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Will FDA Data Exclusivity Make Biologic Patents Passé?

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ARTICLES

WILL FDA DATA EXCLUSIVITY MAKE BIOLOGIC PATENTS PASSÉ?

Vincent J. Roth†

Abstract

Much controversy has ensued over the current twelve-year data exclusivity period afforded to biosimilars, pursuant to the Biologics Price Competition and Innovation Act of 2009 (BPCI).

Many commentators speculate whether data exclusivity will overtake patents as the preferred method of intellectual property protection for new biologic drugs. A comparison of data exclusivity with the patent system, however, reveals few similarities and many differences. Moreover, legislative gaps and absent industry mechanisms leave a void that is a barrier to entry in the biosimilars market, referred to here as "regulatory impracticality."

A survey was conducted with senior management at biopharma companies regarding data exclusivity as compared to patenting. Respondents indicated their perceived value in using patents to attract investment, their views of data exclusivity as effective protection, their preferred period of data exclusivity, a perception that patents provide better protection than data exclusivity, and an intent to continue or increase their level of patent activity.

This article also contains recommendations for statutory amendments to address regulatory impracticality. It also explains that, because of the limitations and uncertainties of FDA data exclusivity and its different yet complimentary characteristics with the patent system, it is likely data exclusivity will not supplant patents, but will be one more weapon in the fight for market share.

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I. INTRODUCTION

Bringing new drugs to market entails considerable financial risk.[1] Because of the significant investment biotechnology research and development (R&D) requires and the risk of failing to meet expected returns, the biotechnology industry urged Congress to provide data exclusivity: a protection for innovators of drug development data from competitors who desire to reference such data.[2] The result was the current legislative period of 12 years of data exclusivity for innovators, during which imitators cannot develop follow-on biologics (FOBs), also called "biosimilars."[3] This twelve-year period is pursuant to the Biologics Price Competition and Innovation Act of 2009 (BPCI) which provides for accelerated drug approval of biosimilars through the Food and Drug Administration (FDA).[4]

Data exclusivity is a period of time during which the FDA allows an innovator exclusive use of its own data. This means the FDA will not allow another drug developer, i.e., an imitator, to rely on the development data of the originator when submitting data and results of clinical studies to the FDA for approval of the imitator's drug candidate.[5] Data exclusivity is automatic upon new drug approval,[6] thereby providing a measure of monopoly for new drug developers. The patent system, in contrast, requires affirmative efforts and additional investment from biotech companies. The BPCI was designed, among other things, to create an abbreviated regulatory approval pathway for biosimilars, which has generated considerable

1. *See Average Cost To Develop a New Biotechnology Product Is $1.2 Billion, According to the Tufts Center for the Study of Drug Development*, MARKETWIRE (Nov. 9, 2006, 9:00 AM), http://www.marketwire.com/press-release/average-cost-develop-new-biotechnology-product-is-12-billion-according-tufts-center-711827.htm.

2. *See* Stephen Albainy-Jenei, *Senate Committee: 12 Years of Data Exclusivity Is Cool*, DRUG DISCOVERY NEWS (Aug. 2009), http://www.drugdiscoverynews.com/index.php?newsarticle=3160.

3. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 7002(a)(2)(k)(7)(A), 124 Stat. 119, 807 (2010) [hereinafter PPACA].

4. Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 804 (2010) [hereinafter BPCI] (Title VII, Subtitle A of PPACA).

5. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(c)(3)(E), (j)(5)(F) (2011)) [hereinafter FD&C]; *see also* BPCI § 7002(k)(7)(A)-(B) (under § 7002(k)(7)(A) a biosimilar may not be approved for 12 years from when the reference product was first licensed, but under § 7002(k)(7)(B) an application may be submitted after four years after the date the reference product was first licensed).

6. This applies to new chemical entities (NCEs). *See* 21 U.S.C. § 355(j)(5)(F)(ii) (2011).

attention and debate.[7] Legislators expect that biosimilars, like generic drugs, would get on the market quicker through the abbreviated process, thus producing cost savings in the development and approval process. The abbreviated process, however, is too new and not sufficiently effectuated to determine the actual savings to the marketplace, threats to the innovator, or benefits to the imitator.

Some commentators suggest that data exclusivity is more important and effective in protecting intellectual property for drug developers than the patent regime. Some predict that innovators will come to rely more on data exclusivity than on patenting to protect their competitive advantage. However, the abbreviated approval process for biosimilars is not yet fully defined, thus it is difficult to predict its impact. More importantly, data exclusivity provides very different benefits than patent law. One critical characteristic of data exclusivity that commentators overlook is that until Congress recently defined data exclusivity period for biosimilars, the biotech industry in the United States has experienced "continuous data exclusivity," as this author calls it, since the inception of the biotech industry in the early 1980s.[8] The passage of the BPCI did not create new data exclusivity protection; it shortened it to 12 years.

While the patent system is going through its own changes due to the America Invents Act, data exclusivity is being challenged as well. The Obama Administration is proposing to reduce the data exclusivity period from 12 years to 7 years.[9] Since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and viable weapon in the intellectual property arsenal.

This article examines the interplay between data exclusivity and patenting with regard to costs of patent prosecution, R&D and FDA regulatory approval costs, profits of drug commercialization, actual

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7. *See* Karen Tumulty & Michael Scherer, *How Drug-Industry Lobbyists Won on Health-Care*, TIME MAGAZINE (Oct. 22, 2009), http://www.time.com/time/magazine/article/0,9171,1931729,00.html; *see also* FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 39-46 (2009), *available at* http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf; Kevin E. Noonan, *Data or Market Exclusivity? (Perhaps) Only Congress Knows for Sure*, PATENT DOCS (Jan. 26, 2011), http://www.patentdocs.org/2011/01/data-or-market-exclusivity-perhaps-only-congress-knows-for-sure.html.

8. *See infra* Part II.A.

9. Mike Palmedo, *Obama's Deficit Plan Would Reduce Data Exclusivity for Biologics and Ban Pay-for-Delay Patent Settlements*, INFOJUSTICE.ORG (Sept. 20, 2011), http://infojustice.org/archives/5585.

protections experienced, and other benefits—whether real or perceived—that data exclusivity and patenting provide. Part II examines the background of drug development with some legislative history, points out the difference between generic drugs and biologics, distinguishes data exclusivity from market exclusivity, and explains the current regulatory terrain. Part III reviews protections the patent system provides the pharmaceutical and biotechnology industries as well as some of the drawbacks of the U.S. patent system. Part IV considers the incentives available through the drug approval process as compared to patent law. A comparison of data exclusivity with the patent system will reveal a few similarities and many differences.

Part V reveals legislative gaps and absent industry mechanisms, referred to in this article as "regulatory impracticality," which acts as another barrier to entry in the biosimilars market. Part VI contains a survey conducted for this article to elicit opinions of senior management in biotech companies regarding their opinions and expectations about data exclusivity as compared to patenting. As of August 6, 2012, 73 respondents provided their opinions regarding FDA data exclusivity and the U.S. patent system. Respondents indicated patents are still quite valuable in attracting investment. While few companies in this population are developing biosimilars, the majority perceives data exclusivity as a valuable and effective protection from competition and favors a period of 9-12 years of data exclusivity. This article's survey also reveals a perception that patents provide better protection than data exclusivity and that even with the availability of data exclusivity as an extra protection, most respondents intend to continue or increase their level of patent activity.

Part VII provides recommendations for statutory amendments to address regulatory impracticality. This article concludes with an explanation that, because of the limitations and uncertainties of FDA data exclusivity and its different yet complimentary characteristics with the patent system, it is likely data exclusivity will not supplant patenting, but will be one more weapon in the fight for market share.

II. THE REGULATORY FRAMEWORK FOR BIOLOGICS

In addition to the traditional intellectual property regimes of patent law, trademark law, copyright law, and trade secret law, life science companies[10] can also protect their intellectual property

10. Broadly defined, life science companies may encompass a variety of companies. For purposes of this article, pharmaceutical companies, or "pharma," are companies that produce

through data exclusivity, the regulatory framework of the FDA. The following section provides some background on the biotechnology industry.

A. *Generics versus Biologics*

The biotechnology industry was created after Stanley Cohen and Herbert Boyer made their initial discoveries of recombinant DNA technology in 1973.[11] Early methods in biotechnology lead to the first biologic product, recombinant human insulin, approved by the FDA in 1982.[12] The biotechnology industry has been flourishing ever since with over 400 biologic drugs marketed to treat over 200 conditions.[13] The drug development pipeline in 2011 in the United States contained approximately 900 biologics.[14]

Faced with the goal of creating an incentive structure in the pharmaceutical industry to increase competition and reduce the cost to the marketplace for drugs, Congress enacted the Hatch-Waxman Act in 1984 (Hatch-Wax).[15] The act implemented an accelerated FDA approval process for generic drugs,[16] which successfully introduced generic, small-molecule drugs to the market by allowing for substantial costs savings in drug development.[17] The advent of the generic drug market drove down costs of small-molecule drugs by an average of almost 75%.[18] While Hatch-Wax was successful in

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traditional small molecule drugs through chemical processes, called "chemical drugs." Biotechnology companies, or "biotech," are companies that produce large protein molecules using living organisms, called "biologics."

11. *See Biotechnology at 25: The Founders*, U.C. BERKELEY LIBRARY (May 23, 2000), http://bancroft.berkeley.edu/Exhibits/Biotech/25.html.

12. JUDITH A. JOHNSON, CONG. RESEARCH SERV., RL 34045, FDA REGULATION OF FOLLOW-ON BIOLOGICS 1 (2010).

13. Zach Patton, *Complex Rx: Biologic Meds Are The Wonder Drugs of Our Time. Can We Afford Them?*, GOVERNING (Oct. 2007), http://www.governing.com/topics/politics/Complex-Rx.html.

14. Grady Forrer, *900 New Medicines in Development Show the Biotechnology Medical Revolution Is Going Strong*, PHRMA (Sept. 14, 2011, 11:18 AM), http://www.phrma.org/catalyst/900-new-medicines-development-show-biotechnology-medical-revolution-going-strong.

15. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35 U.S.C.).

16. *See* 21 U.S.C. § 355(j) (2011).

17. LAURENCE J. KOTLIKOFF, STIMULATING INNOVATION IN THE BIOLOGICS INDUSTRY: A BALANCED APPROACH TO MARKETING EXCLUSIVITY 10 (Sept. 2008), *available at* http://people.bu.edu/kotlikof/New%20Kotlikoff%20Web%20Page/Kotlikoff_Innovation_in_Biologics21.pdf.

18. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 32-33 (1998) (showing

creating a generics market for chemical drugs, it failed to create a generics market for biologics.

Chemical drugs are based on small molecules that typically contain dozens of atoms, while biologics are based on large molecules that may consist of millions of atoms.[19] The figures below show an example of the difference in the scale of a molecule of caffeine, which is a small and fairly simple molecule, and a molecule of human growth hormone, which is a large and very complex protein molecule.

Figure 1. Caffeine (generic)

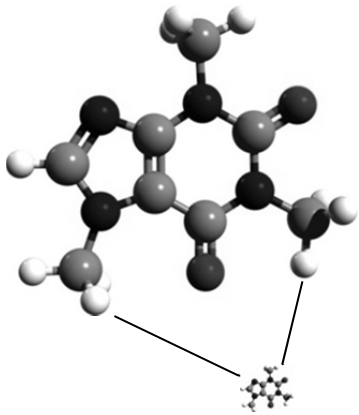
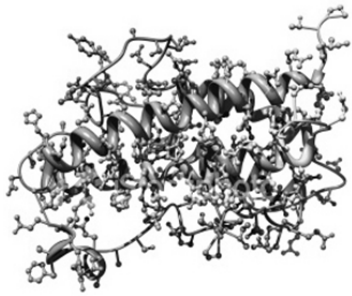


Figure 2. Human Growth Hormone (biologic)



The scale of size is not the only dramatic difference. Small molecule drugs are made using commonly known chemical processes.[20] Biologics, however, often being protein-based drugs,[21] are made using biological processes inside living organisms.[22] The process for manufacturing a biologic is much more complex and much more expensive than the chemical methods for making small-molecule drugs,[23] resulting in a higher cost product.

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the average generic price was 22.40% of the innovator in 1994).

19. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 2-3 (2009).

20. *Id.*

21. Biologics include a "wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins." *What Is a Biologic?*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (June 2, 2009), http://answers.hhs.gov/questions/3262.

22. SCHACHT & THOMAS, *supra* note 19, at 3.

23. Michał Nowicki, *Basic Facts about Biosimilars*, 30 KIDNEY & BLOOD PRESSURE RES. 267, 268 (2007).

Biologics on average cost 20 times that of the average chemical drug.[24] Yet even with such high price tags, the market share for biologics is expected to grow. In 2000, biologics sales accounted for 11% of all U.S. drug sales.[25] In 2012, biologics represented 20% of the drugs on the market with projections that by 2014 approximately 50% of the drugs on the market will be biologics.[26] Also in 2000, there was only one biologic in the top ten drugs on the market, but by 2008, half of the top ten drugs were biologics.[27] In 2007, sales of biologics were $75 billion worldwide.[28] Although actual numbers are not available at this time to confirm 2012 predictions, by the end of 2012, sales of biologics were expected to exceed $175 billion worldwide.[29] In 2011, over 2,900 drugs were in development in the United States[30] with 900 being biologics.[31] Experts predicted half the drugs approved by the FDA in 2012 would be biologics.[32]

Drug developers use biologics to treat ailments in a number of ways.[33] Over time, biologics have expanded and diversified

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24. Tumulty & Scherer, *supra* note 7. For example, the treatment of arthritis with one of the most expensive small-molecule drugs costs about $300 each year, whereas treatment for arthritis with Enbrel, a brand name biologic, costs about $20,000 per year. Patton, *supra* note 13. The breast cancer drug Herceptin can cost up to $48,000 for a year of treatment. Tumulty & Scherer, *supra* note 7. The colon cancer drug Avastin costs about $100,000 per year and Cerezyme, a brand name biologic that treats Gaucher disease, a life-threatening enzyme deficiency, costs between $200,000 and $500,000 per year. Kathleen Jaeger, Editorial, *Creating a Workable Biogenerics Pathway for Patients*, 5 J. OF GENERIC MEDS. 1, 1 (2007).

25. Patton, *supra* note 13.

26. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 41483, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 1 (2012).

27. Erwin A. Blackstone & Joseph P. Fuhr, Jr., *Innovation and Competition: Will Biosimilars Succeed?*, 9 BIOTECH. HEALTHCARE, no. 1, 2012, at 24.

