

# RECENT DEVELOPMENTS IN PATENTING MEDICAL BIOTECHNOLOGY: *MYRIAD GENETICS* AND THE AFFORDABLE CARE ACT AS STEPS TOWARDS GREATER PATIENT ACCESS

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## I. INTRODUCTION

On June 13, 2013, the U.S. Supreme Court reversed years of precedent by the U.S. Patent and Trademark Office (USPTO) and found that DNA, as a naturally occurring phenomenon, could not be patented.<sup>1</sup> For pioneers in the booming medical biotechnology<sup>2</sup> field, this spelled a loss of many highly

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1. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2117–19 (2013).

2. Generally, the term biotechnology is defined as “any technological application that uses biological systems, living organism, or derivatives thereof, to make or modify products or processes for specific use.” U.N. Convention on Biological Diversity, *opened for signature* June 5, 1992, 1760 U.N.T.S. 3 (entered into force Dec. 29, 1993). As of January 14, 2014, the Convention had 193 parties. *List of Parties*, CONVENTION ON BIOLOGICAL DIVERSITY, <http://www.cbd.int/convention/parties/list/> (last visited Feb. 22, 2014). In the

profitable patents involved in the creation of biotechnology-derived drugs and tests.<sup>3</sup> But for others, the decision was a crucial first step in advocating for more accessible medical treatment and a more open research environment.<sup>4</sup> One year earlier, the Court upheld the Affordable Care Act,<sup>5</sup> which includes a framework for approving biosimilar applications.<sup>6</sup> Those in the medical biotechnology industry generally viewed this decision as damaging to their profitability as well,<sup>7</sup> while those hoping for increased medical access and research rejoiced. Together, these decisions, as well as recent developments in the patentability of medical biotechnology outside of the United States, have reinvigorated the debate on finding a sustainable balance between incentivizing medical innovation and ensuring greater accessibility for all patients.

This Recent Development focuses on the scope of patentability of medical biotechnology and how current patent laws affect innovation and issues of access. Part II of this Recent Development will outline the development of medical biotechnology patent regulation and current issues. Part III will explain the potential failures of the current system and compare and analyze several approaches to remedy these issues, including: reform within traditional intellectual property structures, alternative intellectual property mechanisms, and methods for approving and regulating biosimilars. The European Union and Indian patent law systems will be used comparatively throughout this Recent Development to help analyze various methods for balancing incentives to innovate for biotechnology companies with increased access for patients.

## II. BACKGROUND

The United States is home to the largest domestic medical biotechnology industry, which enjoys high private investment.<sup>8</sup> In 2002, the domestic

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advanced medical context, “biotechnology” refers to the “use of recombinant deoxyribonucleic acid (DNA) technologies supported by research on genetic information (genomics).” ALBERT SASSON, *MEDICAL BIOTECHNOLOGY: ACHIEVEMENTS, PROSPECTS AND PERCEPTIONS* 4 (2005).

3. See Karen McVeigh, *US Supreme Court Rules Human Genes Cannot Be Patented*, *GUARDIAN* (June 12, 2013), <http://www.theguardian.com/law/2013/jun/13/supreme-court-genes-patent-dna> (“By declaring isolated forms of human DNA patent ineligible, [the Supreme Court’s decision] robs genome research companies of a huge commercial incentive to continue researching into DNA.”).

4. See Maggie Fox, *A Patent on Your DNA? What the Supreme Court Ruling Means for You*, *NBC NEWS* (June 5, 2013, 5:27 PM), <http://www.nbcnews.com/health/patent-your-dna-what-supreme-court-ruling-means-you-6C10261058> (noting that DNA patentability may lead to monopolistic control over human DNA by individual companies).

5. *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2608 (2012).

6. Affordable Care Act, Pub. L. No. 111-148, § 7002, 124 Stat. 119, 804 (2010).

7. Corey Hadley, *The Affordable Care Act – Impact on the Life Sciences Industry*, *ENLIGHT RES.* (Sept. 21, 2012, 11:23 AM), <http://www.enlightresearch.com/insights/2012/9/21/the-affordable-care-act-impact-on-the-life-sciences-industry.html> (noting the various costs that companies will face to comply with the Affordable Care Act); see also John Ransom, *Another Cost of Obamacare: Biotech*, *TOWNHALL FIN.* (May 28, 2013), <http://finance.townhall.com/columnists/johnransom/2013/05/28/another-cost-of-obamacare-biotech-n1607373/page/full> (“[U]nder Obamacare, and the other regulatory burdens on banking and investment, biotech will have a much harder time.”).

8. OFFICE FOR LIFE SCIS., U.K. DEP’T FOR BUS., INNOVATION & SKILLS, *STRENGTH AND OPPORTUNITY 2012: THE LANDSCAPE OF THE MEDICAL TECHNOLOGY, MEDICAL BIOTECHNOLOGY, INDUSTRIAL BIOTECHNOLOGY AND PHARMACEUTICAL SECTORS IN THE UK* 10 (2012) [hereinafter *STRENGTH AND*

industry's annual turnover reached \$33 billion, with one-third of that attributable to the top five medical biotechnology firms.<sup>9</sup> This profitability is at least in part attributable to the ability of developers to patent their discoveries. Under the U.S. Patent Act, developers have been able to patent microorganisms, methods, and biotechnology-derived tests and drugs.<sup>10</sup> However, whether these claims are suitable subject matter for patents is debatable, and attempts have been made at limiting the patentability of medical biotechnology.

The unique nature of medical biotechnological inventions opens the applicability of each of the U.S. Patent Act requirements—novelty, utility, and patentable subject matter—up to debate. The Act also requires applicants to supply a sufficient written description of their claim.<sup>11</sup> The element of novelty, or non-obviousness, has been particularly contested in DNA sequencing cases, where some scholars and scientists feel the methods used to isolate genes are “obvious in light of the prior art” and should not be patentable.<sup>12</sup> Additionally, the utility requirement is often raised in biology and chemical patent cases, despite being considered ineffectual in other fields in recent years.<sup>13</sup> The requirement has been challenged in the biotechnology context, as the full potential use of isolated DNA sequences may not be known at the time a patent application is filed.<sup>14</sup> The written description requirement of the Patent Act has also been strictly enforced for biotechnology patents.<sup>15</sup> In 2008, the U.S. Patent Office published training materials that increased the burden on meeting the written description requirement by requiring that the applicant draw a

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OPPORTUNITY], available at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/36736/12-p90-strength-and-opportunity-2012.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/36736/12-p90-strength-and-opportunity-2012.pdf). Globally, “medical biotechnology products captured 19% of the . . . pharmaceutical market, amounting to \$142 [billion in] sales” in 2011. *Id.* at 9.

9. SASSON, *supra* note 2, at 6–7. The top five firms are Amgen, Genentech, Genzyme, Chiron, and Biogen. *Id.*

10. *E.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980) (“A live, human-made micro-organism is patentable subject matter under § 101.”). See generally Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. TECH. & INT’L. PROP. 280 (2010) (discussing the impact of the Supreme Court’s expanded acceptance of patent claims for medical processes).

