

## The New Era of Biologic Regulation and Patenting Under the America Invents Act

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# INTELLECTUAL PROPERTY POLICY FORUM COMMENTS

## **The New Era of Biologic Regulation and Patenting Under the America Invents Act**

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## I. INTRODUCTION

In the pharmaceutical industry, regulation of biological drugs creates unprecedented challenges to the formulation of innovative patents in the intellectual property field.<sup>1</sup> Revenue once generated by these companies is now threatened by health care reform, increased competition, and government regulation in bringing new drugs to market.<sup>2</sup>

Biological drugs are products manufactured “from living matter or manufactured in living cells using recombinant DNA biotechnologies.”<sup>3</sup> They comprise a wide range of medical products including “vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.”<sup>4</sup> Biologics are made of “sugars, proteins, or nucleic acids or complex combinations of these substances, or may be [from] living entities such as cells and tissues.”<sup>5</sup> In the United States, these specialty drugs have become increasingly popular for their ability to treat medical conditions where conventional drugs fail.<sup>6</sup>

Although drug sales are predicted to rise by more than four percent in 2014,<sup>7</sup> there still remains a looming threat to break-through innovations in the biomedical industry: the newly enacted Leahy-Smith America Invents Act (AIA).<sup>8</sup> The AIA makes extensive alterations to the U.S. patent framework by attempting to harmonize the U.S. system with international patent law.<sup>9</sup> It does this by changing the U.S. patent filing system from a first-to-invent standard to

1. Accenture, *Six Tech Trends That Will Shape the Pharmaceutical Industry in 2013*, INDUS. WEEK, Dec. 10, 2012, available at <http://www.industryweek.com/emerging-technologies/six-tech-trends-will-shape-pharmaceutical-industry-2013>.

2. *Id.*

3. FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION i (2009), available at [www.ftc.gov/os/2009/06/P083901biologicsreport.pdf](http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf).

4. *What Are “Biologics” Questions and Answers*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm> (last visited Mar. 17, 2013).

5. *Id.*

6. *Id.* Conventional drugs are chemically synthesized products with known chemical structures. *Id.* Biologics on the other hand, are complex mixtures that are not easily identifiable or characterized. *Id.* “Biological products . . . tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs.” *Id.*

7. Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES (Mar. 18, 2013) [http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?hp&\\_r=1&](http://www.nytimes.com/2013/03/19/business/use-of-generics-produces-an-unusual-drop-in-drug-spending.html?hp&_r=1&). Drug sales are expected to rise due to economic growth in international markets, fewer brand-name drugs losing patent protection, the influx of newly insured patients under new federal health care law. *Id.*

8. Leahy-Smith America Invents Act (AIA 2011), Pub. L. No. 112–29, 125 Stat. 284 (2011).

9. Candice Decaire et al., *Negotiating A New Legal Landscape: The Advent of Follow-On Biologics*, 46 U.S.F. L. REV. 1029, 1058 (2012).

a first-to-file standard.<sup>10</sup> The new filing system provides “greater certainty for inventors that their patent will not be invalidated by someone [claiming] an earlier date of invention.”<sup>11</sup>

However, in the biopharmaceutical context, the AIA puts additional pressure on biomedical companies to patent biological inventions earlier in the research and development (R&D) process. The biotechnological industry is extremely competitive, and drug companies require a large amount of capital to research and develop innovative products. These funds are acquired from private investors, who prefer investing in companies with patent protected innovations. Without patent protection, venture capitalists are wary of providing capital because it might become too easy for competitors to undercut the biomedical company’s market price with their own similar drugs.<sup>12</sup> Now that the U.S. patent filing system has changed from a first-to-invent standard to a first-to-file standard, biopharmaceutical companies will be forced to file provisional applications earlier in the R&D process, or risk pre-emption from competing firms, which could deter investors from providing capital to the business for future R&D of drugs.

Therefore, pressure to avoid being pre-empted by competitors will cause biologic companies to file provisional applications prematurely, which will result in overly broad biological patents that fail to meet the 35 U.S.C. § 112 disclosure requirements. However, due to the unpredictable nature of biotechnology, the USPTO will likely approve many of these patent applications. Furthermore, market exclusivity, which is granted to biologic drugs approved by the FDA, will also exacerbate the situation by enabling biomedical firms to file overly broad patents on biologic drugs, and by allowing them to maintain their product monopolies in the field, even if their patents are later invalidated.

As a result, the new rules will induce the production of poorly constructed patents that fail to fully and completely characterize biological products.<sup>13</sup> These non-innovative patents will be susceptible to validity challenges, but competitors will not contest their validity due to regulatory provisions under the Biologic Price Competition and Innovation Act (BPCIA).<sup>14</sup>

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10. See AIA 2011.

11. Decaire, *supra* note 9.

12. *Patents and Innovation: Trends and Policy Challenges*, ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT 9–10 (2004), available at <http://www.oecd.org/science/sci-tech/24508541.pdf>.

13. *Id.* Poor patent claim construction is a result of overly narrow/broad language in the specification section of the patent.

14. *Id.* Biologics Price Competition and Innovation Act, Pub. L. No. 111–148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010).

This Comment explores the unanticipated effect the AIA will have on biological patents under the BPCIA starting March 16, 2013, and the need for modification of the BPCIA to maintain innovation in the biopharmaceutical field. Specifically, there are two viable ways to safeguard innovation in the biologic field: (1) by modifying the BPCIA so that market exclusivity is withdrawn upon invalidation of a biological patent, or (2) denying biological inventors the ability to file provisional patents.

Part II of the paper presents background on the regulatory history of biological patents in the United States. Part III describes the patent provisions (pre-AIA and post-AIA) relevant to analyze the BPCIA. Part IV defines the role of market exclusivity in patents. And, Part V explains the dangers of granting market exclusivity to biologics in a first-to-invent system, and viable solutions to ensure continued innovation in the biomedical industry.

## II. THE REGULATORY HISTORY OF BIOLOGICS IN THE UNITED STATES

Regulation of biological products began in the nineteenth century when pharmacies became the common source for medicine.<sup>15</sup> It was during this time that the use of vaccines in the United States became prevalent, and governmental agencies and public laboratories began providing vaccination services to the general public.<sup>16</sup> However, regulation of drugs was thought to be a state responsibility, rather than a federal matter.<sup>17</sup> It was not until the 1890s that the federal government became significantly involved in “vaccination science and policy.”<sup>18</sup>

Before federal oversight existed, the popularity of biological treatments enticed private entities to manufacture vaccines and antitoxins at a scale never seen before.<sup>19</sup> Many small firms engaged in dishonest behavior, such as providing fake smallpox vaccines, and producing contaminated batches of medicine sold to the general public.<sup>20</sup> These drugs caused the death of thirteen children, and consequentially, Congress’s foray into biologic regulation.<sup>21</sup>

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15. David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 145 (2005).

16. *Id.* at 146.

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.* Margaret Pittman, *The Regulation of Biological Products, 1902-1970*, in *National Institute of Allergy and Infectious Disease: Intramural Contributions, 1887-1997*, at 61 (H.R. Greenwald & V.A. Harden eds., 1987).

### A. *The Biologic Control Act of 1902*

In 1902, Congress passed the Biologic Control Act in response to tetanus contamination of smallpox vaccines and diphtheria antitoxin that killed many people.<sup>22</sup> The 1902 Act enabled the federal government to exert jurisdiction over “viruses, therapeutic serums, toxins, antitoxins, or analogous products”, such as biologics, that were intended for the “prevention and cure of diseases of man.”<sup>23</sup> These categories of biologics represented immunologic agents, and “Congress . . . select[ed] these . . . substances out of particular concern for immunologic, allergenic, and . . . [possible] contagious side effects.”<sup>24</sup>

The 1902 Act also gave the federal government the power to monitor the production, labeling, and interstate traffic of biologics.<sup>25</sup> However, the Act did not allow the government to regulate biologic products directly.<sup>26</sup> Instead, regulatory powers were granted to the Hygienic Laboratory, which is the precursor to the National Institutes of Health (NIH).<sup>27</sup>

In addition, the 1902 Act set groundbreaking precedents in the U.S. by modifying common law notions of punishment for intentional and reckless conduct, by instead favoring “pro-active safety measures” for entities, and by

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22. *Id.* at 147; Biologics Control Act of 1902 Pub. L. No. 57–244, ch. 1378, 32 Stat. 728 (July 1, 1902) (“An Act To regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia; to regulate interstate traffic in said articles, and for other purposes.”).