28. LEIGH PURVIS, AARP PUB. POLICY INST., BIOLOGICS IN PERSPECTIVE: THE CASE FOR GENERIC BIOLOGIC DRUGS 1 (2009).

29. Sheela AK, *Biologics Market—G7 Industry Size, Market Share, Trends, Analysis, and Forecasts 2012-2018*, SBWIRE (Oct. 11, 2012), http://www.sbwire.com/press-releases/biologics-market-g7-industry-size-market-share-trends-analysis-and-forecasts-2012-2018-170890.htm.

30. *Medicines in Development*, PHRMA, http://www.phrma.org/research/new-medicines (last visited Jan. 18, 2013).

31. Forrer, *supra* note 14.

32. Val Brickates Kennedy, *Generic Versions of Biologic Medications Are Coming*, MARKETWATCH (Sept. 3, 2009, 12:22 PM), http://www.marketwatch.com/story/generic-versions-of-biologic-medications-coming-2009-08-28.

33. *See, e.g.*, Billy Tauzin, *Biotechnology Research Continues to Bolster Arsenal Against Disease with 633 Medicines in Development*, *in* PHARM. RESEARCH & MFRS. OF AM., MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY 1 (2008) (explaining that early biotechnology medicines targeted fairly simple protein deficiencies and were produced by splicing genes into bacteria to produce proteins such as insulin for diabetes, blood clotting factors for hemophilia, and human erythropoietin for treating anemia).

considerably.[34]

Although Hatch-Wax encouraged the introduction of generic small-molecule drugs, it failed for biologics because the manufacturing processes for producing biologics are far more complex than the chemical processes of small-molecule drugs. The sensitivity of biological production to manufacturing conditions is far greater than that of chemical production. Variations in manufacturing conditions result in variation of the biologic structure. Thus, the production process cannot guarantee certainty in the structure of a protein drug.[35] Differences in starting materials or manufacturing conditions may result in structural variations between biologics intended to be identical.[36] For these reasons, a biologic is unlikely to be an exact replica of an originator's product.[37] Furthermore, a change in structure may result in different characteristics or performance, such as efficacy, biological activity, and mechanism of action.[38] Small-molecule generics, in contrast, typically achieve structural identity to the brand name chemical drug.

Because biologics are highly complex molecules, manufactured in living organisms with a high sensitivity to changes in manufacturing process, exact replication is nearly impossible.[39] The best that current scientific techniques can offer is to determine whether a biosimilar is similar to an innovator.[40] Biosimilars cannot truly be "generic" biologics because biosimilars can only achieve similarity, not identity.[41] Thus, the FDA does not consider pioneering biologics capable of having "generics" and instead the FDA uses the term "biosimilar" or "follow-on biologics" to refer to imitator

34. *Id.* Monoclonal antibodies, for example, are laboratory-made versions of the antibodies that comprise the body's natural defense against invaders. Interferons affect a cell's ability to reproduce, and can treat many diseases such as osteoporosis, chronic granulomatous disease, genital warts, multiple sclerosis, hairy cell leukemia. Antisense technology creates a mirror image of a defective gene that binds to it to prevent the body from producing a harmful protein. Therapeutic vaccines spur the body's immune system to fight disease and gene therapy can treat disease by augmenting, replacing, or inactivating existing genes. *Id.*

35. Linfong Tzeng, Note, *Follow-On Biologics, Data Exclusivity, and the FDA*, 25 BERKELEY TECH. L.J. 135, 138 (2010).

36. *Id.*

37. Aparna Yerramilli, *Biologics and Biosimilars: Are They?*, CARDIOLOGY TODAY (Apr. 2011), http://www.healio.com/Cardiology/news/print/cardiology-today/%7BC6296C4C-ACB6-4EC3-868D-C39592E2D35D%7D/Biologics-and-biosimilars-Are-they.

38. *Id.*

39. Nowicki, *supra* note 23, at 268.

40. Tzeng, *supra* note 35, at 139.

41. *Id.*

biologic drugs.[42]

Structural similarity does not translate into matching therapeutic properties either, because small differences in structure affect the biologic function of the biosimilar.[43] A biosimilar may have structural similarity to a brand name drug, it may treat the same medical indication, and it may utilize the same mechanism of action, but subtle differences in structure may translate into variations in safety or efficacy of the biosimilar as compared to the innovator drug.[44] Because current scientific analysis cannot account for or anticipate differences in safety or efficacy, biologics present the FDA with regulatory concerns over immunogenicity and interchangeability not encountered with generics.

"Immunogenicity" refers to the immune response the human body has to the biosimilar.[45] An originator's product may experience a particular immune response in the body, but the slight variation in the biosimilar's structure might trigger a much greater, or lesser, immunogenic response. Similarly, a brand name product will have a certain effect in the body, but, again, a biosimilar with even a slight difference in structure may have a dramatically greater or lesser effect. It is this unknown difference in efficacy that is the concern behind interchangeability. This is generally not a concern with generics because their structure is identical to the brand name drug.[46] "Interchangeability" refers to whether a biosimilar may be safely substituted for the innovator drug during the course of treatment.[47] If a biosimilar causes a wildly different reaction, it may not be interchanged with the originator's drug.

Interchangeability is achieved with the reference biologic if the "risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."[48] If a biosimilar is interchangeable with the reference product, the biosimilar "may be substituted for the reference product without the intervention of the

42. JOHNSON, supra note 12, at 1.

43. *See* Simon D. Roger, *Biosimilars: How Similar or Dissimilar Are They?*, 11 NEPHROLOGY 341, 342 (2006).

44. *Id.* at 342-43.

45. *Id.* at 343.

46. Tzeng, *supra* note 35, at 139.

47. *Id.* at 150.

48. Affordable Health Care for America Act, H.R. 3962, 111th Cong. § 2575(a)(2) (2009).

health care provider who prescribed the reference product."[49]

Many people experience interchangeability with generics in their daily lives—after a visit to one's physician for seasonal allergies one might go to the pharmacy with a prescription for Flonaze, a brand name nasal allergy medication, and instead simply request the generic version, Fluticasone. Neither the pharmacist nor the patient needs to confer with the prescribing physician and thus Fluticasone is interchangeable with Flonaze. This is not the case with biosimilars. Scientists in the United States have yet to find biologics that are interchangeable. The FDA purportedly determines interchangeability, like biosimilarity and immunogenicity, on a case-by-case basis. Unfortunately, at today's state of scientific development, only clinical trials can inform whether structural variations in biologics translate into changes in safety or efficacy.[50] Therefore, expensive and time-consuming clinical trials must be used to determine immunogenicity and interchangeability of biosimilars.[51] The FDA, however, has indicated that it does not believe current technology is evolved enough to truly establish interchangeability.[52]

Since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and worthwhile method of protecting intellectual property for drug developers. The next section explores data exclusivity.

B. Incentives for Innovators and Imitators

There are many reasons to develop and market a new drug product, such as commercial interests in generating sales, revenues, and profits, as well as humanitarian interests in improving health and lifestyles. Pharmaceutical companies expend tremendous amounts of money developing new drugs. The average cost of developing a new chemical drug is $802 million,[53] whereas the average cost of

49. *Id.* § 2575(b)(3).

50. Tzeng, *supra* note 35, at 140.

51. *Id.*

52. Kevin E. Noonan & James V. DeGuilio, *The Biosimilar Drug Approval Pathway: Draft FDA Guidance and Beyond*, MCDONNELL BOEHNEN HULBERT & BERGHOFF, LLP (Mar. 27, 2012) (remarks of James V. DeGuilio, Associate Attorney, McDonnell Boehnen Hulbert & Berghoff, LLP, during webinar presentation), *available at* http://www.mbhb.com/events/xpqEventDetail.aspx?xpST=EventDetail&event=44.

53. *Innovative R&D Strategies Remain Key to Developing New Medicines, According to the Tufts Center for the Study of Drug Development*, BUSINESSWIRE (Jan. 5, 2005), http://www.businesswire.com/news/home/20050105005039/en/Innovative-Strategies-Remain-Key-Developing-Medicines-Tufts.

developing a new biologic is $1.2 billion.[54] In passing Hatch-Wax, Congress wanted to balance the public's interest in having cheaper, generic drugs on the market without discouraging the investment in innovation necessary to create new treatments.[55] Various incentives in the drug approval process encourage inventors to expend the significant resources required to bring a drug to market. Congress built three different mechanisms into the drug approval scheme to help protect the investment of developers, providing developers with the hope that they will recoup their costs and make a profit, which, in turn, benefits society by providing new and improved treatments. These mechanisms are: patent term extensions, data exclusivity, and market exclusivity.

1. Patent Term Extension

Hatch-Wax offers innovators the possibility of patent extension.[56] A patent provides the patent owner the right to exclude others from making, using, or selling the patented invention.[57] In the drug industry a patent may cover a drug's composition, its manufacturing process, the method of use or a combination of these. A patent application is usually filed early in the drug development stage because an application typically must be filed within one year of the discovery or invention[58] and, if issued, the patent will have a term of 20 years from the date of filing.[59] Clinical trials, however, may take over six years to complete and FDA approval may take another year

54. *Average Cost to Develop a New Biotechnology Product Is $1.2 Billion, supra* note 1.

55. *See* Arie M. Michelsohn, *"Follow-On" Biologics: What Will It Take?*, SCITECH LAW., Fall 2008, at 4, 6.

56. The Hatch-Waxman Act allows patent term extension for small-molecule drugs under the Federal Food Drug and Cosmetic Act of 1938, as amended, and for biologics under the Public Health Service Act of 1944, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 201-300bbb (2011)), to allow for the time required to obtain FDA approval. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35 U.S.C.).

57. 35 U.S.C. § 271(a) (2011) ("Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.").

58. *Id.* § 102(b) ("A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States . . . ."). There are some exceptions to the one year filing period.

59. *Id.* § 154(a)(2) ("Subject to the payment of fees under this title, such grant shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed . . . .").

or two.[60] The average total time in drug development, from preclinical testing to FDA approval, is 8.5 years, with a possible maximum of 20 years.[61]

Assuming a patent is issued, a substantial portion of patent life may lapse before the drug reaches the market. To accommodate this regulatory "delay," Hatch-Wax provides an opportunity to add up to five years of patent term to account for the time pursuing FDA approval.[62] Such an applicant may only have one patent extended per product even if the product undergoing FDA approval is covered by multiple patents.[63] Another limitation on the patent term extension is that the rights that are extended are limited to the uses for which the drug was subject to FDA regulatory approval delays, and thus the extension does not restore the full scope of traditional patent rights.[64] Nonetheless, after extension, the average innovator of a chemical drug retains about 11-13 years of patent protection upon FDA approval.[65]

2. Data Exclusivity

In addition to patent extension, Hatch-Wax provides a five year period of data exclusivity for new drugs.[66] For generics providers, Hatch-Wax established a pathway to obtain abbreviated approval.[67] Specifically, section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) allows generic drug companies to rely on an innovator's FDA filings to demonstrate safety and effectiveness, provided that the generic drug is "bioequivalent" to the originator's

60. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECONS. 469, 475 (2007).

61. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVS.: DRUG DISCOVERY 417, 418 fig.1 (2004).

62. 35 U.S.C. § 156. The Hatch-Waxman Act allows for restoration of half the time spent in clinical trials and the full time spent by the FDA during final approval, up to five years, but caps the maximum patent life after restoration at 14 years, so the full five year restoration is not available if the drug developer retains a patent term of greater than nine years prior to patent term extension under the Hatch-Waxman Act.

63. JOHN R. THOMAS, PHARMACEUTICAL PATENT LAW 284-85 (2005).

64. *Id.* at 300.

65. Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECONS. 491, 495-96 (2007).

66. 21 U.S.C. § 355(j)(5)(F)(ii) (2011). After a drug containing a new chemical entity is approved, no one else may submit an application "for a drug product that contains the same active moiety as in the new chemical entity for a period of 5 years from the date of approval of the first approved new drug application." 21 C.F.R. § 314.108 (2012).

67. *See* 21 U.S.C. § 355(j).

drug.[68] A generic drug is considered bioequivalent if the subsequent applicant shows identical chemical structure for the active ingredient in the drug and other similar characteristics, such as route of administration, dosage, strength, and therapeutic formulation.[69] If these are demonstrated, the generic provider may then rely on the originator's clinical trial data in the generic filer's drug application process.[70] Demonstrating bioequivalence is far less expensive in drug development because Hatch-Wax excuses the generic applicant from conducting full clinical trials.

Clinical trials typically require three phases of testing on humans: a Phase 1 trial of a small population to test safety and toxicity, a Phase 2 trial in a moderate population to test the optimum dosage level of the new drug, and a Phase 3 trial in a large population to test the efficacy of the drug.[71] The FDA establishes for the applicant a recommended size for each population.[72]

By way of example, a Phase 1 clinical trial for a particular drug might require testing on 30 patients, with a Phase 2 trial on 100 patients and a Phase 3 trial on perhaps 500 or more patients.[73] Thus an innovator, in this example, must test the drug on over 630 patients. A generic applicant able to show bioequivalence will still have to conduct a Phase 1 trial, say on 30 patients, to demonstrate safety, but then would conduct what is called a "pivotal trial," which has combined elements of the typical Phase 2 and Phase 3 trials for showing optimum dosage and efficacy.[74] This is required on a modest patient population similar to the size of a Phase 2 trial.[75] Thus the generic applicant may only have to test on 130 patients in order to get its drug approved if it can show bioequivalence and rely on the innovator's data.[76]

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68. *Id.* § 355(j)(2).

69. *Id.*

70. *Id.*

71. Interview with Judi Appleman, Director of Regulatory Affairs, Phage Pharmaceuticals, Inc., in San Diego, Cal. (Feb. 13, 2012).

72. *Id.*

73. This example is a very small patient population; the FDA may require thousands of subjects to be tested in clinical trials for a new chemical entity or new indication submitted under 21 U.S.C. § 355(b)(2). *See* PETER E. CARLSON, NAT'L CTR. ON EDUC. & ECON., CLINICAL RESEARCH INDUSTRY TRENDS 5 (2007), *available at* http://www.workforcesolutionsalamo.org/pdf/NCEE%20Clinical%20Research%20Industry%20Report.pdf.

74. Interview with Judi Appleman, *supra* note 71.

75. *Id.*

76. *Id.*

The cost per patient varies widely by drug depending on the therapeutic indication and may vary from phase to phase in the clinical trials. Assume, however, for this example that it costs a drug developer $20,000 to treat each test subject. The innovator would spend over $12.6 million testing its 630 patients, while the generic provider demonstrating bioequivalence would spend only $2.6 million testing 130 patients. This hypothetical, representing a very small example, holds a $10 million savings. The cost benefit of using the abbreviated drug approval process is quite dramatic.

