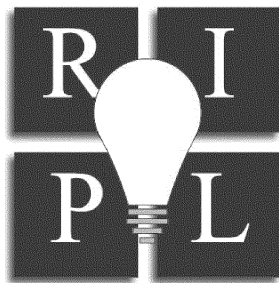


# THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



## THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS

KATHERINE N. ADDISON

### ABSTRACT

The Biologics Price Competition and Innovation Act of 2009 provides an abbreviated FDA approval pathway for biosimilars. The passage of this biosimilar legislation is a positive step toward retaining a robust biotechnology industry in the United States while also protecting innovators. The Act's increased FDA exclusivity is welcome, but FDA exclusivity alone is insufficient to encourage and protect innovation and investment in biosimilars. Instead, the exclusivity provided by a patent term, together with the ability to adjust this term to compensate an applicant for U.S. Patent and Trademark Office and FDA delays, is necessary to ensure development of highly specialized and resource-intensive biologics. This article suggests a closer correlation of the patent term with FDA market approval. The author argues that while it may be difficult to strike a perfect balance, all will benefit when innovator biologics have strong patent protection coupled with long FDA exclusivity periods.

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KATHERINE N. ADDISON

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## THE IMPACT OF THE BIOSIMILARS PROVISION OF THE HEALTH CARE REFORM BILL ON INNOVATION INVESTMENTS

KATHERINE N. ADDISON\*

### I. INTRODUCTION

For the first time, the United States has a statutory abbreviated approval pathway for biosimilars to enter the market. This pathway, called the Biologics Price Competition and Innovation Act of 2009 (the “Act”)<sup>1</sup> was signed by President Obama in March 2010. The abbreviated approval pathway provided for by the Act is timely as traditionally small-molecule pharmaceutical companies devote more resources to biologics development.<sup>2</sup> The biopharmaceutical industry is now worth nearly \$600 billion for manufacturers internationally and the United States constitutes almost half of that market.<sup>3</sup> Despite economic downturn, the industry has still progressed, and was expected to increase by five percent in 2010.<sup>4</sup> Medical market analysts predict that the market for pharmaceuticals will be almost \$800 billion by 2015, representing more than a six percent growth in five years.<sup>5</sup>

In 2010, it was estimated that fifty percent of all new drugs approved by the U.S. Food and Drug Administration (“FDA”) would be biologics, and sales of biologics were expected to exceed \$60 billion by the end of the year.<sup>6</sup> Biosimilar producers can

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<sup>1</sup> The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 98 Stat. 1585, (codified at 42 U.S.C.A. § 18001 (West 2011)). The Biosimilars provision is included in the Patient Protection and Affordable Care Act. *Id.* The individual mandate included in the Patient Protection and Affordable Care Act (health care law), that requires Americans to have commercial insurance, has been challenged four times since it was enacted for being unconstitutional. Kevin Sack, *Federal Judge Rules That Health Law Violates Constitution*, N.Y. TIMES, Feb. 1, 2011, at A1. Twice it has been declared constitutional, and twice it has been declared unconstitutional. *Id.* The most recent holding by the U.S. District Court for the Northern District of Florida held that the individual mandate of the health care law was not only unconstitutional, but also “inextricably bound” to the rest of the bill, rendering the health care law in its entirety was unconstitutional. *Florida v. U.S. Dept. of Health & Human Service* 2011 WL 285683, at \*33–34 (N.D. Fla. Jan. 31, 2011). The previous three conflicting holdings coupled with this most recent holding clear a path to take the issue to the Supreme Court. Sack, *supra* note 1.

<sup>2</sup> *Emerging Health Care Issues: Follow-on Biologic Drug Competition* FED. TRADE COMM’N, i (June 2009), <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>.

<sup>3</sup> Bruce Carlson, *Biologics Pipeline Set to Replenish Coffers*, GENETIC ENG’G & BIOTECH. NEWS (Aug. 1, 2010), <http://www.genengnews.com/gen-articles/biologics-pipeline-set-to-replenish-coffers/3366>.

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> See Press Release, Rep. Henry A. Waxman, Bipartisan Group of Members Introduces “Promoting Innovation and Access to Life-Saving Medicines Act” (Mar. 11, 2009), <http://www.henrywaxman.house.gov/News/DocumentSingle.aspx?DocumentID=115183>; see Henry

take advantage of this economic opportunity. Accordingly, there arose a need for regulation to prevent the public from unscrupulous, opportunistic copycats that attempt to free ride off the goodwill of more reputable establishments.<sup>7</sup>

### A. Definition of Biologics

“Biologics” are medicines created through a combination of living organisms.<sup>8</sup> Most pharmaceuticals, comprised of small molecules, are much less complex than biologics.<sup>9</sup> Biologics are commonly referred to as protein-based drugs in contrast to small-molecule drugs.<sup>10</sup> Recombinant therapeutic proteins are complicated products made up of a variety of organisms including bacteria, yeast, mammal cells and enzymes.<sup>11</sup> The characteristics of recombinant drugs are heavily influenced by the production process.<sup>12</sup> The concentration of proteins, temperature of production, amino acid arrangement, and molecular weight all affect the final product.<sup>13</sup>

The development of biologics has provided new avenues to treat multiple diseases including HIV/AIDS, cancers, arthritis, hemophilia, and many others.<sup>14</sup> The development of an in vitro production system has allowed for recombinant human genetic material to be used to create new drugs.<sup>15</sup> Further, the development of monoclonal antibody technology, combined with knowledge acquired in the Human Genome Project, has paved the way for target medicines.<sup>16</sup> Both gene therapy and cell therapy have emerged as new methods of attacking diseases.<sup>17</sup>

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Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFFAIRS 1291, 1291 (2006) (explaining that biologics are growing at twice the rate of prescription drugs).

<sup>7</sup> See generally Jay Pil Choi & Marcel Thum, *Market Structure and the Timing of Technology Adoption with Network Externalities*, 42 EUR. ECON. REV. 225, 230 (1998) (explaining that when many entities enter a market, as is the case for emerging technologies, prices are competitively low); see FTC, *supra* note 2, at 1.

<sup>8</sup> Matthew J. Seamon, *Antitrust and the Biopharmaceutical Industry: Lessons From Hatch-Waxman and an Early Evaluation of the Biologics Price Competition and Innovation Act of 2009*, 34 NOVA L. REV. 629, 650 (2010).

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> Benjamin Leader et al., *Protein Therapeutics: A Summary and Pharmacological Classification*, 7 NATURE REV. 21, 21 (2008).

<sup>12</sup> See *id.*

<sup>13</sup> Wen-Ching Chan et al., *Learning to Predict Expression Efficacy of Vectors in Recombinant Protein Production*, BIOMED CENT. (Jan. 18, 2010), <http://www.biomedcentral.com/1471-2105/11/S1/S21>.

<sup>14</sup> See Hearing on the Potential Need for Measurement Standards to Facilitate the Research and Development of Biologic Drugs, House Sci. & Tech. Subcomm. on Tech. & Innovation, 111th Cong. (2009) (statement of Anthony Mire-Sluis, Exec. Dir. of Global Prod. Quality at Amgen); PHARM. RESEARCH & MFRS. OF AM., 418 BIOTECHNOLOGY MEDICINES IN TESTING PROMISE TO BOLSTER THE ARSENAL AGAINST DISEASE (2006), *available at* <http://www.allhealth.org/briefingmaterials/PhRMA418BiotechMeds-415.pdf>; Arachu Castro & Michael Westerhaus, *How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?*, 3 PLOS MED. 1230, 1232 (2006).

<sup>15</sup> See, e.g., Robert Boehm, *Bioproduction of Therapeutic Proteins in the 21st Century and the Role of Plants and Plant Cells as Production Platforms*, 1102 ANN. N.Y. ACAD. SCI. 121–34 (2007).

<sup>16</sup> *Id.*

<sup>17</sup> See *id.*

### *B. Differences Between Biologics and Small-Molecule Drugs*

Biologics are not classified in a scientific manner the same as small-molecule drugs because they are much larger and more complex.<sup>18</sup> It is not possible to create a “generic” biologic that is identical to the innovator biologic.<sup>19</sup> Because of the complexity of the production process, biosimilars are difficult to replicate exactly.<sup>20</sup> A biologics producer would not have access to the original process, formulas, or equipment, all which affect the outcome.<sup>21</sup> Some have gone as far to say the process cannot be replicated exactly.<sup>22</sup> Notably, these changes can have serious ramifications on the safety of the drug.<sup>23</sup> The differences in production of two similar biologics can trigger very different immunogenic responses.<sup>24</sup> Even a small temperature change during manufacturing can result in a change in immunology.<sup>25</sup> Therefore, unlike simple or common chemical drugs, a change in biologics, including biosimilars, can have serious consequences and create health concerns.<sup>26</sup>

Biosimilars are not generic drugs.<sup>27</sup> Generic drugs are copies of innovative drugs, are similar in composition and safety, and have met the same standards of the FDA.<sup>28</sup> Alternatively, conventional pharmaceuticals are composed of small molecules through chemical reactions.<sup>29</sup> It is possible to make an exact copy of small-molecule drugs, even if the drug is branded and patent-protected.<sup>30</sup> For example, both Tylenol® and a generic version of the drug are made up of the same atoms in the same structure.<sup>31</sup> Biologics, however, are far more complex.<sup>32</sup> For example, Herceptin® is a popular anti-cancer biologic comprised of about 25,000 atoms. This is more than a thousand times the number of atoms in Tylenol®.<sup>33</sup> It follows then,

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<sup>18</sup> See *Biosimilars*, MASSBIO, [http://www.massbio.org/public\\_policy/federal\\_issues/biosimilars](http://www.massbio.org/public_policy/federal_issues/biosimilars) (last visited Mar. 25, 2011); see also Comm’r Pamela Jones Harbour, Remarks at the ABA Sections of Antitrust and Intellectual Property Law Meeting: The Competitive Implications of Generic Biologics 3, 5 (June 14, 2007), <http://www.ftc.gov/speeches/harbour/070614genbio.pdf> (explaining that biologics are known as large molecules and are hard to classify chemically compared to small-molecule drugs).

<sup>19</sup> Sally Pipes, *A Primer for Follow-on Biologics*, REAL CLEAR POLITICS (June 6, 2008), [http://www.realclearpolitics.com/articles/2008/06/a\\_primer\\_for\\_followon\\_biologic.html](http://www.realclearpolitics.com/articles/2008/06/a_primer_for_followon_biologic.html); see Harbour, *supra* note 18, at 5.

<sup>20</sup> See Harbour *supra* note 18, at 6.

<sup>21</sup> See *id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> Basant G. Sharma, *Manufacturing Challenges for Biosimilars—The Process Defines the Product*, 13 EUR. J. HOSP. PHARMACISTS PRACS. 54, 55 (2007).

<sup>26</sup> See *Understanding Generic Drugs*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm> (last updated Mar. 25, 2011); Mary Shedden, *A Dose of Safety*, TAMPA TRIB., May 31, 2008, at 14 (explaining that generic drugs must be therapeutically interchangeable).

<sup>27</sup> Barbara Mounho et al., *Global Regulatory Standards for the Approval of Biosimilars*, 65 FOOD & DRUG L.J. 819, 825 (2010).

<sup>28</sup> See *Understanding Generic Drugs*, *supra* note 26.

<sup>29</sup> See Pipes, *supra* note 19.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

that it would be a much more complicated manufacturing task to try and consistently arrange 25,000 atoms.

