵¹

The problem with the scientific property proposal of the 1920s was implementation: Deep thinkers on the subject, even those in favor of scientific property in principle, found themselves unable to develop the details of such a right. Rogers, for example, wondered how scientific property would deal with multiple contributors to one discovery: “Who, for example, ‘discovered’ electricity? Was it Franklin, Ampere, Ohm or the chap that made the Leyden jar?”⁵² Industries worried about unexpected liability, leading the Committee on Intellectual Cooperation to add into its proposal an “insurance scheme designed to safeguard industry interests.”⁵³ A former chief clerk of the U.S. Patent Office questioned whether scientific property patents could be written without being too vague and speculative.⁵⁴

Scientists themselves, however, mounted the strongest opposition to the proposed scientific property right. The American Association for the Advancement of Science report worried that “the legal and practical difficulties involved in enforcing any scientific property would eventually arouse an unfavorable public opinion against scientists, owing to the difficulty of enforcing scientific property and the inherent nature of its broad monopoly”; it further predicted that a scientific property right “would only lead to greater confusion and uncertainty and multiply the complexity of an already complex structure” of patent law.⁵⁵ The report went on to quote other scientific organizations:

49. See *Opposes Royalties on Scientific Ideas*, N.Y. TIMES, Feb. 11, 1931, at 15.

50. See Joseph Rossman et al., *The Protection by Patents of Scientific Discoveries: Report of the Committee on Patents, Copyrights and Trade Marks*, 79 SCIENCE supp., 40 (Jan. 1934); Miller, *supra* note 34, at 316.

51. See Ilosvay, *supra* note 34, at 184.

52. *Opposes Royalties on Scientific Ideas*, *supra* note 49.

53. Miller, *supra* note 34, at 313; see Ilosvay, *supra* note 34, at 184.

54. See W[illia]m I. Wyman, *Patents for Scientific Discoveries*, 11 J. PAT. OFF. SOC'Y 533, 552–53 (1929) (“A patentable invention . . . must define the inventible contribution so that the limits of protection accorded may be legally determined. The scope of a publication of a scientific discovery on the contrary and of necessity, cannot be determinable . . .”). Wyman served as chief clerk until 1923, whereupon he returned to being a patent examiner for buildings, bridges, and roads. See Change in Office of Chief Clerk, 307 Off. Gaz. Pat. Off. 233 (Feb. 13, 1923); BUREAU OF THE CENSUS, DEP'T OF COMMERCE, OFFICIAL REGISTER OF THE UNITED STATES 98 (1929).

55. Rossman et al., *supra* note 50, at 40.

- NATIONAL RESEARCH COUNCIL: It is “the almost unanimous opinion of its members that the protection by law of a scientist’s property rights to his discoveries is not feasible, and it is of doubtful desirability.”⁵⁶
- AMERICAN ENGINEERING COUNCIL, in a survey of other organizations and societies: “The majority of those who have taken action are adverse to any plan for protecting discoveries in pure science, on the ground that it is not only impractical but unnecessary Seven societies take the view that ‘to extend into pure science research the privilege of patenting a mere scientific fact would enable the Patent Office and the courts to go far beyond the points safe for engineering and industry.’”⁵⁷

The AAAS report concluded that “no effort should at present be made to develop a plan for protecting scientific property. There appears to be no need for such legal protection from the view-point of incentive to the scientist or public policy.”⁵⁸

These concerns remain relevant today: Inventions continue to involve multiple contributors,⁵⁹ and patents frequently impose on modern industry vague and uncertain language, unexpected liability, and costly litigation.⁶⁰ Any modifications to § 101 that could enable patents that approach coverage of scientific discoveries ought to be considered cautiously in view of this history.

B. Deterrence of Downstream Research

Consistent with this historical experience, recent experience shows that patents on natural phenomena, in particular patents on human genes, have deterred important research.

The patents at issue in *Myriad* characterize the research-inhibitory character of patents on genes. Prior to its patents being deemed ineligible in 2013,⁶¹ Myriad reportedly used its patents on the BRCA1 and BRCA2 gene markers of breast cancer risk, not just to shut down competitor genetic testing services, but

56. *Id.* at 38.

57. *Id.*

58. *Id.* at 40.

59. See, e.g., Stefan Wagner, *Are “Patent Thickets” Smothering Innovation?*, YALE INSIGHTS (Apr. 22, 2015), <https://insights.som.yale.edu/insights/are-patent-thickets-smothering-innovation>; Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, 1 INNOVATION POL’Y & ECON. 119, 121–22 (2001).

60. See James Bessen, Jennifer Ford & Michael J. Meurer, *The Private and Social Costs of Patent Trolls*, REGULATION, Winter 2011–2012, at 26, 28, <http://object.cato.org/sites/cato.org/files/serials/files/regulation/2012/5/v34n4-1.pdf> (discussing lawsuits over patents with “fuzzy boundaries,” which cause “the loss of billions of dollars of wealth”).

61. See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 585 (2013).

also to stop research. Yale genetic researcher Allen Bale said that he was forced to stop a large-scale study on breast cancer because Myriad refused to allow him to sequence the BRCA1 gene.⁶² Though empirical evidence on Myriad's impact on research is sparse, scientists have noted several dramatic cases in which researchers reported stopping work because of Myriad's patents and further observed that Myriad's ambiguous stance on patent enforcement against researchers "equates to a chilling effect in zones of uncertainty."⁶³

Problems for researchers were not limited to Myriad's patents. A 2003 survey of 122 directors of genetic testing laboratories found that 53% of them had "decided not to develop or perform a test/service for clinical or research purposes because of a patent."⁶⁴ Another study of 119 laboratories found that 30% were not testing for a genetic indicator of hemochromatosis at least partly because of a patent on the relevant gene.⁶⁵ An economic study found that one firm's intellectual property on certain genes "appears to have generated economically and statistically significant reductions in subsequent scientific research and product development, on the order of 20–30 percent."⁶⁶ Thus, "what the empirical evidence demonstrates is a real fear on behalf of clinical laboratory directors and researchers based on the belief that patent holders can and will prevent them from conducting their research."⁶⁷

As a result of these negative effects of gene patents on scientific research, scientists have vocally opposed such patents. Dr. Francis Collins, director of the National Institutes of Health and former director of the National Human Genome Research Institute, wrote in 2010 that human genetics "is so fundamental, and requires so much further research to understand its utility, that patenting it at the earliest stage is like putting up a whole lot of unnecessary toll

62. See Kimberly Blanton, *Corporate Takeover: Exploiting the US Patent System, a Single Company Has Gained Control over Genetic Research and Testing for Breast Cancer. And Scientists, Doctors, and Patients Have to Play by Its Rules*, BOSTON GLOBE MAG., Feb. 24, 2002, https://web.archive.org/web/20021014222141/http://www.boston.com:80/globe/magazine/2002/0224_patent_part1.htm.

63. Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, 12 GENETICS MED. S15, S28 (2010).

64. Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 5 (2003).

65. See Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Haemochromatosis*, 415 NATURE 577, 577 (2002).

66. Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 4 (2013).

67. E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS MED. S39, S66 (2010) (citing Cho et al., *supra* note 64; Merz et al., *supra* note 65).

booths on the road to discovery.”⁶⁸ Sir John Sulston, a Nobel laureate biologist, said that patents on human genes are “going to get in the way of treatment” and “going to get in the way of research,” and thus admonished that “scientists and lawmakers must resist attempts by corporations and individuals to patent human genes.”⁶⁹ A 2001 survey of 1,229 geneticists found that “a clear majority (75%) disapprove of patenting DNA altogether”; indeed, “61% of industry scientists disapprove.”⁷⁰

One might think that the exception to patent infringement for experimental use would alleviate these concerns about patents inhibiting scientific research, but that exception is too constricted to solve these problems. As the Federal Circuit held in *Madey v. Duke University*, that exception is “very narrow and strictly limited” to use of a patent “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.”⁷¹ Insofar as *Madey* considered “educating and enlightening students,” “increas[ing] the status of the institution and lur[ing] lucrative research grants” to be “business objectives” beyond the pale of the experimental use exception, it seems impossible for even the most academic of researchers to avail themselves of this exception.⁷²

As an attempt to allow corporations and individuals to patent human genes, the draft legislation is directly contrary to the expressed views of these and other research scientists. If nothing else, that suggests an urgent need for policymakers to solicit the views of the research science community on this legislative proposal, akin to how the American Bar Association solicited the input of the American Association for the Advancement of Science in the 1930s.⁷³ Indeed, a representative of the ABA Patent Section in 1932 regretted failing to consult the scientific community first, saying that “the cart was put before the horse” when the Patent Section surveyed lawyers before scientists.⁷⁴ It would seem to behoove the Senate Intellectual Property Subcommittee to make that same outreach to scientists today.

68. FRANCIS COLLINS, *THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALISED MEDICINE* 113 (2010).

69. Alok Jha, *Human Genome Project Leader Warns Against Attempts to Patent Genes*, THE GUARDIAN (June 24, 2010), <https://www.theguardian.com/science/2010/jun/24/human-genome-project-patent-genes>.

70. Isaac Rabino, *How Human Geneticists in US View Commercialization of the Human Genome Project*, 29 NATURE GENETICS 15, 15 (2001).

71. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

72. *Id.*; see Cristina Weschler, *The Informal Experimental Use Exception: University Research After Madey v. Duke University*, 79 N.Y.U. L. REV. 1536, 1543–44 (2004).

73. See Spencer, *supra* note 41, at 82; Rossman et al., *supra* note 50, at 29.

74. Spencer, *supra* note 41, at 80.

C. Do Patents Motivate Research Scientists?

Perhaps the inhibitory effect of patents on other scientists' research might be tolerable if the holders of those patents were encouraged by virtue of their patent rights to engage in more research themselves. Yet there is little reason to believe that this is the case: Research scientists appear not to be strongly motivated by patent rights.

A 2010 report from the Department of Health and Human Services (HHS) on gene patents concluded that, as a general matter, scientists are motivated by incentives other than patents, including "the desire to advance understanding, help their patients by developing treatments for disease, advance their careers, and enhance their reputations."⁷⁵ Interviews with Alzheimer's researchers found that they "expressed ambivalence about patenting" and were primarily "driven by wanting priority of scientific discovery, prestige, scientific credit, and the ability to secure funding for additional research based on scientific achievement."⁷⁶ A study commissioned by the National Research Council found that only 7% of academic researchers found patents to be of moderate importance to the work they pursued; far more important were scientific importance (97%), personal interest (95%), feasibility of the study (88%), and access to funding (80%).⁷⁷ "If patents added 'the fuel of interest to the fire of genius,' in Abraham Lincoln's famous phrase, it was here at best a tiny pile of kindling at the outer margin of a large conflagration."⁷⁸

Nor do patents on natural laws or products appear to be necessary to stimulate investment in research. While the HHS report found that patents do encourage private investment in genetics, public funding of research plays an

75. SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, & SOC'Y, DEP'T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 20 (Apr. 2010) [hereinafter SACGHS REPORT], https://osp.od.nih.gov/wp-content/uploads/2013/11/SACGHS_patents_report_2010.pdf (citing John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101 (2001)).

76. Katie Skeeahan, Christopher Heaney & Robert Cook-Deegan, *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Alzheimer's Disease*, 12 GENETICS MED. S71, S77 (2010).

77. See JOHN P. WALSH, CHARLENE CHO & WESLEY M. COHEN, PATENTS, MATERIAL TRANSFERS AND ACCESS TO RESEARCH INPUTS IN BIOMEDICAL RESEARCH: FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES' COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS 13 (Sept. 20, 2005), <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.531.1401&rep=rep1&type=pdf>; COMM. ON INTELLECTUAL PROP. RIGHTS IN GENOMIC & PROTEIN RESEARCH & INNOVATION, NAT'L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 122 (Stephen A. Merrill & Anne-Marie Mazza eds., 2006), <https://www.nap.edu/read/11487/chapter/1>.

78. Skeeahan et al., *supra* note 76, at S77.

especially outsized role in stimulating basic research.⁷⁹ Thus, to the extent that subject matter such as genes are ineligible for patenting, public funding is a tested and effective supplement.

It is sometimes suggested that the possibility of patents on discoveries spurs “races” that speed up those discoveries, but history repeatedly shows those races to be detrimental to scientists’ collaborations and to the research itself.⁸⁰ Perhaps most instructive is the “patent race” between the Human Genome Project and Celera in 1990s.⁸¹ HGP had pledged to make the results of its sequencing the human genome “freely available and in the public domain for both research and development, in order to maximize its benefit to society”; Celera, by contrast, attracted \$400 million in investment on the promise that it would patent its discovered genes. Those favoring broad patentability might have predicted that Celera would have the incentives to win this race, but in fact the opposite was true: Celera failed to keep up and in fact ended up *copying the public project’s results wholesale* to keep up appearances that it was moving forward. As Dr. Francis Collins, leader of the public project, wrote:

Today, virtually all observers agree that the complete and immediate public availability of the human genome sequence was a critical component of its success. . . . Had the cries for privatization of this effort won out in 1999, this would now be a very different world.