Although Hatch-Wax grants a generic applicant the ability to reference the originator's clinical trial data, the data exclusivity period granted to the innovator requires the generic applicant to wait five years after the approval of the new innovator drug before the generic developer may file an application that relies on the originator's clinical data.[77] During the data exclusivity period, the innovator enjoys a measure of market protection because generic products are delayed from entering the market, which in turn limits competition.[78]

The average remaining patent life on newly approved drugs that have patent protection is approximately 12 years.[79] In these situations data exclusivity persists for a relatively short time and thus patent protection is the primary means by which chemical drug innovators prohibit entry of generic competition into the marketplace.[80] Only when there is less than five years of patent term remaining after FDA approval does the importance of data exclusivity become more prominent.[81]

With such dramatic costs savings in drug development available, as demonstrated with the above example, Hatch-Wax unquestionably stimulated the generics market.[82] When Hatch-Wax was enacted in

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77. The waiting period is typically five years, but four years under certain circumstances. *See* 21 U.S.C. § 355(j)(5)(F)(ii) (explaining that "no application may be submitted . . . before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii)").

78. A competitor can still enter the market by conducting its own full clinical trials, which may take more time than the abbreviated process, but without the ability to rely on the innovator's data, the high cost of full clinical trials may deter market entry. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 189 (1999).

79. Tzeng, *supra* note 35, at 143.

80. *Id.*

81. *See id.*

82. *Id.* at 144.

1984, generic drugs comprised only 19% of prescriptions.[83] In 2009, generics represented 75% of prescriptions in the United States.[84] Estimates indicate consumers save $8 to $10 billion dollars through the use of generics.[85] Projections for generic dispensing in 2013 are 80% to 90%.[86]

3. Market Exclusivity

Some commentators confuse market exclusivity and data exclusivity, referring to them as one and the same thing.[87] They are not. Data exclusivity is a limitation on a competitor's ability to rely on the data of the innovator. A competitor may still enter the market by developing its own data through its own clinical trial activity. Market exclusivity, however, is a complete bar to competitors for drug approval. "Market exclusivity" is a term that refers to the FDA's refusal to approve another application for a particular drug for commercialization during a period of time after the innovator drug is approved to treat a particular indication.[88]

There are very limited circumstances under which an applicant may procure market exclusivity. Hatch-Wax provides for market exclusivity for orphan drugs and generics seeking accelerated approval if the drug is accompanied by a Paragraph IV certification and the applicant is successful in challenging an innovator's patent in court. The latter is granted market exclusivity for only 180 days. Of more significance and prominence is "orphan drug" status, which provides market exclusivity for seven years.[89] Market exclusivity is

83. FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 7 (2002).

84. *IMS Health Reports U.S. Prescription Sales Grew 5.1 Percent in 2009, to $300.3 Billion*, BLOOMBERG (Apr. 1, 2010), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=au5OPQhtu2bI.

85. *The US Generic Drugs Industry Overview*, THEMEDICA (Apr. 6, 2009. 10:50 AM), http://www.themedica.com/articles/2009/04/the-us-generic-drugs-industry.html.

86. *See* MEDCO, 2011 DRUG TREND REPORT: HEALTHCARE 2020, at 35 (2012).

87. *See, e.g.*, Joyce Wing Yan Tam, Note, *Biologics Revolution: The Intersection of Biotechnology, Patent Law, and Pharmaceutical Regulation*, 98 GEO. L.J. 535, 535-37 (2010).

88. *See* Orphan Drug Act, 21 U.S.C. § 360cc(a)(2) (2011) ("[F]or a drug designated . . . for a rare disease or condition, the Secretary may not approve another application ... for such drug for such disease or condition . . . until the expiration of seven years . . . ."). There is also a marketing exclusivity for a six-month period for pediatric treatments under section 505A of the FD&C Act (called the "pediatric exclusivity"). *See* FD&C Act, 21 U.S.C. § 355a (2011).

89. The Orphan Drug Act (ODA) was passed in the United States in January of 1983 as a means to encourage pharmaceutical companies to develop drugs for diseases that have a small market, which are defined as disorders affecting fewer than 200,000. John Henkel, *Orphan Drug Law Matures into Medical Mainstay*, FDA CONSUMER, May-June 1999, at 29, 30. Companies that develop an orphan drug not only may sell it without competition for seven years, but may

broader than data exclusivity because market exclusivity prevents all competitors from entering the market even if a competitor conducts its own full-scale clinical trials.[90] The FDA will not approve a generic or biosimilar version of the drug for treatment of the same disease or condition during the market exclusivity period.

4. Patent Challenges under the Hatch-Waxman Act

In addition to providing limited patent term extensions, market exclusivity and data exclusivity, Hatch-Wax contains another direct impact on the patent system. When an innovator applies for drug approval with the FDA it must identify each patent it holds that is applicable to the drug. Under Hatch-Wax, subsequent applicants that are seeking the benefit of the abbreviated approval process must file one of four different certifications, known as Paragraph I through Paragraph IV certifications.[91]

Each certification addresses a different situation for the subsequent applicant. A Paragraph I certification is filed if the originator failed to file its patent information with the FDA.[92] A Paragraph II certification is filed if the innovator's patent has expired.[93] A Paragraph III certification is filed if the innovator has a valid patent that will expire and the subsequent applicant is requesting approval on the date after that patent expires.[94] A Paragraph IV certification is filed if the subsequent applicant believes the originator's patent is either invalid or not infringed by the subsequent applicant by the manufacture, use, or sale of the new drug for which

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also receive clinical trial tax incentives. Andrew Pollack, *Orphan Drug Law Spurs Debate*, N.Y. TIMES, Apr. 30, 1990, at D1. The ODA was implemented to encourage R&D investment in diseases with small patient populations, which might otherwise not be appealing for companies to target. During the period from the inception of the ODA in 1983 to May 2010, the FDA approved 353 orphan drugs and granted orphan designations to 2,116 compounds. Walter Armstrong, *Pharma's Orphans*, PHARMACEUTICAL EXECUTIVE, May 2010, at 83, 84. The ODA is widely acknowledged to be a success. *Id.* at 86. Moreover, many other countries—particularly the European Union—have orphan drug laws comparable to the U.S. laws. *See, e.g.*, Carolyne Hathaway, John Manthei & Cassie Scherer, *Exclusivity Strategies in the United States and European Union*, FDLI UPDATE, May-June 2009, at 34, *available at* http://www.lw.com/upload/pubcontent/_pdf/pub2655_1.pdf.

90. 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, 98 (2010).

91. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV) (2011) (containing each of the four certifications as subparagraphs (I) through (IV), respectively).

92. *Id.* § 355(j)(2)(A)(vii)(I).

93. *Id.* § 355(j)(2)(A)(vii)(II).

94. *Id.* § 355(j)(2)(A)(vii)(III).

the application is submitted.[95]

Under a Paragraph IV certification the first applicant to successfully challenge the innovator's patent in court also receives the added benefit of a 180-day market exclusivity period.[96] This limited market exclusivity period is designed to encourage generic developers to file and challenge first. Some commentators believe this added benefit encourages drug developers to both design around others' patents as well as challenge invalid patents.[97]

C. The Biologics Price Competition and Innovation Act of 2009 (BPCI)

The biotech industry has a burgeoning abbreviated regulatory approval pathway for biosimilars, which has generated considerable attention. Regulatory approval for biologics was initiated under the Public Health Service Act of 1944 (PHS Act) pursuant to which the FDA currently approves "biological products."[98] This approval process for biologics resembles the pathway for chemical drugs under the FD&C Act.[99]

An innovator faces similar requirements whether it seeks approval of a biologic under the PHS Act or a chemical drug under the FD&C Act. However, a subsequent applicant seeking to reference the innovator's clinical trial data faces significantly different requirements under these two regimes. Approval of a new drug, biologic or chemical, begins with an application to the FDA, and upon allowance by the FDA the drug then undergoes clinical trials to determine its safety and efficacy.[100] As noted above, clinical trials progress from small-scale human testing in Phase 1 to large-scale human testing in Phase 3, with costs increasing at each phase.[101]

While Hatch-Wax created an abbreviated approval process allowing generics to rely on an originator's clinical trial data,[102] no such provision existed for biologics under the PHS Act. Thus, since the advent of biotechnology techniques in 1982, biotech companies have enjoyed what will be called here "continuous data exclusivity."

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95. *Id.* § 355(j)(2)(A)(vii)(IV).
96. *Id.* § 355(j)(5)(B).
97. FED. TRADE COMM'N, *supra* note 83, at 7.
98. Public Health and Welfare Act, 42 U.S.C. § 262 (2011).
99. *See* JOHNSON, *supra* note 12, at 6.
100. 42 U.S.C. § 262(a)(2)(C).
101. DiMasi & Grabowski, *supra* note 60, at 472.
102. *See* 21 U.S.C. § 355(j) (2011).

Except for one limited case, which will be discussed in a moment, imitators have not been able to rely on an innovator's data for the last 30 years—amounting to continuous data exclusivity. Thus new market entrants must bear full costly and time-consuming clinical trials in order to attain approval for a biosimilar.[103] While the European Union and Canada have more developed regulatory pathways for biosimilars and a number of biosimilars approved and on their markets, the United States currently has only one biosimilar approved, Omnitrope, a human growth hormone (HGH) product by Sandoz.

Sandoz is the generic drug unit of the Swiss pharmaceutical group Novartis. Sandoz filed its new drug application (NDA) for Omnitrope in 2003. In order to get its product approved, Sandoz sued the FDA in 2005 complaining that the FDA was "dragging its feet."[104] This was years before the BPCI, and thus Sandoz sought accelerated approval under the FD&C Act pursuant to Hatch-Wax, again marking the failure of Hatch-Wax with regard to biologics. Later that year, the FDA informed Sandoz it was unable to decide whether to approve Omnitrope, citing various scientific and legal issues.[105] This is not surprising, as an accelerated approval process for biosimilars was not yet established because of the immunogenicity and interchangeability issues described above in Part II.A.

Nevertheless, the FDA staff later apparently informed Sandoz that Omnitrope was safe and effective for its intended use but that it was indistinguishable from Pfizer's innovator product, Genotropin.[106] Sandoz filed suit complaining that the FDA had failed to act on the NDA for Omnitrope within the statutory time frame, also alleging that the FDA had no basis in fact or law to deny its approval.[107] While the Sandoz story is an aberration, it punctuates the quandary in the United States—legislation that provides for a biosimilar market but no concrete means to implement it.

Establishing a biosimilars market involves considerations not encountered in the generic pharmaceutical marketplace. Neither Hatch-Wax nor the PHS Act addressed these concerns (e.g., immunogenicity and interchangeability), nor could they. The next

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103. *See* JOHNSON, *supra* note 12, at 6.

104. Phil Taylor, *Sandoz Takes Issue with FDA over Biogenerics*, IN-PHARMA TECHNOLOGIST.COM (Sept. 15, 2005), http://www.in-pharmatechnologist.com/Regulatory-Safety/Sandoz-takes-issue-with-FDA-over-biogenerics.

105. *Id.*

106. *Id.*

107. *Id.*

attempt to foster a biosimilars market was the BPCI. It was introduced in 2007, but was not passed until it was incorporated into the Patient Protection and Affordable Care Act (PPACA), which was signed into law by President Obama on March 23, 2010.[108] Being intertwined with the PPACA, the BPCI was in jeopardy as a result of the controversy that ensued over the PPACA.[109]

Twenty-six states, private individuals, and organizations of independent businesses collectively brought action against the federal Health and Human Services, Treasury, and Labor Departments and their Secretaries challenging the constitutionality of the PPACA.[110] Much uncertainty ensued over whether the BPCI would survive and whether an accelerated biologics approval process was going to materialize.[111] On June 28, 2012, however, the Supreme Court upheld the PPACA with a 5-4 vote.[112] The BPCI remains intact and life science industry participants are examining how to move forward with biosimilars development.[113]

The BPCI amended the PHS Act to implement, among other things, an accelerated approval process for biosimilars[114] through an abbreviated drug license application under new subsection 351(k).[115]

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108. *See* PPACA, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended at 42 U.S.C. §§ 18001-18121 (2011)).

109. *See* Nat'l Fed'n of Indep. Bus. v. Sebelius (*NFIB*), 132 S. Ct. 2566 (2012). The PPACA has no severability clause, so if it is struck down, the BPCI would be struck down as well. *See* Michael A. Swift, Linda D. Bentley & Kelly Davis, *Biosimilar Regulations and CMOs*, FIERCEBIOTECH (June 26, 2012), http://www.fiercebiotech.com/offer/baxterjune?source=baxterhouse (remarks of Kelly Davis, Regulatory Affairs Associate Director, Baxter BioPharma Solutions, during webinar).

110. *NFIB*, 132 S. Ct. at 2572.

111. During a webinar sponsored by the Intellectual Property Owners Association on March 22, 2012, the presenters, Henry Hadad, Vice President and Deputy General Counsel of Bristol-Myers Squibb Co., Suzanne Drennon Munck, Chief Counsel for Intellectual Property for the Federal Trade Commission, Erika Lietzan, Partner at Covington & Burling LLP in Washington, D.C., and Pamela Sherrid, the host of IPOA's IP Chat Channel, were asked by participants over the Internet for insight as to whether the BPCI would survive the constitutional challenge of the PPACA; all presenters declined to answer or speculate. *See* Henry Hadad, Erika Lietzan & Suzanne Munck, *The FDA's Guidance on Biosimilars: Understanding the Impact on Patent Prosecution and Litigation*, INTELL. PROP. OWNERS ASS'N (Mar. 22, 2012), https://ipoevents.webex.com/ec0605l/eventcenter/recording/recordAction.do?siteurl=ipoevents&theAction=poprecord&path=pop_program_info&recordID=6321187 (webinar presentation).

112. *NFIB*, 132 S. Ct. 2566.

113. Alex Philippidis, *R&D Changes Foreseen After Supreme Court Obamacare Decision*, GENETIC ENG'G & BIOTECH. NEWS (July 5, 2012), http://www.genengnews.com/insight-and-intelligence/r-d-changes-foreseen-after-supreme-court-obamacare-decision/77899641/.

114. *See* PPACA §§ 7001-7003, 124 Stat. 804 (2010).