23. Biologics Control Act of 1902 ch. 1378.

24. *See* Dudzinski, *supra* note 15, at 147. *Immunologic Agents*, DRUGS.COM, <http://www.drugs.com/drug-class/immunologic-agents.html> (last visited Feb. 9, 2013) (“Immunologic agents are drugs that can modify the immune response, either by enhancing or suppressing the immune system. They are used to fight infections, prevent and treat certain diseases. Immunologic agents include drugs used for immunosuppression to prevent graft rejection. They can be used as cancer chemotherapy agents. Some immunologic agents can down-regulate the inflammatory process and can be used to treat inflammatory conditions such as rheumatoid arthritis, autoimmune conditions and so on.”).

25. Biologics Control Act of 1902 ch. 1378.

26. *See* Dudzinski, *supra* note 15, at 148.

27. *Id.* *A Short History of the National Institutes of Health: The Move to Washington*, OFFICE OF NIH HISTORY, [http://history.nih.gov/exhibits/history/docs/page\\_02.html](http://history.nih.gov/exhibits/history/docs/page_02.html) (last visited Feb. 9, 2013) (“In 1901, the [Hygienic] [L]aboratory was . . . [created] when Congress authorized \$35,000 for construction of a new building in which the laboratory could investigate ‘infectious and contagious diseases and matters pertaining to the public health.’”); *A Short History of the National Institutes of Health: Biologics*, OFFICE OF NIH HISTORY, [http://history.nih.gov/exhibits/history/docs/page\\_03.html](http://history.nih.gov/exhibits/history/docs/page_03.html) (last visited Feb. 9, 2013) (“The Biologics Control Act was a second piece of legislation enacted in 1902 that had major consequences for the Hygienic Laboratory. It charged the laboratory with regulating the production of vaccines and antitoxins, thus making it a regulatory agency four years before passage of the better-known 1906 Pure Food and Drugs Act.”); *About NIH*, OFFICE OF NIH <http://www.nih.gov/about/> (last visited Feb. 9, 2013) (“The National Institutes of Health [is] a part of the U.S. Department of Health and Human Services [and is] the nation’s medical research agency—making important discoveries that improve health and save lives.”).

also becoming the first “premarket approval statute.”<sup>28</sup> Therefore, companies wishing to market biological products needed their manufacturing facilities to pass federal inspection before they could market their drugs to the public.<sup>29</sup>

*B. The Pure Food and Drug Act and the Federal Food, Drug, and Cosmetic Act*

Four years after the Biologics Act of 1902, Congress enacted the Pure Food and Drug Act (PFDA) to prevent the adulteration and misbranding of food and drugs.<sup>30</sup> However, the PFDA “did not include any controls over manufacturing establishments, unlike the pre-existing Biologics Act.”<sup>31</sup> As a result, there was no form of premarket control over new drugs to ensure their safety before entering the market.<sup>32</sup>

To alleviate the problem, Congress passed the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>33</sup> The law gave the federal government power to regulate food, drugs, medical devices, and the entities that manufactured and distributed such products.<sup>34</sup> It also “required [manufacturers] to submit evidence of a new drug’s safety to the government in a premarket new drug application (NDA)” before the manufacturers could sell the drug.<sup>35</sup> Furthermore, the FDCA broadened laws regarding adulteration, and added “drugs or medical devices that were contaminated, manufactured, or held in conditions under which such product might become contaminated or degraded.”<sup>36</sup>

*C. The Public Health Service Act*

Several years after the FDCA’s enactment, the Public Health Service Act (PHSA) was approved by Congress to control the manufacturing process of

28. See Dudzinski, *supra* note 15, at 147.

29. *Id.*

30. Pure Food & Drug Act, Pub. L. No. 59–384, ch. 3915, 34 Stat. 768 (1906) (“An Act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.”) (repealed 1938).

31. Gary E. Gamerman, *Regulation of Biologics Manufacturing: Questioning the Premise*, 49 FOOD & DRUG L.J. 213, 218 (1994).

32. *Id.*

33. *Id.* at 218–19; Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75–717, 52 Stat. 1040 (1938).

34. Gamerman, *supra* note 31, at 218.

35. *Id.*

36. *Id.* at 218–19.

biologics.<sup>37</sup> In addition, the Biologics Act was also reenacted.<sup>38</sup> However, Congress altered the biologics statute by adding mandatory product licensure and specific criteria for issuing license approvals of biologics.<sup>39</sup> Under the revised statute, licenses for both establishments and products had to meet standards “designed to insure [sic] the continued safety, purity, and potency of such products, prescribed in regulation.”<sup>40</sup> This revision to the Biologics Act aligned biologic regulation with drug regulation under the FDCA.<sup>41</sup>

#### *D. Natural Source Biological Products and the Hatch-Waxman Act*

In general, biological products are regulated under the PHSA, and chemical drugs are regulated under the FDCA.<sup>42</sup> However, the Food and Drug Administration (FDA) has been given authority to regulate certain natural source biological products.<sup>43</sup> For example, Congress granted the FDA authority to market insulin.<sup>44</sup> This authorization is important because the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the “Hatch-Waxman Act”), “provides a mechanism for the approval of generic drugs under the [FDCA], but not under the [PHSA].”<sup>45</sup>

Therefore, under the Hatch-Waxman Act, a generic manufacturer can enjoy an abbreviated approval process for a drug, by relying on the safety and effectiveness of clinical-trial data produced by a reference-product sponsor’s (RPS) already approved drug application.<sup>46</sup> So long as the generic manufacturer shows that its drug has ‘the same’ active ingredient as the reference drug and is also bioequivalent to the reference drug, it will acquire FDA approval.<sup>47</sup>

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37. *Id.* at 219; Public Health Service Act, Pub. L. No. 78–410, § 351, 58 Stat. 682, 702 (1944) (codified at 42 U.S.C. § 262). This is in contrast to drug and medical device regulation under the FDCA, which focused on ensuring safety and effectiveness of the final product, with control of the manufacturing process being only of secondary concern.

38. Gamerman, *supra* note 31 at 219.

39. 42 U.S.C. § 262 (2012).

40. Gamerman, *supra* note 31 at 219.

41. *Id.*

42. Judith A. Johnson, *FDA Regulation of Follow-On Biologics*, CONG. RES. SERV. (2010), available at [http://assets.opencrs.com/rpts/RL34045\\_20090224.pdf](http://assets.opencrs.com/rpts/RL34045_20090224.pdf).

43. *Id.*

44. *Id.* (“In the 1940s, insulin was obtained in the same manner as many biologics, namely extraction from animals. Despite this similarity with biologics, insulin was regulated by the FDA.” This also applied to a small set of hormones including: “glucagon, human growth hormone, hormones to treat infertility, hormones used to manage menopause and osteoporosis, and certain medical enzymes (hyaluronidase and urokinase).”) *Id.* at 6–7.

45. *Id.* at 7; *see* 21 U.S.C. § 355 (2006).

46. Johnson, *supra* note 42.

47. *Id.* at 7.

However, this abbreviated process was not made available to biologics.<sup>48</sup> Congress concluded that biologic proteins were too large and complex, and the utilization of biological material in the manufacturing process would be too difficult to characterize and accurately copy the reference biologic consistently enough to reproduce the desired product.<sup>49</sup> Even the smallest alteration to a biologic or the manufacturing process could completely differentiate a biologic from its reference product, and have an effect on the biologic's safety and effectiveness.<sup>50</sup> These differences could be difficult to detect.<sup>51</sup> Therefore, Congress excluded biologics from the abbreviated approval process, until recently.<sup>52</sup>

#### *E. The Biologics Price Competition and Innovation Act (BPCIA)*

In 2010, President Obama signed the Patient Protection and Affordable Care Act (PPACA) into law.<sup>53</sup> The legislation amends the PHS Act by creating an abbreviated pathway for biological products that are shown to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product.<sup>54</sup> The pathway is detailed in the PPACA under the BCPIA section.<sup>55</sup>

Under the BPCIA, a RPS applicant must show that the biological product is “safe, pure, and potent” and that “the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.”<sup>56</sup> Upon approval of a reference product, the sponsor is granted four years of data exclusivity and twelve years of market exclusivity, if the biologic product was not previously licensed.<sup>57</sup>

48. *Id.*

49. *See id.*

50. *Id.* at 10.