11. 35 U.S.C. § 112 (2012).

12. Donna Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1627 (2001).

13. Geertrui Van Overwalle, *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches*, 1 U.C. IRVINE L. REV. 433, 464 (2011). Previously, patent applicants were required to submit human clinical data to meet the utility requirement for certain pharmaceutical applications. *Abbott Labs. v. Bayer HealthCare LLC*, Civil Nos. 09-40002-FDS, 09-40061-FDS, 2010 WL 4340565, at \*4 (D. Mass. Oct. 25, 2010), *appeal dismissed*, 458 F. App’x 895 (Fed. Cir. 2011). The Federal Circuit altered this requirement and held that laboratory results would be sufficient to establish utility in 1995. *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995).

14. Gitter, *supra* note 12, at 1625–26.

15. Van Overwalle, *supra* note 13, at 475. Applicants whose inventions “depend on the use of microorganisms or other biological material ‘must take additional steps to comply’” with the writing requirement, including “making of a deposit of the microorganism or other material in a depository that is readily accessible to the public . . .” *Amgen, Inc. v. Chugai Pharmaceutical Co.*, No. 87-2617-Y, 1989 WL 169006, at \*47 (D. Mass. Dec. 11, 1989) (citing MANUAL OF PATENT EXAMINING PROCEDURE, § 608.01(p)(C)), *aff’d in part, vacated in part*, 927 F.2d 1200 (Fed. Cir. 1991).

correlation between structure and function.<sup>16</sup>

Whether medical biotechnology applications are patentable subject matter has been extraordinarily controversial in U.S. courts. In *Diamond v. Chakrabarty*, the Supreme Court held that “anything under the sun” could be patented, except “the laws of nature, physical phenomena, and abstract ideas.”<sup>17</sup> The Court then granted a patent for a microorganism.<sup>18</sup> The Court has also granted patents for medical methods, though they are not enforceable against doctors or hospitals.<sup>19</sup> The extent to which methods can be patented, however, is hotly contested.<sup>20</sup> In March 2012, the Supreme Court struck down patent claims for a method of drug dosage administration.<sup>21</sup> Besides recognizing Congress’s ban on patents for genetically-modified humans,<sup>22</sup> the Court has otherwise refused to establish any definitive standard or test for patent eligibility across technologies.<sup>23</sup>

In June 2013, the U.S. Supreme Court decided the controversial *Myriad Genetics* case.<sup>24</sup> The case, in which Myriad defended patent claims to isolated DNA sequences used to diagnose breast and ovarian cancers, embodies many of the issues discussed. The BRAC test, which uses the contested isolated DNA, is an incredibly powerful tool for women’s health as it can predict one’s likelihood of developing breast and ovarian cancer in time for a patient to act pre-emptively.<sup>25</sup> However, the cost of the test is extremely high, making it unavailable to many patients,<sup>26</sup> and Myriad has fiercely defended its patents, limiting which doctors or researchers can administer or study the test.<sup>27</sup> The

16. U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, WRITTEN DESCRIPTION TRAINING MATERIALS 37–39 (2008), available at <http://www.uspto.gov/web/menu/written.pdf>; see also Patrick Brian Giles, *How to Claim a Gene: Application of the Patent Disclosure Requirements to Genetic Sequences*, 27 GA. ST. U. L. REV. 695, 698 (2011) (explaining the Patent Office’s change in position).

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

18. *Id.*

19. 35 U.S.C. § 287(c) (2012). See generally Jeff S. Rundle, Note, *The Physician’s Immunity Statute: A Botched Operation or a Model Procedure?*, 34 J. CORP. L. 943, 948 (2009) (analyzing the strengths and weaknesses of the physician’s immunity and proposing amendments to the statute to better address biotechnology patents).

20. See generally Kubick, *supra* note 10 (discussing the debate surrounding medical process patents).

21. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

22. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011); Van Overalle, *supra* note 13, at 449.

23. *Bilski v. Kappos*, 130 S. Ct. 3218, 3226 (2010); see Dan Hoang, Note, *Prometheus Laboratories v. Mayo Clinic’s Gift to the Biotech Industry: A Study of Patent-Eligibility of Medical Treatment and Diagnostic Methods After Bilski*, 9 NW. J. TECH. & INTELL. PROP. 457, 457 (2011) (explaining the effects of the Court’s decision in *Bilski*).

24. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107 (2013).

25. *BRACAnalysis*, MYRIAD, <https://www.myriad.com/products/bracanalysis/> (last visited Mar. 5, 2014).

26. Currently, the primary BRCA test that Myriad offers costs \$3,340 and the supplementary test is \$700. Meredith Cohn, *Gene Patents Case Could Impact Patients, Research*, BALTIMORE SUN (Sept. 22, 2012), [http://articles.baltimoresun.com/2012-09-22/health/bs-hs-brca-patents-20120922\\_1\\_myriad-genetics-patents-brca](http://articles.baltimoresun.com/2012-09-22/health/bs-hs-brca-patents-20120922_1_myriad-genetics-patents-brca). Myriad argues that ninety-five percent of the tests are paid for through insurance or its own financial assistance program. *Id.* However, the petitioners in the case, several of which are patients, allege that they are unable to receive their test results and that the lack of access violates their ability to get adequate health care. *Petition for Writ of Certiorari at 6, Myriad*, 133 S. Ct. 2107 (No. 12-398).

27. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1314–16 (Fed. Cir.), cert. granted in part, 133 S. Ct. 694 (2012), and aff’d in part, rev’d in part, sub nom. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

Supreme Court in part invalidated Myriad's patent claims and concluded that DNA is not patentable as it is naturally occurring but that cDNA remains patentable.<sup>28</sup>

Commentators suggest that the final decision in this case could have major ramifications for the medical biotechnology industry.<sup>29</sup> Some argue that without the revenue streaming from their intellectual property protection, biotechnology companies will not be able to create the medical biotechnology products that have so much positive potential for public health.<sup>30</sup> However, many of the patents involved in the BRAC tests are for cDNA and medical methods, which remain patentable. Others see the case as a landmark step towards developing a patent scheme that better protects the interests of patients and researchers.<sup>31</sup> Either way, lingering legal uncertainty may scare away investors and cool biotechnology companies' research on isolated DNA.<sup>32</sup>

### III. DISCUSSION & RECOMMENDATIONS

#### A. *Problems Within the Current System*

Medical biotechnology and patents for medical biotechnology inventions raise ethical concerns, as well as concerns about research access and final product access. The recent decisions in *Prometheus*,<sup>33</sup> *Myriad*,<sup>34</sup> and *Novartis AG v. Union of India*<sup>35</sup> have reinvigorated discussion of these problems and potential solutions. Of course, any solutions must be in balance with the

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28. *Myriad*, 133 S. Ct. at 2111.

29. See *Myriad: Keeping a Low Profile*, WORLD INTELL. PROP. REV. (Jan. 12, 2012), <http://www.worldipreview.com/article/keeping-a-low-profile> (quoting industry sources describing the case as "billed within the biotech industry as a potential landmark case" and a "watershed event").