115. Hadad et al., *supra* note 111.

Much debate ensued over what the time period for data exclusivity should be, such that innovators can recoup the enormous R&D expenditures required to commercialize a new drug before biosimilars enter the market. A popular Duke study concluded it takes 12.9 to 16.2 years for innovators to break even on new biologics.[116] A study funded by Teva Pharmaceuticals, however, concluded that seven years was sufficient.[117] Scrutinizing much of this data, one commentator suggested the appropriate balance to foster innovation and protect investment lies in no less than 17 years.[118] In its final version, however, the BPCI provides for 12 years of data exclusivity.[119]

BPCI provides for the licensing of "biosimilar" and "interchangeable" biological products.[120] A follow-on product will be considered "biosimilar" if it is "highly similar"[121] to the original product (called the "reference product"[122]) and "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."[123] A product will be considered "interchangeable" if it "can be expected to produce the same clinical result as the reference product in any given patient,"[124] and the risk of switching the patient from the original product to the biosimilar product is expected not to be significantly greater, in terms of safety or diminished effectiveness, than the risk of continuing to use the original product.[125] Approved interchangeable products "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."[126] However, with immunogenicity and interchangeability issues still unsurmounted, no

116. Henry Grabowski, *Follow-On Biologics: Data Exclusivity and the Balance Between Innovation and Competition*, 7 NATURE REVS.: DRUG DISCOVERY 479, 486 (2008).

117. ALEX M. BRILL, PROPER DURATION OF DATA EXCLUSIVITY FOR GENERIC BIOLOGICS: A CRITIQUE 4, 11 (2008), *available at* http://www.tevadc.com/Brill_Exclusivity_in_Biogenerics.pdf.

118. John A. Vernon, Alan Bennett & Joseph H. Golec, *Exploration of Potential Economics of Follow-On Biologics and Implications for Data Exclusivity Periods for Biologics*, 16 B.U. J. SCI. & TECH. L. 55, 71 (2010).

119. 42 U.S.C. § 262(k)(7)(A) (2011) (section 7002(a)(2) of the PPACA).

120. *Id.* § 262(k).

121. *Id.* § 262(i)(2)(A) (section 7002(b)(3) of the PPACA).

122. *Id.* § 262(i)(4).

123. *Id.* § 262(i)(2)(B).

124. *Id.* § 262(k)(4)(A)(ii).

125. *Id.* § 262(k)(4)(B).

126. *Id.* § 262(i)(3).

biosimilars have been approved yet under the BPCI,[127] and thus there is still no biosimilars market in the United States.

Under continued pressure from the biotechnology industry, regulators have struggled to clarify and solidify a meaningful approval pathway for biosimilars. The need for a biosimilars market is felt on four fronts: (1) the government wants it,[128] (2) consumers want it, (3) even biotech companies want it,[129] and (4) the United States is clearly behind its foreign counterparts—the European Union, for example, has 14 biosimilars on the market.[130] After much controversy, pressure and debate, the FDA finally released initial guidance documents on February 10, 2012 to help facilitate biosimilar approval. The FDA even conducted a seminar on February 15, 2012, which included experts to discuss the guidance documents with industry participants.[131] Unfortunately, concepts such as "clinically meaningful differences" are still undefined and the best the FDA has to offer is that it says that it wants to facilitate the biosimilars market by meeting with developers "early and often" throughout the approval process.[132] But what constitutes "biosimilarity" will be determined "on a case by case basis."[133] Again, the FDA offers no clarity.[134] Notwithstanding, since this guidance was released the FDA has received 35 meeting requests for proposed biosimilars on 11 undisclosed reference products, which rely on the as-yet untried FDA guidance.[135] The FDA, however, has not received any applications as of June 26, 2012 under the new act.[136]

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127. *Biosimilar*, WIKIPEDIA, http://en.wikipedia.org/wiki/Biosimilar (last modified Jan. 16, 2013).

128. Congress estimates that biosimilars will save the government up to $25 billion in healthcare spending over the next decade. *See* Patricia F. Dimond, *What Will FDA Biosimilars Guidelines Mean for Industry?*, GENETIC ENG'G & BIOTECH. NEWS (Feb. 16, 2012), http://www.genengnews.com/insight-and-intelligenceand153/what-will-fda-biosimilars-guidelines-mean-for-industry/77899555/.

129. The global biosimilars market is expected to range between $11-25 billion by 2020 and is very appealing to pharma and biotech companies that can successfully manufacture and market biosimilars. *See id.*

130. Rachel E. Sherman, *Biosimilar Biological Products*, U.S. FOOD AND DRUG ADMIN. (Feb. 15, 2012), https://collaboration.fda.gov/p13473376/?launcher=false&fcsContent=true&pbMode=normal (webinar presentation).

131. *Id.*

132. *Id.*

133. *Id.*

134. *See* Swift et al., *supra* note 109.

135. *See* Interview with Judi Appleman, *supra* note 71; Noonan & DeGuilio, *supra* note 52.

136. Swift et al., *supra* note 109.

Legislators expect the biosimilars market to produce cost savings through competition in a similar fashion as what occurred with the advent of the generic drug market. While estimates of the potential savings vary,[137] the Obama Administration indicates a biosimilars approval pathway may save the federal government $14 billion over the next decade,[138] with consumer savings between $71 billion[139] and $108 billion during this period.[140] About 32 biologics may lose patent protection by the end of 2015, which represents $51 billion in sales in the United States.[141] This offers an opportunity for a profitable biosimilars market. However, the abbreviated process is still undefined and too new to determine the actual benefits on the marketplace or to the innovator or imitator. Since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and viable weapon in the intellectual property fund. The next section examines patent protection.

III. ASSESSING THE QUALITIES OF THE U.S. PATENT SYSTEM

A patent is an exchange between society and the inventor whereby government provides a limited monopoly to the inventor in recompense for the inventor fully disclosing the discovery, so that society can avail itself and enjoy the benefits of the new development.[142] In the United States, once a patent is issued, the holder is able to exclude others from making, using, having made, selling, offering to sell, or importing anything that practices the patented invention.[143] A patent does not give an inventor an absolute right to practice the invention; it grants only the right to exclude others. Exploitation by the owner depends on whether *others* have patents that overlap the invention's subject matter and whether the practice of the invention is subject to other existing laws.

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137. JOHNSON, *supra* note 12, at 4.

138. *Id.*

139. *Id.*

140. Tumulty, *supra* note 7.

141. MEDCO, *supra* note 86, at 53.

142. *See id.*

143. 35 U.S.C. § 262 (2011) ("Joint owners. In the absence of any agreement to the contrary, each of the joint owners of a patent may make, use, offer to sell, or sell the patented invention within the United States, or import the patented invention into the United States, without the consent of and without accounting to the other owners.").

A. Patent Terms in Pharmaceuticals and Biotechnology

Subject to successful prosecution and payment of applicable fees, patents are effective and enforceable beginning on the date on which the patent is issued by the United States Patent and Trademark Office (USPTO) and ending 20 years from the date on which the application for the patent was filed in the United States (or an earlier application if the application contains a specific reference to an earlier filed application).[144] A December 2011 report indicated that the average time for a patent to issue was 33.7 months,[145] or just shy of three years. Other commentators indicate the average time for prosecution of a U.S. patent is 3.4 years, but the average period for a biotech patent is 4.4. years.[146] Assuming four years for prosecution, upon issuance a biotech patent has 16 years of effectiveness.

As noted earlier, however, clinical trials may take over six years to complete, and FDA approval may take another year or two.[147] In addition, upon approval various steps toward commercialization need to be taken, and thus a substantial portion of patent life may lapse before the drug reaches the market. As also noted, there is some availability for limited patent term extension to accommodate some of the time spent pursuing FDA approval.[148] Nonetheless, even with extensions, as of 2010 the average effective patent life of a new drug is 11.7 years.[149] Hence, the BPCI provides for 12 years of data exclusivity. These figures for patent terms are, of course, averages. It is possible, for example, if a patent is prosecuted quickly and a new drug emerges from FDA approval quickly, one might enjoy a patent term of 17 years. The converse is also true: if patent prosecution and/or drug approval are protracted, there may be very little patent term remaining for a drug upon approval. Thus, while data exclusivity is a fixed period from the date of drug approval, the remaining term

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144. *Id.* § 154(a)(2).

145. Jim Singer, *How Long Does Patent and Trademark Prosecution Take? (2011 Update)*, IP SPOTLIGHT (Dec. 14, 2011), http://ipspotlight.com/2011/12/14/1780/.

146. Dennis S. Fernandez & James T. Huie, *Strategic Balancing of Patent and FDA Approval Processes to Maximize Market Exclusivity*, 7 ASIA PAC. BIOTECH NEWS 998, 998 (2003), *available at* http://www.iploft.com/PTO-FDA.pdf.

147. DiMasi & Grabowski, *supra* note 60, at 475.

148. 35 U.S.C. § 156. The Hatch-Waxman Act allows for restoration of half the time spent in clinical trials and the full time spent by the FDA during final approval, up to five years, but caps the maximum patent life after restoration at 14 years, so the full five year restoration is not available if the drug developer retains a patent term of greater than nine years prior to patent term extension under the Hatch-Waxman Act.

149. Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 116 (2000).

for any patents issued on such drug will vary from case to case.

B. Reasons for Patenting

Why do inventors and their employers file for patents? There are many reasons for seeking a patent, assuming the discovery or innovation satisfies the subject matter criteria for patentability. A number of widely recognized reasons for patenting are: (1) patent holders can sell products at higher than marginal costs; (2) patents can prevent competition and allow a holder to maintain supernormal profits; (3) patents allow an inventor to utilize litigation as a tool for enforcement; (4) some implement a "defensive" patenting strategy, using patents to stop infringement suits through counterclaiming or by lodging prior art to invalidate another's patent or prevent another from getting a patent issued; (5) patents are used as strategic "bargaining" chips, for example, in cross-licensing negotiations where the one with fewer patents often pays licensing fees to the holder of the most patents; (6) patents are viewed as valuable assets and help secure financing and investment, especially for smaller companies, which, in turn, funds R&D efforts; (7) as valuable assets, patents increase the value of a company for exit strategies, such as for an initial public offering (IPO), an acquisition, or liquidation; (8) patents may allow a company to gain access to a competitor's technology through the threat value of the incumbent's patents versus the entrant's technologies or patents, sometimes called "patent bullying;" (9) some implement a strategy of deploying "blocking patents" to stop evolution of others' technology, which might also include patent suppression to prevent a technology from developing; (10) patents have a cache for marketing, where even the "patent pending" moniker appeals to consumers; and (11) patents may increase one's reputation in an industry or simply satisfy vanity interests.[150]

C. Shortcomings of the U.S. Patent System

Commentators have noted that the U.S. patent system is deficient in at least four serious ways.[151] The first criticism is that the USPTO issues patents too freely, resulting in patents issued with various

150. Ted Sichelman, Professor of Law, Patent Law Policy Class Lecture at the University of San Diego School of Law (Jan. 24, 2012) (on file with author).

151. Ted Sichelman, *The Vonage Trilogy: A Case Study in "Patent Bullying"* 3 (San Diego Legal Studies Paper No. 11-057, 2011), [hereinafter *Patent Bullying*] *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1856703. *See generally* Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341 (2009) [hereinafter *Commercializing Patents*].

problems in the patent claims. Some contain claims that are anticipated or obvious in light of preexisting inventions.[152] Some claims are considered overly broad in relation to the disclosures contained in the specification of the patent.[153] Other claims are either vague and ambiguous or are otherwise hard to understand.[154] There are also claims that are introduced or amended years after the original patent application was filed.[155] The problem with copious "bad" patents is that once a patent is issued, it carries with it a presumption of validity. To challenge this presumption requires litigation to invalidate the patent, which may cost, on average, a million dollars or more.[156]

A second defect in the U.S. patent system is that there are excessively high transaction costs involved with litigation and negotiating licenses for patent rights.[157] These transaction costs are largely the result of widespread uncertainty and variability in various patent law principles.[158] These costs can be particularly distorted in fields where it is difficult to search for or analyze patents.[159] Many critics of the U.S. patent system remark that patent boundaries are hidden, unclear, or unpredictable and that, since infringement lawsuits are usually filed against firms exploiting new technologies, innovators are exposed to excessive risk of inadvertent infringement.[160]

A third problem is that patent holders can assert their rights at their discretion. This may not sound problematic on its face, but some patent holders will wait until a particular market is more developed before asserting their rights, allowing infringement to occur and persist while the market develops and participants become accustomed to certain technologies. Then, when the patent owner steps up, the purported and often innocent infringers may incur

152. Sichelman, *Patent Bullying*, *supra* note 151, at 3.

153. *Id.*

154. *Id.*

155. *Id.*

156. *Id.*

157. *Id.* at 3-4.

158. *Id.* at 4.

159. *Id. See also* Sichelman, *Commercializing Patents*, *supra* note 151, at 385-87 (discussing substantial transaction costs inventors face in light of broad patent claims).

160. JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 14 (2008); *see also* FED. TRADE COMM'N REPORT, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 75-76 (2011), *available at* http://www.ftc.gov/os/2011/03/110307patentreport.pdf.

exorbitant costs in substituting a non-infringing technology.[161]

A fourth deficiency is that different players in patent litigation have widely disparate resources, stakes and levels of risk aversion.[162] For example, non-practicing entities (NPEs, often called "patent trolls"), large patent holders, and startup companies each have disparate interests and resources in comparison to one another when lawsuits ensue. These inequalities sometime cause highly disproportionate litigation outcomes.[163]

Nonetheless, the frequency of patent litigation has tripled since the 1980s.[164] Despite this, profits associated with worldwide patents in the chemical and pharmaceutical industries far exceed the average cost of litigation to alleged infringers in the United States.[165] Thus despite increased litigation costs, patents appear to maintain significant value in the chemical and pharma fields. These, along with other indicators, suggest that the U.S. patent system still provides positive incentives for chemical and pharmaceutical inventors to innovate.[166]

These indicators diverge, however, as to small-molecule chemical drugs versus biologics. The uniqueness of a specific small molecule may be more easily demonstrated than the complexity of a biologic. That is, when trying to prove infringement, it is easier to show another small molecule is identical to the innovator's patented material. In contrast, because of the complexity of large biologic molecules and differences in manufacturing processes, one biologic likely has a different structure than a similar biologic, and, in turn, may display different properties. In this regard, chemical drug patents might provide stronger exclusion because they are more likely to be successfully enforced. In other words, it is easier to determine whether a competitor's chemical drug infringes. For biologics, however, structural differences may not only be different enough to avoid infringement, but they might give rise to different properties or bioactivity in the body, whereby those different features may be patentable in their own right.

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161. *See* Ted Sichelman, *Purging Patent Law of "Private Law" Remedies* 21-23 (San Diego Legal Studies, Working Paper No. 11-077, Sept. 23, 2011), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1932834.

162. *See generally* Stuart J.H. Graham & Ted Sichelman, *Why Do Start-Ups Patent?*, 23 BERKELEY TECH. L.J. 1063 (2008).

163. *See id.* at 1080-81.

164. BESSEN & MEURER, *supra* note 160, at 17.

165. *Id.* at 15-16.

166. *Id.* at 16, 27.