Additionally, the manufacturing process for biologics is far more complicated. Most biologics must be grown in living organisms, and many involve modified DNA.<sup>34</sup> In fact, “[e]ach molecule of a biologic may have a slightly different structural pattern—even if it has the same chemical formula and is made according to the exact same process.”<sup>35</sup> For larger molecules it is more difficult to control the resulting structural pattern.<sup>36</sup>

A biosimilar, unlike generic drugs, “is a product that is similar to, but not the same as, the innovator drug.”<sup>37</sup> Because of the complexity involved, the FDA and foreign regulators have determined that the approval pathway for generic drugs would not be sufficient for complex biologics.<sup>38</sup> Even small differences in biotechnology drugs have been known to lead to uncertain outcomes in effectiveness and safety, and also to create health hazards such as immunogenicity (causing an immune response).<sup>39</sup>

The FDA prohibits generic drug makers, from obtaining data on drugs targeted for copying until five years after they have been approved.<sup>40</sup> In Europe, this “data

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<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> See Simon D. Roger & Ashraf Mikhail, *Biosimilars: Opportunity or Cause for Concern?*, 10 J. PHARMACY PHARM. SCI. 405, 405 (May 18, 2007).

<sup>37</sup> *Taking the Pulse: FDA to Hold Hearings on Biosimilars*, BIOTECH NOW (Oct. 6, 2010, 2:16 PM), <http://biotech-now.org/section/health/2010/10/06/taking-pulse-fda-hold-hearings-biosimilars>.

<sup>38</sup> See generally Richard G. Frank, *Regulation of Follow-on Biologics*, 357 NEW ENG. J. MED. 841 (2007) (explaining that the Hatch-Waxman framework for small-molecule drugs, which creates a regulatory pathway for generic competition, does not apply to biopharmaceuticals, and arguing that Congress must create a new regulatory regime for biopharmaceuticals if it wishes to foster generic competition in the field); Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301–399d (2006). The FDA regulates how biologics enter the market under the PHSA and the Federal Food Drug and Cosmetic Act (“FDCA”). *Id.* Two organizations previously shared the regulatory responsibility including pre-market and post-market evaluations. See *The Law of Biologic Medicine: Hearing before the Senate Comm. on the Judiciary*, 108th Cong. (2004). These organizations are the Center for Biologics Evaluation and Research (“CBER”), which handles, for example, gene therapy and vaccines; and the Center for Drug Evaluation and Research (“CDER”), which handles, for example, monoclonal antibodies. See *Center for Biologics Evaluation and Research (CBER) Responsibilities Questions and Answers*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/CBER/ucm133072.htm> (last updated Apr. 30, 2009). Prior to the Act, when a biologic entered the market, the innovator company was required to file an Investigation New Drug (“IND”) application. *Id.*; see also *About the Center for Drug Evaluation and Research*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/CDER/default.htm> (last updated Nov. 29, 2010). The approval process involves preclinical development, clinical development, approval, and marketing oversight. *Development & Approval Process (Drugs)*, FDA, <http://www.fda.gov/drugs/developmentapprovalprocess/default.htm> (last updated Oct. 27, 2010). Section 351 of the Public Health Service Act requires the innovator company to file a Biologics License Application (“BLA”). The FDA has approved some biologics, such as insulin, however, through the traditional process for small molecule drugs provided by the Hatch-Waxman Act.

<sup>39</sup> Daniel E. Troy, *The Difference with Biologics: The Scientific, Legal, and Regulatory Challenges of any Follow-On Biologics Scheme*, BIO INDUS. ORG., 7 (Apr. 25, 2007), <http://www.bio.org/healthcare/followonbkg/WhitePaper.pdf>.

<sup>40</sup> See Pipes, *supra* note 19.

exclusivity” period is six or ten years, depending on the country.<sup>41</sup> The recently passed legislation for biosimilars in the United States provides manufacturers of new biologics products twelve years of exclusivity.<sup>42</sup> Interpretation as to whether the twelve years of exclusivity means data exclusivity or marketing exclusivity is currently under debate,<sup>43</sup> but at the present time the FDA seems to characterize it as the latter.<sup>44</sup> In any case, the four-year wait-to-file period provided by the recently passed legislation may operate as a data exclusivity period. At a minimum it should prevent biosimilar producers from making use of innovator data following approval of the innovator’s biologics license application (“BLA”).

### C. Historical Background

#### 1. Europe Procedure

Compared with the European regulation of biologic pharmaceuticals, which includes already adapted procedures for approving secondary versions of a drug, the United States is behind in the process.<sup>45</sup> The approval procedure is predicated on a showing of comparability of a similar product to an already approved product.<sup>46</sup>

Europe adopted a case-by-case analysis for applications of new biosimilars.<sup>47</sup> This standard for creating a duplicate of an original drug offers little insight into the amount of testing—how little or how much relative to the original testing—that may be required in order to gain approval.<sup>48</sup> Ultimately, the European Medicines Agency (“EMA”) will determine the scrutiny of the testing for a secondary product, with some data on efficacy and safety considered for market approval.<sup>49</sup> The EMA has

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<sup>41</sup> Eur. Generic Med. Ass’n, *Data Exclusivity*, EGA GENERICS, <http://www.egagenerics.com/gen-dataex.htm> (last visited Mar. 25, 2011).

<sup>42</sup> Tracy L. Muller & Timothy J. Shea, Jr, *New U.S. Law Establishes Long Awaited Abbreviated Approval Pathway for Biosimilars*, NAT’L L. REV. (Apr. 12, 2010), <http://www.natlawreview.com/article/new-us-law-establishes-long-awaited-abbreviated-approval-pathway-biosimilars>. The exclusivity term is extendable to twelve and a half years when pediatric studies are undertaken. *Id.*

<sup>43</sup> Emily K. Strunk, *Debate Over Exclusivity in Biologics Provision of PPACA Heats Up*, HEALTH REFORM RESOURCE CTR., <http://aghealthreform.com/2011/02/14/debate-over-exclusivity-in-biologics-provision-of-ppaca-heats-up> (last visited Mar. 25, 2011).

<sup>44</sup> See Approval Pathway for Biosimilar and Interchangeable Biological Products, 75 Fed. Reg. 61,497, 61,498, 61,500 (Oct. 5, 2010).

<sup>45</sup> Linda Park, *The Generic Pharmaceutical Industry*, REG. SCI. – UNIV. S. CAL., 19, <http://regulatory.usc.edu/Articles/GenericPharmaceuticalIndustry.pdf> (last visited Mar. 25, 2011) (article adapted and edited by Daya Perkins, Roger Clemens & France Richmond).

<sup>46</sup> See Comm. for Med. Prods. for Human Use, *Guideline on Similar Biological Medicinal Products*, EUR. MEDICATION AGENCY (Oct. 5, 2005), <http://www.ema.europa.eu/pdfs/human/biosimilar/043704en.pdf>.

<sup>47</sup> Mark Senak, *What Can be Learned from Europe’s Regulation of Biogenerics?*, BIOTECH 360 <http://www.biotech360.com/biotechArticleDisplay.jsp?biotechArticleId=100016> (last visited Mar. 25, 2011).

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*; see Grabowski, *supra* note 6, at 1297.



approved two human growth hormone products, Sandoz's Omnitrope and Biopartners' Valtropin®, which are similar to Somatropin.<sup>50</sup>

Europe appears to be more receptive to approving biosimilars, although recent positive recommendations and approvals have been focused around the red-blood-cell-stimulating drug erythropoietin.<sup>51</sup> This drug is the main component of Johnson & Johnson's Eprex®, which is marketed by Amgen and Johnson & Johnson as Epogen® in the United States.<sup>52</sup> It is not surprising that second-comer "generic" drug-makers want a piece of the action, provided that the drug currently costs patients \$10,000 or more per year in the United States.<sup>53</sup>

The year 2007 marked the beginning of the biosimilars era in Europe.<sup>54</sup> In August 2007, Novartis received marketing approval for its epoetin alfa equivalent to treat anemia, commonly associated with chronic renal failure and chemotherapy.<sup>55</sup> In October 2007, Hospira received a positive recommendation from the Committee for Medicinal Products for Human Use ("CHMP") for its follow-on version of epoetin zeta, which it named Retacrit®, and in December 2007 the European Commission (which usually follows the CHMP's recommendation) gave marketing approval.<sup>56</sup> Hospira began marketing the drug in Europe in 2008 (initially in Germany and Austria in January and February and in the United Kingdom in May).<sup>57</sup>

## 2. United States Development, Legislative History

Prior to 2010, there was not a clear pathway for biosimilar approval in the United States.<sup>58</sup> Although the Drug Price Competition and Patent Restoration Act of 1984 ("Hatch-Waxman Act"),<sup>59</sup> and its corresponding regulations provide a complex set of rules to govern the approval and market-entry of generic drugs, the Act's

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<sup>50</sup> See *Europe Clears Second Biosimilar Product*, PHARMA TIMES ONLINE (May 5, 2006), [http://www.pharmatimes.com/Article/06-05-05/Europe\\_clears\\_second\\_biosimilar\\_product.aspx](http://www.pharmatimes.com/Article/06-05-05/Europe_clears_second_biosimilar_product.aspx).

<sup>51</sup> See Melissa J. Heinrichs & Gary M. Owens, *Where Generics and Biologics Meet*, AM. HEALTH & DRUG BENEFITS, 23 (June 2008), <http://www.ahdbonline.com/article/where-generics-and-biologics-meet>.

<sup>52</sup> Andrew Pollack, *Amgen and Johnson & Johnson Recall Anemia Drugs*, N.Y. TIMES BLOG (Sept. 24, 2010, 12:34 PM), <http://prescriptions.blogs.nytimes.com/2010/09/24/amgen-and-johnson-johnson-recall-anemia-drugs/>.

<sup>53</sup> Bruce Jaspen, *Hospira Drug Processes in Europe*, CHI. TRIB. ONLINE (Oct. 25, 2007), [http://www.chicagotribune.com/business/chi-thu\\_notebook\\_1025oct25,0,233584.story](http://www.chicagotribune.com/business/chi-thu_notebook_1025oct25,0,233584.story).

<sup>54</sup> See, e.g., Media Release, Sandoz, Sandoz Receives European Commission Approval for Biosimilar *epoetin alfa* (Aug. 31, 2007), <http://hugin.info/134323/R/1150279/220459.pdf>.

<sup>55</sup> *Id.*

<sup>56</sup> Comm. for Medicinal Prods. for Human Use, *October 2007 Plenary Meeting Monthly Report*, EMEA (Oct. 25, 2007), [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Committee\\_meeting\\_report/2009/10/WC500006238.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Committee_meeting_report/2009/10/WC500006238.pdf).

<sup>57</sup> See Transcript of Hospira, Inc., Q1 2008 Earnings Call (May 7, 2008), <http://seekingalpha.com/article/76200-hospira-inc-q1-2008-earnings-call-transcript>.

<sup>58</sup> See Anurag Rathore, *Biosimilars*, 64 PDA J. PHARM. SCI. & TECH. 289, 289 (2010).

<sup>59</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.). Congress enacted the Hatch-Waxman Act as a compromise between competing public policy interests. The legislation sought to create an incentive for innovator companies to develop and market new small molecule drugs to counter the cost regulatory requirements of the USPTO and the FDA. It also sought to create incentives for generic drug companies to introduce generic versions of drugs.