30. See Susan Decker & John Lauerma, *Human Genes as Company Property Tested by Myriad Patent Case*, BLOOMBERG SUSTAINABILITY (July 18, 2012, 11:00 PM), <http://www.bloomberg.com/news/2012-07-19/human-genes-as-company-property-tested-by-myrriad-patent-case.html> (quoting industry actors who claim the biotechnology industry "absolutely depends on intellectual property").

31. *Id.* Researchers at the Harvard Personal Genome Project know that they may be in violation of Myriad's patent, and though they have not been enforced against yet and know they may not be, they believe it would be more reassuring and beneficial to know that the genes are not patented. *Id.* Myriad also claims that researchers have had plenty of access to the patented material; 18,000 scientists, it claims, have studied the patented materials and published over 9,000 papers since the patents were first filed in 1995. Cohn, *supra* note 26. However, Dr. James Watson, who wrote a brief in support of the petitioners, argues that, "researchers shouldn't expect a 'windfall' for revealing the sequence of DNA that encodes various genes. DNA's importance flows from its ability to encode and transmit the instruction for creating humans." *Id.*

32. Cohn, *supra* note 26.

33. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1289 (2012).

34. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107 (2013).

35. *Novartis AG v. Union of India*, AIR 2013 SC 1311 (India), available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>. On April 1, 2013, the Supreme Court of India denied Swiss drug maker Novartis's patent claim. Arvind Subramanian, *5 Take-Home Points from India's Historic Novartis Patent Case*, ASIAN SCIENTIST (Apr. 29, 2013), <http://www.asianscientist.com/features/5-take-home-points-historic-novartis-patent-case-india-2013/>. The decision elicited backlash from Western governments, including the United States, but has been supported as a binding decision by the head of the World Trade Organization (WTO). Narayan Lakshman, *U.S. Trade Office Hits Out at Novartis Ruling*, HINDU (May 2, 2013, 11:52 PM), <http://www.thehindu.com/business/Industry/us-trade-office-hits-out-at-novartis-ruling/article4677416.ece>.

continued need to incentivize companies to develop new drugs.<sup>36</sup> Patents are particularly important to the medical biotechnology field as a source of this type of incentive. Patents play a large role in helping biotechnology start-up companies compete in the market, even more so than in other technology fields.<sup>37</sup> Therefore, it is important that any solution maintain intellectual property rights as much as possible.

### 1. *Inadequate Incentives to Develop Products for Low-Income Patients*

Under the current framework, the broadest medical biotechnology patents are granted to pioneering innovations, while subsequent inventions are granted narrower protection.<sup>38</sup> This system incentivizes development of what are known as “blockbuster” drugs—those for which the company can expect a high return on investment.<sup>39</sup> Such drugs tend to be those created for Western patients with sufficient insurance and access to healthcare.<sup>40</sup>

Currently, there is very little incentive for companies to develop drugs or tests for diseases that disproportionately affect patients in developing countries or low-income patients.<sup>41</sup> Annually, “\$160 billion is spent globally on health research and development, but only 3% of that is directed at diseases that disproportionately affect developing countries.”<sup>42</sup> When such a drug is developed, because the research, development, and production is so costly, many potential beneficiaries do not have access to the drug or test due to the final product price.<sup>43</sup> For example in *Myriad*, one of the many concerns expressed was that low-income women would not have access to the life-saving test due to its cost.<sup>44</sup> Antiretroviral therapy for HIV/AIDS is another example of this dilemma from traditional pharmaceuticals. When Big Pharma was properly motivated to produce treatment for HIV/AIDS, many patients

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36. See *Biotechnology Indus. Org. v. Dist. of Columbia*, 505 F.3d 1343, 1347 (Fed. Cir. 2007) (“[I]t was precisely the balance between these two interests [innovation and public interest] that Congress intended to carefully calibrate when it passed the Hatch-Waxman Act.”); Diane V. Havlir & Scott M. Hammer, *Patent Versus Patient? Antiretroviral Therapy in India*, 353 NEW ENG. J. MED. 749, 751 (2005) (“[W]e need to provide incentives for major pharmaceutical companies . . . . Protection of intellectual-property rights and tiered pricing arrangements are key elements in maintaining this commitment.”).

37. Stuart J.H. Graham et al., *High Technology Entrepreneurs and the Patent System: Results of the 2008 Berkeley Patent Study*, 24 BERKELEY TECH. L.J. 1255, 1262 (2009). However, executives from these companies report that patent protection is less of a factor than had generally been believed. *Id.* at 1283. Biotechnology companies reported that patents generally provide moderate incentives in the innovation process, higher than software and other technology-related fields. *Id.* at 1286.

38. Van Overwalle, *supra* note 13, at 482.

39. EUROPEAN COMM’N, PHARMACEUTICAL SECTOR INQUIRY FINAL REPORT 6 (2009), available at [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

40. See Scott Kaufman, *Bayer Pharmaceutical CEO: Cancer Drug Only ‘for Western Patients Who Can Afford It.’* RAW STORY (Jan. 26, 2013, 2:13 PM), <http://www.rawstory.com/rs/2014/01/26/bayer-pharmaceutical-ceo-cancer-drug-only-for-western-patients-who-can-afford-it/> (discussing how Bayer created a drug for wealthier patients).

41. Ann Weilbaecher, *Diseases Endemic in Developing Countries: How to Incentivize Innovation*, 18 ANNALS HEALTH L. 281, 288 (2009). Often, these are referred to as “neglected diseases” or Type II and III diseases, as categorized by the World Health Organization. *Id.* at 284.

42. *Id.* at 282.

43. *Id.* at 281.

44. Petition for Writ of Certiorari, *supra* note 26, at 26.

could not afford it.<sup>45</sup> Leaders in developing countries began producing generic versions of the antiretrovirals at costs as low as four percent of the price of the Western-produced originals.<sup>46</sup> Countries like Brazil, China, and India were able to continue to produce the critical drugs to provide to their citizens and to those of other developing countries despite attempts by the United States to challenge their ability to do so as patent infringement.<sup>47</sup> As foreign courts continue to restrict patentability, Western biotechnology firms will have to find a new way of partnering and licensing with countries where it appears their drugs will be sold with or without their approval.

## 2. *Insufficient Access for Researchers*

Patents on medical biotechnology innovations also block access to the materials for researchers. To take advantage of the widest possible protection, many companies apply for patents far upstream, at the first innovative stage of development, as opposed to downstream—where the invention is in, or close to, its final form.<sup>48</sup> Doing so often blocks other researchers from studying the subject of the original patent, slowing overall progress, and concentrating drug development in the hands of a few large firms. Blocking access for research is seen as one of the largest problems of the current system and often results in two types of problems: the development of an anti-commons and the creation of patent thickets.<sup>49</sup> The idea of the anti-commons is that by patenting medical biotechnology far upstream, research is limited to the patent holder and is restrained by the patents held by others for other components of medical biotechnology.<sup>50</sup> The researcher must sort through the numerous rights holders in order to conduct research that involves multiple biotechnology innovations.<sup>51</sup> Nothing remains within the public domain, and potential research benefiting the public may be stifled. However, some studies show that “researchers are largely oblivious” to whether or not they are infringing patent rights.<sup>52</sup> If the studies are accurate, this makes the largely-held fear of the anti-commons less frightening. Nonetheless, maintaining a system of overlooking infringement on its face seems to be a temporary and unstable solution. Similarly, patent thickets occur when many cumulative patents surround a single drug or test.<sup>53</sup> This makes licensing cost-prohibitive. While

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45. See generally Havlir & Hammer, *supra* note 36 (discussing the inability of most of the world’s HIV/AIDS patients to pay for Western-produced antiretrovirals).