Furthermore, the patent specification must be sufficient to inform a person having ordinary skill in the art (PHOSITA) how to make and use the patented subject matter for its intended purpose.[167] This enablement requirement presents a unique problem for biologic inventions because they involve living materials, whereby a written account with a complete description may be insufficient to enable others to make and use the biological invention.[168] The enablement requirement has been interpreted to require the patent specification to provide enough information such that a PHOSITA may make and use the claimed invention without undue experimentation.[169] Manufacturing processes vary and some of the finer details of a manufacturer's process are often closely guarded trade secrets.[170] If a subsequent PHOSITA is unable to reliably reproduce the biologics product without access to additional information or without undue experimentation, then the patent may not be enabling and by definition be invalid.[171]

A unique patent implication that arises from the complexity of biologics is the "sweet spot" phenomena, whereby a biologic is similar enough for accelerated approval, but not identical for purposes of patent infringement.[172] Being in such a place would allow an imitator to enjoy the best of both worlds: accelerated drug approval without patent infringement. Other challenges the biotech industry faces with regard to the patent system will be discussed further below.

D. New Challenges for the Technology Industry with the America Invents Act

The America Invents Act (AIA) was signed into law by President Obama on September 16, 2011, with certain components

167. The enablement requirement is embodied in 35 U.S.C. § 112(a) (2011) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . . .").

168. THOMAS, *supra* note 63, at 208.

169. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984).

170. *BIO Principles on Follow-On Biologics*, BIOTECH. INDUS. ORG. (Jan. 18, 2008), http://www.bio.org/articles/bio-principles-follow-biologics.

171. *See* Gregory N. Mandel, *The Generic Biologics Debate: Industry's Unintended Admission That Biotech Patents Fail Enablement*, 11 VA. J.L. & TECH. 1, 24 (2006).

172. David S. Harper, Partner, McDonnell Boehnen Hulbert & Berghoff LLP, Presentation at the Association of University Technology Managers' Annual Meeting: Follow-On Biologics (Mar. 1, 2011).

yet to become effective.[173] The AIA is the subject of considerable controversy and debate of its own, which will not be covered in this article. Some commentators propose that technology companies will be subjected to an unprecedented wave of patent lawsuits that will stifle innovation.[174] Others argue the AIA may prevent startups from raising the capital required to commercialize their inventions.[175] Opponents of the AIA contend that venture funding may be diverted to less risky investments.[176] Some suggest that a startup that relies on patents for protection from competitive risk will lose certain protections available today, protection that allow them to gather the capital, strategic partners, and time for R&D and testing.[177] In addition, critics indicate that startups exposed to the risk of copying by more established companies will be unable to attract venture capital, and so will lack the financial resources necessary to commercialize their inventions and grow their companies.[178]

Whether any of this is true remains to be seen. For purposes of this article, it is simply noted that the AIA introduces new dubiety into an already murky patent system. Nevertheless, since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and sustainable defense in the fight for intellectual property.

IV. COMPARISON OF DATA EXCLUSIVITY WITH PATENTING

Some commentators suggest that data exclusivity periods are more important and more effective in protecting intellectual property

173. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); Ted Sichelman, Professor of Law, Patent Law Policy Class Lecture at the University of San Diego School of Law (Feb. 7, 2012) (on file with author).

174. *See, e.g.*, Tracie L. Bryant, *The America Invents Act: Slaying Trolls, Limiting Joinder*, 25 HARV. J.L. & TECH. 673, 675-76 (2012); *Leahy-Smith America Invents Act*, WIKIPEDIA, http://en.wikipedia.org/wiki/Leahy-Smith_America_Invents_Act (last modified Jan. 12, 2013); Matthew Yglesias, *America's Patent Crisis*, SLATE (July 5, 2012, 4:49 PM), http://www.slate.com/articles/business/small_business/2012/07/patents_innovation_and_the_america_invents_act_how_a_new_law_encouraging_more_efficient_patent_processing_could_stifle_american_innovation_.html.

175. *See Leahy-Smith America Invents Act*, *supra* note 174; Eric Savitz, *New Patent Law Means Trouble for Tech Entrepreneurs*, FORBES (Sept. 20, 2011, 4:04 PM), http://www.forbes.com/sites/ciocentral/2011/09/20/new-patent-law-means-trouble-for-tech-entrepreneurs/.

176. *Leahy-Smith America Invents Act*, *supra* note 174.

177. *Id.*

178. Gary M. Lauder, *Venture Capital—The Buck Stops Where?*, 2 MED. INNOVATION & BUS. 14, 14–19 (2010).

for biotech companies than the patent regime.[179] Some predict that biotech firms will come to rely more on data exclusivity over patenting their inventions to protect their competitive advantages.[180] Admittedly, the patent system is far from perfect and has its own host of issues and uncertainties. Regardless, however, the drug approval process and the patent system each provide very different benefits to biotech firms, even if some of the impact of these regimes produces similar effects in protecting one's space in the marketplace.

The debate over data exclusivity periods has been particularly significant because of what some commentators view as a critical examination of the effectiveness of patent law in advancing technology.[181] Some suggest recent Supreme Court decisions reflect a movement towards narrowing patent protections.[182]

Data exclusivity provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation embodied in the newly approved drug.[183] Exclusivity is available for new chemical entities (NCEs), which are by definition innovative, and for significant changes in already approved drug products, such as a new use.[184]

As noted earlier, the abbreviated drug approval process expressly permits the FDA to rely on data not developed by the applicant.[185] This could be published literature or the FDA's finding of safety and effectiveness of the innovator's previously approved drug.[186] Data exclusivity operates in two ways: (1) it precludes approval of certain applications under section 505(b)(2) of the FD&C Act and certain abbreviated new drug applications (ANDAs) for prescribed periods of time,[187] and (2) it delays the submission of section 505(b)(2) applications and ANDAs for certain periods of time.[188]

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179. *See* Morgan, *supra* note 90, at 93.

180. *Id.*

181. *Id.*

182. *Id.*

183. *See id.*

184. Tam, *supra* note 87, at 553.

185. *See* 21 U.S.C. § 355(b)(2) (2011).

186. *See id.*

187. *See id.* A 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

188. *Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069962.

Essentially, the FDA may not approve another application for a drug for which the investigations described in the application and relied upon by the applicant (here, an imitator) for approval of the application were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use from the originator for whom the investigations were originally conducted.[189] This last concept is important in that an imitator could procure a right of reference or use from the originator by either purchasing the data or licensing the rights to use, and thereby rely on the data much akin to licensing the rights to practice under another's patent. Data exclusivity and patenting are similar in this fashion, but they differ in significant ways.

A. Scope and Predictability

Two major differences between data exclusivity and patents are the scope of protection and its predictability. The scope of patents may be narrowing, as some commentators suggest,[190] and the greater number of patents that get issued in a particular field the narrower the ultimate claims might be when patents are issued; but a patent still has the potential of covering a much broader scope than data exclusivity. As noted above, data exclusivity protects a newly approved drug against a generic or a biosimilar—essentially, a competitor with the same type of drug. Data exclusivity might also protect a significant improvement or new use, but, again, it would only protect against an imitator seeking approval for *that same improvement or use*. A patent, however, may have far greater reach, depending on the interpretation of the scope of its claims.

A prominent, and probably extreme example, is U.S. Patent No. 4,528,643 ('643 patent), issued in 1985, which was for a kiosk that produced digital audio tapes in retails stores. The owner, E-Data, was successful in enforcing its patent against a host of e-commerce businesses.[191] E-commerce was not only a different technology, but did not even exist when '643 patent was issued. The Court of Appeals, however, concluded in 2001 that the "point of sale location" covering E-Data's kiosks also included bedrooms, offices, and anywhere else with an Internet connection.[192] The scope of the '643

htm (last visited Jan. 21, 2012).

189. *See* 21 C.F.R. 314.3 (2012); *see also* FD&C § 505(b)(2).

190. Morgan, *supra* note 90, at 93.

191. BESSEN & MEURER, *supra* note 160, at 2.

192. *Id.* at 9.

patent was unforeseen when issued and unpredicted before this ruling. Data exclusivity, however, has no unpredictable scope: it protects the data of the innovator held by the FDA. Even market exclusivity is predictable in scope: the FDA will not approve a generic or biosimilar for the indication, or treatment, for which approval is granted. Thus patents have the ability to protect a much broader area than data exclusivity.

Moreover, while market exclusivity—a patent—is a complete bar to competition, data exclusivity is not. A patent might prohibit one from practicing the scope of the patent during its term, but data exclusivity only precludes an imitator from relying on the innovator's clinical trial data. An imitator motivated enough to expend the resources may still compete if it has the wherewithal to conduct its own clinical trials. In fact, this behavior had already occurred before the BPCI was enacted. Despite the absence of an abbreviated approval process for biosimilars, six generic manufactures of HGH were able to obtain regulatory approval from the FDA by conducting their own comprehensive clinical trials.[193] Thus even the "continuous data exclusivity" that persisted did not prevent these competitors from entering the market. Such comprehensive clinical trial efforts were likely wasteful and redundant, and may be remedied if the new FDA guidance on biologics leads to accelerated approvals. Nonetheless, this behavior underscores a limitation of data exclusivity protection.

B. Preexisting Competition

Patent protection begins upon the USPTO issuing a patent. Arguably and to a lesser extent, a company simply touting an innovation or discovery as "patent pending" might also create some modest deterring effect and thus provide some measure of protection even before a patent is issued. However, having a patent does not necessarily prevent another from engaging in what might constitute infringing conduct. In fact, another entity might already be infringing one's patent even before or upon the issuance of the patent, whereby the patent holder might immediately file suit for infringement.

Data exclusivity, however, arises upon approval of a new drug, and by the drug being *new* there is no analogous "infringement." This is so because another company cannot legally commercialize a drug in the United States without first procuring FDA approval, which

193. *See* Henry Grabowski, Ian Cockburn & Genia Long, *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFF. 1291, 1293-94 (2006), *available at* http://content.healthaffairs.org/content/25/5/1291.full.html.

constitutes a license to market the drug. Selling drugs is a very complex business with other factors at play in addition to FDA approval, such as approval for reimbursement by medical plans, approval for listing on doctors' formularies so that doctors are aware of the availability of the drug, and acceptance in the medical community of the drug for treatment of either its approved use or an "off-label" use. With these and other considerations present, the barriers to entry are so high that competition for the newly approved drug may be minimal and perhaps nonexistent, whereas with a patented product, competition or infringement may already exist in the marketplace.

C. Passive versus Proactive

Another difference between data exclusivity and patenting is that data exclusivity is automatic. The innovator does not have to do anything—a passive characteristic. Upon drug approval, the innovator is already entitled to protection of its data and, indeed, the FDA will not allow an imitator to rely on the innovator's data in introducing a competing product. Furthermore, no additional cost is required to enjoy data exclusivity.

Patents, however, require affirmative action on the part of the patent holder: efforts to prosecute patent applications and enforce issued patent (which could possibly lead to expensive, complex, and uncertain litigation to guard against infringers)—proactive behavior. Nonetheless, despite costly litigation, worldwide profits on patents in the chemical and pharmaceutical industries exceed the aggregate cost of litigation in the United States against alleged infringers.[194] One commentator indicated that in 2000 the aggregate cost of U.S. patent litigation was just over $4 billion, while worldwide profits on patents were about $15 billion.[195]

D. Patent Thickets versus Downstream Reward

Another area where the utility of the patent system has been questioned is the "patent thickets" problem. The pharma and biotech industries are generally seen as areas where the financial value of the limited monopolies that patents offer is a key incentive for innovation of new products.[196] In 1980, however, the University and Small Business Patent Procedures Act (the Bayh-Dole Act) was passed to

194. BESSEN & MEURER, *supra* note 160, at 15-16.
195. *Id.* at 15.
196. Morgan, *supra* note 90, at 101.

encourage universities and other recipients of federal research funds to patent their R&D.[197] This has caused a proliferation of intellectual property rights in what is called "upstream" bioscience research that in the past was freely available and in the public domain for innovators to use. This research is now often tied up by patent holders and requires licensing of multiple patents from various upstream sources.[198]

This "patent thicket" is a phenomenon where multiple patent holders each have the right to exclude others from using a portion of the common information pool. Thus, because of transaction costs and strategic considerations, the rights to the information pool will not be allocated efficiently to allow for optimum use.[199] This creates significant pressure on downstream developers by way of search costs, licensing transaction costs, hold-up problems, and royalty-stacking problems.[200] Data exclusivity, on the other hand, does not bear this problem because it is designed to reward successful end-product development. The payoff—i.e., the license the FDA issues by approving a drug—focuses on the downstream effort: successful completion of the approval process.

E. Financial Considerations

The total cost for issuance of one patent for a startup biotech company ranges from $52,000 to $62,000.[201] This appears small in comparison to the overall costs of drug development, but biologics developers face considerably higher costs enforcing patents. Hatch-Wax itself, as noted above, has provisions that encourage generic providers to challenge the validity of innovators' patents. The BPCI has similar provisions.[202] The patent system's ability to serve as an incentive to innovation is undoubtedly impacted when one has to consider whether to pursue these lawsuits and risk patent invalidation

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197. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998), *available at* http://www.sciencemag.org/content/280/5364/698.full.

198. *Id.* at 698-701.

199. *Id.*

200. Morgan, *supra* note 90, at 102-03.

201. Ted Sichelman, Professor of Law, Patent Law Policy Class Lecture at the University of San Diego School of Law (Feb. 14, 2012) (on file with author).

202. *See* BPCI § 351(*l*)(1)(D) (explaining that the applicant seeking accelerated approval must provide information to the innovator sufficient for the innovator to determine "whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k)").

or enter into costly reverse-payment settlements with generic challengers.[203] A lawsuit to invalidate a patent typically costs a million dollars or more.[204]

The biotech industry has expressed concern that patent protection is narrower for biologics than pharmaceuticals because imitators can more easily design around patents to avoid infringement.[205] Some commentators suggest that utilizing FDA exclusivity as the primary motivator for innovation may entirely eliminate the costs of litigation and patent challenges and uncertainties with patenting.[206] Such logic is naïve because it ignores the possibility that an innovator that relies solely on data exclusivity and has no patents may still be subject to patent suits by others who might claim the innovator infringes *their* patents. Such an innovator would be at a disadvantage because it would have no patents to assert back against the aggressor.

Furthermore, while data exclusivity is part and parcel of the FDA approval process, and thus has no added cost, the FDA approval process alone is very expensive in comparison to patenting. As noted earlier, the average cost of bringing a new biologic to market is $1.2 billion[207] and the simple generic hypothetical showed an innovator spending $12.6 million on clinical trials with an imitator spending only $2.6 million on clinical trials, if able to use an accelerated approval process. Assuming the cost of obtaining a patent is on the high end of the $52,000-$62,000 range, and a hypothetical developer has three patents covering various aspects of a particular drug, the budget for the patent portfolio would be $186,000. This, of course, does not take into consideration any costs incurred with potential patent infringement. Regardless of whether one uses the hypothetical average cost of $1.2 billion for a new biologic or $12.6 million just for clinical trials, the costs of patenting is such a small fraction: only 1.5% of a $12.6 million budget, and unnoticeable in a budget of $1.2 billion.

