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# Why Primary Patents Covering Biologics Should Be Unenforceable Against Generic Applicants Under the Biologics Price Competition and Innovation Act

*Yaniv Heled\**

## I. BACKGROUND

On March 21, 2010, as part of the healthcare reform, Congress passed the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”).<sup>1</sup> BPCIA amends section 351 of the Public Health Services Act,<sup>2</sup> the Federal Food, Drug and Cosmetic Act (“FFDCA”),<sup>3</sup> and several sections under Title 35 of U.S. Code (“Patent Act”<sup>4</sup>), creating a regulatory pathway for the licensing of biological products as “biosimilar to”<sup>5</sup> and/or “interchangeable with”<sup>6</sup> an already approved biological product (“reference product”<sup>7</sup>).<sup>8</sup>

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1. Patient Protection and Affordable Care Act, Pub. L. Nos. 111-148 & 111-152, §§ 7001-7003 (2010) (passing the Biologics Price Competition and Innovation Act of 2009 that amended § 351 of the Public Health Services Act, codified at 42 U.S.C. §262) [hereinafter PPACA].

2. 42 U.S.C. § 262 (2011) [hereinafter BPCIA].

3. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (2011) [hereinafter FFDCA].

4. 35 U.S.C. §§ 101 *et seq.* (2011).

5. Under BPCIA, the term ‘biosimilar’ or ‘biosimilarity’ means that “the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components” and that “there are no clinically meaningful differences between the biological product and the [original] product in terms of the safety, purity, and potency of the product.” BPCIA, *supra* note 2, § 262(i)(2) (2011).

6. Under BPCIA, the term ‘interchangeable’ or ‘interchangeability’ means that “the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.” BPCIA, *supra* note 2, § 262(i)(3) (2011).

7. Under BPCIA, the term ‘reference product’ means the single biological product

Once a biological product is deemed “interchangeable with” a reference product, under BPCIA it may be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product.<sup>9</sup>

BPCIA sets a twelve-year market exclusivity period in original biologics<sup>10</sup> and a four-year data exclusivity period for the data submitted in support of the application for the original biologic.<sup>11</sup> BPCIA also provides for a possible extension of the twelve-year market exclusivity and four-year data exclusivity periods by an additional six-month period for having the biological product tested and approved for use in pediatric populations.<sup>12</sup> Thus, BPCIA creates market exclusivity periods in original biological products of up to 12 ½ years and data exclusivity periods of up to 4 ½ years.

The exclusivity period is intended to run in parallel and in addition to any patents that may apply to such approved biological pharmaceutical products, which would also grant the developers of these products monopolies in the underlying technologies on which such products are based. This seeming redundancy raises questions regarding the need and justification for having patent protection on biologics in *addition* to statutory exclusivities.

The idea of providing developers of biologics with statutory exclusivity in their products originated from the perception that patents alone are insufficient for protecting proprietary interests in biological products, for several reasons. First, biologics are subject to especially high barriers to patentability that do not exist in other areas of technology. Second, due to the “product of nature” doctrine and heightened written description, best mode, enablement, and utility requirements pertaining to biologics, there are various types of biologics for which patentability is limited or uncertain. Third, the complexity of biologics and the processes of making them lend themselves to potential variations, which could be used for “designing-around” patent claim limitations covering such compounds and their manufacturing processes. This tension is further exacerbated by the

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licensed under PHSA § 351(a) against which a generic biological product is evaluated in an application submitted under BPCIA. *See* BPCIA, *supra* note 2, § 262(i)(4) (2011).

8. PPACA § 7002(a) (codified at 42 U.S.C. § 262).

9. *Id.* § 7002(b) (codified at 42 U.S.C. § 262(i)(3)).

10. *Id.* § 7002(a) (codified at 42 U.S.C. § 262(k)(7)(A)). Under BPCIA, during this period, the FDA may not make effective the approval of applications for biosimilar and/or interchangeable products until the date that is 12 years after the date on which the reference product was first licensed by the FDA.