46. *Id.* at 750.

47. *Id.*

48. See Rebecca Goulding, Emily Marden, Rachel Manion & Ed Levy, *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 204 (2010) (“[T]he genomics research landscape is characterized by numerous patents on basic upstream research.”).

49. *Id.*

50. Tina Saladino, Note, *Seeing the Forest Through the Trees: Gene Patents & the Reality of the Commons*, 26 BERKELEY TECH. L.J. 301, 317 (2011).

51. See *id.* (“Applied to genetics, an excessive fragmentation of patent rights may prevent coherent aggregation of rights that are essential for future biomedical research.”).

52. Goulding et al., *supra* note 48, at 204; Saladino, *supra* note 50, at 321–23.

53. Goulding et al., *supra* note 48, at 204 (“A patent thicket . . . is commonly understood as ‘a dense

there are no patent thickets yet developed in the United States, they remain a concern in both Australia and Europe.<sup>54</sup>

### B. *Potential Mechanisms for Reform*

In order to continue to encourage the production of drugs and diagnostic tests, provide greater research access to medical biotechnology innovations, and address the need for medical biotechnology-derived drugs and tests for low-income patients, the United States should explore reform within traditional intellectual property rights structures, test mechanisms for alternative intellectual property rights, and develop an effective system for approving and regulating biosimilars.

As discussed, the present intellectual property system is seen as an important provider of incentives to continue researching and producing goods that benefit society's health despite disproportional distribution of benefits. Possession of patents may also aid in attracting investment.<sup>55</sup> Additionally, some believe that researchers are actually encouraged to share their research and findings under the current system because protection begins from the time the researcher files the patent application, allowing the developer to publish the research without fear of losing the monopoly over his or her creation.<sup>56</sup> Similarly, through the written description requirement, patent applications "signal to scientists which areas of technology may require more research and development," fueling research overall.<sup>57</sup> Nevertheless, these benefits do not outweigh the access problems, nor do they foreclose potential reform. Already, several attempts at reforming the patent system for medical biotechnology inventions have been suggested and tried by various interested actors.

#### 1. *Traditional Intellectual Property Approaches*

Within the U.S. intellectual property rights system, there are various reforms or re-interpretations that could better address issues of access while continuing to encourage innovation. Judicial interpretation of the Patent Act requirements could be tailored to encourage more downstream patents.<sup>58</sup> By

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web of overlapping intellectual property rights that a company must [get] through in order to actually commercialize [a] new technology." (quoting Gavin Clarkson & David DeKorte, *The Problem of Patent Thickets in Convergent Technologies*, 1093 ANNALS N.Y. ACAD. SCI. 180, 180 (2006)).

54. *Survey Patent Licensing in Medical Biotechnology in Australia and Europe: A Survey on Common and New Licensing Practices*, CENTRE FOR L. & GENETICS ONLINE SURV., <http://www.lawgenecentre.org/Survey.html> (last visited Mar. 5, 2014).

55. Saladino, *supra* note 50, at 316.

56. *Id.* at 315.

57. *Id.* at 315–16.

58. For example, it has been proposed that the patentability test for naturally-derived products (like isolated DNA) be that the product is "in a purely man-made form (and thus is 'new') and the form in which it is claimed has a practical utility disclosed in the Specification (and thus is 'useful')." Susan McBee & Bryan Jones, *The Supreme Court Should Be Mindful of Naturally Derived Products Other Than Nucleic Acids When Deciding Myriad*, SCOTUSBLOG (Feb. 7, 2013, 10:16 AM), <http://www.scotusblog.com/2013/02/the-supreme-court-should-be-mindful-of-naturally-derived-products-other-than-nucleic-acids-when-deciding-myriad/>.



heightening the utility requirement, courts could force patents downstream and alleviate anti-commons and patent thicket problems. Courts could also reinterpret the research exemptions<sup>59</sup> and physician's immunities<sup>60</sup> to give these tools some enforcement power, as in Europe.<sup>61</sup> Additionally, tightening the patentable subject matter restrictions could help avoid these problems.<sup>62</sup>

Already, the judiciary has restricted traditional intellectual property protections for biotechnology in the *Myriad* decision.<sup>63</sup> The legislature could also act to address these issues, particularly by issuing a bright line rule on such patent-eligibility issues and by introducing compulsory licensing, public domain requirements, and biosimilar approval process regulation. An advisory committee issued a report to the Department of Health and Human Services in 2010, which concluded that "patents would limit the development and availability of [diagnostic] tests, limit access to testing if a patent provider does not accept a patient's insurance, and limit multigene testing, which has the greatest potential future benefits."<sup>64</sup> In Europe, India, and many other jurisdictions, courts are able to order a patent holder to license the invention out to others upon a finding that the patent is unworkable, is preventing the public from accessing an important product, is against the public good or public health, or for any other number of reasons.<sup>65</sup> The United States is

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59. 35 U.S.C. § 271(e)(1) (2012); Van Overwalle, *supra* note 13, at 489–90. See *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (applying the § 271(e)(1) exemption only to "the use of patented drugs in activities related to the federal regulatory process"). The judicially created exemption for use of patented material for research has been strictly limited. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (suggesting that any research with ultimate commercial aims cannot take advantage of the exemption); see also Emily Marden, *Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?*, 11 MINN. J.L. SCI. & TECH. 217, 264–65 (2010) (reviewing the *Merck KGaA* and *Madey* cases and concluding that "[t]hese decisions have complicated reliance on a research exemption for researchers").

60. 35 U.S.C. § 287(c) (2012). See generally Rundle, *supra* note 19, at 961–62 (discussing the development and effects of the physician immunity statute and suggesting reforms to § 287 as it applies to biotechnology).