The evidence that patents on scientific discoveries will encourage research is mixed at best and condemnatory at worst. Lawmakers must carefully consider the above evidence before upending longstanding expectations of the scientific community.

IV. EFFECTS FOR DRUG PRICES AND HEALTH CARE

Patents on genes and scientific discoveries, as enabled by the draft legislation, will increase costs and decrease quality and availability of American health care. This result should be especially concerning to Congress and policymakers, coming at a time when 30% of American patients report not taking

79. See SACGHS REPORT, *supra* note 75, at 25–26.

80. See Kurt Kleiner & Phyllida Brown, *Patent Row Splits Breast Cancer Researchers*, NEW SCIENTIST (Sept. 24, 1994), <https://www.newscientist.com/article/mg14319440-300-patent-row-splits-breast-cancer-researchers/> (research laboratory “decided to stop working with the researchers at the University of Utah because of disagreement over the ethics of patenting DNA”; laboratory director “fears that the split will weaken future research”).

81. This is based on COLLINS, *supra* note 68, at 301–05.

a medicine as prescribed due to cost,⁸² and when American voters consistently rate drug pricing as their number one priority for Congress.⁸³

Indeed, even scholars skeptical of the recent Supreme Court decisions on § 101 reject the approach the draft legislation takes. Professor Dreyfuss and colleagues explain that a “dramatic expansion of patentable subject matter” will raise questions as to “the patient access problems that animated the *Myriad* case in the first place.”⁸⁴ After observing that the effect of *Myriad* was that “patient access to BRCA diagnostics improved rapidly,” they write: “Surely, the goal cannot be to roll back the potential for these developments.”⁸⁵ Yet that is surely what the present draft text does.

A. A Tool for Drug Patent Evergreening

Expanding patent eligibility will enable pharmaceutical companies to extend the duration of patent protection and delay entry of cost-cutting generics and biosimilars. This is because the newly eligible subject matter will be a prime target for the practice of “evergreening,” in which a drug company obtains a patent on a minor modification to a known drug compound, often years after the initial patent application on the drug was filed.⁸⁶

The most common strategy for evergreening is for a pharmaceutical company to obtain patents on methods of using a drug, such as forms of delivery or dosage amounts.⁸⁷ Currently, under *Mayo*, at least one form of evergreening is impermissible: patenting a correlation between a diagnostic test and adjustment of administration of a drug.⁸⁸ The draft legislation, by abrogating *Mayo*, would enable that type of patent as an evergreening strategy. Indeed, drug companies

82. Ashley Kirzinger et al., *KFF Health Tracking Poll—February 2019: Prescription Drugs*, HENRY J. KAISER FAM. FOUND. (Mar. 1, 2019), <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>.

83. See POLITICO & HARVARD T.H. CHAN SCH. OF PUB. HEALTH, AMERICANS’ PRIORITIES FOR THE NEW CONGRESS IN 2019, at 2 (Dec. 2018), <https://cdn1.sph.harvard.edu/wp-content/uploads/sites/94/2018/12/Politico-Harvard-Poll-Dec-2018-Priorities-for-New-Congress-in-2019.pdf>; Rachel Rouben, *Politico–Harvard Poll: New Congress Should Fight Hate Crimes, Tackle Drug Prices*, POLITICO (Jan. 3, 2019), <https://www.politico.com/story/2019/01/03/politico-harvard-poll-hate-crimes-drug-prices-1077879>.

84. Rochelle C. Dreyfuss et al., *Patenting Nature—A Comparative Perspective*, 5 J.L. & BIOSCIENCES 550, 580 (2018).

85. *Id.*

86. See generally Gregory H. Jones, Michael A. Carrier, Richard T. Silver & Hagop Kantarjian, *Strategies That Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, 127 BLOOD 1398, 1399–400 (2016) (describing “evergreening” or “product hopping” as “a brand-name company switching the market for a drug, prior to its patent expiration date, to a reformulated version that has a later-expiring patent, but which offers little or no therapeutic advantages”).

87. See *id.* at 1399 (“The newer version, for example, could have a slightly different tablet or capsule dose or a slow-release formulation (given once a day rather than twice daily).”).

88. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 87 (2012).

have already repeatedly tried to obtain eligibility-questionable patents in an effort to broaden and preserve their patent monopolies over drugs and medical treatments.⁸⁹

When generic entry is delayed through strategies such as this, American consumers pay the price. Commentators report that “the average markup for patented drugs is nearly 400%,” and “introducing generic competition can cause prices to fall to as little as 6% of the patent-protected price.”⁹⁰ A month’s supply of the cholesterol-lowering drug atorvastatin (Lipitor) cost about \$165 while under patent and \$15 after the patent expired.⁹¹ All these cost savings stand to be lost if inventors can extend their patents by delaying filing. Extending the patent on Lipitor, for example, would have cost Americans about \$41 million *per day*.⁹²

The draft legislation also appears to abrogate, perhaps unintentionally, the doctrine of obviousness-type double patenting, a “judicially-created doctrine” which derives from § 101.⁹³ That doctrine is recognized as exceptionally important to prevention of evergreening.⁹⁴

Evergreening is valuable for drug companies—and costly to American patients and consumers. The draft legislation, by enabling a wholly new class of

89. See, e.g., *Vanda Pharm. Inc. v. W.-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1120–21 (Fed. Cir. 2018) (disputing under § 101 a method-of-use patent that would extend patent protection by 11 years), *petition for cert. filed sub nom. Hikma Pharm. USA Inc. v. Vanda Pharm. Inc.*, No. 18-817 (U.S. petition filed Dec. 27, 2018); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349, 351 (D. Mass. 2015) (rejecting under *Mayo* a patent directed to a “correlation between a naturally-occurring mutation in a cancer cell, and the likelihood that a particular type of known pharmaceutical compound will be effective in treating that type of cancer”).

90. Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 284–85 (2016) (citing FDA and other studies); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. MGMT. STRATEGY 75, 83–84 & fig. 2 (1997) (finding that generic drug prices drop to below 50% of the patent-based price within 3 years of patent expiration).

91. See W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 NOTRE DAME L. REV. 1611, 1622 & n.67 (2017) [hereinafter Price 2017].