11. *Id.* (codified at 42 U.S.C. § 262(k)(7)(B)). Under BPCIA, during this period, generic applicants may not submit applications for the approval of their versions of biologics biosimilar to original biological products.

12. *Id.* § 7002(g) (codified at 42 U.S.C. § 262(m)).

uncertainty surrounding the application of the doctrine of equivalents to this relatively new area of technology. And fourth, for many biologics, one of the most difficult and important aspects of bringing the product to the market is the development of manufacturing know-how, which is especially difficult to protect under patent law.

Combined with the already increased likelihood of patent challenges that characterize the area of pharmaceuticals in recent years, industry representatives have argued that they cannot rely on patents to protect the proprietary interests of developers of biological products, which may in turn result in curbing of research and development (“R&D”). FDA-granted statutory exclusivities on the other hand, whether data or market exclusivity, are obtained and enforced automatically, as a by-product of the FDA approval proceedings, and their practice does not require their beneficiary to take any specific action. Also, statutory exclusivities do not lend themselves to the skirmishes that characterize patent infringement disputes. Rather, in dispute situations statutory exclusivities provide a relatively predictable outcome, which represents not only significant cost savings but also minimization of investors’ risks, thereby creating a business environment favorable to investment in R&D.

Interestingly, while the underlying rationales for market exclusivity under BPCIA and the five-year New Chemical Entity (“NCE”) statutory exclusivity under the Hatch-Waxman Act (on which the BPCIA market exclusivity is modeled) are similar, their function/”mechanism of action” is different. In both cases, the intention was to provide developers of pharmaceutical products with sufficient incentives to invest in R&D. However, the five-year NCE statutory exclusivity was meant to work its effect where no incentives existed from a patent perspective (e.g. where the drug product contains a well known active compound that is not patentable) whereas the 12 to 12 ½ year market exclusivity under BPCIA appears to have been devised as a “fallback” option to patents, namely, as “insurance” in case they fail. In other words, market exclusivity under BPCIA is meant to provide an “iron-clad, litigation-proof” protection of the interests of developers of biological products in case their patents fall short. Viewed in this light, in the context of biologics, statutory exclusivities are sometimes referred to as “insurance policies” meant to protect the interests of developers of biological products where patents might fail in doing so.

## II. HOW PATENT TERM COMPARES WITH THE PERIOD OF MARKET EXCLUSIVITY UNDER BPCIA

The R&D and approval of biologics, from the first synthesizing of the biologic or a closely related compound through the approval of the biologic license application (“BLA”) by the FDA typically takes over a decade. A

rough estimate of a typical timeline for the development of a biological product consists of about four to five years of preclinical studies, six to nine years dedicated to clinical trials prior to the submission of a BLA and another twelve to sixteen months for the FDA to process and decide on the BLA. In sum, the development of a biological product typically takes about 11 to 15 ½ years.<sup>13</sup>

Based on the abovementioned timeframes and in view of the fact that the statutory exclusivities in biologics would only “kick in” upon FDA approval, BPCIA effectively dictates that (1) manufacturers of generic versions of biologics would only be able to file applications for generic versions of biologics after fifteen to twenty years from the inception of development of the original biological product,<sup>14</sup> and (2) the FDA may only approve such applications after twenty-three to twenty-eight years from the inception of development of the original biologic.<sup>15</sup>