Going beyond just this simple hypothetical, it might be helpful to examine the cost of actual patent portfolios against the average new

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203. Morgan, *supra* note 90, at 104.

204. Sichelman, *Patent Bullying, supra* note 151, at 3.

205. *See* BIOTECH. INDUS. ORG., A FOLLOW-ON BIOLOGICS REGIME WITHOUT STRONG DATA EXCLUSIVITY WILL STIFLE THE DEVELOPMENT OF NEW MEDICINES 3-4 (2007), *available at* http://bio-org.preview.interworks.com/articles/follow-biologics-regime-without-strong-data-exclusivity-will-stifle-development.

206. Morgan, *supra* note 90, at 104.

207. *Average Cost to Develop a New Biotechnology Product Is $1.2 Billion, supra* note 1.

biologics price tag of $1.2 billion. Some commentators conducted a study in 2008 through the Berkeley Center for Law and Technology on patenting behaviors of startup companies whereby they received responses form 1,332 unique companies.[208] This study gathered results from two populations: one set of companies through Dun & Bradstreet (D&B) and another set through venture capital (VC) resources. In that study, the D&B companies in biotechnology demonstrated an average cost of patenting of $52,000[209] and an average number of patents held by each company as 9.7.[210] This translates into a budget of $504,400 for the entire patent portfolio for the average biotech startup in this group. The VC companies reported average cost of patenting of $62,000[211] and an average number of patents and applications held as 34.6.[212] This reflects a total budget of $2,145,200 for the patent portfolio of the average biotech startup in this study.

Even at the high end of $2,145,200, the entire patent portfolio cost is still a mere pittance, less than 0.2% of a drug development budget of $1.2 billion. While the patent system may not be perfect, it seems that such a relatively small dollar amount would indicate that, if an aspect of a drug product was patentable, the developer likely would—or at least ought to—seek patent protection.

F. Effects on Innovation

Another criticism of the patent system in the biologics world is that reliance on patenting deters innovators from investing R&D efforts into unpatentable drugs. This may be true. The biotech industry, particularly as to small companies, relies on patents as a source of fund raising.[213] Small biotech companies play an important role in filling the innovation space between the research conducted at universities and the product development being done at large firms.[214] The United States has over 1,500 biotechnology companies, most of which are relatively small.[215] Small biotech companies often depend

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208. Stuart J.H. Graham & Ted Sichelman, *Patenting by High Technology Entrepreneurs*, *in* CREATIVITY, LAW AND ENTREPRENEURSHIP 156, 157, 162 (Shubha Ghosh & Robin P. Malloy eds., 2011).

209. Sichelman, *supra* note 201.

210. Graham & Sichelman, *supra* note 208, at 165 tbl. 9.1.

211. Sichelman, *supra* note 201.

212. Graham & Sichelman, *supra* note 208, at 165 tbl. 9.1.

213. *Id.* at 170-72.

214. *See* Grabowski et al., *supra* note 193, at 1294.

215. David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant*

on their patent portfolios to attract venture financing and equity capital.[216]

It is likely that unpatentable drugs in a small company's development pipeline would be less attractive to investors (and more specifically to venture capital) than a more robust patent portfolio. Regardless of whether a biologic is patentable, it might still be a viable therapeutic with significant commercial and social value. If reliance on data exclusivity increases, it likely would cause drug developers to view unpatentable therapeutics as more appealing endeavors.

If reliance on data exclusivity causes a decrease in reliance on patents for protection, some commentators wonder whether innovation at the small biotech level would be impaired. While this argument may be plausible, and on its face intuitive, it neglects the fact that not all companies rely on patent protection.

That same 2008 Berkeley study revealed several reasons why startup companies chose *not* to patent certain inventions. Some reasons for not patenting were: (1) not wanting to disclose the invention, (2) cost of filing, (3) ease of competitors inventing around, (4) a belief that trade secret protection was adequate, (5) the cost of enforcing, (6) a belief that the invention was not patentable, and (7) a belief that the invention did not need protection.[217] Those results demonstrated that small biotech companies already have a number of reasons why they do not pursue patents. The availability of FDA data exclusivity may be just one more reason they might choose not to patent.

G. Incongruent Terms

Another difference is the incongruence between the terms of each system. As noted above, data exclusivity is for a specific period running from the date of drug approval. A patent's term, however, runs for a period of 20 years from the date of filing, regardless of when the patent issues (assuming it issues at all) and regardless of when or if drug approval occurs. These terms are clearly asynchronous. This is not to suggest these periods should be

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to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies, 60 FOOD & DRUG L.J. 143, 178 (2005). A biotech company may also be considered "small" under the definition the USPTO uses for small patent filers, which is a company of 500 or fewer employees. *See* 13 C.F.R. §§ 121.801-.805 (2012).

216. Morgan, *supra* note 90, at 110.

217. Graham & Sichelman, *supra* note 208, at 173-74.

harmonized; these protections will cover different periods and whether one is more dominant in providing protection will differ from case to case. Thus one cannot conclude based on time frames alone that patenting or data exclusivity is superior over the other.

H. Public versus Proprietary

One difference between the FDA approval process and the patent system that appears to have garnered little conversation is that the patent system is designed to foster complete disclosure of the invention such that a person having ordinary skill in the art can practice the invention. At present there is no comparable requirement with the FDA. The FDA treats clinical trial data as proprietary[218] to the innovator that submits it under application for approval, and it is not subject to disclosure.[219] This may further lend credibility to the argument that an increase in reliance on data exclusivity might focus more attention on unpatentable drugs.

This also seems to suggest that if patent prosecution is questionable—that is, a patent might not issue—or if a drug developer believes it has valuable trade secrets that it would not want disclosed through the patent system, an innovator would retain trade secret protection by pursuing drug approval through the FDA alone. This is especially true in a risky situation where a patent might not ultimately issue, yet the invention will be disclosed when the application publishes. The trade secrets would then be forfeited as a result of public disclosure, with no patent protection to follow, thereby jeopardizing intellectual property value.

Data exclusivity has its protective features, but patents clearly have different and broader protections. Table 1 shows a number of characteristics of data exclusivity side by side with patenting discussed here. This helps to illustrate at a glance the few similarities they share, but how different these protections are. Since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and viable weapon in the intellectual property arsenal.

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218. *See* 21 U.S.C. § 331 (2011) ("The following acts and the causing thereof are prohibited: . . . (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired . . . concerning any method or process which as a trade secret is entitled to protection . . . .").

219. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 380 (2007).

Table 1. Comparison Between Characteristics of Data Exclusivity and Patents

CRITERIA	COMPARISON	
	DATA EXCLUSIVITY	PATENTS
Decision-making	No choice	Must decide early (one year) but can forego
Becomes effective	Automatic	Requires effort to prosecute
Effort required	Passive	Proactive
Focus on protection	Downstream reward	Upstream—patent thickets
Outcomes	Predictable	Uncertain
Coverage	Single product	Possibly multiple products/processes
Scope	Narrow scope—specific Rx*; specific Tx**	Broad scope (potentially)
Approach	Single strategy—protects only your data	Multiple strategies can be deployed***
Value	Undetermined value	Valuable for fundraising/investment
Intersection with competition	Precedes competition	Possible preexisting competition
Cost of protection	No additional cost (but Rx approval expensive)	$52K-$62K each
Effect on innovation	Encourages innovation†	Encourages innovation (chemical/pharma)†
Duration	Term runs 12 years from Rx approval	Term runs 20 years from filing (+ extension)
Information	Proprietary (+ regulatory impracticality)	Public

† similar characteristic
* Rx—medical shorthand for "drug"
** Tx—medical shorthand for "treatment"
*** Litigation as a tool; defensive strategies (counterclaiming, lodging prior art, etc.); bargaining chips; bullying (gaining access to competitor's technology); blocking strategies; cache/reputation

V. REGULATORY IMPRACTICALITY—AN IMPEDIMENT TO BIOSIMILARS

In exploring the nature of FDA data exclusivity in relation to the patent system, a few characteristics have surfaced that indicate a barrier to entry that has gone unaddressed. There are gaps in legislation: the BPCI, for example, has terse, limited and unclear definitions. With limitations in today's science and no practical access to innovators' manufacturing processes, the industry also lacks mechanisms to effectively develop biosimilars. These circumstances amount to an obstacle to entering the biosimilar market. The effect of these impediments seems to dangle on the fringes of dialogue among commentators and industry professionals without really being articulated or acknowledged. This concept is referred to here as "regulatory impracticality."

As noted earlier, manufacturers often maintain aspects of their manufacturing processes as trade secrets. Moreover, all application materials, including manufacturing processes and test results from trials, are kept proprietary when submitted to the FDA. It is true that the law allows an applicant to rely on information for approval that was "not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use."[220] Yet although the current law permits an imitator to rely on the innovator's clinical trial data, the law does not provide a mechanism for the imitator to get that data. The FDC&A allows the FDA to rely on data not developed by the imitator, which the FDA has in its coffers, but because this data is proprietary, the FDA cannot share it and an imitator has no access to it.[221] An overlooked circumstance is that access to an innovator's data is highly unlikely to occur because an innovator has no motivation to voluntarily cooperate with an imitator. Therefore, the biosimilar developer does not know and will not know what the data is in order to make use of it and reference it. This is an aspect of regulatory impracticality.

Because biologics are so complex, the imitator necessarily needs to know the innovator's manufacturing process in order to determine how similar or different that process is to the imitator's.[222] Otherwise the imitator has no way of assessing or predicting, if it can, how

220. *See* 21 U.S.C. § 355(b)(2) (2011).

221. Telephone Interview with David Harper, Partner, McDonnell Boehnen Hulbert & Berghoff LLP (Mar. 14, 2012).

222. Interview with Wei Chen, Chief Scientific Officer, Phage Pharmaceuticals, Inc., in San Diego, Cal. (Mar. 7, 2012).

similar the structure of its product might be as compared to the innovator.[223] This has not been an issue in the small-molecule, chemical world. Because of the simplicity of their molecular structures, different manufacturing processes can still arrive at an identical compound, thus achieving structural identity. However, because of the size and complexity involved with biologics, not knowing how the product is made is an impediment in developing a biosimilar.[224] The regulatory regime has not accounted for this issue, which makes it impractical for companies to rely on another's data to effectively develop biosimilars, thus creating regulatory impracticality.

The current regulatory environment has also failed to provide a meaningful pathway to develop a biosimilar, which contributes to regulatory impracticality. Even with the FDA's recently released guidance documents, webinar, and teleconference, vague terms in the statute like "highly similar" and "no clinically meaningful differences" remain undefined. [225] Worse, they are hardly enhanced by the FDA with its further bewildering and imprecise guidance: that accelerated approval will be considered under the "totality of the evidence" on a "case by case basis."[226] The BPCI does not require FDA guidance,[227] and what guidance the FDA provided is still in draft form. The industry awaits "final" guidance from the FDA to implement the BPCI.[228] Thus unlike the small-molecule approval process, where reduced clinical trial activity (and concomitant cost savings) can be anticipated, a biosimilar developer has no idea at this time how much clinical trial activity the FDA will require in order to demonstrate biosimilarity.[229] Furthermore, even though the FDA indicates it wishes to interact with biosimilar developers "early and often" during the drug approval process,[230] the current state of science does not have mechanisms for one to prove immunogenicity and interchangeability without clinical trials.[231] A biosimilar developer

223. *Id.*

224. *Id.*

225. Sherman, *supra* note 130.

226. *Id.*

227. Swift et al., *supra* note 109.

228. Philippidis, *supra* note 113.

229. Noonan & DeGuilio, *supra* note 52 (noting that the FDA has provided no clarity on the extent of evidence or criteria applied).

230. Sherman, *supra* note 130.

231. Noonan & DeGuilio, *supra* note 52 (noting that the proposed rules still fall short of providing a clear understanding of the best way to develop this market and further noting the FDA has provided no specific guidance on biosimilarity assays or preferred ranges for

cannot predict how much or how little testing may be required and thus cost savings and time to accelerated approval cannot be estimated.[232] Again, the regulatory environment does not provide a clear pathway—another characteristic of regulatory impracticality.

Innovators may be on more sure footing in that regulatory impracticality prevents or at least delays development of biosimilars.[233] Again, since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and feasible deterrent in protecting one's intellectual property.

VI. A SURVEY OF INDUSTRY PROFESSIONALS ON DATA EXCLUSIVITY AS COMPARED TO PATENTS REGARDING BIOSIMILARS

Much of the discussion about the interplay between patenting and data exclusivity in the coming biosimilars market so far is hypothetical and intuited from limited industry data. It is not yet known how FDA data exclusivity will affect patenting behavior, if at all. To get some perspective of what some industry practitioners think, the author conducted a limited survey of senior managers at biotechnology companies. Respondents could be chief executive officers, chief financial officers, chief operating officers, general counsel, chief scientific officers, regulatory affairs personnel, or other senior staff. They were asked to complete an anonymous survey posted online using SurveyMonkey.com that consisted of 10 questions. Managers at companies in Southern California were approached first, all from small biotech companies. The number of respondents in this group was limited, however, so the survey request was posted on biotech and pharma group message boards on LinkedIn, particularly those interested in biosimilars. Thus the final group of respondents could have been from across the nation and possibly international. The survey questions pertained to the U.S. FDA and the USPTO and patent system, so even an international respondent would be acceptable if she or he had experience or familiarity with these systems. As of August 6, 2012, a total of 73 people answered the survey.

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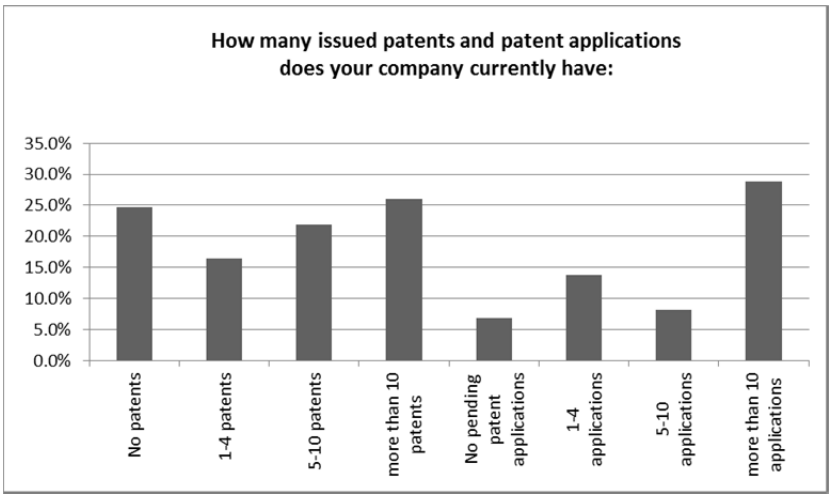
demonstrating biosimilarity).