92. That number is computed as follows: The U.S. Census Bureau estimates the population of Americans aged 40 and over at 147 million in 2012. The CDC reports that 27.9% of that population used a cholesterol-lowering medication, and 20.2% of them used atorvastatin. See QIUPING GU ET AL., NAT’L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, NCHS DATA BRIEF NO. 177, PRESCRIPTION CHOLESTEROL-LOWERING MEDICATION USE IN ADULTS AGED 40 AND OVER: UNITED STATES, 2003–2012, at 1–2 (Dec. 2014), <https://www.cdc.gov/nchs/data/data-briefs/db177.pdf>. Thus, 8.29 million Americans used atorvastatin in 2012. The difference between the on-patent and off-patent daily cost is \$5 (\$150 per month divided by 30 days), leading to a nationwide cost of \$41.45 million per day.

93. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001); *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 619 F.3d 1329, 1341 (Fed. Cir. 2010).

94. See Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition*, 14 NW. J. TECH. & INTELL. PROP. 317, 320 (2017).

evergreening, would be a win for the pharmaceutical industry and a loss to everyone else.

B. Development of Diagnostic Tests and Treatments

Patents on genes and natural principles will not simply raise prices for health care; they will delay or perhaps even prevent the development of critical treatments. As discussed above,⁹⁵ science researchers report that patents on genes or discoveries of natural laws can stall their research. When they are unable to conduct research, they cannot produce improved diagnostic tests or even new medicines and treatments.

The possibility that important and threatening disorders will go unresearched and thus untreated is no mere hypothesis; it is proven by history. Prior to the Supreme Court's 2013 *Myriad* decision, patents on genes were routinely issued.⁹⁶ During that period, multiple studies found examples of important research being stalled. The Department of Health and Human Services reported that owners of gene patents used those patents to stop research on breast cancer, hearing loss, Alzheimer's disease, long QT syndrome, Canavan disease, and leukemia among others.⁹⁷ Indeed, gene patents demonstrably failed to speed up innovation. After researching numerous instances of gene patents, researchers found that "in no case that was studied was a holder of exclusive intellectual property rights to a gene the first to develop a test. Rather, intellectual property rights are typically invoked only after numerous laboratories have already developed testing and then are used to clear the market of competition."⁹⁸

Furthermore, gene patents during that period prevented patients from obtaining critical genetic tests at all. As Dr. Roger Klein observed in 2007, "Holders or licensees of patents on genes, genetic variants and their biological correlations are already using the threat of litigation to prevent pathologists and other laboratory professionals from performing clinical, diagnostic molecular genetic tests."⁹⁹ A 10-year-old girl named Abigail was reportedly unable to obtain a test for long QT syndrome due to assertion of a patent on the gene; she died as a result.¹⁰⁰

95. See Section III.B *supra* notes 61–74 and accompanying text.

96. See Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J. L. SCI. & TECH. 157, 176–79 (2010).

97. SACGHS REPORT, *supra* note 75, at 40–42.

98. James P. Evans, *Putting Patients Before Patents*, 12 GENETICS MED. S3, S3 (2010), <https://www.nature.com/articles/gim2010139.pdf>.

99. Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE BIOTECH. 989, 989 (2007).

100. See *Stifling or Stimulating—The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 40 (Oct. 30, 2007), <https://www.govinfo.gov/content/pkg/CHRG->

The pharmaceutical industry has tried to pin the blame for lack of access to medical treatments on health insurance policy, in an attempt to avoid responsibility due to patents.¹⁰¹ Yet the 2010 HHS report considered this argument and flatly rejected it, noting that a patent holder had full discretion to refuse to perform testing under health insurance plans; “It is the decision of a [patent] rights-holding sole provider . . . that has caused access problems for some patients,” not problems with insurance policy.¹⁰²

C. Ability to Obtain Second Opinions

Expansion of patentable subject matter will further injure American health care by preventing patients from obtaining second opinions. It is a time-honored practice that a patient, before undergoing major medical treatment in view of a single practitioner’s diagnosis, seek a second opinion. A second opinion “remains the best method of ensuring the highest diagnostic accuracy for cancer patients and patients with other serious conditions who go to an institution for definitive treatment.”¹⁰³

Yet where the owner of a patent on a human gene refuses to license the patent to other testing services in order to clear the market of competitors—a common practice when gene patents were considered valid¹⁰⁴—no alternative exists, meaning no second opinion is possible. As a result, medical professionals warned that patents on genes were “eliminating patient opportunities . . . to confirm the accuracy of test results.”¹⁰⁵

To the extent that American patients are unable to obtain second opinions because of diagnostic or gene patents, the quality of health care suffers. More troublingly, there will be at least some patients who opt for surgery or serious medical treatment, who would not have done so had they obtained a conflicting second opinion.¹⁰⁶ The granting of patents on genes or diagnostics that blockade

110hrg38639/pdf/CHRG-110hrg38639.pdf (statement of Dr. Marc Grodman, CEO of Bio-Reference Laboratories, Inc.). Apparently the test was unavailable at the relevant time because the patent owner, University of Utah, licensed the relevant patents to only one testing firm at a time; the licensee in 2002 went bankrupt, leaving no available testing service until 2004. *See id.* at 48–50 (statement of Dr. Wendy Chung); Misha Angrist et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Long QT Syndrome*, 12 GENETICS MED. S111, S120 (2010), <https://www.nature.com/articles/gim2010145>.

101. *See* SACGHS REPORT, *supra* note 75, at 45.

102. *Id.*

103. Timothy Craig Allen, *Second Opinions: Pathologists’ Preventive Medicine*, 3 ARCH. PATH. & LAB’Y MED. 310, 310 (2013).

104. *See* SACGHS REPORT, *supra* note 75, at 33.

105. Klein, *supra* note 99, at 990; Cook-Deegan et al., *supra* note 63, at S30 (“Myriad’s patent position has made it in effect a sole provider of clinical *BRCA* testing in the United States . . .”).

106. *See* Suzanne Zuppello, *I Had a Mastectomy to Lessen My Risk of Breast Cancer. Does New Science Say That Was a Mistake?*, THE OUTLINE (Sept. 18, 2018), <https://theoutline.com/post/>

second opinions will thus impose wasteful costs on the health care system—not to mention traumatic costs to patients who receive unnecessary mastectomies or other treatments.

D. Safety and Efficacy of Medical Tests

To make matters worse, there is historical reason to believe that even the limited services made available by holders of gene or diagnostic patents will be subpar in both quality and safety, producing wrong or even dangerous results.