Viewing the abovementioned timeframes from a patent perspective, it is important to acknowledge several additional milestones. First, biologics may be, and often are, the subject of numerous patents that may cover (1) specific biological compounds, their precursors, possible metabolites and other derivatives, (2) processes of making these compounds, (3) formulations containing the compounds, and (4) methods of using the biological compound in the treatment of illnesses. Since the natural course of development of most biologics first involves the identification, making, and isolation of a biologic having therapeutic properties (not necessarily in that order), the first patent applications commonly seek to claim the biological active compound (a.k.a. active pharmaceutical ingredient or API), closely related compounds and methods of making them and are filed very early in the development process, typically between the time immediately after the identification of the biological API and right before the beginning of clinical trials in human subjects. In other words, if the beginning of the R&D efforts is marked as the “0” time-point and clinical trials normally begin after four to five years of preclinical studies, then the filing of the first patent application pertaining to the biological product would normally occur between “development years” one and four to five (depending on the length of the preclinical trials stage).<sup>16</sup>

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13. This calculation is based on adding the estimated four to five years of preclinical studies, six to nine years of clinical trials and 1 to 1 ½ years it takes for the FDA to approve BLAs and then rounding the result (11 to 15 ½ years) to the closest half-year increment.

14. This calculation is based on adding the estimated 11 to 15 ½ years it takes to put a typical biologic on the market to the 4 to 4 ½ years of data exclusivity under BPCIA.

15. This calculation is based on adding the estimated 11 to 15 ½ years it takes to put a biologic on the market to the 12 to 12 ½ years of market exclusivity under BPCIA.

16. Notably, the first patent application is not necessarily the first submission to the USPTO, which is frequently of a provisional application containing little more than preliminary data and a rudimentary concept of the invention and whose purpose is merely to

Patents generally expire twenty years from the filing date of the original application.<sup>17</sup> Thus, as a general proposition, the primary patents – namely, patent issued from one of the first patent applications to be filed early in the R&D of the biological product and covering, typically, the biological API itself (often as a purified, isolated compound), its manufacturing and/or the first known methods of using it – would be set to expire between “development years” twenty-one to twenty-five, whereas the market exclusivity period pertaining to the products covered by these patents would expire around “development years” twenty-three to twenty-eight.

However, when comparing the term of statutory exclusivities to the term of primary patents it is necessary to take into account patent term extensions available to one patent per FDA-approved product.<sup>18</sup> If we make the most patent-term-favorable assumptions that virtually all first primary patents (i.e. the first primary patent to issue for any given biological product) would merit an extension of four to five years,<sup>19</sup> then it is possible to argue that for any biological product there would be one patent whose term would be extended 1 ½ to 2 years beyond the expiration of the 12 to 12 ½ year market exclusivity period.<sup>20</sup> Thus, while generally primary patents covering biological products would expire within twenty-one to twenty-five years following the onset of development, under the above patent-term-favorable assumptions, one of the primary patents would expire within about twenty-five to thirty years from that date.<sup>21</sup> However, in

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“buy” the inventors another year for further development of their invention. *See* 35 U.S.C. §§ 111(b), 119(e) (2011).

17. *See* 35 U.S.C. § 154 (2011).

18. 35 U.S.C. §§ 156(a)(4), 156(c), 156(f)(2)(A), 156(g)(1), 156(g)(6) (2011); 21 U.S.C. § 355(i) (2011); 42 U.S.C. § 262(j) (2011). Under these sections, the term of patents pertaining to biological products “shall be extended by the time equal to the regulatory review period for the approved product” up to a total period of 14 years from the date of approval of the biological product but not exceeding 5 years, whereas the “regulatory review period” is calculated as half the time in which the product was in clinical trials, plus the period it took the FDA to review and approve the BLA.

19. Given the length of clinical trials of biologics and the average 12 to 16 months needed for FDA review of BLAs, it is prudent to assume that the majority of biological products would merit the maximum patent term extension of half the clinical trials’ period plus the time needed for FDA review of the application up to a maximum of five years. Basing the calculation on the estimated times herein, the term extension could be roughly estimated as equal to ½ of six to nine years plus 1 to 1 ½ years, namely 4 to 5.83 years. Given the upper limit of five years, a typical patent term extension period would be four to five years.