51. Kate S. Gaudry, *Exclusivity Strategies and Opportunities in View of the Biologics Price Competition and Innovation Act*, 66 FOOD & DRUG L.J. 587, 589 (2011) (“Consequences of seemingly minor structural deviations may include, for example, aggregation and incorrect folding and structural anomalies, such as truncation, proteolysis and amino-acid modifications. Each of these results may have an effect on a product’s effectiveness and safety. Additionally, due to the large size of biologics, there is a sizable risk that the immune system will attack the agent, causing adverse side effects.”).

52. Johnson, *supra* note 42.

53. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–48, 124 Stat. 119 (codified as amended in scattered sections of 42 U.S.C.).

54. *How Drugs are Developed and Approved*, FOOD AND DRUG ADMINISTRATION <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/default.htm> ((last visited Mar. 17, 2013)).b

55. Biologics Price Competition and Innovation Act, §§ 7001–7003.

56. 42 U.S.C. § 262(a)(1)(C) (2010).

57. 42 U.S.C. § 262(k)(7)(A).

Data exclusivity prevents a “follow-on-biologic (FOB) applicant”<sup>58</sup> from filing for a biosimilar license on an identical or similar drug using the RPS’s data.<sup>59</sup> Therefore, a FOB applicant can only file an application four years after the reference product is licensed.<sup>60</sup> If the FOB applicant wishes to get earlier approval, it must gather its own data by conducting independent research and clinical trials.<sup>61</sup>

In addition, the BPCIA creates an abbreviated application process for FOB applicants.<sup>62</sup> Unless the FDA determines that the process is unnecessary, “the applicant must submit information demonstrating that the FOB and reference product: (1) are biosimilar; (2) use the same mechanism of action for the applicable condition to the extent that the reference product’s mechanism is known; and (3) share the same conditions of use, route of administration, dosage form, and strength.”<sup>63</sup> Furthermore, the “facility in which the biologic is manufactured, processed, packed, or held must meet the standards designed to ensure that the biologic continues to be safe, pure, and potent.”<sup>64</sup>

### III. THE OLD AND NEW PATENT PROVISIONS RELEVANT TO THE BPCIA

The basis of the United States patent system is derived from the Article I, Section 8 of the U.S. Constitution, which grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>65</sup> Based on this power, Congress enacted the Patent Act of 1790,<sup>66</sup> which rewarded a patent to anyone who was the “first and true inventor or discoverer” of a particular invention.<sup>67</sup>

Three years later, Congress passed additional legislation<sup>68</sup> that provided for binding arbitration “in case[s] of interfering applications” for a patent.<sup>69</sup> The procedure enabled an infringer to invalidate a patentee’s patent if the infringer could prove that the patentee was not the first inventor of the invention.<sup>70</sup>

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58. Also known as a generic biologic manufacturer applying for a drug license.

59. Gaudry, *supra* note 51, at 592.

60. 42 U.S.C. § 262(k)(7)(B).

61. Gaudry, *supra* note 51, at 592.

62. 42 U.S.C. § 262(k)(2).

63. Gaudry, *supra* note 51, at 597; 42 U.S.C. § 262(k)(2).

64. Gaudry, *supra* note 51, at 597; 42 U.S.C. § 262(i)(2).

65. U.S. CONST. art. I, § 8, cl. 8.

66. Patent Act of 1790, ch. 7, 1 Stat. 109 (repealed 1793).

67. *Id.*

68. Patent Act of 1793, ch. 11, 1 Stat. 318 (repealed 1836).

69. 3A-10 DONALD S. CHISUM, CHISUM ON PATENTS § 10.02(1) (2012).

70. See Patent Act of 1793, ch. 11, 1 Stat. 318 (repealed 1836). The 1793 Patent Act contained similar provision to the 1790 Act, but used “true inventor” rather than “first and true inventor.”

Decades later, the legislature passed the Patent Act of 1836, which created the United States Patent Office (USPTO) and the patent examination system.<sup>71</sup> More importantly, the 1836 Act established the first-to-invent filing system, which continues to determine the priority date of invention for patent claims filed before March 16, 2013.<sup>72</sup>

*A. The First-To-Invent Filing System Under the Patent Act of 1952*

In 1893, Judge Taft stated the first-to-invent rule, which became the filing framework used under the Patent Act of 1952.<sup>73</sup> He held that

the man who first reduces an invention to practice is prima facie the first and true inventor, but . . . the man who first conceives, and, in a mental sense, first invents . . . may date his patentable invention back to the time of its conception, if he connects the conception with its reduction to practice by reasonable diligence on his part.<sup>74</sup>

One way to show reduction to practice was by filing a patent application.<sup>75</sup> The Patent Act of 1952 stated that the first person to invent or conceive the invention, even if he was not the first person to file, would be granted a patent so long as he could show diligence in filing his application or otherwise reducing the invention to practice.<sup>76</sup>

Although the general rule granted patent protection to the first inventor, the “public use statutory bar” in the 1952 Act was used as a safeguard to ensure that the first inventor disclosed his invention to the public in a timely fashion.<sup>77</sup> Under this statutory bar, public use occurred “when the inventor allow[ed] another person to use the invention without limitation, restriction or obligation of secrecy to the inventor.”<sup>78</sup> If the inventor wished to receive patent protection,

Chisum, *supra* note 69 § 10.02(1).

71. Patent Act of 1836, ch. 357, 5 Stat. 117.

72. Chisum, *supra* note 69, § 10.02(2)(b); AIA 2011. The invention date for patent claims filed before March 16, 2013 will continue to be analyzed under § 102 and § 103 of the Patent Act of 1952. *Id.* § 10.10.

73. Patent Act of 1952, 35 U.S.C. §§ 1–376 (1997); *See id.* § 102(g) (2006).

74. *Christie v. Seybold*, 55 F. 69, 76 (6<sup>th</sup> Cir. 1893); *see also* *Marconi Wireless Tel. Co. v. United States*, 320 U.S. 1, 34 (1943) (“It is well established that as between two inventors priority of invention will be awarded to the one who by satisfying proof can show that he first conceived the invention.”).

75. *See* Chisum, *supra* note 69, § 10.03(1).

76. *See* 35 U.S.C § 102(g).

77. 35 U.S.C. § 102(b).

78. *See* UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2133.03(a) (9th ed., Aug. 2012, last rev. Jan 2013) (citing *In re Smith*, 714 F.2d 1127, 1134 (Fed. Cir. 1983)).

he had to file a patent application within one year of such public use.<sup>79</sup> This rule was designed to avoid two problems in the first-to-invent system.<sup>80</sup>

First, it stopped inventors from waiting for others to independently create the invention, so that they could assert priority over the independently created invention, and demand profits accrued by the independent inventors.<sup>81</sup> Second, the statutory bar prevented inventors “from bringing a product to market, starting to profit from the invention, and then waiting to file for a patent until many years later when competition [arose], thereby depriving the public of the full knowledge of the invention and preventing improvements in the invention.”<sup>82</sup> Thus, the statutory bar kept inventors from acquiring a market monopoly past the time limit granted by Congress and ensured timely public disclosure of their inventions.<sup>83</sup>

### B. *The-First-To-File System Under the AIA*

Under the AIA, the first-to-invent framework has been replaced by the new standard called the “first inventor to file” system.<sup>84</sup> The AIA filing framework is often characterized as “a race to the patent office” because the inventor who files a patent application first is granted a patent even if another independent inventor of the same invention was the first to conceive and/or create the invention.<sup>85</sup> In addition, “prior art” language has been broadened to deny patentability to an invention if it has been “patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.”<sup>86</sup>

The filing rule also grants inventors a grace period under the new 35 U.S.C. § 102(b)(1)(B).<sup>87</sup> Under this section, an inventor who publicly discloses the nature of his invention less than a year before filing an application to the USPTO will not have his invention classified as prior art for the purposes of his

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79. 35 U.S.C. § 102(b).