Abbreviated New Drug Application (“ANDA”) provisions specifically exclude biologics.<sup>60</sup> Congress likely did not include biologics within the scope of the Hatch-Waxman Act’s ANDA provisions because only a few biotechnology-derived drugs existed when the Hatch-Waxman Act was enacted in 1984. Additionally, perhaps Congress appreciated the difficulty in verifying bioequivalence in biologically derived drugs given the extant technology.<sup>61</sup> Evolving technology has significantly improved the ability to produce and test bioequivalence for biologically derived drugs.<sup>62</sup>

Henry A. Waxman’s new bill, Promoting Innovation and Access to Life-Saving Medicine Act, is designed “to provide for the licensing of biosimilar and biogeneric products.”<sup>63</sup> The introduction of this bill was one of many other similar attempts to create a system for biosimilar approval.<sup>64</sup> The numerous bill proposals, like Representative Waxman’s, created a sense of urgency to address the biosimilars issue.<sup>65</sup> Consequently, the Patient Protection and Affordable Care Act contains sections that permit approval of biosimilars.<sup>66</sup>

Only a few biosimilars have been authorized in the United States under the ANDA procedures, such as Menotropins (in January 1997) and Enoxaparin (in July 2010), and eight others.<sup>67</sup> The FDA has permitted regulatory approval of biological

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<sup>60</sup> See Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,951 (Apr. 28, 1992) (comments to the new rules stating that “[t]hese procedures are inapplicable to antibiotics (which are approved under section 507 of the act) and biological drug products licensed under 42 U.S.C. 262”).

<sup>61</sup> *Id.*; see also John A. Little, Jr., *Taking from Trailblazers: Learning from Those Who Have Gone Before When Approving Biosimilars*, 44 GA. L. REV. 1097, 1118 (2010).

<sup>62</sup> See Comm. for Medicinal Prods. for Human Use, *Guideline on Similar Biological Medicinal Products Containing Monoclonal Antibodies*, EUR. MED. AGENCY (Nov. 18, 2010), [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2010/11/WC500099361.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/11/WC500099361.pdf).

<sup>63</sup> H.R. 1427, 111th Cong. (2009).

<sup>64</sup> See, e.g., Pathway for Biosimilars Act, H.R. 5629, 110th Cong. (2008); Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. (2007); Access to Life-Saving Medicines Act, H.R. 1038, 110th Cong. (2007).

<sup>65</sup> Amber W. Aagaard, et al., *Review, Approval, and Marketing of Biosimilars in the United States*, BIOPROCESS INT’L, 12 (Dec. 2010), [http://www.bioprocessintl.com/multimedia/archive/00111/BPI\\_A\\_100811AR02\\_O\\_111127a.pdf](http://www.bioprocessintl.com/multimedia/archive/00111/BPI_A_100811AR02_O_111127a.pdf).

<sup>66</sup> Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119 (2010) (codified in scattered sections of title 28, 29, 35, and 42 U.S.C.) (enacting Biologics Price Competition and Innovation Act of 2009, H.R. 3590, 111th Cong.). H.R. 3590 provides for the licensing of “biosimilar” and “interchangeable” biological products. See *id.* § 7002(a)(2). A follow-on product will be considered “biosimilar” if it is “highly similar” to the original product and “there are no clinically meaningful differences between the biological product and the [original] product in terms of the safety, purity, and potency of the product.” *Id.* § 7002(b)(3). A product will be considered “interchangeable” if it is biosimilar, it “can be expected to produce the same clinical result . . . in any given patient,” and the risk of switching the patient one or more times between the original product and the biological product can be expected to be not significantly greater, in terms of safety or diminished effectiveness, than the risk of continuing to use the original product without such switching. *Id.* § 7002(a)(2). Approved interchangeable products “may be substituted for the [original] product without the intervention of the health care provider who prescribed the [original] product.” *Id.* § 7002(b)(3); Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Bill, With a Flourish*, N.Y. TIMES, Mar. 24, 2010, A19.

<sup>67</sup> See Krista H. Carver et al., *An Unofficial Legislative History of the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 671, 685–86 (2010); Aagaard, *supra* note 65 (explaining the FDA has approved 10 follow in biologics through December 2010).

products under § 505(b)(2), as new drug applications (“NDA”).<sup>68</sup> This kind of application relies on the FDA’s prior approval of a drug’s safety, requiring only a showing of similarity to the already approved drug.<sup>69</sup> The law requires the new applicant to show that any difference between the second drug and the originally approved drug does not change the safety or effectiveness of the second drug.<sup>70</sup> Additionally, a § 505(b)(2) applicant must certify and explain that the application does not infringe on an already existing patent listed in the “Orange Book.”<sup>71</sup> The original inventor, however, could bring a lawsuit under 35 U.S.C. § 271, which could end up in a thirty-month delay of approval while the suit is carried out.<sup>72</sup> Products marketed under § 505(b)(2) applications, can receive an “AB” Orange Book rating, meaning they are formulaically and therapeutically similar.<sup>73</sup>

In 2004, the acting commissioner of the FDA explained there was not sufficient legal basis upon which to approve biosimilars, which were based on biologics originally approved under the Public Health Service Act.<sup>74</sup> Since 2004, the FDA has held public meetings on follow-on protein products and Congress has held hearings on the issues.<sup>75</sup> On March 17, 2009, the Pathway for Biosimilars Act was introduced

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<sup>68</sup> See *Guidance for Industry: Applications Covered by Section 505(b)(2)*, FDA (1999), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079345.pdf>; Little, *supra* note 61, at 1108–09.

<sup>69</sup> Donna M. Gitter, *Innovators and Imitators: An Analysis of Proposed Legislation Implementing an Abbreviated Approval Pathway for Follow-On Biologics in the United States*, 35 FLA. ST. U. L. REV. 555, 569–70 (2008).

<sup>70</sup> See, e.g., 21 C.F.R. § 314.54 (2010) (“Procedure for Submission of an Application Requiring Investigations for Approval of a New Indication for, or Other Change from, a Listed Drug”).

<sup>71</sup> See 21 U.S.C. § 355 (2006); Letter from Osmotica to FDA (July 24, 2009), <http://www.regulations.gov#!documentDetail;D=FDA-2009-P-0356-0001>; *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FDA, <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated Dec. 21, 2010).

<sup>72</sup> See Cynthia Luchetti, *Market Exclusivity Strategies for Pharmaceuticals*, 23 PHARM. MED. 77, 81, 83 (2009).

<sup>73</sup> See Mukesh Kumar & Hemant Jethwani, *The 505(b)(2) Drug Development Pathway: When and How to Take Advantage of a Unique American Regulatory Pathway*, FDA (Apr. 2010), [http://www.amarexero.com/articles/docs/RAPS\\_Focus\\_505b2\\_Apr2010.pdf](http://www.amarexero.com/articles/docs/RAPS_Focus_505b2_Apr2010.pdf).

<sup>74</sup> See Dr. Lester Crawford, Acting Comm’r FDA, Statement before the Senate Comm. on the Judiciary, *The Law of Biologic Medicine* (June 23, 2004), <http://www.fda.gov/NewsEvents/Testimony/ucm113745.htm>; see also *Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29, 40 (D.D.C. 2006) (granting the biosimilar producer’s summary judgment regarding egregious delay in FDA reviewing an ANDA under 505(b)(2)). In 2003, Sandoz submitted an ANDA to the FDA under section 505(b)(2) for a growth hormone that was a biosimilar. *Id.* at 31. The active ingredient in the product was the same as Pfizer’s Genitropin, a recombinant growth hormone that had been on the market for fifteen years prior to Sandoz’s ANDA filing. *Id.* The ANDA was based upon the FDA approval of Genitropin and Sandoz claimed the products were indistinguishable. *Id.* Following pressure from Pfizer to reject the application, the FDA deferred evaluation of the application due to the complexity and nature of the biologic. *Id.* Over a year later, Sandoz took action against the FDA due to the long delay in evaluating the application. *Id.* The court granted Sandoz’s motion for summary judgment and the FDA subsequently approved Sandoz’s FOB. *Id.* The FDA cautioned in its approval that they did not intend to approve all FOBs using the Hatch-Waxman small molecule pathway to marketability of generics and explained they did not have the authority to approve future FOBs. *Id.*

<sup>75</sup> See, e.g., *Follow-On Protein Products: Regulatory and Scientific Issues Related to Developing*, FDA, <http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/ucm085854.htm> (last updated June 22, 2010); Janet Woodcock, Deputy Comm’r, FDA, Statement before the SubComm. on

in the House.<sup>76</sup> Then, on March 23, 2010, President Obama allowed approval of biosimilars when he signed the Patient Protection and Affordable Care Act, which created the Biologics Price Competition and Innovation Act (“BPCIA”).<sup>77</sup>

## II. THE NEW LEGISLATION

### A. Terms

As expected, because of the complex nature of biologics compared to traditional chemically synthesized drugs, the new legislation is quite rigorous in its demands on biosimilars or “subsection (k) applicants” (“Applicants”).<sup>78</sup> In fact, the BPCIA requires Applicants to submit analytical, animal, and clinical studies.<sup>79</sup> Analytical studies must demonstrate that the biological product is highly similar to the referenced product notwithstanding minor differences in clinically inactive components.<sup>80</sup> Animal studies must include an assessment of toxicity.<sup>81</sup> Clinical studies must include an assessment of immunogenicity and pharmacokinetics or pharmacodynamics sufficient to demonstrate safety, purity, and potency in one or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biosimilar product.<sup>82</sup>

Additionally, Applicants must disclose evidence to support the same mechanism or mechanisms, to the extent known, of action as the pioneer biologic or reference product.<sup>83</sup> Applicants must also demonstrate that the biosimilar product is appropriate for the same conditions of use previously approved for the reference product and that the biosimilar product has the same route of administration, dosage form, and strength as the reference product.<sup>84</sup> Applicants can only rely on one previously approved reference product per subsection (k) follow-on application.<sup>85</sup> Thus, an Applicant cannot rely on two or more reference products in attempt to gain approval for a combination follow-on product.<sup>86</sup> Finally, Applicants must consent to an inspection of the facility in which the biosimilar is made.<sup>87</sup>

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Health, House Comm. on Energy and Commerce (May 2, 2007), <http://www.fda.gov/NewsEvents/Testimony/ucm154017.htm>.

<sup>76</sup> See *H.R. 1548 Pathway for Biosimilars Act*, OPENCONGRESS, <http://www.opencongress.org/bill/111-h1548/show> (last visited Mar. 25, 2011).

<sup>77</sup> See *H.R. 3590: Patient Protection and Affordable Care Act*, GOVTRACK.US, <http://www.govtrack.us/congress/bill.xpd?bill=h111-3590> (last visited Mar. 25, 2011).

<sup>78</sup> See 42 U.S.C.A. § 262(l)(1)(A) (West 2011).

<sup>79</sup> *Id.* § 262(k)(2)(A)(i)(I)(bb).

<sup>80</sup> *Id.* § 262(k)(2)(A)(i)(I)(aa).

<sup>81</sup> *Id.* § 262(k)(2)(A)(i)(I)(bb).

<sup>82</sup> *Id.* § 262(k)(2)(A)(i)(I)(cc).

<sup>83</sup> *Id.* § 262(k)(2)(A)(i)(II).

<sup>84</sup> *Id.* § 262(k)(2)(A)(i)(III)–(IV).

<sup>85</sup> *Id.* § 262(k)(5)(A).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* § 262(k)(3)(B).