61. Van Overwalle, *supra* note 13, at 486. Research exemptions in Europe vary by country, but most are considerably broader than those in the United States. *Id.* The majority of the exemptions permit experiments on the patented subject matter, but not experiments with the patented subject matter. *Id.*

62. For example, the European Patent Convention, which requires the same elements (novelty, utility, and patentable subject matter) as the U.S. Act, includes an explicit list of exclusions from patentable subject matter. European Patent Convention art. 52, Aug. 2010, available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/\\$FILE/EPC\\_14th\\_edition.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf) [hereinafter EPC]; see Van Overwalle, *supra* note 13, at 452 (explaining that methods for medical treatment or diagnosis are not patentable in the signatory countries to the EPC). See generally Ralf Perrey & Konstanze Lenhard, *Recent Developments in the Patentability of Inventions Relating to Medicine, Pharmaceuticals, and Technology According to European Patent Practices*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 479, 480 (2007) (providing an overview of how the European Patent Convention approaches medical methods claims). Likewise, the Indian Patent Act includes a list of exceptions to what is patentable, including processes for "medicinal, surgical . . . or other treatment of human beings . . ." Patents (Amdt.) Act Ch. 2(3)(c) (2005). For an example of attempts to limit patentable subject matter in the United States, see Genomic Research and Accessibility Act, H.R. 977, 110th Congress (2007); Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 296 (2007) (discussing the proposed bill), and see also Kevin E. Noonan, *Congressman Becerra Once Again Tries to Ban Gene Patenting by Statute*, PATENT DOCS (Apr. 8, 2010, 11:59 PM), <http://www.patentdocs.org/2010/04/hes-baaack.html> (condemning the attempt to ban gene patents as a threat to scientific progress).

63. See generally *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2107 (2013) (restricting patent eligible subject matter in biotechnologies).

64. Cohn, *supra* note 26.

65. Van Overwalle, *supra* note 13, at 489. E.g., EPC, *supra* note 62, art. 53(a); Patents (Amdt.) Act Ch.

generally considered not to have such a mechanism, at least not explicitly.<sup>66</sup> Of course, a judge can refuse to grant an injunction to the patent owner, effectively allowing infringement to continue,<sup>67</sup> but enforcing a system of permissible infringement allows neither party to rely on the law and likely results in very different outcomes across the court system.

If the United States were to formalize a positive compulsory licensing mechanism, Congress could be given the opportunity to create guidelines under which judges would have discretion in deciding what was required by the public good or public health, and more researchers or patients would be able to petition patent holders for increased access. The Agreement on Trade Related Aspects of Intellectual Property expressly permits WTO members to issue compulsory licenses, and it was confirmed in the Doha Declaration that public health needs are a legitimate reason for issuing such licenses.<sup>68</sup> While some consider compulsory licenses to be contrary to American property rights,<sup>69</sup> such mechanisms have worked within U.S. law for sometime, albeit in limited situations. Section 1498 of the U.S. Code creates a system in which the government essentially pays a reasonable licensing fee retroactively for use of a patented product.<sup>70</sup> For example, Boeing brought a suit for patent infringement against the U.S. government for the use of patented materials by NASA and Lockheed Martin in building the Space Shuttle.<sup>71</sup> The court used a variety of factors to calculate what would have been a fair and reasonable licensing fee at the time NASA and Lockheed Martin began using the material and required the government to pay only that amount in damages.<sup>72</sup> A compulsory license mechanism can also be found in copyright law.<sup>73</sup> Though criticized, this may serve as a helpful model, as it includes a process through which various interested parties are able to negotiate fair fee agreements in

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2(3)(b) (2005). For a list of compulsory license laws for all World Intellectual Property Organization members, see Survey On Compulsory Licenses Granted By WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights, World Intellectual Property Organization, CDIP/4/4 Rev./Study/INFO/5, available at [http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_4/cdip\\_4\\_4\\_rev\\_study\\_inf\\_5.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf).

66. Van Overwalle, *supra* note 13, at 489.

67. *Id.*

68. Mingchanok Tejavanija, Note, *A New Kind of Drug War: Thailand's Taking on the Pharmaceutical Industry to Improve Access to HIV/AIDS Drugs Through the Use of Compulsory Licensing*, 28 ARIZ. J. INT'L & COMP. L. 659, 659–60 (2011).

69. For example, the U.S. Trade Representative placed Thailand on a watch list after the country implemented a compulsory license scheme for HIV/AIDS medications. *Id.* at 674. However, some members of Congress were in support of Thailand's decision. *Id.* at 675.

70. 28 U.S.C. § 1498 (2012) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”). See *Boeing Co. v. United States*, 86 Fed. Cl. 303, 310 (2009) (“[T]he waiver of sovereign immunity in section 1498(a) . . . authorizes an action analogous to one for a non-exclusive taking of a license under the Fifth Amendment.”).

71. *Boeing*, 86 Fed. Cl. at 307–10; see Daniel Cahoy, *Breaking Patents*, 32 MICH. J. INT’L L. 461, 494 (2011) (explaining the Boeing/Lockheed Martin licensing mechanism).

72. *Boeing*, 86 Fed. Cl. at 325.

73. 17 U.S.C. § 115 (2012); see Cahoy, *supra* note 71, at 498–99 (explaining mechanical licenses used for cover songs).

advance of litigation.<sup>74</sup> Therefore, while compulsory licenses may appear controversial, such mechanisms have been functioning within the United States for some time without disrupting markets and may be a critical compromise in medical biotechnology patenting.<sup>75</sup>

The legislature, or agencies, could also regulate access by requiring that certain innovations remain within the public domain. For example, the government required that investigators publish all information to a publically available database when funding the Human Genome Project.<sup>76</sup> Generally, the decision to keep an innovation within the public domain has been a voluntary undertaking—of which there have actually been several—but it could be that organizations like the National Institute of Health (NIH) require at least some level of public access when providing federal grants for research.<sup>77</sup> This may not affect the large firms, however, that rely solely on private investments.

Because these measures perhaps do not adequately address all concerns, several alternative intellectual property approaches have been suggested, including initiatives to be undertaken by the government, by technology transfer offices, and by researchers themselves. The aim of these approaches is to “embrace an alternative to conventional [intellectual property] rights to allow simultaneously (1) a model of contribution and open participation in innovation[,] and (2) an approach to drug development that does not allow for the monopoly rents imposed by patent exclusivity.”<sup>78</sup>

## 2. *Licensing: Open Source Initiatives and Patent Pools*

Open source initiatives were first used to promote “collaborative innovation” in the software industry.<sup>79</sup> This idea, coined “copyleft,” provided that the innovation could be made freely available to anyone per the license so long as it continued to be made available to others on the same terms.<sup>80</sup> Similarly, with a Creative Commons license, one could use the product and conduct further research but was bound not to apply for any patents on what he or she created and to credit the original source in any publication.<sup>81</sup> An open source movement has gained some momentum within the biotechnology field in response to concerns that traditional patents have “negative implications for

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74. See Cahoy, *supra* note 71, at 499 (“Further, the existence of a defined licensing fee has enabled private negotiation to exist concurrently. The U.S. copyright office, in consultation with interested parties, determines the fee.”).

75. See *id.* (“Since the early part of the 20th century, U.S. law has provided for a compulsory license—referred to as a ‘mechanical license’—or the subsequent recording of musical works that have been distributed to the public on phonorecords. . . . It is actually a functional system in many respects.”).

76. Goulding et al., *supra* note 48, at 213.

77. See *id.* at 216 (describing the NIH’s guidelines, which encourages funded researchers to share their ideas for greater academic freedom). Interestingly, the NIH was originally involved in Myriad’s research into the currently contested BRAC1 and BRAC2 patents. Daniel J. Kevles, *Can They Patent Your Genes*, N.Y. REV. BOOKS (Mar. 7, 2013), <http://www.nybooks.com/articles/archives/2013/mar/07/can-they-patent-your-genes/>.