80. Suzanne Konrad, *The United States First-to-Invent System: Economic Justifications for Maintaining the Status Quo*, 82 CHI.-KENT L. REV. 1629, 1636 (2007).

81. *Id.*

82. *Id.*

83. *Id.*

84. AIA 2011 § 3; Chisum, *supra* note 69, § 10.10 (On March 16, 2013, the filing system “shift[ed] from the long-standing first to invent priority principle to a “first inventor to file” priority principle. The Act amend[s] Section 102 and Section 103 to remove references to invention dates, including Section 102(g). The changes to Sections 102 and 103 are effective for patent claims entitled to effective filing dates after March 15, 2013.”).

85. Wendell Ray Guffey & Kimberly Schreiber, *America Invents Act: The Switch to A First-to-File Patent System*, 68 J. MO. B. 156 (2012).

86. AIA 2011 §§ 102(b)(1), 102(a)(1).

87. AIA 2011 §§ 3(b)(1), 102(b)(1).

application; however, it will count as prior art for other independent applicants attempting to patent their inventions.<sup>88</sup>

### C. Provisional Patents

Provisional patents under the AIA are a way to initiate the patent process at a lower filing cost and also align the U.S. patent system more closely to the international patent framework.<sup>89</sup> These patents are governed by 35 U.S.C. § 111(b), which states that a provisional application must include a specification<sup>90</sup> and a drawing<sup>91</sup> if necessary to understand the invention.<sup>92</sup>

A provisional patent provides the examiner with an approximate date that a patent applicant conceived and constructively reduced an invention to practice.<sup>93</sup> These patents are not closely examined by the USPTO, and are typically used by a patent applicant to extend the patent approval process.<sup>94</sup> At the applicant's discretion, the inventor can file a corresponding non-provisional application within twelve months of the provisional application's filing date.<sup>95</sup>

The non-provisional application will be substantively examined by the USPTO,<sup>96</sup> and so long as the invention claimed in the non-provisional application is adequately supported by the disclosure in the provisional patent, the applicant will be able to claim the benefit of the provisional patent's filing date, thus backdating the patent application by up to twelve months.<sup>97</sup> In other words, when the USPTO examiner compares the claims of the non-provisional application with prior art for purposes of assessing novelty and non-obviousness, the examiner will only consider prior art with an effective filing date earlier than the filing date of the provisional patent.<sup>98</sup>

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88. AIA 2011 §102(b)(1)(B); *see also* 1–SA02 DONALD S. CHISUM, CHISUM ON PATENTS § 3.

89. H. Roy Berkenstock, *The Provisional Application for Patent: Its Place in Intellectual Property Protection*, 24 THE COMPUTER & INTERNET LAWYER 6, 14 (2006).

90. 35 U.S.C. § 112.

91. 35 U.S.C. § 113.

92. AIA 2011 § 111(b).

93. *See* Charles E. Van Horn, *Practicalities and Potential Pitfalls When Using Provisional Patent Applications*, 22 AIPLA Q.J. 259, 299 (1994). In addition, a provisional patent can establish the filing date for foreign patent applications under the "Patent Cooperation Treaty", which is an area of law that this comment does not examine. *See Patent Cooperation Treaty*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, available at [http://www.wipo.int/pct/en/texts/articles/a11.htm#\\_11](http://www.wipo.int/pct/en/texts/articles/a11.htm#_11).

94. Horn, *supra* note 93 at 291.

95. 37 C.F.R. § 1.53(c)(3)(ii).

96. *See* 35 U.S.C. § 111(a).

97. *See* 35 U.S.C. § 119(e)(1). For an example of an unsuccessful attempt to claim during litigation the benefit of a provisional application's filing date in order to avoid a 35 U.S.C. § 102(b) statutory bar, *see* *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290 (Fed. Cir. 2002).

98. *See* 35 U.S.C. § 119(e)(1).

Furthermore, when the patent examiner determines that the claims in question are adequately supported by the disclosure of the provisional patent<sup>99</sup> and the applicant decides to claim the benefit of his provisional filing date, the examiner will treat the provisional application date in one of two ways: (1) as the applicant's invention date under the pre-AIA version of 35 U.S.C. § 102,<sup>100</sup> or (2) the effective filing date for an application filed on or after March 16, 2013 (post-AIA).<sup>101</sup> In either situation, if another individual files for a U.S. patent on the same or similar invention, or publishes information on the invention, such material will not be considered prior art against the inventor's non-provisional application, and the patent examiner will ignore such prior art when determining patentability of the invention.<sup>102</sup>

#### *D. The Disclosure Requirement*

“To obtain a valid patent claiming a new, useful, and nonobvious product or process, the inventor must file with his or her application a specification fully disclosing the invention and how to make and use it.”<sup>103</sup> Under 35 U.S.C. § 112 ¶ 1, the inventor “must adequately set forth and describe three items: (1) the invention (the [adequate written] description requirement); (2) the manner and process of making and using the invention (the enablement requirement); and (3) the best mode contemplated by the inventor of carrying out his invention (the best mode requirement).”<sup>104</sup> For the purposes of this Article, only the adequate written description requirement and enablement requirement

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99. The claims are adequately supported when the specification of the provisional contains a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms, 35 U.S.C. § 112(a), to enable an ordinarily skilled artisan to practice the invention claimed in the nonprovisional application. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 201.11.I.A (9th ed., Aug. 2012, last rev. Jan 2013).

100. See 35 U.S.C. § 102 (The invention date for the purposes of analyzing novelty, loss of right, and non-obviousness); UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §201.11.I.A (8th ed., Aug. 2001) (stating that “[i]f the filing date of the earlier provisional application is necessary, for example, in the case of an interference or to overcome a reference, care must be taken to ensure that the disclosure filed as the provisional application adequately provides (1) a written description of the subject matter of the claim(s) at issue in the later filed nonprovisional application, and (2) an enabling disclosure to permit one of ordinary skill in the art to make and use the claimed invention in the later filed nonprovisional application without undue experimentation.”).

101. See AIA 2011 § 100(i)(1)(B) (the filing date of the earliest application for which the . . . application is entitled, as to such invention, to a right of priority under section 119 . . . .”); AIA 2011 § 119(e)(1) (domestic priority).

102. See UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 201.11.I.A (9th ed., Aug. 2012, last rev. Jan 2013).

103. Chisum, *supra* note 69, § 7.01.

104. Chisum, *supra* note 69, § 7.01.

are examined.

The written description requirement is designed to ensure that the inventor had possession of the claimed subject-matter upon submission of the original application.<sup>105</sup> The first paragraph of 35 U.S.C. § 112 states that

[t]he specification shall contain a *written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .<sup>106</sup>

Therefore, in order to “satisfy the written description requirement, the specification must describe the claimed invention in sufficient detail, so that one skilled in the art can reasonably conclude that the inventor had *possession* of the claimed invention.”<sup>107</sup> In other words, “the specification must describe the claimed invention in a manner understandable to a person of ordinary skill in the art and show that the inventor actually invented the claimed invention.”<sup>108</sup>

Additionally, the claims in the application must also satisfy the written description requirement: including “original claims that are part of the disclosure as filed.”<sup>109</sup> While many of these original claims will satisfy the written description requirement, some will not.<sup>110</sup>

For example, patent applications that describe claims with generic language in the original disclosure can fail to satisfy the requirement when they do not support the scope of the genus claimed.<sup>111</sup> A claim can also fail the written

105. See UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE §§ 2163–2163.04 (9th ed., Aug. 2012, last rev. Jan 2013); *In re Herschler*, 591 F.2d 693, 700–01 (C.C.P.A. 1979); *In re Kaslow*, 707 F.2d 1366 (Fed. Cir. 1983).

106. AIA 2011 § 112 (emphasis added).

107. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161.01 (9th ed., Aug. 2012, last rev. Jan 2013) (emphasis added) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991)).

108. *Id.*

109. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161.01 (9th ed., Aug. 2012, last rev. Jan 2013) (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)).