The BPCIA distinguishes between biosimilarity and interchangeability.<sup>88</sup> As a result, biosimilars that are also interchangeable must satisfy additional criteria.<sup>89</sup> Biosimilar is defined as: “(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.”<sup>90</sup> Interchangeable means that the “biological product may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.”<sup>91</sup> Thus, in order to find a biosimilar interchangeable, the FDA must establish that, for a drug administered multiple times, substitution of an Applicant’s product for an approved pioneer biologic does not increase risks associated with treatment or decrease efficacy.<sup>92</sup> A major advantage of a finding of interchangeability is that an exclusivity period of one year, from first commercial marketing, or other relevant period is granted against subsequent biosimilars relying on the same reference product.<sup>93</sup>

### *B. Procedure*

The BPCIA grants an exclusivity period of twelve years to the reference product or pioneer biologic for which a biologics license application has been previously approved.<sup>94</sup> Thus, the FDA will not approve a biosimilar for an Applicant effective until twelve years after the date of approval of the reference product on which it relies.<sup>95</sup> Additionally, the Applicant must wait until four years after the approval of the reference product before filing the subsection (k) application alleging biosimilarity and interchangeability.<sup>96</sup> These wait-to-file and exclusivity periods do not apply when the same manufacturer that made the reference product creates a supplemental or new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength.<sup>97</sup>

Biosimilar applications under subsection (k) are treated as confidential by the FDA and only made available to reference product sponsors, patent owners, the legal counsel of both groups, and select others.<sup>98</sup> In fact, it is the Applicant’s duty to provide a copy of the application to the reference product sponsor, along with any other information that describes the process or processes used to manufacture the

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<sup>88</sup> *Id.* § 262(i)(2)–(3).

<sup>89</sup> *See id.* § 262(k)(4).

<sup>90</sup> *Id.* § 262(i)(2).

<sup>91</sup> *Id.* § 262(i)(3).

<sup>92</sup> *See* Judith Johnson, *FDA Regulation of Follow-On Biologics*, CONG. RESEARCH SERV., (Apr. 26, 2010) [http://www.primaryimmune.org/advocacy\\_center/pdfs/health\\_care\\_reform/Biosimilars\\_Congressional\\_Research\\_Service\\_Report.pdf](http://www.primaryimmune.org/advocacy_center/pdfs/health_care_reform/Biosimilars_Congressional_Research_Service_Report.pdf).

<sup>93</sup> 42 U.S.C.A. § 262(k)(6). *Contra* 21 U.S.C. § 355 (2006) (providing 180 days of exclusivity to the first ANDA filer).

<sup>94</sup> *See* 42 U.S.C.A. § 262(k)(7)(A).

<sup>95</sup> *Id.*

<sup>96</sup> *Id.* § 262(k)(7)(B). This term extends to four and a half years if pediatric studies are undertaken.

<sup>97</sup> *Id.* § 262(k)(7)(C).

<sup>98</sup> *Id.* § 262(l).

follow-on biological product that is the subject of the application.<sup>99</sup> The applicant must do this within twenty days after receiving notification that the subsection (k) application has been accepted for review.<sup>100</sup> Then, within sixty days of receipt of the application, the reference product sponsor has the opportunity to notify the Applicant of a list of potentially infringed patents that it owns or licenses along with those patents, if any, it is willing to license to the Applicant.<sup>101</sup> The Applicant has sixty days to respond to the reference product sponsor's list of patents with either a statement that it does not intend to begin commercial marketing of the biological product before the patent expires; or a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of the Applicant's opinion that such patent is invalid, unenforceable or not infringed by the commercial marketing of the Applicant's subsection (k) biological product.<sup>102</sup> The reference product sponsor and Applicant then have fifteen days to reach an agreement as to which patents will be infringed.<sup>103</sup> If no agreement is reached, then the reference product sponsor has thirty days to bring a patent infringement action.<sup>104</sup> The Applicant has an affirmative duty to notify the Secretary of the Department of Health and Human Services of any subsequent infringement action.<sup>105</sup>

While the recent legislation mandated an abbreviated approval pathway for biologics, the details of this pathway remain to be tested with a first case.<sup>106</sup> In order to implement the new legislation, the FDA created the Biosimilar Implementation Committee.<sup>107</sup> The committee will hold public meetings and solicit commentary from stakeholders, experts, innovators, patients, and the public on the various issues with the new approval process.<sup>108</sup> Although the Committee has hosted several meetings already and requested public comments, it is estimated that it will take several years for the FDA to fully implement a procedure.<sup>109</sup> FDA spokesperson Karen Mahoney has not confirmed any hearings or provided any insight as to when generic biologics

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<sup>99</sup> *Id.* § 262(l)(2).

<sup>100</sup> *Id.*

<sup>101</sup> *Id.* § 262(l)(3).

<sup>102</sup> *Id.* § 262(l)(3)(B).

<sup>103</sup> *Id.* § 262(l)(4)(B).

<sup>104</sup> *Id.* § 262(l)(6)(B).

<sup>105</sup> *See id.* § 262(l)(2)–(6).

<sup>106</sup> *See* Michael P. Dougherty, *The New Follow-On-Biologics Law: A Section by Section Analysis of the Patent Legislation Provisions in the Biologics Price Competition and Innovation Act of 2009*, 65 FOOD & DRUG L.J. 231, 245 (2010).

<sup>107</sup> *Implementation of the Biologics Price Competition and Innovation Act of 2009*, FDA, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm> (last updated Mar. 10, 2011).

<sup>108</sup> *Id.*

<sup>109</sup> *See* Janet Woodcock, Deputy Comm'r for Operations, U.S. Dep't. of Health & Human Services, Statement on Heparin Testimony before Comm. on Energy & Commerce (Apr. 29, 2008), <http://www.hhs.gov/asl/testify/2008/05/t20080429a.html>; Maxwell R. Morgan, *Regulation of Innovation Under Follow-On Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93, 100 (2010); *FDA Holds Public Hearing on Biosimilar Pathway*, GENERICS AND BIOSIMILARS INITIATIVE (Oct. 29, 2010), <http://www.gabionline.net/Biosimilars/News/FDA-holds-public-hearing-on-biosimilars-pathway>.

may be approved.<sup>110</sup> In fact, she has stated, “There are so many factors that will impact when biosimilar products will enter the market, [t]herefore, it is not reasonable to speculate.”<sup>111</sup> A candid statement from Congressman Michael C. Burgess is consistent with this sentiment: “This is a difficult concept, and it does involve a lot of moving parts, and a lot of different contingencies. For your average member of Congress—or even for your member of Congress with some background in health—it does become difficult to think about these things.”<sup>112</sup>

### *C. Beneficiaries*

There are numerous beneficiaries of the new legislation including the innovators (reference product sponsors), the biosimilar manufacturers (subsection (k) applicants), and members of the general public who purchase biologics. The following section outlines the ways in which each of these distinct beneficiary groups is affected by a biosimilar approval pathway.

#### *1. Innovators*

Reference product sponsors are rewarded for their efforts to bring products to market with twelve years of FDA exclusivity.<sup>113</sup> Even in the absence of enforceable patents to cover the pioneer products, the BPCIA provides an independent avenue to achieve exclusivity for a limited period of time.<sup>114</sup> Due to uncertainty and a long wait period in obtaining a patent, this guaranteed exclusivity provides investors with greater security that the research and development costs incurred in bringing a product to market and obtaining FDA approval will be recouped.<sup>115</sup> When investors have greater security and sense less risk, they are more likely to invest and to invest larger amounts.<sup>116</sup> With more investment, then development, and a move from academia to the lab to the marketplace, is likely for a greater number of potentially life-saving biological products.<sup>117</sup>

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<sup>110</sup> See Denise Napoli, *Generic Biologics’ Safety Questioned as Approval Process Stalls*, SKIN & ALLERGY NEWS (Sept. 1, 2010), [http://www.skinandallergynews.com/index.php?id=372&cHash=071010&tx\\_ttnews\[tt\\_news\]=16835](http://www.skinandallergynews.com/index.php?id=372&cHash=071010&tx_ttnews[tt_news]=16835).

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> See 42 U.S.C.A. § 262(k)(7) (West 2011).

<sup>114</sup> See Morgan, *supra* note 109, at 98.

<sup>115</sup> Emily K. Strunk, *Debate Over Exclusivity in Biologics Provision of PPACA Heats Up*, HEALTH REFORM RESOURCE CTR., <http://aghealthreform.com/2011/02/14/debate-over-exclusivity-in-biologics-provision-of-ppaca-heats-up> (last visited Mar. 25, 2011); see Hilary Greene, *Patent Pooling Behind the Veil of Uncertainty: Antitrust, Competition Policy, and the Vaccine Industry*, 90 B.U. L. REV. 1397, 1431–51 (2010) (discussing the economic impact of patent exclusivity in pharmaceutical production).

<sup>116</sup> See Ted Buckley et al., *Data Exclusivity Period Length and Federal Government Savings from Enactment of the Biologics Price Competition and Innovation Act of 2007* (Working Paper, Jan. 26, 2009), <http://ssrn.com/abstract=1333263>.

<sup>117</sup> See *id.*

## 2. Biosimilar Producers

Under the BPCIA, Applicants benefit because less money is required to obtain product approval and enter the marketplace than before.<sup>118</sup> Applicants have to wait four years after a reference product is approved before filing their biosimilar application and twelve years either: (i) to actually use the data in the reference product application to get their biosimilar product approved; or (ii) to market their approved biosimilar, depending on how the exclusivity period granted by the Act is ultimately construed.<sup>119</sup> Before passage of the BPCIA there was no pathway for obtaining approval of a complex biologic (biotech or biopharmaceutical) product without receiving enough funding to undertake lengthy clinical trials.<sup>120</sup> Now, with the opportunity to rely on some of the research investments and findings of others (reference product sponsors) after a fixed time period, the BPCIA allows a greater number of biologics manufacturers to enter the marketplace by reducing the barriers to entry.<sup>121</sup> This enables these same manufacturers to use their resources on product improvements and other future problems.<sup>122</sup>

## 3. Public Consumers

With reduced barriers to entry, and more companies in the marketplace producing similar or interchangeable biologic products, consumers benefit through reduced prices.<sup>123</sup> These consumers include patients in need of biologic therapeutics, their employers, health insurance providers, and taxpayers in general who fund public health programs including Medicare for the elderly and Medicaid for the poor.<sup>124</sup> Reduced prices, caused by greater competition, benefit each of these groups by reducing the amount spent on healthcare.<sup>125</sup> Money spent in any one place has an opportunity cost of not being spent in another place; reducing money spent on healthcare allows cost saving benefits to be realized.<sup>126</sup> Furthermore, spending the saved money in other areas could stimulate the U.S. economy.<sup>127</sup> To employers: less expensive healthcare plans, due to decreased biologic treatment costs, translates to higher profit, which allows the companies to hire more employees.<sup>128</sup>

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<sup>118</sup> See Henry Grabowski et al, *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFFAIRS 1291, 1293 (2006).

<sup>119</sup> See 42 U.S.C.A. § 262(k)(7)(A)–(B) (West 2011).

<sup>120</sup> See Morgan, *supra* note 109, at 96; see also Grabowski *supra* note 118, at 1292.

<sup>121</sup> See Grabowski, *supra* note 118, at 1293.

<sup>122</sup> See Strunk, *supra* note 115.

<sup>123</sup> Richard Epstein, OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION 96 (2006).

<sup>124</sup> See Napoli, *supra* note 110.