While regulatory systems such as Food and Drug Administration approval ensure a baseline level of efficacy and safety of medical treatments, it has always been the case that the strongest driver of quality is market competition. Competition forces firms to out-innovate each other and to produce better products at lower costs compared to their rivals.¹⁰⁷ Absent competition—such as when a firm faces no rivals because it possesses a patent—that firm has diminished incentives both to ensure that its product is of high quality and to improve upon its product offerings. This is no less true in the medical diagnostics industry.

Experience with Myriad's patents on breast cancer testing show these concerns to be real. Researchers have observed that Myriad's testing protocol failed to identify numerous mutations of the relevant genes, and because Myriad was the exclusive provider of such testing in view of its patents, no better testing protocol was publicly available in the United States.¹⁰⁸ A comparative study of breast cancer screening between the United States and France determined that, because Myriad limited the American market to a single testing technique while French hospitals used several, patients in France enjoyed substantially lower costs for services of equal quality.¹⁰⁹ And Myriad's use of its patents against science researchers meant that "technology assessment research by third

6257/i-had-a-mastectomy-to-lesser-my-risk-of-breast-cancer-does-new-science-say-that-was-a-mistake.

107. See Philippe Aghion et al., *The Effects of Entry on Incumbent Innovation and Productivity*, 91 REV. ECON. & STAT. 20, 21–22, 27 (2009); Charles Duan, *Of Monopolies and Monocultures: The Intersection of Patents and National Security*, 36 SANTA CLARA HIGH TECH. L.J. 369, 399–400 (2020).

108. See Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS'N 1379, 1380 (2006); Cook-Deegan et al., *supra* note 63, at S30; Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. MED. GENETICS 388, 388 (2001).

109. See Christine Sevilla et al., *Impact of Gene Patents on the Cost-Effective Delivery of Care: The Case of BRCA1 Genetic Testing*, 19 INT'L J. TECH. ASSESSMENT HEALTH CARE 287, 295–96 (2003).

parties, for example to evaluate test performance metrics such as sensitivity, specificity, or positive predictive value, is particularly jeopardized.”¹¹⁰

Certainly it is the nature of patents generally that they will diminish competitive pressure toward quality and safety; this observation should not be taken to mean that medical technology ought categorically to be unpatentable. But the effects of patent exclusivity on genetic and diagnostic tests are especially severe—errors lead to improvident surgery or undiagnosed deadly disorders—and as discussed elsewhere in this article, patents for gene and diagnostic discoveries appear to be a weak incentive for discovery or innovation in those industries.¹¹¹ Furthermore, unlike patents on human-created technologies, patents on genes or diagnostic correlations cannot be designed around: One cannot change one’s own genetic code to avoid patent infringement.¹¹² Those consequences are good reason for the patent system specifically to exclude human genes and laws of nature from eligibility for patenting.

V. EFFECTS FOR INNOVATION

Against these concerns about impediments to medical treatment and scientific research weighs the possibility that expanded patent protection for laws and products of nature will stimulate invention and innovation. Yet there is substantial reason to doubt this and to worry, in fact, that patents on genes and diagnostic tests will undermine innovation rather than advance it.

A. Development of Genetic Testing Services

The particular nature of genetic testing means that gene patents are especially detrimental to innovation. Because the cost of sequencing is relatively cheap, genetic testing services often sequence complete genomes.¹¹³ Furthermore, genetic diagnostic services generally focus not on identification of a single gene, but on packages of genes of interest.¹¹⁴

As a result, where patents are issued on individual genes, innovators will need to obtain licenses to many or all of them. A whole-genome sequencing

110. Vural Ozdemir et al., *Shifting Emphasis from Pharmacogenomics to Theragnostics*, 24 NATURE BIOTECHNOLOGY 942, 943 (2006).

111. See *supra* Section III.C, *infra* Section V.B.

112. See SACGHS REPORT, *supra* note 75, at 15 (“It is generally difficult if not impossible to “invent around” patent claims on genes and associations.”).

113. See Megan Molteni, *Now You Can Sequence Your Whole Genome for Just \$200*, WIRED (Nov. 19, 2018), <https://www.wired.com/story/whole-genome-sequencing-cost-200-dollars/>.

114. See *The State of Patent Eligibility in America: Part III: Hearing Before the Subcomm. on Intellectual Property of the S. Judiciary Comm.*, 116th Cong. 3 (2019) (testimony of Sean George, Invitae Corp.), <https://www.judiciary.senate.gov/imo/media/doc/George%20Testimony.pdf> (describing panel testing for multiple genes as “now the standard of care”).

service would theoretically need to obtain a license for “all or many of the thousands of human genome sequences subject to patent protection,” for example.¹¹⁵ This leads to a problem that scholars have called the “tragedy of the anticommons”: When the field of genetics is finely subdivided among thousands of patent owners, it creates “a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research,” thereby “adding to the cost and slowing the pace of downstream biomedical innovation.”¹¹⁶ “Navigating the complex intellectual property landscape of DNA patents,” write two scientists, “could slow some promising clinical technologies.”¹¹⁷

In considering his experience as a laboratory researcher, NIH Director Dr. Francis Collins found gene patents to be an impediment rather than an incentive for innovation in genetics. After noting the ordinary merit of patents for encouraging commercialization of inventions, he wrote:

I think this argument falls flat when it comes to diagnostic applications. . . . [T]he supposed need to provide an incentive for companies to develop DNA diagnostics is unconvincing. In that situation, many of us would argue that it would be better for the public to have competition in the marketplace, in order to provide an incentive for higher quality and lower price.¹¹⁸

That perspective, characteristic of many prominent figures in the scientific community, should give lawmakers pause given the draft legislation’s contrary view.

B. Can Patent Ineligibility Encourage Innovation?

By contrast, the lack of patent eligibility for human genes and diagnostic tests since 2012 does not appear to have diminished innovation in these spaces.

115. See, e.g., Dan Vorhaus & John Conley, *Whole-Genome Sequencing and Gene Patents Coexist (For Now)*, GENOMICS L. REP. (RENAMED PRIVACY REP.) (Aug. 11, 2009), <https://theprivacyreport.com/2009/08/11/whole-genome-sequencing-and-gene-patents-coexist-for-now/>. Some scholars have disputed this, claiming that there are whole-genome sequencing technologies that avoid infringing gene patents. See, e.g., W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won’t Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601, 1606 (2012) [hereinafter Price 2012]; Dreyfuss et al., *supra* note 84, at 551 & n.5. These arguments underestimate the capability of skilled patent practitioners, and they further assume the continued viability of *Mayo*, which the draft legislation would abrogate. See Price 2012, *supra*, at 1618.

116. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998).

117. Subhashini Chandrasekharan & Robert Cook-Deegan, *Gene Patents and Personalized Medicine—What Lies Ahead?*, 1 GENOME MED. 92, 93 (2009).

118. COLLINS, *supra* note 68, at 112.

Research by Professors Arti Rai and Colleen Chien found “[n]o clear evidence” of any decline in innovation in diagnostic methods following the *Mayo* decision restricting patents in that space, and indeed find increases in biomarker transactions and FDA diagnostics approvals since the decision.¹¹⁹ As they explain, “We looked for clear evidence of a sustained decline in diagnostic patent applications and transactions post-*Mayo*. We didn’t find it.”¹²⁰ As Professor Shubha Ghosh said, “When Myriad was decided in 2013, everybody sounded the death knell of biotechnology. . . . It certainly isn’t that.”¹²¹

In a study of barriers to the development of personalized medicine (PM) technology, researchers reviewed 32 articles on intellectual property and 20 on incentives for PM development.¹²² After noting commentary both supporting and opposing expanded patent rights for personalized medicine, the researchers concluded:

What is clear from the literature is a lack of consensus on whether (i) patents act as necessary incentives to PM investment, innovation, and development such that they should be strengthened, or (ii) patents stifle innovation and investment, particularly in the device space, such that novel incentives are needed and patent rights should be curtailed.¹²³

Similarly, economists find no increase in innovation resulting from patents on genes. In a study of gene patents in the early 2000s, two economists find that those genes for which a patent is applied tend to be economically more valuable

119. Arti K. Rai with Colleen Chien, Presentation at the Duke Center for Applied Genomics and Precision Medicine: Intellectual Property in Precision Medicine 24–26 (Feb. 15, 2018), <https://precisionmedicine.duke.edu/about/calendar/genomic-and-precision-medicine-forum-arti-rai-jd>.

120. Colleen V. Chien & Arti K. Rai, Presentation at the USPTO Roundtable on Section 101: Dx Innovation in Decline? An Empirical Analysis Post-*Mayo* 19 (Dec. 5, 2016), <https://www.uspto.gov/sites/default/files/documents/RT2%206-2%20Colleen%20Chien.pdf> (emphasis removed).

121. Turna Ray, *Supreme Court Patent Cases Haven’t Hindered Diagnostics Innovation, Preliminary Data Suggest*, GENOMEWEB (Dec. 5, 2016), <https://www.genomeweb.com/molecular-diagnostics/supreme-court-patent-cases-havent-hindered-diagnostics-innovation-preliminary>. By contrast, Professor Taylor’s recent survey purports to find evidence of startup investors’ choices of investments being affected by the Supreme Court’s decisions. See David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019, 2027–28 (2020). There are several reasons to question the usefulness of this study, though. The response rate to his survey was less than 4%; given that his survey invitation specifically asked about views on the Supreme Court decisions, a reasonable inference is that 96% of investors do not care about them. See *id.* at 2051 & n.120. Taylor further concedes that those who responded to his survey were uncharacteristic of the overall population, further limiting the reliability of his results. See *id.* at 2051–52.

122. See Lori Knowles et al., *Paving the Road to Personalized Medicine: Recommendations on Regulatory, Intellectual Property and Reimbursement Challenges*, 4 J.L. & BIOSCIENCES 453, 492–93 (2017).

123. *Id.* at 493.

(unsurprisingly, since one would not spend the money applying for a patent on something without value), but find no evidence that the presence of a patent stimulated greater research and development compared to the denial of one.¹²⁴

The views of genetic testing services themselves are significant in this respect. In an *amicus curiae* brief filed with the Supreme Court, two genetic testing laboratories explained that they were perfectly happy to have their discoveries of particular genes be published in academic literature and entered into the public domain. Noting that they were able to obtain patents on “applications of laws of nature such as new drugs, reagents, or equipment,”¹²⁵ the laboratories asserted that publication, not patenting, of discoveries of genes would “allow for inventions to be created and for doctors to treat patients more effectively.”¹²⁶ The laboratories accordingly would continue to research and even publish new genes even without the possibility of patent protection.¹²⁷

The views of those labs echo the Supreme Court’s words in *Chakrabarty* when it considered the patentability of naturally occurring bacteria:

The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.¹²⁸

In the end, the evidence from the research and development community suggests that patents for human genes and other natural phenomena are likely

124. See Bhaven Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome*, 109 AM. ECON. REV. 203, 231–32 (2019). The authors take this conclusion also to mean that patents do not deter follow-on research by others, but this conclusion is questionable for several reasons. For one thing, the authors hypothesize that the USPTO’s requirement of especially detailed disclosure of gene sequences is the actual driver of follow-on research. *See id.* at 231. Other fields of research do not trigger the same stringent disclosure requirements, so the same level of follow-on research should not be expected elsewhere. *See id.* Furthermore, the thrust of the paper is to reject the hypothesis that the grant of a patent will deter innovation while the denial of a patent application will not, but that ignores the fact that the filing of the application itself may be sufficient to deter follow-on innovation in the first place.

125. Brief for ARUP Laboratories, Inc. and Laboratory Corporation of America Holdings (d/b/a LabCorp) as *Amici Curiae* in Support of Petitioners at 19, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (Sept. 9, 2011) (No. 10-1150), https://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/10-1150_petitioneramcuarupandlabcorp.pdf.

126. *Id.* at 17.

127. *See id.* at 16–17.

128. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

not a significant factor in stimulating innovation. Given the potentially immense harms to the public and to scientific research that those patents could cause, the balance of public policy ought to tilt heavily against upsetting the historic limitations on patent ineligibility of natural laws and phenomena.

VI. EFFECTS FOR SCIENTIFIC NORMS, MEDICAL ETHICS, AND HUMAN RIGHTS

Scholars and commentators have recognized that patents on laws and products of nature are in tension with important normative and societal values.

Scientific norms. Under the generally accepted Mertonian view of scientific ethics, “The substantive findings of science are a product of social collaboration and assigned to the community,” so the responsibility of the scientist is to share discoveries with the world such that all may benefit from those discoveries and conduct further research based on them.¹²⁹ The National Research Council has said that “scientific progress requires that research results be open for all to use, attempt to replicate, and evaluate.”¹³⁰ The Royal Society similarly has said: “Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward”; thus, “pure knowledge about the physical world should not be patentable under any circumstances.”¹³¹

Patents on scientific discoveries obviously are irreconcilable with these principles of openness and collaboration in science.