110. *Ariad*, 598 F.3d at 1349; see also *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1343–46 (Fed. Cir. 2005); *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

111. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161.01 (9th ed., Aug. 2012, last rev. Jan 2013) (citing *Ariad*, 598 F.3d at 1350); *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002) (holding that generic claim language appearing *in ipsius verbis* in the original specification did not satisfy the written description requirement because it failed to support the scope of the genus claimed.); *Fiers v. Revel*, 984 F.2d 1164, 1170 (Fed. Cir. 1993) (rejecting the argument that “only similar language in the specification or

description requirement when the original claim describes the invention in functional language, but the specification does not provide adequate instructions on how to produce the claimed function.<sup>112</sup>

Furthermore, satisfying the written description requirement can be challenging in situations where a patent applicant writes a genus claim that uses functional language to define the boundaries of a claimed genus.<sup>113</sup> In such instances, the functional claims may assert a desired result but fail to adequately describe the species that achieved that result.<sup>114</sup> Therefore, the written description requirement in such situations is only met when, “the specification [has] demonstrate[d] that the applicant has made a generic invention that achieves the claimed result and . . . show[s] that the applicant has invented species sufficient to support a claim to the functionally-defined genus.”<sup>115</sup>

The enablement requirement, on the other hand, calls for the inventor to set forth in the patent specification sufficient information to enable a person skilled in the relevant art to *make and use* the invention.<sup>116</sup> “The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.”<sup>117</sup> The purpose of such a requirement is to ensure that invention is communicated to the interested public in a meaningful way.<sup>118</sup> The information contained in the disclosure of an application “must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.”<sup>119</sup> However, to comply with 35 U.S.C. § 112 ¶ 1, it is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.”<sup>120</sup> “Detailed procedures for making and using the invention [are not always] necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.”<sup>121</sup> However, although an applicant in most circumstances is not required to reduce

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original claims is necessary to satisfy the written description requirement.”).

112. *Ariad*, 598 F.3d at 1349 (“[A]n adequate written description of a claimed genus requires more than a generic statement of an invention’s boundaries.”) (citing *Eli Lilly*, 119 F.3d at 1568).

113. *Ariad*, 598 F.3d at 1349.

114. *Id.*

115. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161.01 (9th ed., Aug. 2012, last rev. Jan 2013) (citing *Ariad*, 598 F.3d at 1349).

116. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164 (9th ed., Aug. 2012, last rev. Jan 2013); *see also* *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372 (Fed. Cir. 2000) (citing *Chisum*, *supra* note 69).

117. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.

118. *Id.*

119. *Id.*

120. *Id.* (citing *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003)).

121. *Id.*

the invention to practice prior to filing an application, the presence or absence of examples in the patent specification may be a factor in determining the extent to which claims involving unpredictable technology—such as biotechnology—are enabled.<sup>122</sup>

It is important to note that the enablement requirement is separate and distinct from the adequate written description requirement.<sup>123</sup> As the USPTO explains:

[T]he fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally filed does not necessarily mean that the limitation is also not enabled. In other words, the statement of a new limitation in and of itself may enable one skilled in the art to make and use the claim containing that limitation even though that limitation may not be described in the original disclosure. Consequently, such limitations must be analyzed for both enablement and [adequate written] description using their separate and distinct criteria.<sup>124</sup>

#### IV. THE ROLE OF MARKET EXCLUSIVITY IN PATENTS

Market exclusivity confers patent-like protection to an individual's product against competitors.<sup>125</sup> It is best understood as “an economic measure designed to promote costly investments in innovation . . . .”<sup>126</sup> Typically, such regulation prevents, for a specified period of time, another pharmaceutical applicant (commonly referred to as the “second entrant”) “from obtaining a marketing authorization for its drug . . . through a facilitated procedure . . . .”<sup>127</sup> The procedure usually entails reliance by the second entrant on the preclinical and clinical data generated by the RPS when the second entrant submits that data in support of its own drug application.<sup>128</sup> Therefore, the drug that the second applicant requests for marketing approval is identical or similar to the RPS's drug, which makes the reference drug's pre-clinical and clinical data relevant

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122. See *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988).

123. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, (Fed. Cir. 1991) (“[t]he purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’ . . . .”).

124. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164 (9th ed., Aug. 2012, last rev. Jan 2013).

125. Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479 (2004).

126. Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 FORDHAM L. REV. 477, 483 (2003).

127. Junod, *supra* note 125, at 479.

128. *Id.* at 479–80.

to assess the second entrant's application.<sup>129</sup>

In most instances, market exclusivity prevents the second entrant from using the RPS's data to evaluate its own application.<sup>130</sup> As a result, the second entrant will only be able to obtain market approval "if it generates its own data supporting the safety and efficacy of its drug."<sup>131</sup> The process of generating this data can be extremely expensive, so second entrants usually wait for the expiration of the RPS's exclusivity period to avoid this expense.<sup>132</sup> Therefore, market entry, especially for generic manufacturers in the drug industry, is typically delayed until the market exclusivity period of the RPS expires.<sup>133</sup>

#### A. Market Exclusivity in the Biologic Industry

In 1984, Congress provided for periods of marketing exclusivity in the pharmaceutical industry ranging from four to seven and a half years under the Hatch-Waxman Act.<sup>134</sup> In 2010, the biopharmaceutical industry persuaded Congress to confer twelve years of marketing exclusivity before "the FDA can approve products that are biosimilar to previously approved biological products."<sup>135</sup>

Under this regulatory scheme, an application for a biosimilar license may not be filed for four years (data exclusivity), and its approval may not be made effective for twelve years (market exclusivity), after the licensing of the reference product.<sup>136</sup> Unlike the Hatch-Waxman Act, however, there is no provision for the FDA to stay regulatory approval of a biosimilar license pending resolution of litigation between two opposing parties.<sup>137</sup>

In addition, modification to the structure of a biological product that results in a change to safety, purity, or potency, is granted its own twelve-year period of market exclusivity under the BPCIA.<sup>138</sup> An extra six months of "pediatric exclusivity" to both the four-year data exclusivity, and to the twelve-year market exclusivity before a license may become effective is also available

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129. *Id.*

130. *Id.*

131. *Id.* at 480.

132. *Id.*

133. *Id.*

134. Pub. L. No. 98-417, 98 Stat. 1585 (1984); REBECCA S. EISENBERG, *THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY* 188 (Patricia M. Danzon & Sean Nicholson eds. 2012).

135. Eisenberg, *supra* note 134; The Biologics Price Competition and Innovation Act of 2009, signed into law as Title VII, Subtitle A, §§ 7001-03 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (H.R. 3590) (2010).

136. Eisenberg, *supra* note 134, at 189; 42 U.S.C. §§ 262(k)(7)(A)-(B) (2010).

137. Eisenberg, *supra* note 134; *see* 42 U.S.C. § 262(l).

138. Eisenberg, *supra* note 134, at 190; 42 U.S.C. §§ 262(k)(7)(C)(ii)(I)-(II).

under the conditions applicable to pediatric exclusivity for biologic drugs.<sup>139</sup>

### B. The Defense for Market Exclusivity

Proponents of biopharmaceutical market exclusivity believe the regulation is necessary for a number of reasons. For instance, the cost of developing new specialty drugs (including those that fail testing) is typically around \$1.2 billion.<sup>140</sup> Furthermore, the average preclinical and clinical development of a drug can take over ten years.<sup>141</sup> Without market protection, a biomedical company faces potential generic competition caused by delayed regulatory approval of its own drug.<sup>142</sup> This places the RPS at risk of losing profits, or even worse, failing to recover revenue from R&D of the product. A competitor's ability to file an abbreviated biologic application, based on the RPS's own clinical data, reduces a competitor's own R&D costs, which enable it to sell the generic drug at a significantly reduced price.<sup>143</sup>

To address this unsatisfactory situation, biopharmaceutical companies argue that marketing exclusivity is necessary to promote incentives for innovation in the field.<sup>144</sup> Without such exclusivity, pharmaceutical companies will be less inclined to research both innovative and less cutting-edge areas of biomedical treatment because of the inability to predict whether early investments will lead to strong and valid patents that produce profits.<sup>145</sup>

Biopharmaceutical companies also argue that marketing exclusivity is necessary to encourage innovation because brand-name companies can have their patents invalidated even though their drugs are innovative.<sup>146</sup> For example, a patent may be denied or invalidated because the inventor published his research prior to filing a patent application.<sup>147</sup> Marketing exclusivity mitigates this risk because once exclusivity is granted it offers strong product protection.<sup>148</sup>

Last of all, biomedical companies believe “the scope of regulatory exclusivity . . . corresponds better to relevant product markets than do patents. Regulatory exclusivity tracks the terms of regulatory product approvals, while

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139. *Id.*; 42 U.S.C. § 262(m).