232. *Id.* (noting that the FDA has provided no clarity on the amount of investment required for manufacturers of biosimilars).

233. *Id.* (noting that because lingering uncertainty may discourage use of abbreviated pathway, no interchangeable biosimilar products will be approved in the near future and that there is no threat to market share from biosimilar competitors).

First, to get a perspective of how relevant these issues might be to these managers or their businesses, the questions asked how many patents and patent applications their respective companies held, as well as how many drug products each had either commercialized or in development. The results for patents and patent applications are in the following chart:

Figure 3. Number of Issued Patents and Patent Applications



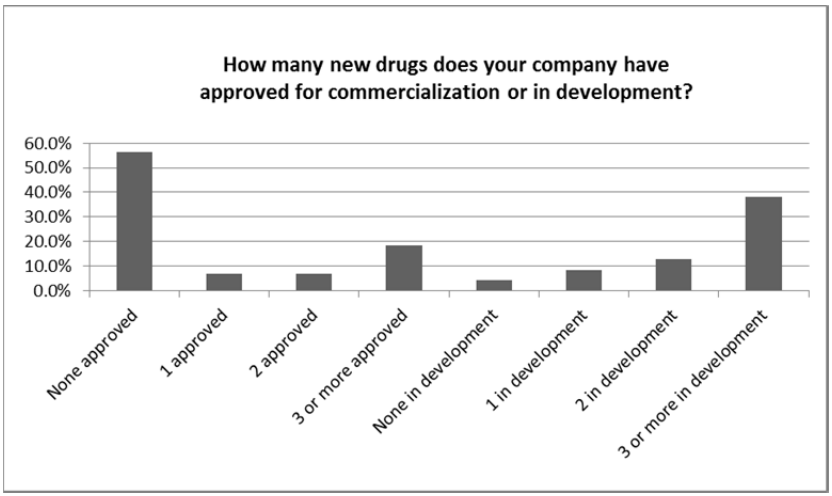
Surprisingly, 18 respondents, representing 24.7% of the survey population, have no patents issued from the USPTO. A dozen, representing 16.4%, have one to four patents. Sixteen, or 21.9%, have 5-10 patents and the largest segment, 19, or 26.0%, reported more than 10 issued patents. With regard to patent applications, only five respondents, or 6.8% of the population, reported no pending applications. Ten, or 13.7%, reported 1-4 applications. Six, or 8.2%, reported 5-10 applications pending and almost a third, 21 respondents representing 28.8%, reported they have more than 10 patent applications pending with the USPTO.

Respondents were then asked whether they believe patents adequately protect their companies from competition. Almost two thirds (43 respondents), or 59.7%, answered "Yes." Twenty-nine respondents, or 40.3%, reported they do not believe patents adequately protect their companies. One respondent skipped this question. Just over two thirds (48 respondents), or 66.7%, reported that their companies use patents as a means of raising money or

attracting investors. About a third (25 respondents), or 34.7%, reported they do not. Curiously, this adds up to 101.4%, which suggests that a respondent may have checked both "Yes" and "No." Regardless, it reflects that just more than a supermajority of this population uses patents for fundraising.

With regard to their product pipelines, senior management was asked how many drugs their companies have approved for commercialization and in development. The results are in the following chart:

Figure 4. Number of New Drugs Approved for Commercialization or in Development



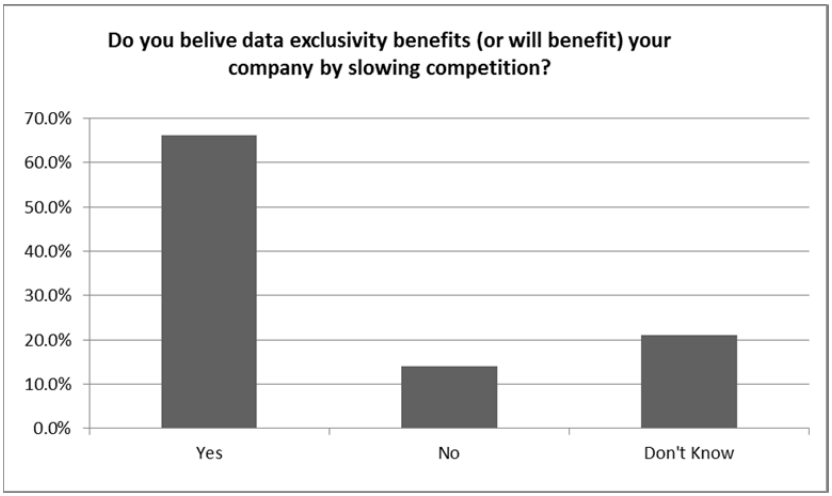
Forty companies, or 56.3%, are in development stage, that is, with no approved drugs. Five, or 7%, have one drug on the market. Another 7% reported having two drugs commercialized and 13, or 18.3%, reported having three or more drugs approved.

Respondents were also asked how many drugs each has in development. Three respondents, 4.2%, reported no drugs in development. A half dozen, 8.5%, reported having one drug in development. Nine companies, or 12.7%, reported having two drug candidates and 27 respondents, 38%, are pursuing three or more drug products. Two respondents skipped this question. This suggests respondents were primarily development stage companies, with almost two thirds having no drugs on the market, yet over a third are pursuing three or more candidates.

Almost two thirds of the respondents (46), or 63.9%, reported no biosimilars in development. Five respondents, 6.9%, however, reported one biosimilar in development and a half dozen, 8.3%, have two biosimilars in development. Fifteen, or 20.8%, indicated three or more biosimilars in development. This is helpful insight because it appears to support the industry perception that developing biosimilars is so expensive that small companies do not have the resources to bring biosimilars to market.[234] Even if so, however, the response here shows the foray of some small companies in the biosimilars marketplace.

It seemed important to get an understanding as to where these companies were positioned with regard to their patenting efforts and drug development efforts, in order to get insight into whether they might have an appreciation for data exclusivity. Seeing that the majority demonstrated a decent amount of patent activity and a decent portion had some development efforts directed at biosimilars, it is likely that many are able to consider whether data exclusivity is meaningful to their respective companies. The results are as follows:

Figure 5. Perceived Benefit of Data Exclusivity



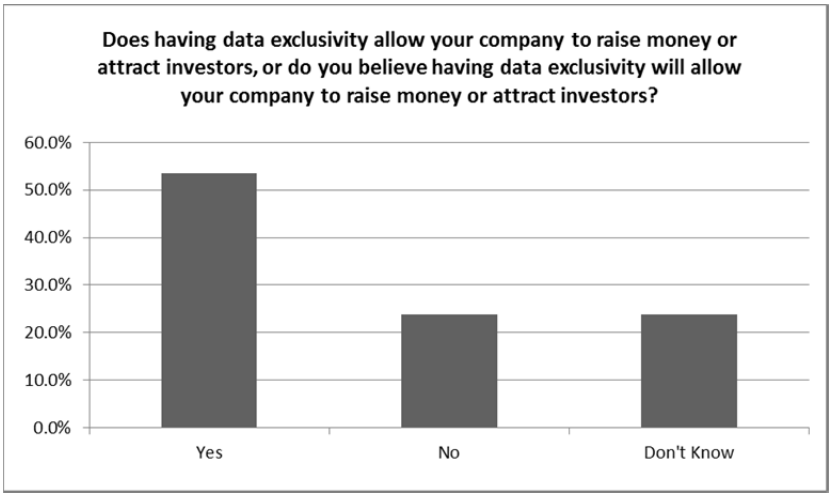
Just about two thirds (47 respondents), or 66.2%, reported that they believe data exclusivity does or will benefit their companies by slowing competition. Ten, or 14.1%, however, said they do not

234. Hadad et al., *supra* note 111 (remarks of Erika Lietzan, Partner at Covington & Burling LLP in Washington, D.C.).

believe data exclusivity does or will slow competition. Fifteen respondents, representing 21.1%, answered that they do not know.

Similar to asking about the role of patents in fund raising, it seemed reasonable to inquire whether respondents think data exclusivity has similar value. The results to this question are as follows:

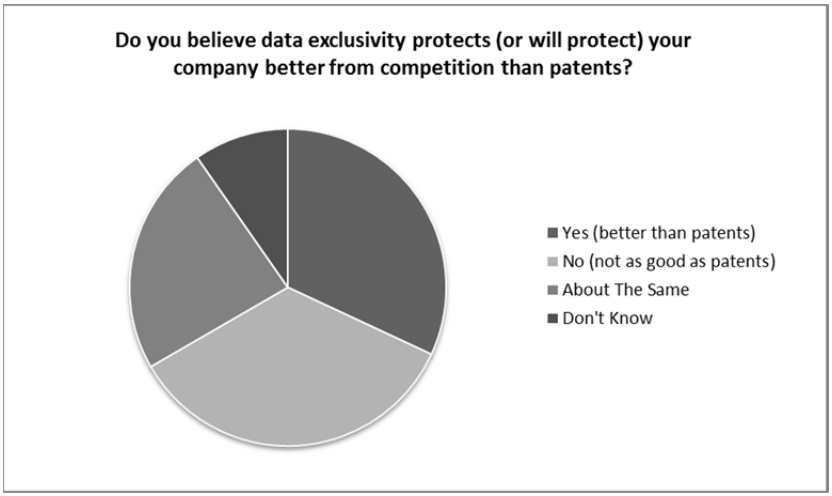
Figure 6. Using Data Exclusivity to Raise Money or Attract Investors



Interestingly, the overwhelming majority, 38 people or 53.5% of the survey population, reported that they believe having data exclusivity does or will allow them to raise money or attract investors. Seventeen, or 23.9%, said they do not believe data exclusivity allows or will allow them to raise money or attract investors. Another 17, 23.9%, said they do not know, and two respondents skipped this question.

In comparing patent protection with data exclusivity, senior managers were asked whether they believe data exclusivity protects their companies better from competition than patents. The results are reflected in the following chart:

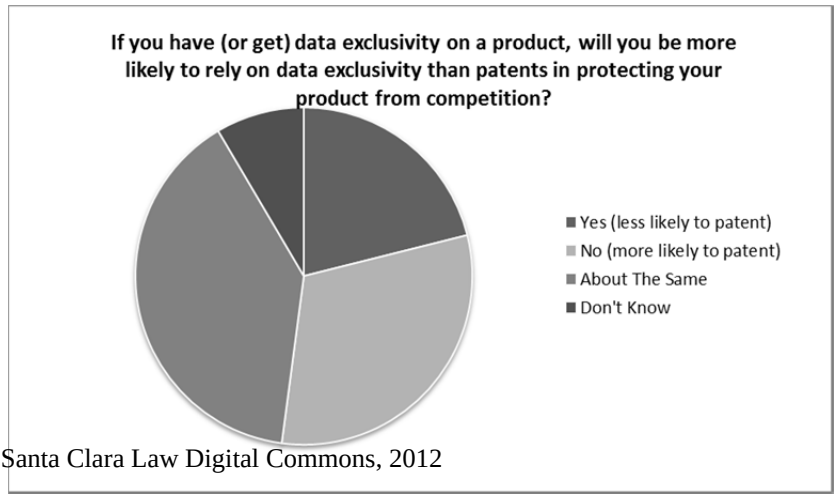
Figure 7. Data Exclusivity Protection versus Patent Protection



Twenty-three people, 31.9%, said they believe data exclusivity protects or will protect their companies from competition better than patents. Twenty-five, 34.7%, however, stated patents provide better protection. Seventeen, or 23.6%, believe data exclusivity will protect their companies about the same as patents. Seven respondents, 9.7%, said they do not know whether data exclusivity protects better than patents. One respondent skipped this question.

The next question in the survey asked whether having data exclusivity on a product would make one less likely to seek patent protection. The following chart displays the responses:

Figure 8. Reliance on Data Exclusivity versus Patents



Over a fifth of the population (15 respondents), or 21.1%, agreed. Almost a third (22), or 31%, said they would be more likely to patent. Almost two fifths (28), or 39.4%, reported that they believe they would still engage in about the same amount of patent activity. A half dozen, representing 8.5%, said they do not know whether their patenting behavior would change.

This answer is telling because it runs directly counter to the position of commentators who believe data exclusivity will replace or reduce patenting. Along this vein, the Intellectual Property Owners Association (IPOA) took a poll during a webinar held on March 22, 2012, asking attendees what they believed the impact of the twelve-year data exclusivity period would be on the importance of patent protection for biotech companies.[235] Sixty-eight percent of attendees said patents will continue to be very important; while 32% answered patents will diminish in importance.[236] This IPOA question is very similar to the survey question on the expected importance of patents. Combining those from the survey that indicated they would patent the same or more results in 70.4%. As noted, 21.1% indicated they are less likely to patent. These results are quite similar to the IPOA poll during which webinar attendees answered 68% and 32%, respectively.[237] The IPOA webinar attendees were purportedly biotech professionals (though not necessarily senior management), and thus, the population is likely similar to the survey respondents for this article, who were also purportedly biotech professionals.

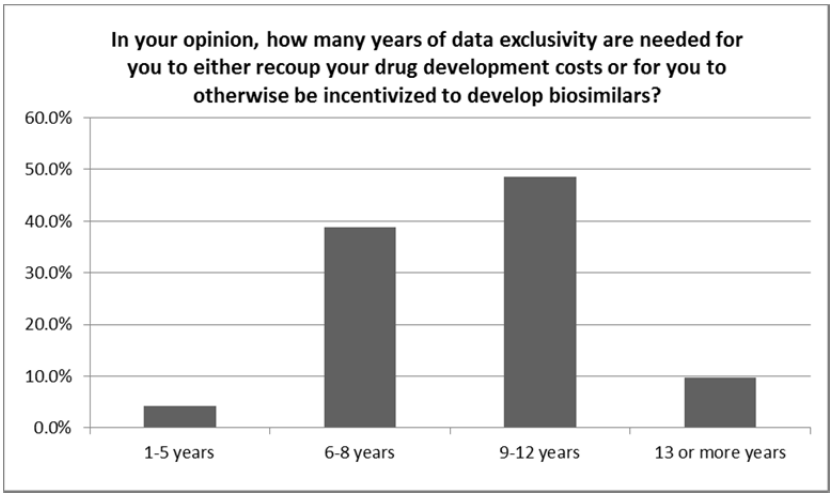
Lastly, respondents were asked to give their opinion as to what number of years they believed was necessary for their companies to either recoup their drug developments costs or otherwise be incentivized to develop biosimilars. The survey informed them of the current twelve-year period and the proposed seven-year period being considered by the Obama Administration. The following chart shows the opinions of the respondents:

235. *See* Hadad et al., *supra* note 111.