<sup>125</sup> See *id.*; *Improving Health Care: A Dose of Competition*, DEP'T OF JUSTICE, 4 (July 2004), <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

<sup>126</sup> Uwe E. Reinhardt et al., *U.S. Health Care Spending In an International Context*, 23 HEALTH AFFAIRS 10, 18–19 (2004), <http://content.healthaffairs.org/content/23/3/10.full.html>.

<sup>127</sup> *Id.*

<sup>128</sup> Cf. *Improving Health Care*, *supra* note 125 (discussing the substantial burden and stress that increased costs of healthcare have imposed on health care providers and the employment-based health insurance system).



### III. DATA EXCLUSIVITY VS. MARKET EXCLUSIVITY

In a recently published article, Maxwell Morgan highlights the distinction between data exclusivity and market exclusivity and advocates for the latter.<sup>129</sup> As mentioned, the type of exclusivity intended under the BPCIA is currently under debate. It was initially thought that the BPCIA would provide the former, data exclusivity. Data exclusivity would prevent biosimilar companies from substituting an innovator's data to obtain FDA approval for a full twelve years.<sup>130</sup> Conversely, market exclusivity would prevent biosimilar producers from having their applications approved and marketing their products for twelve years from the date of approval of the pioneer biologic.<sup>131</sup> In a sense, market exclusivity is stronger because it would prevent generic firms from entering the market, even if they were willing to replicate the original trials. Although data exclusivity does not extend this right, it could be potentially more powerful (assuming generic producers do not want to or cannot incur the costs of generating their own data) because it delays the date on which generic producers can submit their subsection (k) applications.<sup>132</sup> Applications not submitted until after twelve years of data exclusivity will not be simultaneously approved and accordingly, the effective exclusivity period would be longer than twelve years. As Morgan notes, an example of market exclusivity is provided with the Orphan Drug Act, which induces investment into research on rare diseases with small patient populations by assuring pioneer investors the entire small patient population market for a term.<sup>133</sup>

### IV. INTERPLAY OF PATENT PROTECTION AND FDA EXCLUSIVITY

#### *A. Overlap*

With both patent protections providing the right to exclude others from copying along with automatic FDA exclusivity upon obtaining approval, there is likely to be some overlap in exclusivity terms.<sup>134</sup> The terms, however, serve different needs and are awarded for satisfying different objectives.

Patent exclusivity is granted for disclosing a product that is useful, novel, and not obvious in view of what has come before it.<sup>135</sup> In order to obtain a patent, an applicant must present a detailed and thorough written description sufficient to enable a person skilled in the art to make and use the invention, including disclosure of the best mode for practicing the invention.<sup>136</sup> This detailed information is

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<sup>129</sup> See Morgan, *supra* note 109, at 98–99.

<sup>130</sup> *Id.* at 98.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> See 35 U.S.C. § 154(a)(2) (2006). Market exclusivity to prevent others from coming within the scope of the patent claims (infringing) although others can still enter the market with similar products that fall outside or design around the scope of the claims.

<sup>135</sup> 35 U.S.C. §§ 101–103 (2006).

<sup>136</sup> *Id.* § 112.

published eighteen months from the earliest priority date claimed although the patent may not be granted until five or more years after the earliest application is filed.<sup>137</sup> The delay for a patent is so long due to the backlog at the U.S. Patent & Trademark Office (“PTO”).<sup>138</sup> This backlog results in a long wait time before the applicant even receives an initial substantive response from a patent examiner at the PTO, followed by a period of communication in which the applicant amends the claims and/or presents arguments to the PTO as to why the invention is patentable in view of cited reference art. Most patents are not granted in the first office action but require a period of negotiating the scope and language of the claims.<sup>139</sup>

In contrast, information provided in an FDA application is not immediately or promptly available to the general public but may be held in confidence for a longer time period or indefinitely.<sup>140</sup> Additionally, the information that required for FDA approval may prove safety and effectiveness of a product but it does not necessarily enable others to make and use the product.<sup>141</sup> Furthermore, a product that is safe and effective, though useful, is not necessarily novel or non-obvious and thus may not meet the threshold for patentability.<sup>142</sup>

Awarding exclusivity for a patent serves the need for public disclosure of information in order to spread knowledge and spur innovation.<sup>143</sup> Patent exclusivity also satisfies the objective of providing a reward to truly significant leaps in technology.<sup>144</sup> The patentable material must not only be new or novel but also not obvious in view of the referenced art.<sup>145</sup> To determine whether the claimed subject matter of a patent application is not obvious in view of what has come before it the PTO and courts consider the perspective of a “person having ordinary skill in the art.”<sup>146</sup> The question is whether it would have been obvious to this person.<sup>147</sup> Tests have been developed through the case law and incorporated into the Manual of Patent Examining Procedures (“MPEP”), a reference guide for patent examiners and applicants, to help determine whether something is obvious or not.<sup>148</sup> One test is the “teaching-suggestion-motivation” (“TSM”) test which serves to prevent against hindsight bias.<sup>149</sup> Even assuming the inventive subject matter is a combination of known elements, it may still be patentable if there was no teaching, suggestion, or motivation existing (at the time the application was filed or the invention was

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<sup>137</sup> *Id.* § 122(b)(1).

<sup>138</sup> *See, e.g., Patent Inventory Statistics—FY09*, U.S. PAT. & TRADEMARK OFFICE <http://www.uspto.gov/patents/stats/appbacklog.jsp> (last visited Mar. 25, 2011).

<sup>139</sup> *See First Office Action Pendency (months)*, DATA VISUALIZATION CTR. (Feb. 2011), <http://www.uspto.gov/dashboards/patents/main.dashxml>; *General Information Concerning Patents*, U.S. PAT. & TRADEMARK OFFICE (Jan. 2005), <http://www.uspto.gov/web/offices/pac/doc/general>.

<sup>140</sup> *See, e.g., Dennis S. Fernandez & James T. Huie, Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity*, 7 ASIAN PAC. BIOTECH. NEWS 998, 999 (2003).

<sup>141</sup> U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2164.05 (8th ed. 8th Rev., July 2010) [hereinafter MPEP].

<sup>142</sup> *See, e.g., Astrazeneca LP v. Apotex, Inc.*, 97 U.S.P.Q.2d 1029, 1047 (Fed. Cir. 2010).

<sup>143</sup> *See* U.S. CONST. art. I, § 8, cl. 8; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–51 (1989).

<sup>144</sup> *See Bonito Boats*, 489 U.S. at 150–51.

<sup>145</sup> 35 U.S.C. §§ 102–103 (2006).

<sup>146</sup> *See id.* § 103(a).

<sup>147</sup> *Id.*

<sup>148</sup> MPEP, *supra* note 141, § 2141.

<sup>149</sup> *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006).

conceived).<sup>150</sup> Another well-known inquiry to elucidate the meaning of “obvious” is consideration of factors (“The Graham Factors”) outlined by the U. S. Supreme Court in *Graham v. John Deere Co.*<sup>151</sup> The Court held that obviousness should be determined by looking at: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness.<sup>152</sup> Factors that show “objective evidence of nonobviousness” are: (1) commercial success; (2) long-felt but unsolved needs; and (3) failure of others.<sup>153</sup>

For example, commercial success assists to prove that the invention provides something truly valuable to the marketplace for which there are not ready alternatives.<sup>154</sup> Long-felt but unsolved need supports the theory that the invention which solves the needs is not obvious or it would have been solved earlier.<sup>155</sup> Evidence of the failure of others trying to address the same problem with which the invention is concerned suggests the solution was not readily ascertainable or obvious to people of ordinary skill in the art.<sup>156</sup> Long-felt but unsolved needs and failed attempts of others can also lead to teaching away from addressing the problem with certain methods.<sup>157</sup> If an invention has nonetheless managed to resolve the problem with methods that other people of ordinary skill in the art advise against then there is a greater chance that the invention is not obvious because contemporary authorities were pointing in a different direction to find the solution.<sup>158</sup> Non-patentable products can have economic value too, but patentable products are likely to have greater value because they must pass the nonobvious inquiry.<sup>159</sup> Products that are not obvious are less likely to have readily available alternatives or substitutes and are more likely to offer something original to society.<sup>160</sup> A biologic or pharmaceutical product can be safe and effective, and gain FDA approval without being nonobvious—without being patentable—or, in other words, while being obvious.<sup>161</sup> It makes sense to provide a greater reward in the form of a patent term longer than the FDA exclusivity period, for products that are patentable and nonobvious because they are less likely to have readily available alternatives and substitutes and are more likely to require greater resources to conceive.<sup>162</sup> To take on greater risk, investors require greater reward.<sup>163</sup> Previously unserved groups of

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<sup>150</sup> See *KSR Int'l v. Teleflex, Inc.*, 550 U.S. 398, 405–06, 415, 419 (2007).

<sup>151</sup> 383 U.S. 1, 17–18 (1966).

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Graham*, 383 U.S. at 17–18.

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> See *United States v. Adams*, 383 U.S. 39, 52 (1966).

<sup>158</sup> See *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986).

<sup>159</sup> See *Assessing the Value of a Patent: Things to Bear in Mind*, WORLD INTEL. PROP. ORG., [http://www.wipo.int/sme/en/documents/valuing\\_patents.htm](http://www.wipo.int/sme/en/documents/valuing_patents.htm) (last visited Mar. 25, 2011).

<sup>160</sup> Lauren J. Stiroh et al., *Market Power in Technology Markets*, in ANTITRUST/INTELLECTUAL PROPERTY CLAIMS IN HIGH TECHNOLOGY MARKETS: LITIGATING AND ADVISING (ALI-ABA Course of Study) (1999), available at WL, SD72 ALI-ABA 61.

<sup>161</sup> *Astrazeneca LP v. Apotex, Inc.*, 97 U.S.P.Q.2d 1029, 1047 (Fed. Cir. 2010).

<sup>162</sup> See Fernandez, *supra* note 140.

<sup>163</sup> See, e.g., Robert J. Rhee, *The Application of Finance Theory to Increased Risk Harms in Toxic Tort Litigation*, 23 VA. ENVTL. L.J. 111, 123–24 (2004).

consumers benefit from new products.<sup>164</sup> A nonobvious product without alternatives or substitutes is more likely to serve these consumers or to address a previously unresolved, ignored, or marginalized class of problems.<sup>165</sup>

Granting FDA exclusivity for new market-approved products serves the need of stimulating the translation of biochemical theories and lab experiments to safe and effective marketable products.<sup>166</sup> FDA exclusivity satisfies the objective of providing a reward for investing in the lengthy and expensive clinical trials necessary to establish safety and effectiveness.<sup>167</sup>

The patent term may overlap the FDA exclusivity term at the beginning of the exclusivity term if the patent was filed and is granted early.<sup>168</sup> The patent term may also overlap the FDA exclusivity term at the end of the exclusivity term if the patent was filed late or is granted late.<sup>169</sup> If the patent application is filed and the patent is granted late then a patent term at the end of the FDA exclusivity term could provide a total exclusivity period longer than the current twenty year patent term.<sup>170</sup> This could generate additional revenue for late filers that obtain patents. With filing later, there is the inherent gamble that while one is investing sums in clinical trials for a product, the rights to the future product are uncertain. There is the risk that someone else is going to file on the same or equivalent subject matter first and then a party developing the product that does not file for patent protection may infringe the filing party's patent and expose the non-filing company to liability. Alternatively, the non-filing company may be forced to infringe, pay a royalty license, or pay a larger fee to purchase a patent. Filing early makes it more likely no one else will get the rights to a product first and one will not have to choose between not entering the market, entering and risking infringement, or trying to negotiate a license or purchase from the patent owner.