140. Wendy H. Schacht & John R. Thomas, *Follow-On Biologics: The Law and Intellectual Property Issues*, CONG. RES. SERV. (2011), available at <http://www.fas.org/sgp/crs/misc/R41483.pdf>.

141. *See* Junod, *supra* note 125, at 481.

142. *Id.* at 482.

143. *Id.* at 481.

144. *Id.* at 482.

145. *See id.* at 483.

146. *Id.* at 484.

147. *Id.*; *see generally* 35 U.S.C. § 112.

148. Junod, *supra* note 125, at 484.

patent claims, drafted to distinguish an invention from the prior art, may correspond less closely to any commercial product.”<sup>149</sup>

## V. THE DANGER OF GRANTING MARKET EXCLUSIVITY FOR BIOLOGICS IN A FIRST-TO-INVENT SYSTEM AND THE NEED FOR MODIFICATION OF THE BPCIA

### A. *The Rise of the Biomedical Industry*

Due to technological limitations in the past, biotechnology has only recently become an important source of life-saving drugs. As a result, biopharmaceuticals are a widely unexplored area of medicine that holds the potential for large-scale production of new innovative products.

In the United States, companies have started to recognize this budding field and invest greatly into R&D to create new biological products.<sup>150</sup> For instance, in 2008, R&D expenditures of biologics were at \$30.4 billion, a significant increase from the \$26.1 billion spent in 2007.<sup>151</sup> These specialty drugs have become so popular that for several consecutive years, “biotech companies have secured more product approvals than their big pharma counterparts, even though big pharma significantly outspends the biotechnology industry on research and development[.]”<sup>152</sup> In addition, patient spending on biomedical drugs, “which account for about a quarter of all prescription drug costs, increased by 18.4 percent in 2012 even as the cost of traditional drugs dropped.”<sup>153</sup> These trends indicate that biotechnology is the pathway the drug industry will follow in the future.

### B. *Disincentives to Innovation in a Post-AIA Framework*

However, despite the huge increase in R&D of biologics, the AIA in conjunction with the BPCIA will create disincentives to the pioneering of innovative biological inventions in the biomedical field. These disincentives are a result of the AIA filing system, which grants the “first-inventor-to-file” a patent, even if another independent inventor already created the invention. As a result, competing inventors will be forced to file applications as early as possible to ensure patent protection of their products.

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149. Eisenberg, *supra* note 135, at 194.

150. Schacht, *supra* note 140, at 3.

151. *Id.*

152. ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 1 (Guatam Jaggi ed., 2007).

153. Thomas, *supra* note 7.

### 1. Provisional Patent and Disclosure Disincentives

In the case of biologics, provisional patents will be utilized to protect incomplete drug R&D due to the extremely competitive nature of the biomedical industry. Drug companies require a substantial amount of capital to research and develop innovative products.<sup>154</sup> To acquire such funds, these firms need financing from private investors.<sup>155</sup> However, investors do not provide financing for R&D without some indication that a product will generate future profits.<sup>156</sup> Therefore, patent protection on inventions is needed to encourage investors to provide capital to drug companies.

The enablement requirement produces a number of issues that affect investor confidence. For example, one problem is determining whether a specification that sets forth only “a single or a limited number of examples can be enabling of broad claims when the subject matter concerns biological materials or reactions, which are generally considered to be unpredictable.”<sup>157</sup> Both the USPTO and the Federal Circuit have often held that a small number of examples do not sufficiently enable an invention in such circumstances.<sup>158</sup> Due to increased pressure to file patent applications early,<sup>159</sup> there is a greater risk of inventors submitting specifications that fail to meet the enabling requirement. Although many of these patents will be approved of by the

154. See ALEX M. BRILL, PROPER DURATION OF DATA EXCLUSIVITY FOR GENERIC BIOLOGICS: A CRITIQUE 6 (Nov. 2008), available at [http://www.tevad.com/Brill\\_Exclusivity\\_in\\_Biogenetics.pdf](http://www.tevad.com/Brill_Exclusivity_in_Biogenetics.pdf).

155. See *id.*

156. See *id.*

157. See *Chisum*, supra note 69, § 7.03[4][d][i].

158. See *Ex parte* Forman, LEXIS 24, 4 (B.P.A.I. 1986) (noting that ultimate question is “whether or not the specification contains a sufficiently explicit disclosure to enable one having ordinary skill in the relevant field to practice the invention claimed therein without the exercise of undue experimentation.”); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991) (holding that the USPTO did not err in rejecting applicants’ generic claims to hybrid genes and transformed cells because “[t]here is no reasonable correlation between the narrow disclosure in [applicants’] specification and the broad scope of protection sought . . . .”); *In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993) (holding that the USPTO did not err in rejecting applicant’s broad claims to pathogenic RNA virus vaccines because his specification gave only a single working example); *In re* Goodman, 11 F.3d 1046 (Fed. Cir. 1993) (holding that the USPTO did not err by rejecting applicant’s broad claims to a method for producing mammalian peptides in any plant cell when applicant’s specification gave only a single working example, which involved the dicotyledonous species, tobacco, and a gene coding for gamma-interferon); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1377 (Fed. Cir. 1999) (holding that “the breadth of enablement in the patent specifications is not commensurate in scope with the claims, as the quantity of experimentation required to practice antisense in cells other than *E. coli* at the filing date would have been undue.”); For more in-depth analysis of the aforementioned cases, see *Chisum*, supra note 69, § 7.03[4][d][i].

159. As explained previously in the article, the AIA filing rules encourage inventors to file for patent protection earlier than under the Patent Act of 1952 because protection is now granted on a first-come-first served basis.

USPTO,<sup>160</sup> investors will be less prone to funding biomedical ventures because the patents will be more vulnerable to successful enablement challenges by competitors, which will increase the risk that these biologic patents will be invalidated

Another issue is whether a deposit of biological material is necessary.<sup>161</sup> Ordinarily, a deposit of biological material is not necessary if the specification provides sufficient guidance on how to produce the claimed invention from “publicly available source material.”<sup>162</sup> The Federal Circuit has determined that:

Where an invention depends on the use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written [description]. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues. . . . A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public. Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials. . . . No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation.<sup>163</sup>

In practice, the USPTO Board has sometimes held that a deposit is not necessary because the written specification was sufficiently enabling.<sup>164</sup>

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160. See *Ex parte* Goeddel, LEXIS 3, 3 (B.P.A.I. 1985).

161. *In re* Wands, 858 F.2d 731, 735–36 (Fed. Cir. 1988).

162. See Chisum, supra note 69, § 7.03[4][d][iii]; e.g., *Hybritech, Inc. v. Abbott Labs.*, 4 U.S.P.Q.2d 1001, 1011 (C.D. Calif. 1987), *aff'd*, 849 F.2d 1446, (Fed. Cir. 1988) (“the biological materials need not be deposited when the invention can be practiced without undue experimentation from biological materials available in prior art.”)(citation omitted); *Compare* *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 131 (2001) (for a utility patent on a plant, “the plant must meet the specifications of § 112, which require a written description of the plant and a deposit of seed that is publicly accessible. See 37 CFR §§ 1.801–1.809 (2001).”).

163. *In re* Wands, 858 F.2d at 735–36 (footnote omitted).