20. Since under 35 U.S.C. § 156 patent term extension cannot extend the patent term beyond fourteen years from the date of FDA approval of the product and the statutory market exclusivity under BPCIA extends for 12 to 12 ½ years from that date, then, arguably, no patent term could be extended more than two years beyond the expiration of a twelve-year market exclusivity or 1 ½ years beyond the expiration of a 12 ½ year market exclusivity.

21. This calculation is based on adding the estimated four to five years of patent term

reality not all primary patents are entitled to a patent term extension, as in some instances the term of primary patents already extends beyond fourteen years from the date of FDA-approval. Thus, even with patent term extension, extended primary patents are expected to expire, on average, about five to eleven months subsequent to the expiration of the 12 to 12 ½ year market exclusivity period under BPCIA.<sup>22</sup>

Thus, arguably, based on the above calculations, the market exclusivity period under BPCIA would keep competition out of biologic markets, on average, for five to eleven months less than the average monopoly period afforded by primary patents on inventions pertaining to the biological product.

### III. WHY HAVING CONCURRENT PROTECTION UNDER BOTH PATENTS AND STATUTORY EXCLUSIVITIES REGIMES IS NOT ONLY UNNECESSARY BUT IS ALSO BAD PUBLIC POLICY

Comparing the rationales for granting statutory exclusivities with patent theory, it appears that the reasoning behind both types of monopoly is quite similar, if not identical, especially in the context of biologics. In a nutshell, the incentive-to-disclose and incentive-to-invent/invest patent theories emphasize patents' functional role of incentivizing the disclosure of existing inventions and the pursuit of further R&D activities leading to more inventions. The rationales for granting statutory exclusivities are very similar; the purpose of statutory exclusivities in the context of pharmaceuticals is to provide assurance that developers of original biologics are able to reap the fruits of their investment, thereby ensuring the existence of sufficient incentive-to-invent/invest. Accordingly, at least from a functional perspective, in the context of biologics, both patents and statutory exclusivities seek to achieve the same purpose and incentivize essentially the same behavior by inventors, investors and developers.

However, it appears that affording protection under both patent and statutory exclusivities regimes while both of them are in effect is likely to have undesirable ramifications. First, concurrent protection by both patents and statutory exclusivities would likely lead to a waste of societal

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extension to the 21 to 25 years patent term from the inception of development. The calculation would be slightly different if we were to add 1 ½ to two years to the statutory exclusivity period of 23 to 28 years, resulting in a similar patent term extending 25 to 29 ½ years from the beginning of development.

22. See Heled, *supra* note \*, at Table 1. This period of five to eleven months is based on the average period of time between the term of earliest filed primary patents pertaining to seventy-nine biological products for which primary patents could be identified (excluding insulin and human growth hormone (“hGH”) products) and the hypothetical dates in which the market exclusivity in these products would have expired had these products been subject to BPCIA. I refrained from making any assumptions regarding the potential addition of ½ year of market exclusivity for experimentation in pediatric populations.

resources. The enforcement of patents is an expensive prospect not only for the individual parties involved but also for society at large. Patent systems require substantial investment in education and training necessary to enforce patents. Moreover, maintaining the numerous elements of a patent system dedicated to resolving disputes requires a significant ongoing investment of societal resources.<sup>23</sup> Thus, the investment of resources in the enforcement of patent rights where statutory exclusivities already cover biological products would constitute a waste of the relative portion of societal resources (out of the entire societal investment in maintaining and administering a patent system), which is necessary to facilitate such enforcement.<sup>24</sup> Notably, the social cost of having both patent protection and statutory exclusivities available to biologics is going to be even further exacerbated by the highly complicated and elaborate framework for the resolution of patent disputes arising out of the filing of an application for biosimilar products under BPCIA. This framework would require potential adversaries to obtain extensive legal counseling<sup>25</sup> and, possibly, litigate numerous patent disputes in several different legal arenas over a prolonged period of time.<sup>26</sup>

Second, affording patent protection for biological products in parallel to FDA-instituted exclusivities would likely increase the risk of occurrences of abuse by developers of biological products in a variety of ways which would almost inevitably diminish public access to biological products. Yet, while BPCIA thoughtfully accounts for the risk of abuse of statutory exclusivities by specifically and explicitly disallowing grants of market and data exclusivities under certain circumstances,<sup>27</sup> patent law does not seem to

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23. Notably, the administration of the patent dispute resolution scheme established in BPCIA would require even further investment of societal resources such as those described herein.