Another interesting comparison, aside from the order of the start date of the respective exclusivity terms and chronological position of the overlap, is the independent economic value that each type of exclusivity provides. For example, an FDA exclusivity period can stand alone and generate independent economic value if a patent is not granted.<sup>171</sup> If the FDA exclusivity period is interpreted as data exclusivity, this would restrict the market by making barriers to entry steeper.<sup>172</sup> For example, costs to entry would be higher because any company seeking to have its product approved sooner (before twelve year exclusivity period of pioneer reference product expires) would have to incur the expense of its own clinical trials to produce its own data rather than relying on the data of others. FDA market exclusivity

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<sup>164</sup> See generally Lee Petherbridge, *Road Map to Revolution? Patent-Based Open Science*, 59 ME. L. REV. 339 (2007) (asserting that rights granted by patent law serve as a stimulus for innovation which reaches underserved markets).

<sup>165</sup> See *id.* at 356–68.

<sup>166</sup> See generally Morgan, *supra* note 109 (standing for the proposition that market exclusivity would allow the FDA to adopt rules that would promote research).

<sup>167</sup> *Id.*

<sup>168</sup> See Strunk, *supra* note 115; Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 96–97 (2004).

<sup>169</sup> See Kuhlik, *supra* note 168, at 96–97.

<sup>170</sup> *Id.*

<sup>171</sup> See Morgan, *supra* note 109, at 98 (demonstrating that marketing approval is by obtaining FDA approval and not a patent).

<sup>172</sup> See *id.*

would provide even greater independent economic value. On the other hand, a patent term that protects a product requiring FDA approval prior to marketing is virtually worthless standing alone without FDA approval.<sup>173</sup> If a patent was granted to protect a therapeutic biologic but the biologic cannot gain FDA approval, then it cannot enter the market and the patent's value substantially disappears because the right to exclude others from that which one cannot do has little value compared to the right to exclude others from that which one can do; the former prevents others from getting ahead but does not move one forward, while the latter moves one forward while also preventing others from catching up.<sup>174</sup>

### *B. Is Patent Protection Still Needed?*

There has been some debate in late 2010 and early 2011 on the interpretation of the twelve year exclusivity period set out in the BPCIA.<sup>175</sup> More specifically, whether the twelve year period is for data exclusivity or market exclusivity is at issue. As mentioned, many initially believed the twelve year exclusivity period afforded by the BPCIA was for data exclusivity.<sup>176</sup> Data exclusivity would mean that no biosimilar producer could rely on the data already submitted in the reference product sponsor's application for twelve years, measured from "the date on which the reference product was first licensed."<sup>177</sup> A limitation of data exclusivity is that it does not prevent biosimilar producers from collecting their own data to cover their proposed biosimilar products.<sup>178</sup> A second comer can collect and submit its own independent data to support an independently filed biologics license application ("BLA") and, in the absence of patent protection, if the FDA approves there is nothing the pioneer manufacturer can do to preclude the second comer from competing in the marketplace.<sup>179</sup> Many generic manufacturers are considering this option of collecting their own data and filing a traditional BLA as a way to circumvent any new procedure implemented based on the BPCIA if such new procedures become unduly restrictive, burdensome, or risky. Despite their classification as "generic" manufacturers, many second comer companies have some trade secrets and intellectual property of their own that they would not want to disclose to innovators as required by the BPCIA to the extent that manufacturing processes are critical for evaluation of the characteristics of the biologic product and for evaluation of patent infringement.<sup>180</sup> If the FDA provided market exclusivity instead of data exclusivity for pioneer biologics this would solve the problem of innovators without patent protection being unable to stop biosimilar producers from generating their own data or replicating data to get their own products to market sooner.<sup>181</sup> More recently, it

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<sup>173</sup> See 21 U.S.C. § 355 (2006) (explaining new drugs cannot be marketed without approval).

<sup>174</sup> *Id.*

<sup>175</sup> See Strunk, *supra* note 115.

<sup>176</sup> See 42 U.S.C.A. § 262(k)(2), (k)(7) (West 2011).

<sup>177</sup> See *id.* § 262(k)(7)(A).

<sup>178</sup> See *id.*

<sup>179</sup> See Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. L. REV. 345, 360 (2007).

<sup>180</sup> See *infra* Part II.B.

<sup>181</sup> See Morgan, *supra* note 109; see *infra* Part III.

appears the FDA is characterizing the twelve year exclusivity period referred to in the BPCIA as marketing exclusivity.<sup>182</sup> It seems generic producers would generally support this interpretation because the alternative is that if the twelve year period applied to data exclusivity, the effective marketing exclusivity period would be much longer because Applicants would not be able to submit their subsection (k) applications using the innovators' data until the expiration of twelve years.<sup>183</sup> Then, Applicants would have to wait longer for a response from the FDA, the typical back and forth of prosecution, submitting additional materials, and finally, approval.

While this debate is not yet settled, as there are no implementing regulations or draft guidances for the biosimilar approval pathway made available by the BPCIA, it appears that the likely interpretation will be that the Act provides twelve years of marketing exclusivity with four years of effective data exclusivity in the wait-to-file period. If generic producers are able to rely on innovator data after four years, then they can submit their applications early for review, so that by the time marketing exclusivity of the innovator biologic ends eight years later, their biosimilar products can be immediately or soon thereafter approved under subsection (k).

### *1. Disadvantages of FDA Exclusivity Without Patent Protection*

Without patent protection it is doubtful that enough information will be publicly available for academics and skilled scientists, researchers and engineers to utilize.<sup>184</sup> This lack of publicly available information will hinder progress and result in economic waste as multiple parties spend money pursuing the same aims and efforts.<sup>185</sup> Without the possibility of an economically valuable patent and the chance for a limited term monopoly, inventors and their employers have no incentive to disclose the intimate details of their technologies and it will be economically advantageous and logical to instead keep this information confidential as trade secrets.<sup>186</sup>

Applications for FDA approval do not require of applicants the same burden as applications for a patent. Applications for a patent require

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

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<sup>182</sup> See Approval Pathway for Biosimilar and Interchangeable Biological Products, 75 Fed. Reg. 61,497, 61,498, 61,500 (Oct. 2010) (public hearing and request for comments); Kurt Karst, *Tussle over BPCIA "Market" Versus "Data" Exclusivity Continues, This Time the Generic Supporters Chime In*, FDA LAW BLOG (Jan. 21, 2011), [http://www.fdalawblog.net/fda\\_law\\_blog\\_hyman\\_phelps/2011/01/tussle-over-bpcia-market-versus-data-exclusivity-continues-this-time-the-generics-side-chimes-in.html](http://www.fdalawblog.net/fda_law_blog_hyman_phelps/2011/01/tussle-over-bpcia-market-versus-data-exclusivity-continues-this-time-the-generics-side-chimes-in.html).

<sup>183</sup> See Karst, *supra* note 182 (discussing the arguments from numerous generic drug manufacturers such as Hospira, Momenta Pharmaceuticals, Hospira, Mylan Labs, Teva Pharmaceuticals, and Watson Pharmaceuticals).

<sup>184</sup> See Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 206 (1987).

<sup>185</sup> See Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 CALIF. L. REV. 241, 263 (1998).

<sup>186</sup> See David Friedman et al., *Some Economics of Trade Secret Law*, 5 J. ECON. PERSPS. 61, 62–63 (1991).

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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.<sup>187</sup>

FDA applications are concerned with the safety and effectiveness of a finished product on humans as opposed to how a product is made, why it works, and which method or version is most preferable (unless the process of creating the product affects safety and effectiveness).<sup>188</sup>

Another point of distinction is that patent applications are published after eighteen months from the earliest priority date claimed regardless of whether the patent is granted and often before a patent is granted (given the long wait time for responses from the PTO).<sup>189</sup> For published applications that never result in a corresponding patent the material disclosed is forever donated to the public domain and free for all to access.<sup>190</sup> Today, most publications on cutting edge research are not free to the public but available only for purchase through a journal or online news and database service.<sup>191</sup> In addition, FDA applications are generally treated as confidential, unless the information has been previously disclosed, until the product is approved, licensed, or cleared.<sup>192</sup> The public does not currently benefit from the early disclosure of information in confidential FDA applications for products not yet approved.<sup>193</sup> If policies were changed, however, the public could benefit from early disclosure of information in confidential FDA applications, especially if there is not a corresponding published patent application to cover the product. Mandatory disclosure in published patent applications allows everyone to benefit, at least intellectually if not economically (until expiration of the patent term), from a research team's findings.<sup>194</sup> More specifically, in the biologics context, published patent applications allow other innovators and biosimilar producers to research what is known about a biologic (how it is made, manner of use, test data, etc. . . . as published in the patent application) to serve as an impetus and starting point for determining other mechanisms of treatment and/or other potential biologics for treatment or precursors for further research.<sup>195</sup> Pre-grant or pre-approval publication is especially important when there is a long wait time between the filing date of an application and patent grant or FDA approval. Otherwise, companies and their investors do not have any idea how many other teams are working on the same thing at the same time and they may be wasting time or duplicating research that

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<sup>187</sup> See 35 U.S.C. § 112 (2006).

<sup>188</sup> See 21 C.F.R. § 314.5(d)(5)(iv) (2010).

<sup>189</sup> See 35 U.S.C. § 122(b)(1).

<sup>190</sup> MPEP, *supra* note 141, § 1.14(a)(1)(iii).

<sup>191</sup> See YOCHAI BENKLER, WEALTH OF NETWORKS: HOW SOCIAL PRODUCTION TRANSFORMS MARKETS AND FREEDOM 323–24 (2006).

<sup>192</sup> 21 C.F.R. §§ 601.50–.51.

<sup>193</sup> See *id.* § 601.51.

<sup>194</sup> See WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 294–95 (2003).

<sup>195</sup> See *id.* at 295 (describing how competitors may use the publicly disclosed information in the patent application to “invent around” the invention and find new ways to achieve the same results).

has already been performed by someone else but is not yet publicly available.<sup>196</sup> Even with publication at eighteen months there is an eighteen month unknown waiting period or blackout during which patent applicant innovators do not know what other applications have been submitted to the PTO.<sup>197</sup> There is always the chance that an innovator may realize, the day after filing an expensive application, that a competitor filed an application seventeen months and twenty-nine days earlier disclosing the same or similar technology, which would render the innovator's patent application redundant.

The absence of publicly available pending FDA applications may soon change as part of President Obama's Open Government Initiative.<sup>198</sup> The FDA launched its own Transparency Initiative in June 2009 and in May 2010.<sup>199</sup> This transparency Task Force released a report containing twenty-one draft proposals that would significantly expand the disclosure of industry information by the FDA.<sup>200</sup> This increased openness would be another way that the public could benefit from sharing public knowledge; however, the innovator could risk exposure of valuable trade secrets or patentable subject matter as a consequence. Accordingly, any implantation of transparency at the FDA may make it more imperative to file for patent protection prior to FDA applications becoming publicly accessible.

It has been argued that without patent protection, academics and researchers would be motivated to publish and share information for personal recognition and the greater good of the scientific community.<sup>201</sup> To the extent these endeavors are funded by commercial interests, the author of this paper believes it is more likely that without patents significant advancements will be safeguarded as trade secrets. Many academic researchers are required to sign confidentiality and non-disclosure agreements with the Technology Transfer Offices of their universities and with the companies funding their projects.<sup>202</sup> Publication of independent articles covering technology within the scope of such agreements for personal prestige and/or the greater good would be considered a breach of contract and may have serious repercussions, including potential lawsuits for money damages or against the

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<sup>196</sup> FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY (Oct. 2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

<sup>197</sup> See 35 U.S.C. § 122 (2006).