164. *Flehmg v. Giesa*, 13 USPQ 2d 1052, 1057 (B.P.A.I. 1989) (no deposit of the specific HAV strain (hepatitis A virus) used by the inventor is necessary when HAV is publicly available and the opposing party failed to show that HAV is strain specific); *Ex parte* Rinehart, 10 USPQ 2d 1719, 1720 (B.P.A.I. 1989) (no deposit necessary; the claimed process involved, inter alia, extracting “a

However, there are also a number of cases that have ruled the other way.<sup>165</sup>

The situation is also further exacerbated by the Federal Circuit's interpretation of the written specification requirement.<sup>166</sup> To satisfy the rule, "a [biologic] inventor is required to provide a comprehensive description of the compound for which patent protection is sought."<sup>167</sup> However, this can be particularly challenging for biologic inventors:

[w]hile it may be fairly straightforward to provide a description of a single biologic molecule (i.e., a protein therapeutic or monoclonal antibody) and to provide initial studies showing efficacy for certain indications, it may take several years to explore what changes can be made to the molecule to improve or preserve function.<sup>168</sup>

In addition, "characterizing the complete spectrum of diseases for which the biologic may have therapeutic benefits, developing a stable formulation, and developing large scale culture conditions may take several years."<sup>169</sup> As a result, licensing of follow-on biologics was not permitted until 2009 due to the technological complexity involved in creating biological products.<sup>170</sup>

Furthermore, although technology in the field of biologics has improved over time, biological treatments still remain as a largely unexplored area of medicine. Scientists have yet to identify most biological genera, or the accompanying species that comprise such groups.<sup>171</sup> Therefore, knowledge of how such biological organisms function is limited, and without in-depth research and analysis, patents produced will be poorly constructed by failing to fully characterize and identify claims.

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suitable marine tunicate from the family Didemnidae with MeOH:toluene (3:1)"; "the source of the marine organisms necessary for practice of the invention is described in detail in the specification by reference to specific locations in the sea"; "The marine tunicate are a well known class of marine microorganisms having definitive characteristics . . . [The applicant] has described the phylum, subphylum, class, order and suborder as well as where the organisms are located and how they can be obtained. The marine microorganisms are neither new nor unique but are commonly known and generally available to the public without any undue experimentation.").

165. See e.g. *Ex parte Jackson*, 217 USPQ 804 (B.P.A.I. 1982).

166. See generally, *Ariad*, 598 F.3d 1336. The case narrowed the scope of patent protection for claims that do not fully and completely characterize the invention.

167. Decaire, *supra* note 9, at 1059.

168. *Id.*

169. *Id.*

170. Rachel Macdonald, *Biologic copy-cat drug development is rising, bringing pharmaceutical companies together*, MEDILL REP. CHI. (May 10, 2012), <http://news.medill.northwestern.edu/chicago/news.aspx?id=205418>.

171. UNITED STATES PATENT AND TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2161.01 (9th ed., Aug. 2012, last rev. Jan 2013) (citing *Ariad*, 598 F.3d at 1349).

Poorly constructed patents are problematic for a variety of reasons. For example, patents with overly broad claims can pre-empt future research by enabling patent holders to refuse access to essential technology to follow-on inventors.<sup>172</sup> This has been of particular concern with nascent technologies, such as genetic inventions.<sup>173</sup>

Excessively broad patents can also encourage undesired behavior by patent holders, “who [can] use their titles to appropriate revenue from existing inventions marketed by other companies.”<sup>174</sup> This can result in “a broad patent on a basic invention with no substitutes [that] may be equivalent to having an exclusive right of exploitation over an essential facility, allowing its holder to bar follow-on inventors who would be willing to invest in R&D to create socially useful applications.”<sup>175</sup> In addition, broad patents have a tendency to confer wide-ranging protection, especially in new areas.<sup>176</sup> This protection can grant the patent holder more coverage than what they actually invented or discovered.<sup>177</sup>

Narrowly constructed patents are also problematic. For example, such patents can discourage research that promotes follow-on inventions.<sup>178</sup> “[E]xcessively weak and narrow patents [can also] deter business investment in R&D, as it becomes too easy for an imitator to undercut the inventor’s market price.”<sup>179</sup> Furthermore, narrow patents can encourage “secrecy at the expense of publicity, and harm markets for technology, [thus preventing] diffusion of technology.”<sup>180</sup>

In the context of biologics, poorly constructed patents will become more prevalent because of disincentives created by the new AIA’s filing rules, and disclosure requirements. The new framework will complicate matters by forcing inventors to race to the patent office and by also broadening the language of what constitutes as prior art.<sup>181</sup> As a result, biopharmaceutical companies will have no choice but to file for patent protection early, or else

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172. *Patents and Innovation: Trends and Policy Challenges*, *supra* note 12.

173. *See generally*, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), reh’g denied (Sept. 13, 2011), reh’g denied (Sept. 16, 2011), cert. granted, judgment vacated sub nom.; *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (U.S. 2013) (opinion vacated, appeal reinstated), 467 F. App’x 890 (Fed. Cir. 2012).

174. *Patents and Innovation: Trends and Policy Challenges*, *supra* note 12, at 10.

175. *Id.*

176. *Id.* at 18.

177. *Id.*

178. *Id.* at 10. For more information on how narrow patents can hinder follow-on inventions, please read Judge Bryson’s dissent in *Molecular Pathology*.

179. *Patents and Innovation: Trends and Policy Challenges*, *supra* note 12, at 10.

180. *Id.*

181. *Compare* 35 U.S.C. § 102(b) (2006), *with* AIA 2011 § 102(b).

face possible pre-emption. Without adequate time to fully characterize and identify their biological inventions, biomedical companies will produce more poorly constructed patents.

## 2. Market Exclusivity Disincentives

Another threat to innovation is the grant of market exclusivity to patent invalidated products. While such regulation can provide an additional layer of protection for inventors to encourage costly investments in innovation, it does not always do so.<sup>182</sup>

Under the BPCIA, market exclusivity hinders innovation by providing biopharmaceutical companies with a safety net in case their patents are invalidated. Competitors in such situations are denied the right to market the first-entrant's product, even though the biologic is no longer patent protected. As a result, first-entrant companies are being granted product monopolies even though their drugs are not considered innovative.

This marketing behavior will become more prevalent under the AIA's filing rules, which encourage applicants to file applications early, or risk pre-emption.<sup>183</sup> As a result, biomedical companies will be forced to file applications prematurely, producing more poorly constructed patents that are vulnerable to validity challenges.<sup>184</sup>

Biopharmaceutical companies may argue that market regulation is necessary to finance research into innovative biomedical inventions; however, the pharmaceutical industry's history contradicts this assertion, as shown by the fact that patents have been the main driving factor in encouraging private investments into drug R&D.<sup>185</sup>

### *C. Solutions to Protect Innovation in the Biologic Field*

There are two viable ways to safeguard innovation in the biologic field: (1) by modifying the BPCIA so that market exclusivity is withdrawn upon invalidation of a biological patent, or (2) denying biological inventors the ability to file for provisional patents.

#### 1. The Withdrawal of Market Exclusivity Upon Patent Invalidation

Some scholars have discussed the risks involved with withdrawing market

182. Eisenberg, *supra* note 126, at 487.

183. AIA 2011 § 102.

184. Biologics are still a widely unexplored field. Biomedical competition reduces the amount of time companies have to conduct R&D on prospective products because of competition in the field. Therefore, the claims in patent applications will not fully characterize and identify such biologics. As a result, patent applications that are approved will likely have claims that are overly broad/narrow.

185. Eisenberg, *supra* note 126, at 480.

exclusivity from biologic products that are patent invalidated. For example, Valerie Junod, a prominent pharmaceutical attorney from Geneva, has found that denying market exclusivity to non-innovative/un-patentable research outcomes may discourage firms from investing in biologic R&D.<sup>186</sup> She argues that marketing exclusivity may be necessary to encourage innovation because brand-name companies may lose their patents even though their drugs are innovative.<sup>187</sup> While these arguments may have held weight under the Patent Act of 1952, they no longer apply under the AIA.

Currently, R&D expenditures on biologics are estimated around \$30.4 billion.<sup>188</sup> In fact, data indicates that investments are increasing annually and that biotech companies are securing more product approvals for drugs than their pharmaceutical counterparts.<sup>189</sup> Therefore, denying market exclusivity to invalidated biologic patents will not deter innovation. Instead, it will encourage biomedical innovation by forcing inventors to carefully research and characterize claimed inventions before filing applications, or else risk losing market protection due to later patent invalidation. As a result, withdrawing market exclusivity from patent-invalidated products will protect the original legislative intent of the BPCIA.

## 2. The Removal of Provisional Patents from Biologic Patent Applications

Another viable way to safeguard innovation in the field is to deny biologic inventors the ability to file for provisional patents. Under the AIA, the filing guidelines encourage inventors to file patent applications swiftly, or risk pre-emption by a competitor's own filing. Provisional patents are a popular way to mitigate such risks, and provide benefits such as lower filing cost, the ability to extend the patent approval process, and the ability to pre-empt other inventors.<sup>190</sup> As a result, provisional applications will become more prevalent under the AIA.