78. Marden, *supra* note 59, at 220.

79. Goulding et al., *supra* note 48, at 206.

80. *Id.*

81. *Id.* at 208.

the practice of science, research, and access to ultimate end products.”<sup>82</sup> However, it is unclear that a large-scale open source initiative could provide less costly, more accessible drugs, as patent rights differ greatly from copyrights, and drugs, particularly medical biotechnology-derived drugs, are far more expensive and time-consuming to produce than software.<sup>83</sup> Even if open source initiatives are unable to efficiently develop drugs, they may be able to develop diagnostic testing, a growing portion of medical biotechnology, with the emergence and popularity of personalized medicine.<sup>84</sup> Unlike drugs, diagnostic tests are not subject to strict regulation and approval processes but are currently every bit as expensive and inaccessible as medical biotechnology-derived drugs.

Additionally, open source may be a more reasonable option for the development of drugs designed to treat neglected diseases than it is for creating blockbuster drugs, assuming approval-timing conflicts could be resolved. Firms interested in pro-bono-type work, or graduate students and young professionals seeking experience and building their reputations, could use an open source platform to develop drugs for which there is little financial incentive, and the final product, as it would be unpatentable, would be readily available to patients.<sup>85</sup> The Tropical Disease Initiative<sup>86</sup> is already testing this theory in the United States, and the Indian Open Source Drug Discovery<sup>87</sup> may, as it develops, be a model in the future for what works and what does not.

Patent pools have also been suggested as a mechanism for combating limited access to medical biotechnology innovations.<sup>88</sup> A patent pool is an “arrangement of two or more patent holders assigning or licensing their individual intellectual property rights to one another or to an administrative entity created for such a purpose.”<sup>89</sup> The patents are then made available through non-exclusive licenses at a pre-established rate to anyone who wishes.<sup>90</sup> These pools have the potential to greatly reduce the research access gap and allow those who are motivated to develop less profitable drugs using available patents, which would drastically reduce the cost of development.<sup>91</sup> However, deciding which patents should be pooled may be difficult as it is not clear which patents are complementary and which are needed for the development of certain products.<sup>92</sup> Despite these obstacles, some groups have

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82. *Id.* at 206–07.

83. Marden, *supra* note 59, at 222. Unlike software, drugs do not generally rely on a single patent, and drug development has fixed targets that must be met in a sequential manner for FDA approval. *Id.* at 250, 253. Because a drug or diagnostic test generally must be developed one step at a time, the open approach of multiple developers working on different pieces simultaneously probably would not work. *Id.* at 253.

84. *Id.* at 263.

85. Weilbaeher, *supra* note 41, at 290.

86. *Id.* at 289–90.

87. See generally Seema Singh, *India Takes an Open Source Approach to Drug Discovery*, 133 CELL 201 (2008) (outlining India’s use of an open source model to discovery and develop drugs to treat malaria, tuberculosis, and HIV).

88. Goulding et al., *supra* note 48, at 209.

89. *Id.* at 209–10.

90. *Id.* at 210.

91. Weilbaeher, *supra* note 41, at 308.

92. Goulding et al., *supra* note 48, at 211.

already begun exploring the efficacy of patent pools.<sup>93</sup> UNITAID is working to establish a patent pool for HIV/AIDS medications, as the current patent holders are not producing the new formulations required.<sup>94</sup> GlaxoSmithKline (GSK), a leading drug developer, has agreed to place 500 patents and 300 pending applications into a pool designed to develop treatments for neglected diseases.<sup>95</sup> It is significant that a major drug developer is willing to spearhead this initiative; the Organization for Economic Cooperation and Development (OECD) previously believed that biotechnology companies were too entrenched in their intellectual property rights to do so.<sup>96</sup> The World Health Association (WHA) has also included patent pools in its Global Strategy and Plan of Action.<sup>97</sup>

In the wake of the Bayh-Dole Act, universities and research institutes began to establish technology transfer offices (TTOs) to facilitate such licensing agreements.<sup>98</sup> The terms of any licensing agreements should include provisions that allow for greater access to those working on products designed for treatment of neglected diseases.

The terms of any licensing agreements should include provisions that allow for greater access for those working on products designed for treatment of neglected diseases. Several organizations have already signed agreements to include such provisions.<sup>99</sup> The Nine Points Document & Global Access Licensing, issued by a group at Stanford University in 2007 and signed by a number of prominent universities' TTOs, encourages all universities and research institutions to adopt licensing terms that include global access provisions.<sup>100</sup> Licensing agreements and provisions could also be imposed as conditions on grants and funding from private charitable foundations and organizations like NIH or for certain tax breaks on large pharmaceutical and medical biotechnology firms.

Before any significant open source initiatives or patent pools can develop in the United States, antitrust law enforcement must reach a decision on how to

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93. *Id.* at 212.

94. *Id.* This patent pool is likely to be established under Swiss law and operate in developing nations and therefore will not be subject to U.S. antitrust regulation. *Id.*

95. Weilbaeher, *supra* note 41, at 298; Goulding et al., *supra* note 48, at 212.

96. Weilbaeher, *supra* note 41, at 294.

97. WORLD HEALTH ASSEMBLY, GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY 14 (2008), available at [http://apps.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf) [hereinafter WHA, GLOBAL STRATEGY] (“Develop possible new mechanisms to promote transfer of and access to key health-related technologies [by] examin[ing] the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices . . .”).

98. Goulding et al., *supra* note 48, at 201.

99. For example, Universities Allied for Essential Medicines Proposed Licensing Scheme encourages technology transfer offices to include terms that “encourage [the] accessibility of essential medicines for the developing world.” *Id.* at 219. The proposed Equitable Access License encourages terms that give “freedom to operate in low-middle income countries with respect to products that rely on licensed technology.” *Id.* The Global Access Licensing Framework also urges universities to adopt licensing agreements that maintain an objective of global access to essential medicines. *Id.* at 220.

100. ASS'N OF UNIV. TECH. MANAGERS, IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY (2007), available at <http://newsservice.stanford.edu/news/2007/march7/gifs/whitepaper.pdf>.

regulate intellectual property licensing.<sup>101</sup> Open source projects in other fields have previously raised the question of whether such practices are anti-competitive.<sup>102</sup> Because of the pro-consumer benefits and ability to spur innovation, scholars argue that open source initiatives and patent pools should not be considered per se anti-competitive.<sup>103</sup> Instead, a merger-like approval process should be used to screen such arrangements on a case-by-case basis to consider actual effects on competition, pricing, and consumer benefits.