Medical ethics. Like scientists, doctors have ethical responsibilities to “continue to study, apply, and advance scientific knowledge” and to “make relevant information available to patients, colleagues, and the public.”¹³² The American Medical Association specifically warns against patents on natural products, noting in its ethics opinions that “patents on processes, e.g. to isolate and purify gene sequences, are ethically preferable to patents on the substances themselves,” and that any medical patents “should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form

129. Robert K. Merton, *A Note on Science and Democracy*, 1 J. LEGAL & POL. SOC. 115, 121 (1942).

130. NAT’L RESEARCH COUNCIL, *A PATENT SYSTEM FOR THE 21ST CENTURY* 26 (Stephen A. Merrill et al. eds., 2004), <https://www.nap.edu/catalog/10976/a-patent-system-for-the-21st-century> (citing ROBERT K. MERTON, *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* (1973)).

131. THE ROYAL SOC’Y, *KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL PROPERTY POLICY ON THE CONDUCT OF SCIENCE* para. 3.5, at 8 (Apr. 2003).

132. AMA, *AMA PRINCIPLES OF MEDICAL ETHICS* sec. VII (2001), <https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-of-medical-ethics.pdf>.

of the substance in question.”¹³³ Patents on products of nature and scientific discoveries are contrary to these principles.

Patents on diagnostic tests further conflict with doctors’ obligations toward their patients because they potentially force doctors to withhold medical information from those patients. Consider an example proffered by the Cato Institute, in which a discovery is made that the presence of gum disease correlates with a risk of heart attack.¹³⁴ That discovery is patented. A dentist, in the course of a routine cleaning, observes that indicative gum disease. Is the dentist to inform the patient and infringe the patent, or to honor the patent and thus let potentially lifesaving information go unmentioned?¹³⁵

Human rights. Gene patents have been considered to infringe rights of human integrity and self-determination.¹³⁶ Multiple international bodies have recognized a human right to one’s genetic resources and further observed that the patenting of another person’s genes, particularly without consent, can be concerning from a human rights perspective. The United Nations Educational, Scientific and Cultural Organization’s *Universal Declaration on the Human Genome and Human Rights*, adopted by the General Assembly of the United Nations, provides: “Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.”¹³⁷ Over 80 religious groups have opposed gene patents for similar reasons.¹³⁸

133. COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AMA, AMA CODE OF MEDICAL ETHICS § 7.2.3(c) (2016), <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview>, <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview>.

134. See Brief of *Amici Curiae* Cato Institute et al. in Support of Petitioners at 26, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (Sept. 9, 2011) (No. 10-1150), https://www.americanbar.org/content/dam/aba/publishing/previewbriefs/Other_Brief_Updates/10-1150_petition-eramucucatoinst-reasonfound-andcei.pdf (citing Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759, 760).

135. See *id.* at 27 (noting that the consequence of such a patent is to render mere thought to be infringement). It is unclear whether the exception to patent infringement for medical *treatments* would apply to medical *diagnoses*. See 35 U.S.C. § 287(c)(2)(A) (“the term ‘medical activity’ means the performance of a medical or surgical procedure on a body”). Even if it does, there are plenty of equally concerning situations imaginable. Is it inducement of patent infringement, for example, for a medical instructor to teach the correlation between gum disease and risk of heart attack?

136. See Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL’Y L. & ETHICS 403, 409–11 (2005).

137. *Universal Declaration on the Human Genome and Human Rights*, Gen. Conf. Res. 16, UNESCO, 29th Sess., at art. 12(a), Doc. 29 C/Resolutions, <https://unesdoc.unesco.org/ark:/48223/pf0000110220>, adopted by G.A. Res. 53/152, U.N. GAOR 3d Comm., 53d Sess., Agenda Item 110(b), U.N. Doc. A/RES/53/152, https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/53/152.

138. See Fred B. Charatan, *US Religious Groups Oppose Gene Patents*, 310 BRIT. MED. J. 1351, 1351 (1995), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2549785/pdf/bmj00594-0013.pdf>.

VII. ALTERNATIVES TO THE DRAFT LEGISLATION

To the extent that any revision of § 101 is to be considered, it must be in tandem with substantial other revisions to related sections of the patent laws, as multiple scholars recognize.

For example, Professor Dreyfuss and colleagues—no friends of the current § 101 case law—agree that any alterations of that law must be joined with changes to other patent laws to facilitate research and to lower drug prices. The authors note that the 2010 HHS report called for “creation of exemptions from patent infringement for use of genetic tests for patient care purposes and for use of patent-protected DNA sequences for research purposes,” and in particular expansion of the currently inoperative defense of experimental use.¹³⁹ They also contend that any changes to patent subject matter eligibility should be tied to concomitant limitations on patents, including compulsory licensing, or federal government provision of services competitive with the patent owner’s, or even government cost controls.¹⁴⁰

Similarly, Professor Karshtedt proposes revising subject matter eligibility under § 101 in tandem with the utility and 35 U.S.C. § 112 written description requirements, and specifically calls for a unified “completeness doctrine” either “barring all patent claims directed to objects of basic research” or creating a *sui generis* “partial or intermediate patent right for inventions that . . . fail completeness,” likely “a limited patent that comes only with the remedy of a compulsory license.”¹⁴¹ These proposals of Professors Dreyfuss, Karshtedt and others are further consistent with the League of Nations’ consensus view in the 1920s on creating a right of scientific property, which would only have entailed a right to royalties and no right to exclude.¹⁴²

Comprehensive changes to the disclosure requirements under § 112(a) would also likely be necessary as well. Multiple independent scholars have noted that patents systematically fail to disclose sufficient information on the workings of patented inventions, meaning that the public grants a valuable exclusivity while not receiving adequate knowledge in return.¹⁴³ Indeed, the inadequacy of patent disclosure, in combination with the draft legislation, means

139. Dreyfuss et al., *supra* note 84, at 580 (citing SACGHS REPORT, *supra* note 75, at 89, 94–95).

140. *See id.* at 585–88.

141. *See* Dmitry Karshtedt, *The Completeness Requirement in Patent Law*, 56 B.C. L. REV. 949, 951, 958–59 (2015).

142. *See* League of Nations Doc. A.38.1923.XII A, *supra* note 31, § 14, art. 5, at 25.