However, in the biologic field the new filing rules pose significant risks to biomedical innovation because biologics "are complex mixtures that are not easily identified or characterized."<sup>191</sup> Biopharmaceutical companies compete

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186. Junod, *supra* note 125, at 482.

187. *Id.* It should be noted that Junod's article is really a criticism on market exclusivity. In the paper, she highlights what she believes to be legitimate arguments in favor of market exclusivity.

188. Lynne Taylor, *Big Biotech Growth "Outpacing Big Pharma"*, PHARMATIMES (April 19, 2013) [http://www.pharmatimes.com/article/13-04-19/Big\\_Biotech\\_growth\\_%E2%80%259D\\_Coutpacing\\_Big\\_Pharma%E2%80%9D.aspx](http://www.pharmatimes.com/article/13-04-19/Big_Biotech_growth_%E2%80%259D_Coutpacing_Big_Pharma%E2%80%9D.aspx) ("Revenue growth for Big Biotech grew 40.6% to \$48.6 billion at the end of 2012, from \$34.3 billion three years before, compared to an increase of 17% for Big Pharma, whoses [sic] revenue rose to \$526.8 billion from \$450.1 billion during the same period.")

189. Junod, *supra* note 125, at 482.

190. AIA 2011 § 111(b).

191. *What are "Biologics" Questions and Answers*, *supra* note 4.

in a high-risk, high reward environment, where the first firm to acquire a patent on a product typically reaps the benefits. Therefore, these companies already face significant pressure to file patents early. The AIA further exacerbates the problem by imposing stricter filing guidelines that only grant patents on a first-come-first-serve basis.<sup>192</sup> Thus, inventing and/or conceiving an invention is no longer enough to ensure patent protection.

As a result of the AIA, biopharmaceutical companies will be forced to file for patent protection earlier. Biomedical competition will reduce the time companies have to conduct R&D on prospective inventions, and will force applicants to file applications that fail to fully identify and characterize the biologics. Therefore, applications that are approved, and eventually granted full patent coverage, will provide overly broad/narrow patent protection to non-innovative inventions.

However, modifying the BPCIA so that inventors can no longer acquire provisional patents will solve this issue. Biomedical firms rely on investors to acquire funding for R&D. Removing provisional patents as an option will encourage biotechnology companies to spend more time conducting R&D on their prospective inventions, thus increasing the number of innovative biological patents that fully characterize and identify the biologics. As a result, these patents will be less susceptible to validity challenges, and investors will feel more confident about providing capital to such businesses. Such predictability is an important factor that venture capitalists look at when deciding whether to invest in a business.<sup>193</sup>

In addition, removing provisional patents from the table will also reduce the amount of litigation in the biotechnology field. Without the ability to file provisional patents, biomedical companies will be encouraged to conduct extensive R&D to ensure that the USPTO approves their patent applications. Therefore, biologic patents that are approved will provide detailed specifications, which will discourage competing biologic firms from challenging the validity of innovator companies' patents.

The last benefit this proposal has, is that it will lessen the number of overly broad/narrow biologic patents the USPTO approves. Patents in the biomedical field tend to claim subject matter in broad terms because of uncertainty in the field.<sup>194</sup> As a result, biologic firms are granted protection over subject matter

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192. AIA 2011 § 102.

193. *To Get Venture Capital Funding Know the Risks and Tell a Good Story*, FORBES (March 2, 2012) <http://www.forbes.com/sites/knowledgewharton/2012/03/02/to-get-venture-capital-funding-know-the-risks-and-tell-a-good-story/>.

194. See *Falkner v. Inglis*, 448 F.3d 1357 (Fed. Cir. 2006) (discussing § 2215 (WRITTEN DESCRIPTION REQUIREMENT; NO WORKING EXAMPLE OR GENE SEQUENCE; PRIOR ART PUBLICATIONS): a claimed invention required, inter alia, inactivating an "essential" gene in a

that is not mentioned in detail in their patent specifications. This opens biomedical firms up to enablement and adequate written description challenges, and in the interim, prevents other competing companies from conducting research in the patent protected field, due to the possibility of infringing the patent.

There are a few risks that will arise from the approach proposed. Removing provisional patents as an option in the biopharmaceutical field will decrease the amount of capital invested into biopharmaceutical firms. Investors are sensitive to risk, and removing provisional patents as an option creates a risk that competing firms will file for a patent before the investor's firm is able. Due to the amount of money required to conduct R&D for biomedical firms, investors will be wary of providing capital when the risk of pre-emption is a looming threat. With fewer investors providing capital for research, there will be a decrease in the number of innovative products being produced by biologic companies. In addition, it may also encourage biomedical firms to engage in more secretive behavior to protect their scientific data, which could result in less information being divulged to the public. The government's purpose in granting patents in the first place is to advance scientific knowledge in the national community.<sup>195</sup>

However, although these fears may be warranted in certain industries, the biomedical field is not one of them. As mentioned earlier, biologic research is a booming field in the United States.<sup>196</sup> Despite the small amount of research conducted in the area, biologic drugs already account for around a quarter of all prescription drug costs.<sup>197</sup> Therefore, it is highly unlikely that investors and firms will decrease the level of capital they invest into such businesses to innovate new products. In addition, although biomedical companies may engage in more secretive behavior if provisional applications were no longer allowed, it would only delay dissemination of such information to the public until the firm files for a patent.

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poxvirus vector; a patent specification complied with the written invention description requirement, even though it set forth no working example or gene sequence; prior art publications set forth the poxvirus genome and the locations of "essential regions"; testimony indicated that one skilled in the art would have been able to locate an "essential" gene, even though that may have required extensive time and expense); *Adang v. Fischhoff*, 286 F.3d 1346 (Fed. Cir. 2002); *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338 (Fed. Cir. 2000), cert. denied, 532 U.S. 1019 (2001); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 n.10, (Fed. Cir. 1999) (recognizing that "In view of the rapid advances in science, . . . what may be unpredictable at one point in time may become predictable at a later time.").

195. See U.S. CONST. art. I, § 8, cl. 8.

196. Schacht, *supra* note 140, at 3.

197. Thomas, *supra* note 7.

## VI. CONCLUSION

In conclusion, the AIA in conjunction with the BPCIA will create disincentives to the pioneering of innovative biologic inventions in the biomedical field. These disincentives are a result of the new filing system under the AIA, and can only be solved through modification of the BPCIA. Without reform, drug companies will apply for patent protection prematurely, resulting in poorly constructed non-innovative patents that receive product exclusivity although their patents may be later invalidated. The best solution to safeguard innovation in such circumstances is by modification of the BPCIA so that market exclusivity is withdrawn upon invalidation of a biological patent, or by denying biological inventors the right to file for provisional patents.

Biopharmaceutical companies may argue that market exclusivity is necessary to promote incentives to innovate in the biomedical field, due to the costs associated with developing new biotechnology drugs (around \$1.2 billion).<sup>198</sup> Furthermore, they may assert that such protection is necessary due to potential generic competition caused by delays in regulatory approval of their biologic drugs. However, economic projections of how well biopharmaceutical companies will do in the future, and current estimates on patient spending on biological products, contradict these claims.

In 2012, patient spending on biomedical drugs accounted for around a quarter of prescription drug costs, and in fact, increased by 18.4 percent from 2011.<sup>199</sup> Furthermore, revenues from specialty drugs have continued to rise in the double-digit territory, and have even outpaced the ten percent growth rate seen in 2009 and 2010.<sup>200</sup> Therefore, recent data shows that modification of the BPCIA will not significantly harm the biopharmaceutical industry.

So, in light of these modifications, how can the pharmaceutical industry continue to produce breakthrough innovations in medicine as revenues come under pressure as a consequence of healthcare reform (PPACA), increased competition (AIA), and government regulation (BPCIA) in bringing new drugs to market? The answer remains the same: growth opportunities in emerging biotechnologies.

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198. Schacht, *supra* note 140 at 3.

199. Thomas, *supra* note 7.

200. ERNST & YOUNG, BEYOND BORDERS: GLOBAL BIOTECHNOLOGY REPORT 1 (Guatam Jaggi ed. 2012).

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