### 3. *Incentives: Prizes and Extensions*

Recognizing the unlikelihood of a large firm engaging in open source initiatives or patent pools, which would strip them of their valuable patent rights, some have suggested methods to motivate companies or researchers to engage in these efforts and to make their innovations more accessible. Some private organizations have offered prizes for inventors of drugs or tests designed to meet a specific need, and it has been suggested that the government do the same.<sup>104</sup> In 2008, a group of politicians, scholars, and entrepreneurs suggested providing prizes for medical and environmental inventions.<sup>105</sup> A medical innovation prize fund was also proposed in 2005 and 2007, but never passed Congress.<sup>106</sup> The proposal allowed innovators to receive and enforce a patent for their invention up to the point where the product would be registered for sale, and then the prize fund would begin compensating the inventor in place of the patent fees, allowing the invented product to be sold at an affordable price.<sup>107</sup> The WHA has also proposed potential award schemes for encouraging researchers and developers to work on creating treatments for neglected diseases.<sup>108</sup>

Providing patent extensions may also be used to entice firms to focus some of their resources on neglected disease treatment or to make their innovations available for researchers. “Wildcard extensions” would grant a company that develops a drug or test unlikely to have high financial returns, but needed by patients, an extension on a patent for a high-profile drug that

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101. See, e.g., Michael A. Carrier, *Innovation for the 21st Century: A Response to Seven Critics*, 61 ALA. L. REV. 597, 599 (2010) (describing the evolution of legal approaches to antitrust law as applied to intellectual property licensing).

102. See, e.g., *Wallace v. Int'l Bus. Mach. Corp.*, 467 F.3d 1104, 1107 (7th Cir. 2006) (finding that the open-source nature of Linux was not anti-competitive); see also Ian C. Ballon, *Wallace v. International Business Machines Corp. and Open Source Software*, 3 E-COM. & INTERNET L. 34.11[3] (2012–2013) (explaining the Seventh Circuit's decision in *Wallace* as reflecting “antitrust law's flexibility in dealing with innovations in high technology industries”).

103. Roger B. Andewelt, *Analysis of Patent Pools Under the Antitrust Laws*, 53 ANTITRUST L.J. 611, 619–20 (1985). Furthermore, “collusion may be unlikely because firms that [go] along with artificially high collusive pricing would risk losing large parts of the market to a firm that decide[s] to ‘cheat’ on the collusive arrangement and offer lower prices.” *Id.* at 626.

104. See, e.g., Weilbaecher, *supra* note 41, at 300–04 (describing the success of various prize programs).

105. *Id.* at 299. Those behind the proposal included Senator Bernie Sanders, Senator John Edwards, Senator Lindsey Graham, Secretary of State Clinton, Speaker of the House Newt Gingrich, and economist Joseph Stiglitz. *Id.*

106. *Id.* at 300.

107. *Id.*

108. WHA, GLOBAL STRATEGY, *supra* note 97, at Annex 3.5.

they have already secured.<sup>109</sup> One study showed that costs for the extension, when weighed against the benefit of the new treatment, would be cost neutral in the first ten years of approval of the new treatment and result in billions of dollars worth of savings within twenty years of approval.<sup>110</sup> Critics, however, argue that this would be effectively taxing patients with the disease that the subject of the extended patent is designed to treat.<sup>111</sup>

Allowing companies to extend their patent terms on select high-profile drugs is a valuable incentive that could be tailored to ensure that patients do not suffer high prices on critical drugs in exchange. Extensions could be prohibited for drugs that are categorized as life-saving, and the length of extensions could be left to the discretion of the governing body. For example, it would be more palatable to extend patents for high-sales cosmetic, or “life style” drugs (for example, Viagra) rather than for treatments for diseases like diabetes or heart congestion.

#### 4. *Biosimilars*

The government should also develop an efficient system for approving safe biosimilars<sup>112</sup> so that they can enter the market. As soon as 2015, “biologics with estimated sales revenue of \$20 billion” are expected to come off patent.<sup>113</sup> Without a system in place, producers in other countries are taking advantage of this gap in the market, and patients are not able to access lower-cost alternatives.

Having reached a user-fee agreement with the biotechnology industry, the Affordable Care Act includes an approval pathway for biosimilars, expanded by Food and Drug Administration (FDA) guidelines.<sup>114</sup> The Act allows

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109. Weilbaecher, *supra* note 41, at 304. The term “wildcard” is used because the company would have the choice of which of its drug patents it would like extended. *Id.*

110. *Id.* at 305. This study involved an extension granted as a reward when a company developed one new antibiotic to treat multi-drug-resistant *Pseudomonas aeruginosa*. *Id.* Depending on the patent to be extended and the treatment produced, these numbers would be subject to change, but the legislature (or whoever would be vested with authority to grant the extensions) could specify what patents can be extended.

111. *Id.* By extending the patent, the patient would have to pay the high cost for a longer amount of time before a biosimilar or generic could be developed. This criticism, then, is based on the assumption that a biosimilar/generic would be available and less costly. Such a suggestion has already been made to Congress, but with national security motivations. A proposed amendment to Project Bioshield designed to “encourage pharmaceutical and biotechnology companies to work with NIH to develop antidotes, vaccines, and other products to treat and protect against a number of potential biological weapons” included a wildcard provision that would allow a company that committed to developing a product to target drug resistant pathogens to extend their patent on a high-profile drug already active. *Id.* at 306. Ultimately, however, Congress rejected the proposal. *Id.*

112. “Biosimilar” is the term used to describe generic versions of biotechnology-derived drugs. See Stanton J. Lovenworth, *The New Biosimilar Era: The Basics, the Landscape, and the Future*, BLOOMBERG L., <http://about.bloomberglaw.com/practitioner-contributions/the-new-biosimilar-era-the-basics-the-landscape-and-the-future/> (last visited Mar. 5, 2014) (defining and discussing the requirements for biosimilars).

113. STRENGTH AND OPPORTUNITY, *supra* note 8, at 10.

114. Affordable Care Act, Pub. L. No. 111-148, § 7002, 124 Stat. 804, 804–21 (2010) (amending Public Health Service Act § 351, 42 U.S.C. § 262 (2006)). However, as of May 2012, the FDA had not received any biosimilar applications. Ed Silverman, *The Op-Ed: Moore’s Law and Biosimilars*, PHARMALOT.COM (May 16, 2012, 9:02 AM), <http://web.archive.org/web/20120721061315/http://www.pharmalot.com/2012/05/the-op-ed-moores-law-and-biosimilars/> (last visited Mar. 5, 2014) (accessed through the Wayback Machine Internet Archive). As of January 14, 2013, the FDA has not published approval of any biosimilars. *Information for*

biosimilar producers to use publicly available information regarding the FDA Secretary's determination that the reference product is safe, pure, and potent when filing an application but provides a twelve-year data exclusivity period for reference drug producers.<sup>115</sup> President Obama and the Federal Trade Commission both fought for far shorter or no such period whatsoever.<sup>116</sup> While many biotechnology companies see the provision as an opportunity to begin developing biosimilars at best, or a fair compromise at worst, one company—Abbott Labs—claims the law violates its property rights and has filed a citizen's petition with the FDA to protect its incredibly profitable drug, Humira.<sup>117</sup> The FDA should deny the petition and move swiftly to implement the approval processes to preserve a place in the biosimilar industry for American companies and to provide patients access to critical treatments at affordable prices.