<sup>198</sup> Transparency and Open Government, 74 Fed. Reg. 4685, 4685 (Jan. 21, 2009) (memorandum from President Obama to the heads of executive departments and agencies).

<sup>199</sup> Transparency Initiative: Improving Transparency to Regulated Industry, 76 Fed. Reg. 1180, 1181 (Jan. 7, 2011).

<sup>200</sup> See Press Release, U.S. Dep't of Health & Human Services, FDA, Transparency Initiative: Draft Proposals for Public Comment Regarding Disclosure Policies of the U.S. Food and Drug Administration (May 2010), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm212528.htm>.

<sup>201</sup> Stephen M. Maurer, *Promoting and Disseminating Knowledge: The Public/Private Interface*, 8 (Sept. 2002), [http://gspp.berkeley.edu/iths/Maurer\\_PrivatePublicInterface.pdf](http://gspp.berkeley.edu/iths/Maurer_PrivatePublicInterface.pdf) (symposium paper prepared for the U.S. Nat'l Res. Council).

<sup>202</sup> See, e.g., *Mutual Confidentiality and Non-Disclosure Agreement*, CHILLINGEFFECTS.ORG, <http://www.chillingeffects.org/tradeseecret/resource.cgi?ResourceID=89> (last visited Mar. 25, 2011) (providing an example of a typical non-disclosure agreement); *Non-Disclosure Agreement*, UNIV. OF TEX. SYS. OFFICE OF GEN. COUNSEL, <http://www.utsystem.edu/ogc/intellectualproperty/contract/confid.htm> (last modified Mar. 13, 2007).



university employer, actions to enjoin further research or commercialization, or discharge from a university.

Additionally, a patent term is twenty years from the filing date and the FDA exclusivity period afforded by the BPCIA is twelve years from the date of market approval.<sup>203</sup> The effective term of patent protection to cover different aspects of some products can be extended by filing continuation and continuation-in-part (follow-up) applications on improvements such that a single product, or upgraded versions thereof, is covered by more than one patent.<sup>204</sup> In products that take a long time to achieve market approval after a patent is granted, the end dates for patent and FDA protection might be equal. In many cases, however, a patent term will be longer than the FDA exclusivity period and even a few extra months of a patent monopoly can add up to serious financial returns from selling the protected product directly or through licensing royalty streams.<sup>205</sup>

Many commentators are satisfied with the apparent compromise in a data exclusivity term of twelve years.<sup>206</sup> Data exclusivity protects the clinical trial data that innovators submit in order to gain approval for their drugs, so others cannot access or rely on that data in their own applications during the data exclusivity period.<sup>207</sup> Empirical studies, however, show that twelve years may not be enough time for innovator companies to regain investments.<sup>208</sup> If companies cannot regain initial investments, the twelve years of exclusivity might actually reduce the number of innovator biologics available to consumers.<sup>209</sup> This reduction would be due to: (1) innovator companies not having the capital necessary to reinvest in other biologics in their product pipelines; (2) investors not seeing adequate returns on their biotech investments and therefore choosing to support other more predictable industries instead; and (3) innovator companies not being able to attract new investors.<sup>210</sup>

More recently, it seems the BPCIA will be interpreted and implemented to provide for twelve years of marketing exclusivity and four years of data exclusivity (wait-to-file period). If twelve years of data exclusivity is not likely to be long enough to allow innovators to recoup investments twelve years of marketing exclusivity will be even less likely to allow innovators to recoup investments. This is due to the fact that a data exclusivity period of twelve years would effectively provide a longer marketing exclusivity period if biosimilar producers do not circumvent the biosimilar approval procedure by generating their own data to apply for a traditional BLA. For example, if biosimilar producers cannot access and rely on innovator data from BLAs in their subsection (k) applications until twelve years after the reference product is licensed, then their subsection (k) application cannot be submitted before the

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<sup>203</sup> See 35 U.S.C. § 154 (2006); 42 U.S.C.A. § 262(k)(7)(A) (West 2011).

<sup>204</sup> See 37 C.F.R. §§ 1.53(b), 1.54(a)(2) (2010).

<sup>205</sup> See Françoise Simon, *Market Access for Biopharmaceuticals: New Challenges*, 25 HEALTH AFFAIRS 1363, 1367 (2006) (noting that Epogen sales in 2005 alone were \$2.5 billion).

<sup>206</sup> See Carver, *supra* note 67, at 724–25.

<sup>207</sup> David E. Adelman and Christopher M. Holman, *Misplaced Fears in the Legislative Battle Over Affordable Biotech Drugs*, 50 IDEA 565, 569 (2010).

<sup>208</sup> Letter from Henry Grabowski to the FTC, Re: Emerging Health Care Issues—Follow-On Biologic Drug Competition Comment on Final Report 1, 12 (July 6, 2009), *available at* [econ.duke.edu/~grabow/FDS/FullFTC\\_response.pdf](http://econ.duke.edu/~grabow/FDS/FullFTC_response.pdf).

<sup>209</sup> *Id.* at 10, 13, 15.

<sup>210</sup> *Id.* at 9–10, 13, 15.

expiration of twelve years and will not be approved until some later period, effectively providing a longer exclusivity period to innovators. In contrast, if generic producers can access, rely on, and incorporate innovator data in their applications sooner, and then submit their subsection (k) applications prior to the expiration of twelve years of marketing exclusivity, by the time the twelve years is up their applications are more likely to be immediately ready for approval.

Some commentators, such as Maxwell Morgan, argue that the biosimilars pathway might curtail patenting of innovations.<sup>211</sup> Morgan argues that instead of costly patents, innovators could use the guaranteed FDA market exclusivity period as an adequate incentive for bringing biologics to market.<sup>212</sup> This theory substantially underestimates the necessity of patent rights, both domestically and internationally.<sup>213</sup>

The net benefit of patents is positive to society and the innovator company, even though there are some downsides.<sup>214</sup> For example, one potential negative consequence to society may occur if a company receives a patent on a biologic, thereby excluding all others from producing the biologic, but does not or cannot successfully complete the FDA approval process. If another company has the resources to successfully bring the biologic to consumers but is blocked by the first company's patent rights, the result would negatively affect society. Without the first company's patent, the second company could have provided a valuable drug to the market.<sup>215</sup> Luckily, this negative result would only be temporary because the second company could start the FDA approval process once the patent expires.<sup>216</sup> Alternatively, and more likely, the second company could request a patent license from the innovator company and then use its resources to complete the costly FDA approval process.<sup>217</sup> Alternatively, if the innovator company is unable to obtain or abandons a patent on the biologic after the application is published, the information is donated to the public domain for the benefit of all.<sup>218</sup>

If a company secures patent protection in another country, it can keep others from producing or importing a biologic into that country.<sup>219</sup> If the innovator company only has FDA exclusivity in the United States, it cannot keep others from making,

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<sup>211</sup> See Morgan, *supra* note 109, at 94.

<sup>212</sup> *Id.*

<sup>213</sup> See LANDES & POSNER, *supra* note 194, at 294–95 (noting that patent rights are necessary to protect inventors from copying by competitors, especially important in a field where there is often simultaneous discovery).

<sup>214</sup> *Id.*

<sup>215</sup> See, e.g., *FDA Position on Allowing Patients with ALS Access to Iplex under an IND*, FDA, <http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm118121.htm> (last visited Mar. 25, 2011).

<sup>216</sup> See Richard E. Caves, Michael D. Whinston & Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the US Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY, MICROECON 1, 36–37 (1991).

<sup>217</sup> Donald O. Beers, *GENERIC AND INNOVATOR DRUGS: A GUIDE TO FDA APPROVAL REQUIREMENTS*, app. 34 at 42–43 (Aspen Publishers, 6th ed. 2004).

<sup>218</sup> See 35 U.S.C. § 122 (2006).

<sup>219</sup> See Richard H. Shear & Thomas E. Kelley, *A Researcher's Guide to Patents*, 132 PLANT PHYSIOLOGY 1127, 1128 (2003).

using, selling, or importing the biologic in foreign countries.<sup>220</sup> Thus, patents are essential for international protection in today's global economy.<sup>221</sup> FDA exclusivity would certainly not act as an "adequate surrogate"<sup>222</sup> for patent protection. Innovator companies should continue to aggressively seek patent protection in order to protect their substantial investments. Relying solely on FDA exclusivity would be devastating for the innovator companies and for U.S. consumers.

## 2. Incentives Without Patent Protection

While the author of this paper does not recommend FDA exclusivity alone without adequate patent protection due to the disadvantages discussed above, we nonetheless admit that FDA exclusivities are valuable because they provide an additional independent incentive to innovate. If the patent system fails to grant a patent on a product that required substantial investment, but the product is FDA approved, then the FDA exclusivity grant can be of tremendous importance.<sup>223</sup> A floor of safety with an upside to the duration of monopoly (enhanced profitability) if a patent is granted provides the confidence investors need to loosen their purse strings.<sup>224</sup> Without a patent system there would still be incentives to develop biologics so long as FDA exclusivity is provided and/or biologics' composition and the process of making biologics are maintained as trade secrets.<sup>225</sup> With the reduced disclosure of information (in the absence of published patent applications), however, one discovery will not lead to others as quickly and the momentum of innovation will not escalate as it otherwise would under the patent system.<sup>226</sup> The problem with a patent system alone is that it is somewhat arbitrary and unpredictable with the ever present risk factor that a would-be infringing competitor will dig up some prior art that invalidates the patent.<sup>227</sup> Another problem and benefit of the patent system is that applications are generally published (absent a non-publication request) even if the patent is not granted.<sup>228</sup> This is a problem for the patent applicant and a benefit to society at large, including competitors. Pre-grant publication prevents changing strategies during patent prosecution to instead rely on trade secret protection.<sup>229</sup> Thus, a product that fails to obtain a patent is most likely not eligible for trade secret protection.<sup>230</sup> This leaves the product unprotected and open to copycat competitors, despite the investment required to develop the product. In contrast, until the FDA

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<sup>220</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(a)(1) (2006) (limiting the jurisdiction to "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico").

<sup>221</sup> See Shear, *supra* note 219, at 1128.

<sup>222</sup> Contra Morgan, *supra* note 109, at 94.

<sup>223</sup> Rebecca S. Eisenberg, *Genes, Patents, and Product Development*, 257 SCI. 903, 906 (1992).

<sup>224</sup> *Id.*

<sup>225</sup> See David R. Hannah, *Should I Keep a Secret? The Effects of Trade Secret Protection Procedures on Employees' Obligations to Protect Trade Secrets*, 16 ORGANIZATIONAL SCI. 71, 72–73 (2005).

<sup>226</sup> See Morgan *supra* note 109, at 97–98.

<sup>227</sup> See 35 U.S.C. § 102(a) (2006).

<sup>228</sup> See 35 U.S.C. § 122(b)(1).

<sup>229</sup> See Hannah, *supra* note 225, at 72.

<sup>230</sup> *Id.*

system becomes transparent or requires publication, a product for which an FDA application is filed may still be eligible for trade secret protection.