143. *See* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 551 (2009); Price 2017, *supra* note 91, at 1612–13.

that a clever patent lawyer *could patent a law of nature before it is proven by science*, with obvious repercussions for downstream research.¹⁴⁴

Good disclosure is important for ensuring that patents promote innovation. In one study purporting to show that gene patents did not deter innovation,¹⁴⁵ the authors note that “the USPTO’s specific (and more stringent) requirements for the disclosure of sequenced genetic data may have made the disclosure function particularly effective.” Thus, to the extent that patentability is extended to natural laws and products beyond genes, the required disclosures in patents should be increased. In the software space, for example, many have called for complete disclosure of source code to satisfy the § 112(a) requirement.¹⁴⁶

It is noted that the draft legislation makes a revision to § 112(f),¹⁴⁷ but that revision is neither necessary nor sufficient. By affecting only the interpretation of means-plus-function claims that are primarily noteworthy in software,¹⁴⁸ the amendment to § 112(f) has minimal effect on gene patents or patents on scientific discoveries. It also makes no improvement to the state of patent disclosure as discussed above, which is governed by § 112(a), not § 112(f).

Changes to claiming practice are warranted, but the correct section to amend would be not § 112(f), but § 112(b) and in particular the doctrine of enablement of “the full scope of the claimed invention”¹⁴⁹ and the propriety of single-species disclosures for patent claims covering a broader genus of which the disclosed species is just one example.¹⁵⁰ There is also an ongoing need to strengthen the indefiniteness doctrine under § 112(b) and the obviousness doctrine under 35 U.S.C. § 103, both of which have arguably been construed too

144. See Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 666–67 (2019).

145. See Sampat & Williams, *supra* note 124. But see discussion *supra* note 124 (noting substantial limitations of their study).

146. See, e.g., Kenneth Canfield, *The Disclosure of Source Code in Software Patents: Should Software Patents Be Open Source?*, 7 COLUM. SCI. & TECH. L. REV. 1,1 (2006).

147. See Draft § 101 Text, *supra* note 6, § 112(f).

148. See *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (en banc in this section) (noting the “proliferation of functional claiming” under § 112(f), then numbered ¶. 6); *id.* at 1350–51 (discussing use of words such as “module” in means-plus-function software claims).

149. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); see Bernard Chao, *Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule*, 2009 STAN. TECH. L. REV. 3 (arguing that “the full scope rule is extremely difficult to apply and will cause unnecessary litigation”).

150. See *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (written description sufficient for a genus claim “requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can ‘visualize or recognize’ the members of the genus”); with *id.* at 1366 (Newman, J., dissenting) (“Under this new doctrine, patent applicants will face a difficult burden in discerning proper claiming procedure under this court’s unpredictable written description of the invention requirement.”).

narrowly,¹⁵¹ and to clarify the obviousness-type double-patenting doctrine, on which the Federal Circuit is currently irreconcilably divided.¹⁵²

VIII. CONCLUSION

Legislative revision of § 101 has received a great deal of attention, and the unexpected consequences of that legislation merit attention as well.¹⁵³ This article has reviewed many such effects of the recently proposed § 101 legislation, including its consequences for altering patentability of human genes and laws of nature, effects on drug prices and health care, effects on scientific research, effects on technological progress, and interplay with scientific and social norms and values. It additionally reviews alternative approaches to the proposed legislation that may alleviate problematic effects.

Since the rounds of hearings in June of 2019, progress on legislation appears to have stalled.¹⁵⁴ Nevertheless, interest in the legislation continues, as one of the Senate proponents and several former U.S. Patent and Trademark Officers have expressed.¹⁵⁵ It is likely that Congress will return to legislation on patentable subject matter eligibility in the coming months or years, and should it do so, it is hoped that this article will provide useful guideposts for these efforts, taking into account key issues such as drug prices, health care, and scientific research.

The key lesson to be drawn from this article and from history is that caution is warranted when considering the creation of exclusive rights to the products of scientific discovery. In his 1931 letter advising the Department of Commerce against intellectual property rights in scientific discoveries, Edward Rogers

151. See Brief of Public Knowledge and the Electronic Frontier Foundation as *Amici Curiae* in Support of Petitioner, *Nautilus, Inc. v. Biosig Instruments, Inc.*, No. 15-561 (U.S. Nov. 16, 2015), <https://www.publicknowledge.org/documents/pk-eff-nautilus-ii-cert>; Brief of *Amici Curiae* Public Knowledge and the Electronic Frontier Foundation in Support of Petitioner, *K/S HIMPP v. Hear-Wear Techs., LLC*, 135 S. Ct. 1439 (Jan. 22, 2015) (No. 14-744) (cert. denied), <https://www.publicknowledge.org/documents/pk-and-eff-brief-himpp-v-hear-wear>.

152. See Brief of the R Street Institute and Public Knowledge as *Amici Curiae* in Support of the Petition at 5–8, *Mylan Pharm. v. UCB, Inc.*, No. 18-692 (U.S. Dec. 21, 2018), https://www.supremecourt.gov/DocketPDF/18/18-692/77397/20181221151024017_brief-mylan-ucb-petition.pdf.

153. See KEVIN J. HICKEY, PATENT-ELIGIBLE SUBJECT MATTER REFORM IN THE 116TH CONGRESS 30-33 (Cong. Research Serv., Report No. R45918, 2019).

154. See Kirk M. Hartung, *Supreme Court Passes on 101 Patent Eligibility*, LEXOLOGY (Jan. 14, 2020), <https://www.lexology.com/library/detail.aspx?g=e23916ed-c871-4dde-a89c-21a58bfddd63>.

155. See *AIPLA Q&A with Senator Thom Tillis*, AIPLA (July 1, 2020), <https://www.aipla.org/detail/news/2020/07/01/aipla-q-a-with-senator-thom-tillis>; Andrei Iancu, Dir. of the U.S. Patent & Trademark Office, Remarks at the U.S. Chamber of Commerce Event “How Innovation and Creativity Drive American Competitiveness” (Jan. 19, 2021), <https://www.uspto.gov/about-us/news-updates/remarks-director-iancu-us-chamber-commerce-event-how-innovation-and>.

worried about the experts and academics who wanted to push forward with scientific property without minding the details, the experts like Ruffini who might say, "Adopt the principle and the difficulties will take care of themselves."¹⁵⁶ Rogers countered that the patent and copyright laws themselves took hundreds of years to develop, and anticipated that to get scientific property right, "it is going to take a hundred years or more to do it."¹⁵⁷ It is now just two years shy of the hundredth anniversary of Ruffini's League of Nations proposal, and not much progress appears to have been made since then on the topic of patents and scientific discoveries.

156. *Opposes Royalties on Scientific Ideas*, *supra* note 49.

157. *Id.*