236. *Id.*

237. The author called the IPOA and asked how many attendees had registered or signed on to the webinar on March 22, 2012. The IPOA representative explained there were 60 registrants for the webinar, and while the exact number of respondents to the poll was not known, the IPOA representative explained that 90% of registrants typically attend the webinars; of the attendees, 70% historically answer the polls. Thus, the population of the webinar attendees who answered the poll on March 22, 2012, was about 38 people.

Figure 9. Preferred Length of Data Exclusivity Period



Three respondents, 4.2%, reported 1-5 years of data exclusivity is sufficient. Twenty-eight, or 38.9%, indicated 6-8 years is appropriate. Almost half (35), or 48.6%, want 9-12 years. Seven respondents, representing 9.7%, desire 13 or more years, which is remarkable considering the number of commentators and industry professionals who suggest a much longer period is required.[238] These results are also revealing because they run counter to those commentators who insist that 12 years is insufficient. Combining the first three groups of survey respondents indicates 91.7% can live with somewhere between one and 12 years of data exclusivity.

This is also an interesting outcome because, when considering that many commentators and industry professionals strongly oppose shortening the period, just under half of these respondents, 43.1% (combining the first two groups), are in the 1-8 year range. Thus this segment appears likely agreeable to the Obama Administration's seven-year proposal and they may still be incentivized to pursue biosimilars. Over half, 58.3% (combining the second two groups), prefer more than eight years of data exclusivity and obviously disagree with the seven-year proposal.

Comparing this last question regarding preferred period of data exclusivity to the earlier question of how many biosimilars are in development may provide some insight into the responding

238. Vernon et al., *supra* note 118, at 71 (insisting no less than 17 years of data exclusivity is necessary to recoup development costs).

population. Although, as noted earlier, 63.9% have no biosimilars in development, over a third, 36%, are developing one or more biosimilars. The latter would likely favor a reduced period of data exclusivity so that they can get their biosimilars on the market faster. Yet one would intuit that innovators would prefer a longer period of data exclusivity.

To examine whether there is such a preference, the preferred number of years of data exclusivity was examined against the responses of these biosimilar developers. Twenty-six respondents claim to have one or more biosimilars in development. These are likely imitators, who would prefer a shorter period of data exclusivity so they can bring a biosimilar to market quicker. Of these biosimilar developers, only two respondents, or 8% of this subset, stated that 1-5 years of data exclusivity was sufficient. Nine, or 35%, said 6-8 years is sufficient. Half, or 13 biosimilar developers, said 9-12 years was sufficient. The remaining two, or 8%, want 13 or more years. The dominating preference in this group is obvious: the half that wants 9-12 years. Less than half here believe that eight or fewer years are sufficient. More than half believes nine or more years are needed.

The 46 respondents, 63.9%, with no biosimilars in development were also examined in this fashion. These are likely innovators who would prefer a longer period of data exclusivity, to hold back the biosimilar developers. Of these, only one, 2.2%, selected 1-5 years of data exclusivity. Nineteen innovators, or 41.3% of this subset, said 6-8 years is sufficient. Twenty-two, representing 47.8%, said 9-12 years is the correct period. The remaining five, or 10.9%, want 13 or more years. The total here is 104.2% because one respondent selected both 6-8 years and 9-12 years.

One innovator selected 1-5 years, but a couple of imitators did, suggesting not much difference whether imitators or innovators prefer a shorter period of data exclusivity. Similarly, 43.5% of innovators believe that eight or fewer years are sufficient, while 58.7% believes nine or more years are needed. Very close to this, 43% of imitators want eight or fewer years and 58% want nine or more years. This shows innovators and imitators in the survey population have very similar preferences with regard to the period of data exclusivity.

What about patenting behavior? Some respondents failed to answer one or both parts of the question regarding patents and patent applications. Even so, those who entered answers were examined from the perspective of innovators (those who are not developing any biosimilars) in comparison with imitators (those who reported developing one or more biosimilars). Of the innovators who answered

the patent part of this question (41 respondents), 11, or 27% of innovators, claim to have 10 or more patents issued. Innovators who have any (one or more) patents was 26, or 63%. Of the imitators who answered (22 respondents), 8, or 35%, reported 10 or more issued patents. Imitators who have any (one or more) patents was 21, or 95%. One might expect patenting behavior to be higher with innovators, who presumably would want to protect their innovations from imitators. This survey population, however, demonstrates that imitators have a proportionately greater number of patents.

A similar comparison was done regarding patent applications. Of the innovators who answered the patent application part of this question (25 respondents), almost half (12 respondents), or 48%, claim to have 10 or more patents pending. Of the imitators who answered (17 respondents), 9, or 53%, reported 10 or more patents pending. Innovators who have any (one or more) patents pending were 20, or 80%. Imitators who have any (one or more) patents pending were 17, or 100%. Again, this population demonstrates imitators have a proportionately higher number of patent applications.

Does this mean innovators may come to rely on data exclusivity rather than patents to protect their innovative drugs? It is possible that imitators develop their own innovative approaches around the manufacturing processes. The manufacturing process may be a better source of patentability rather than the composition of the drug because a biosimilar drug will not have any data exclusivity and the drug, itself, may not be patentable if it is so similar to a brand name drug whose patent term expired. While revealing somewhat lower patent activity, innovators have clearly not abandoned their patent efforts for data exclusivity, at least in the survey population. It will be interesting to see whether patenting behavior changes in the coming years. As noted earlier, since there is so much uncertainty regarding drug approval for biosimilars and data exclusivity is a more narrow protection than what patents provide, it is likely that patenting will continue to be an effective and possible weapon in the intellectual property store.

VII. A PROPOSED INTELLECTUAL PROPERTY STRATEGY

Putting this all together, a more effective strategy for an innovator, rather than relying on data exclusivity alone, is to integrate patent efforts with data exclusivity. At the outset, though, a much more effective and comprehensive protection for innovators would be market exclusivity because it is a complete bar to competition for that

drug regardless of patents. But because market exclusivity for biosimilars is only available under very limited circumstances, and, more importantly, market exclusivity has not entered the discussions of legislators, industry professionals, or commentators, it is highly unrealistic to suggest it at this juncture. A more practical approach is recommended here.

Clearly one has a choice whether to patent, but no choice with regard to data exclusivity. If one is an innovator, data exclusivity comes along with drug approval and one cannot choose *not* to seek drug approval.

Considering how narrow data exclusivity is—protecting only the innovator's data on a particular drug for a specific treatment—it seems illogical that one would completely forgo many of the features of patents that are absent with data exclusivity. The ability to use litigation as a tool, defensive strategies—such as counterclaiming and lodging prior art—to prevent competitors from getting patents issued, using patents as bargaining chips in negotiations, and bullying and blocking strategies are all useful characteristics of the patent system that can be deployed in various strategies. A more effective strategy is to deploy patent efforts to target areas not covered by data exclusivity.

With the average clinical trial period being 8.5 years,[239] data exclusivity is not available during early stages when critical patenting decisions need to be made—that is, within a one-year time frame one has to decide whether to patent.[240] The cost of drug development is already so high in comparison to patenting. Nonetheless, companies should consider dedicating some early funds to patent efforts, even for startups with limited funding.

Moreover, the scope of data exclusivity is predictable, thus a strategy can be deployed to dovetail these protections for maximum coverage and efficiency. Knowing a particular drug will be protected for a specific treatment for 12 years, an innovator might focus its patent efforts to cover other areas instead of covering the same subject matter, thereby utilizing resources more efficiently. For example, if the drug license protects the primary invention, one might shift patent efforts to blocking strategies—targeting other drugs, related indications, or alternate delivery methods—rather than the primary invention.

Patent claim drafting strategies may also have to shift as the

239. Dickson & Gagnon, *supra* note 61, at 418 fig.1.

240. *See* 35 U.S.C. § 102(b) (2011) (imposing a one year statutory bar under certain conditions).

biosimilars market develops. For example, the more deviation from the reference product the FDA allows, the broader the claim scope an innovator might need.[241] Similarly, one might have to consider whether a "highly similar" product literally infringes a claim or if an "insubstantially different" biosimilar infringes under the doctrine of equivalents.[242]

One might also coordinate patent terms with the period of data exclusivity to maximize coverage. Perhaps one might push through patent prosecution to try to get a patent issued quicker to thwart early competition, before data exclusivity begins, or delay the patent prosecution process so as to have patent coverage after the data exclusivity period lapses.

Furthermore, while regulatory impracticality may impede biosimilar development at the moment, it is likely to ebb as the regulatory environment evolves. Thus an innovator may then strategically devote extra patent efforts to target those pathways that start opening up for biosimilar competitors in order to block their progress.

These are just a couple of ways data exclusivity and patenting efforts can be united to provide more robust protection. The survey results demonstrate, at least anecdotally, that most innovators are likely not going to abandon patenting efforts in light of FDA data exclusivity. In fact, if the data exclusivity period gets reduced—as is already being contemplated in legislation—biotech companies might realize they made a mistake by forgoing patent protection and end up with areas of exposure they might otherwise have had protected. Again, these protections are likely best deployed together. In so doing, one might need fewer patents. Survey respondents indicated a decent amount of patenting activity. Perhaps they could reduce their patent efforts by a third or even half if coordinated with data exclusivity.

What about the imitator? Imitators also have patent implications to consider. When a biosimilar is put through testing in order to demonstrate biosimilarity to the FDA, if the FDA determines differences in functional characteristics from the reference product, it might suggest innovative features in the biosimilar that might be patent worthy. The more similar a candidate is, the more likely it will receive accelerated approval, but the less similar it is, the more likely

241. Hadad et al., *supra* note 111 (remarks of Erika Lietzan, Partner at Covington & Burling LLP in Washington, D.C.).

242. *Id.*

it may have more patentable elements.

Nonetheless, the landscape has still not matured sufficiently to facilitate the much hoped-for biosimilars market. Science will eventually evolve to provide better tools for demonstrating biosimilarity, but perhaps the law does not have to wait that long. One of the characteristics of regulatory impracticality is that the FDA is required to keep the innovator's data proprietary and confidential. While the FDA knows the data and may extrapolate from it with regard to the reference product, the imitator never sees this data.

Regulatory impracticality can be reduced by amending section 351 of the BPCI to facilitate the flow information from the innovator to the imitator, particularly with regard to the manufacturing processes. This would allow the imitator better insight into the structure of the reference product, which would facilitate reaching biosimilarity. While sharing proprietary information in this fashion may shock or offend some audiences, there already exist provisions in other areas of the BPCI that allow for, and in fact require, certain confidential information of the *imitator* to be provided to the *innovator* so that the innovator may assess potential patent infringement.

Immediately following subsection 351(k) of the BPCI, which allows for accelerated approval of biologics, is new subsection 351(*l*) for "Patents," which sets forth procedures for limited access to confidential information of the biosimilar applicant so that the innovator can evaluate patent infringement.[243] The adage, "what's good for the goose is good for the gander" seems appropriate here. If the imitator must disclose limited confidential information for patent infringement purposes, why should it not be entitled to limited access to the innovator's manufacturing data? True, some of the manufacturing processes may be trade secrets, but if the legislators already found a way to strike a balance in diplomatically handling confidential information from imitator to innovator, it does not seem such a far cry that the legislators could fashion a mechanism to handle sensitive disclosures from innovator to imitator. After all, the purpose of the BPCI is to foster a biosimilars market.

The recommendation here is simply to put some teeth into that policy. Regulatory impracticality may have arisen unintentionally, but let us intentionally resolve it. The recommendation here is not so bold. Risking some trade secret exposure serves the greater good, and

243. BPCI § 351(*l*) (PPACA § 7002(a)(2)).

what is proposed here is essentially a *quid pro quo*: innovator and imitator each receive some limited access. Subsection 351(*l*) limits not only what can be viewed, but who sees it and how it can be used. Similar limitations can be implemented in the recommendation made here so that the value of an innovator's trade secrets is preserved, and downstream use or abuse by the imitator is curtailed, in the course of facilitating the policy of fostering biosimilar development.

Forsaking limited rights is not foreign to the intellectual property world. For example, patent law policy contains provisions that require compulsory licensing, which essentially force a patent holder to forsake some patent rights (such as typical rights to exclude and *not* license the patent). Compulsory licensing forces a patent holder to allow another party to practice the patent in order to serve the greater good of society, which will enjoy the benefit of the invention. The patent holder gets a royalty in exchange for the compulsory license. Similarly, if the BPCI were to be amended such that imitators have limited access to data needed to aid biosimilar development, surely legislators can create an exchange that balances the interests of innovators, biosimilar developers and society.[244]

Perhaps in exchange for sharing sensitive and valuable proprietary information, innovators can have a longer period of data exclusivity, or broader protection, more akin to market exclusivity, or even a financial return analogous to a compulsory license. A royalty in this fashion would make sense in that the imitator would be enjoying a commercial benefit by having access to the innovator's data for the purpose of accelerated approval. After all, if the innovator's data is helping the imitator get to market quicker, the innovator ought to enjoy some of the commercial success, and thus a royalty might be an appropriate solution.

VIII. CONCLUSION

This article explored the current and evolving landscapes of FDA data exclusivity and the U.S. patent system. Comparing FDA data exclusivity with patent protection is like comparing apples with oranges. Both are indisputably forms of intellectual property that protect against competition in the pharma and biotech industries, but the characteristics of these protections are very different. In comparing these two protections and considering discussions from

244. There are strong arguments the other way—that there should be no disclosure of data. Access to data is obviously a highly contentious issue. Further discussion in this area is beyond the scope of this article.

commentators as well as survey feedback from biotech industry practitioners, it appears that data exclusivity and patenting are best used in concert.

Since there is so much uncertainty regarding drug approval for biosimilars, and data exclusivity is a more narrow protection than what patents provide; thus it is likely that patenting will continue to be an effective and viable weapon in the intellectual property arsenal. The accelerated approval process is still being fleshed out between the FDA and legislators. It is too early to tell whether data exclusivity will have the impact on patent behavior that some predict. Legislators would do well to amend the BPCI to reduce and possibly eliminate regulatory impracticality and craft concrete mechanisms to facilitate the biosimilars market they have been trying to foster since the 1980s. In the meantime, companies should continue their patenting efforts, targeting areas that data exclusivity does not cover and keeping an eye out for changes in patenting efforts that may be warranted as the FDA reviews biosimilars. When the biosimilars market develops further in the United States, these inquiries can be reconsidered and any emerging paradigm shifts shall be examined. Undoubtedly, more discussion is forthcoming.