Even if a patent is not granted after publication of the patent application, the published application does offer some advantages even to the would-be patentee. The published application can be cited as prior art against patent applications of others (including competitors) and thereby has defensive properties that prevent others from patenting the material disclosed even if the patent applicant cannot get a patent on the claims as written.

Without patents, there will be an incentive to get products approved quickly under the FDA, if such approval is the only way to achieve exclusivity and protection.<sup>231</sup> Such products will likely be conservative rather than pushing the limits.<sup>232</sup> Moreover, clinical trials required to demonstrate safety and effectiveness are costly.<sup>233</sup> Without a long patent term to recoup investments, such products are likely to piggyback on earlier clinical trials or require less costly trials. For example, it takes up to an estimated \$1.2 billion to develop the average biologic.<sup>234</sup> Then, the innovator can expect to spend another \$250–\$450 million to create the manufacturing facility needed to produce the precise biologic.<sup>235</sup> All of this expense is incurred before the biologic makes any profit. Furthermore, only about a handful of the biologics making it to the manufacturing stage and are introduced into the market, are truly successful.<sup>236</sup>

An FDA exclusivity period alone is unlikely to justify the investment needed to pursue costly yet potentially revolutionary biologics. A longer patent term is needed to provide a more extreme reward for the risk involved.<sup>237</sup> A guaranteed FDA exclusivity period may provide a break-even point to recoup investment for many products, but it is unlikely to provide the timeframe necessary to achieve the extreme profitability that incentivizes undertaking development of the most risky, costly, and potentially revolutionary biologic therapies.

### *C. Shortcomings of Current Patent Procedure and Room for Improvements*

While the patent system provides substantial incentives to innovate, it is not without its problems. Several improvements in the patent system could improve its functioning and more fairly award limited monopoly power to reward innovation and encourage financial investments in critical industries.

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<sup>231</sup> See Morgan, *supra* note 109, at 105–06.

<sup>232</sup> Petra Moser, *How Do Patent Laws Influence Innovation? Evidence from Nineteenth-Century World's Fairs*, 95 AM. ECON. REV. 1214, 1214 (2005).

<sup>233</sup> See Sander, *Genomic Medicine and the Future of Health Care*, 287 SCI. 1977, 1978 (2000); Joseph Palca, *AIDS Drug Trials Enter New Age*, 246 SCI. 19, 19 (1989).

<sup>234</sup> See Pipes, *supra* note 19.

<sup>235</sup> *Id.*

<sup>236</sup> *Id.*

<sup>237</sup> See *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 610 (D. Del. 1997) (citing 7 DONALD S. CHISUM, CHISUM ON PATENTS, § 20.03[3][b][ix]).

*1. Problem: PTO Delays Beyond the Restorative Power of Hatch-Waxman*

One of the problems with the current patent system is that the twenty year patent term frequently has an effective life of much less than that.<sup>238</sup> This discrepancy results from a backlog at the PTO that creates a significant wait time before a first response and then sometimes delays in responding to subsequent correspondence.<sup>239</sup> Additionally, the part of a patent term that starts before the FDA has approved a product has reduced value compared to patent term value after a product protected by it is approved to market.

Various statutory provisions have been made in an attempt to compensate for these issues. One type of patent term adjustment, called extension, which accounts for delays with PTO during patent prosecution, is governed by 35 U.S.C. § 154. Section 154 provides time added back onto a term when the PTO fails to provide initial notifications, subsequent responses, or to issue a patent within certain time periods.<sup>240</sup>

Filing early in anticipation of a lengthy approval process is not enough, as the backlog at the PTO is quite long.<sup>241</sup> The wait time until a first substantive response, the First Action on the Merits varies depending upon art unit, but in some cases can be five years.<sup>242</sup> If delayed prosecution impinges on a patent term it can be restored through the Hatch-Waxman Act, but restoration is not always complete in that it is limited in duration and does not always account for the full length of the delay caused by PTO backlog and slow response time.<sup>243</sup>

Another type of patent term adjustment, called a restoration, was provided by the Hatch-Waxman Act.<sup>244</sup> The Hatch-Waxman Act added a section to the Patent Act creating a term extension for patents on products that are subject to the Federal Food, Drug and Cosmetic Act.<sup>245</sup> The new provision created an extension for patents that were not marketable on account of delayed approval.<sup>246</sup> Further, Congress expanded the list of products eligible for term restoration to include animal drugs and veterinary biological products.<sup>247</sup>

The new § 156 sets out various criteria for any patent extension under the Hatch-Waxman Act.<sup>248</sup> Under these criteria, the product must have been “subject to

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<sup>238</sup> See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 568 (2010).

<sup>239</sup> See Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office’s Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2058 (2009).

<sup>240</sup> 35 U.S.C. § 154 (2006).

<sup>241</sup> See Rai, *supra* note 239, at 2058.

<sup>242</sup> MPEP, *supra* note 141, § 704.11(b); see also *BIO IP PTO Working Group*, BIOTECH. INDUS. ORG., <http://www.bio.org/ip/ptocomm.asp> (last visited Mar. 25, 2011) (discussing instances of a five year wait time).

<sup>243</sup> See *Merck v. Kessler*, 80 F.3d 1543, 1547 (Fed. Cir. 1989).

<sup>244</sup> See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at scattered sections of 15, 21, 28, and 35 U.S.C.).

<sup>245</sup> 35 U.S.C. § 156(a)(4).

<sup>246</sup> *Id.* § 156(a)(5).

<sup>247</sup> Generic Animal Drug and Patent Term Restoration Act of 1988, Pub. L. No. 100-670, § 201, 102 Stat. 3971 (codified as amended at 35 U.S.C. § 156(f)).

<sup>248</sup> 35 U.S.C. § 156(a).

a regulatory review period before its commercial marketing or use.”<sup>249</sup> Second, the Act allows only one restoration period.<sup>250</sup> If a first drug is granted an extension, then a second drug, if similar to the first, will not be granted an extension.<sup>251</sup> Third, the applicant must request the extension within sixty days of agency approval.<sup>252</sup> The PTO calculates the restoration period using the regulatory review period, generally limited to the testing and approval phases, as the basis for a patent term adjustment.<sup>253</sup> Any time an applicant does not reply or perform with diligence, the length of the regulatory review period is reduced.<sup>254</sup> The restoration period cannot exceed five years and the total length of the patent term cannot be longer than fourteen years following agency approval.<sup>255</sup>

A third party may challenge the term extension once the FDA has published its findings.<sup>256</sup> A party has 180 days from publication of the findings to file a due diligence petition, questioning whether the applicant performed the required duties within the appropriate timeframes.<sup>257</sup> The restoration period is claim specific and extends only to products covered by the specific claims.<sup>258</sup>

## 2. Independence of Patent Term and Development Time

Another issue with the current U.S. patent system is that the patent term of the exclusivity period is uniform for all inventions and thus independent of the time and cost to develop different types of inventions.<sup>259</sup> The patent term is also independent of the commercial life of a product covered by the patent.<sup>260</sup> Some inventions are quick to develop and gain approval, and are on the market quickly to earn enough revenue to cover the investment costs (and financially justify their development) within the first few months on the market.<sup>261</sup> Other products take decades to develop, more years to get approved, and take decades or more of sales to become profitable.<sup>262</sup> Given these variations from one invention to another makes it reasonable to conclude that although the current system for determining patent term is relatively easy to administer (at least without taking excessive adjustments into account) it may not be the most economically efficient system.<sup>263</sup> A more variable

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<sup>249</sup> *Id.* § 156(a)(4).

<sup>250</sup> *Id.* § 156(a)(2).

<sup>251</sup> *Id.* § 156(a)(1); see Terry G. Mahn, *Striking the Right Balance Between Innovation and Drug Price Competition: Understanding The Hatch-Waxman Act*, 54 FOOD DRUG L.J. 245, 247 (1999).

<sup>252</sup> 35 U.S.C. § 156(d)(1).

<sup>253</sup> MPEP, *supra* note 141, § 2758.

<sup>254</sup> *Id.*

<sup>255</sup> *Id.*

<sup>256</sup> *Id.*

<sup>257</sup> *Id.*

<sup>258</sup> 35 U.S.C. § 156(b)(1) (2006).

<sup>259</sup> See Amir H. Khoury, *Differential Patent Terms and Commercial Capacity of Innovation*, 18 TEX. INTELL. PROP. L.J. 373, 388 (2010).

<sup>260</sup> *Id.* at 397–98.

<sup>261</sup> *Id.* at 394–95.

<sup>262</sup> See Grabowski et al., *supra* note 6, at 1300.

<sup>263</sup> See Eric E. Johnson, *Calibrating Patent Lifetimes*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 269, 282–85 (2006).

invention-dependent system would better reward innovation and investment without excessively tying up of the competitive marketplace with patent landmines.

*a. Patent Term is Uniform for All Patents, Measured from Filing Date*

Currently a patent term for a U.S. utility patent is twenty years from the date the application is filed with adjustments as necessary to account for PTO and regulatory delays.<sup>264</sup>

*b. Some Products Are Ready to Market when the Patent Is Granted, Other Products Require Additional Steps*

For some inventions a product is ready to be marketed commercially as soon as the patent is granted. For other inventions, several regulatory prerequisites must be met before the product can be marketed and the patent can be exploited.<sup>265</sup> Thus, a portion of a patent term is essentially wasted for some patents because the products that are covered by them cannot be marketed during the entire patent term.

It would make more sense from an investment perspective to have the patent term measured from the earliest date at which both the patent was granted and the product covered by the patent was approved to market in the country where the patent was granted. Another factor that could be factored into patent term determination for economic efficiency would be the amount of investment required to arrive at the patentable product or a related metric, the amount of time required on the market to recoup investment (which would depend on amount of investment and market price).

## V. CONCLUSION

The passage of biosimilar legislation provides hope to retain a robust biotechnology industry in the United States and to protect investors while encouraging innovators. While FDA exclusivity alone is insufficient to encourage and protect innovation and investment in the United States, longer FDA exclusivity times, including the twelve year period for biologics specified in the recently passed BPCIA, should help to encourage investment in biologics. The FDA exclusivity period alone will not be long enough to recoup all of the investment required to develop and obtain approval for many biologics and other inventions, however, it does provide some level of guaranteed exclusivity while awaiting a response from the PTO regarding patentability. This independent exclusivity should encourage companies to get their FDA applications moving forward earlier and for products that are approved it will reduce potential economic loss thereby supporting investment.

The exclusivity that an FDA application provides is clearly not enough to maintain and increase our current rate of biotechnology innovation. The limited

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<sup>264</sup> 35 U.S.C. § 154(a)–(b) (2006).

<sup>265</sup> 21 U.S.C. § 355 (2006).

monopoly term for patents, together with the ability to adjust this term as needed to fairly compensate an applicant for PTO and FDA delays, will still be necessary to ensure highly specialized and resource intensive biologics get developed. The detailed disclosure required of patent applicants is also an important aspect of the patent system. Most importantly, the detailed disclosure is published because individual inventors and companies will likely not share such detailed information if they are not required to or if there is not a potential benefit in the form of a limited monopoly (the rights to exclude others during the patent term). Although difficult and potentially impractical to implement, an interesting future approach might be to more closely correlate the patent term to begin on the date of FDA market approval and to last a period which would depend on the development cost and profitability of the invention. The aim would be to allow profitability such that it justifies the development cost and rewards the risk taken, thereby encouraging further development investments. While it is difficult to strike a perfect balance, innovators, biosimilar companies, and the public all benefit most from innovator biologics having strong patent protection coupled with long FDA exclusivity periods.