Despite the Act and FDA guidelines, critical issues remain, including a determination of how biosimilars will be named. The naming debate remains hotly contested, because biotechnology firms want to maintain the branding connection with their product, but biosimilar producers and those pushing for increased access insist that the naming conventions used for small molecule drugs should carryover.<sup>118</sup> The Act also provides for the approval of "interchangeables"—follow-on biotech drugs that could be exchanged for the reference product, like traditional generics.<sup>119</sup> Advocates support the plan for the potential cost-saving benefits, while biotechnology innovation firms, supported in part by the American Medical Association, insist that such a level of equivalency is impossible and thus allowing biosimilars to be approved as interchangeable with reference products is unsafe.<sup>120</sup> While the Act is crucial

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*Consumers (Biosimilars)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm> (last updated Nov. 3, 2011).

115. Affordable Care Act § 7002.

116. Bill Martin, *Biosimilars: Could This Be a Pearl in the Patient Protection and Affordable Care Act?*, PHARMACY TIMES (Oct. 12, 2012), <http://www.pharmacytimes.com/publications/specialty-pt/2010/Fall2010/BiosimilarsReform>.

117. Citizen Petition for Abbott Laboratories to the FDA (Apr. 12, 2012), available at <http://www.regulations.gov/contentStreamer?objectId=0900006480fe6e4b&disposition=attachment&contentType=pdf>; Stewart Lyman, *Clash of the BioPharma Titans Looms over Biosimilars*, XCONOMY (June 25, 2012), <http://www.xconomy.com/national/2012/06/25/clash-of-the-biopharma-titans-looms-over-biosimilars/>. The FDA continues to accept comments on the petition, many of which are opposed to the petition. Donald Zuhn, *WLF Submits Comments on Abbott's Citizen Petition on Biosimilars*, PATENT DOCS (Mar. 6, 2013), <http://www.patentdocs.org/2013/03/wlf-submits-comments-on-abbotts-citizen-petition-on-biosimilars.html>. The Washington Legal Foundation, however, supports Abbott's claim that such action on the part of the FDA would constitute an unconstitutional taking. *Id.* To see all comments and updates on the petition, visit <http://www.regulations.gov/#!docketDetail;D=FDA-2012-P-0317>.

118. Lovenworth, *supra* note 112. The biosimilar industry, with the support of the Generic Pharmaceutical Association, "argues that unique names may compromise patient safety, as these names do not sufficiently convey the pharmacological similarity between biosimilars and their reference products." *Id.* Conversely, the biotechnology "innovator industry" argues that unique names are necessary for tracking and identifying complications arising from biosimilars and to avoid overbroad regulatory action. *Id.*

119. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119, 804–821.

120. Lovenworth, *supra* note 112; Michael J. Shuster & Pauline Farmer-Koppenol, *A Comparison of US and EU Biosimilars Regimes*, FENWICK & WEST LLP (Jan. 6, 2012), [http://www.fenwick.com/fenwickdocuments/01-06-12\\_comparison\\_us\\_eu\\_biosimilars\\_regimes.pdf](http://www.fenwick.com/fenwickdocuments/01-06-12_comparison_us_eu_biosimilars_regimes.pdf). Demonstrative of the patient



in moving closer to a biosimilar approval system, the FDA must continue to define the standards to make the system workable.

In contrast, the European Medicines Agency (EMA) has already established a system and approved sixteen biosimilar drugs.<sup>121</sup> Like the U.S. Act, biosimilar producers must provide clinical data showing the product is safe and effective and that it is similar to the reference product in terms of quality, safety, and efficacy.<sup>122</sup> Unlike in the United States, there is no “interchangeable” approval, and there are far more post-marketing reporting requirements.<sup>123</sup> The market for biosimilars in Europe indicates that this system has been effective and should be used as a reference in finishing the pathway for approval in the United States. In just two years, from 2007–2009, biosimilar sales rose from 3.3 million euros to 65.5 million euros.<sup>124</sup> Though the introduction of biosimilars has provided savings, and therefore increased access, to patients, the difference in price has been far less drastic than savings from generics—around thirty percent less expensive than the reference product—which should put the biotechnology innovators at ease.<sup>125</sup> India is also already marketing biosimilars, often partnering with U.S. and European companies.<sup>126</sup> From the success of biosimilar regulation systems and sales in these other countries, it is clear that efficient approval for biosimilars is crucial for the United States. The FDA should continue to define its standards, keeping in mind that the price difference is far less than with traditional generics and therefore favors pro-access arguments like maintenance of naming conventions and interchangeability approval.

#### IV. CONCLUSION

Medical biotechnology may very well be poised at the brink of radically improving the health and well-being of people everywhere, but how many people are able to take advantage of this technology will depend on how the industry is regulated and how courts and governments decide to balance access

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savings from traditional generics, a report from the IMS Institute for Healthcare Informatics indicates that the U.S. healthcare payer saved over \$65.2 billion over five years from patent expiration. Lovenworth, *supra* note 112.

121. *European Public Assessment Reports*, EUR. MEDS. AGENCY, <http://www.ema.europa.eu/ema/> (last visited Feb. 18, 2014) (click the “Find medicine” hyperlink, then the “Human medicines” hyperlink; next, select “Browse by type,” select “Biosimilars,” and click “Submit” for the most current list of authorized and refused biosimilars in the EU).

122. EUR. MED. AGENCY, COMM. FOR MEDICINAL PRODS. FOR HUMAN USE, GUIDELINE ON SIMILAR BIOLOGICAL MEDICINAL PRODUCTS (2005), [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003517.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003517.pdf); Lovenworth, *supra* note 112. As of 2012, the EMA is allowing similar applications to use products approved outside the European Union as reference products, an allowance the United States is also considering. Alexander Gaffney, *EMA to Allow Biosimilar Applications to Reference Data from Products Approved Outside EU*, REG. FOCUS (Sept. 28, 2012), <http://www.raps.org/focus-online/news/news-article-view/article/2325/a%C2%80osimilar-applications-to-reference-data-from-products-approved-o.aspx>.

123. Lovenworth, *supra* note 112.

124. *Id.*

125. *Id.*

126. *Id.* Biocon, India’s largest biotechnology company, has partnered with Mylan, a U.S.-based company, to develop biosimilars for biologics with patents up in 2015. *Id.* This is expected to have a market potential of more than \$30 billion. *Id.*

needs with providing incentive to innovators. The denial of patentability for DNA and the establishment of an initial biosimilar approval framework in the Affordable Care Act are important steps towards greater accessibility. However, it remains unclear how strictly courts should interpret the patent elements in biotechnology cases. Additionally, substantial legislation is required to regulate the patented products and patent holders. The FDA must continue to work on providing a clear pathway for biosimilar approval and the Department of Justice or other agencies need to provide regulatory guidance for ensuring that open source initiatives, patent pools, and compulsory license agreements do not violate antitrust laws.

The convergence of the Affordable Care Act, *Myriad* decision, and emergence of the medical biotechnology industry provides the unique opportunity to reevaluate the current medical patent system. By learning from the successes and failures of regulating traditional pharmaceuticals, policy makers can manipulate the patent laws and implement creative incentives to establish a more sustainable balance between profit motivation for medical biotechnology producers and increased access to new life-saving technologies for all patients.