24. To clarify: the argument here is not that the entire societal investment of resources in the creation and maintenance of a patent system constitutes waste, but rather that the relative portion of such an investment which is necessary to support the handling of patent disputes as they pertain to biological products which are already being covered by statutory exclusivities under BPCIA would be wasteful.

25. See PPACA *supra* note 1, § 7002(a) (codified at 42 U.S.C. §§ 262(l)(2)-262(l)(4)).

26. See *id.* (codified at 42 U.S.C. §§ 262(k)(7)(B), 262(l)(6), 262(l)(8) and 262(l)(9)).

27. See *id.* (codified at 42 U.S.C. §§ 262(k)(7)(C)(i)) (stipulates that applications for the approval of biologics that are “supplements” to an original BLA cannot re-trigger the market and data exclusivity provisions); *id.* (codified at 42 U.S.C. §§ 262(k)(7)(C)(ii)(I)) (Determines that applications filed by the same manufacturer or its “licensor, predecessor in interest, or other related entity” would not merit data or market exclusivity if the application is merely for a “modification to the structure of the biological product that does not result in a change in safety, purity, or potency.”); *id.* (codified at 42 U.S.C. § 262(k)(7)(C)(ii)(II)) (an application filed by the same manufacturer for a non-structural change of the biologic and “that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength” would, similarly, not award the manufacturer with an exclusivity period on top of that already awarded for the original biological product).

have the same kind of safeguards against abuse and remains relatively susceptible to it. Thus, protecting biological products under patent law in addition to the statutory exclusivities framework available under BPCIA would create an opening for abuses of the patent system that would delay the entry of generic biologics into the market.

Accordingly, it would be preferable that any particular biological product be subject to protection under *either* the BPCIA instituted statutory exclusivities regime *or* patents covering the underlying inventions pertaining to the biological product. In the context of biologics, statutory exclusivities have numerous advantages over patents. As discussed earlier, at least in the context of biologics, patents are a cumbersome, inefficient and often ineffective way of “promot[ing] the Progress of Science and useful Arts.”<sup>28</sup> FDA granted statutory exclusivities, on the other hand, appear to be more comprehensive and easily enforceable, would significantly reduce costs involved in litigation, are less prone to abuse and would create legal certainty that is currently missing from the protection of technological innovation under patent law.

Furthermore, statutory exclusivities guarantee that only “worthy technologies” are granted monopolies. While the patent system utilizes an array of “surrogate” or “proxy” – arguably irrelevant – standards to indirectly appraise the societal value of advancements, including biological products,<sup>29</sup> the FDA’s expertise and understanding in the area of biologics enables it to evaluate the potential medical benefits of biologics and weigh them against possible risks, thereby directly determining the true societal value of specific biological products. Thus, at least in the context of biologics, a statutory exclusivities regime has an economic advantage over a patent regime, as it is more likely to guarantee that monopolies are only awarded for “socially valuable” technologies.

#### IV. PROPOSAL: MAKING PRIMARY PATENTS UNENFORCEABLE AGAINST GENERIC APPLICANTS UNDER BPCIA

To avoid the negative ramifications of concurrent protection by both statutory exclusivities and patents, it is advisable that upon the onset of the statutory exclusivity period under BPCIA developers of the approved products would no longer be able to enforce their patents as they pertain to

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Notably, by not affording additional statutory exclusivity for approval of additional indications of the same biological product, the statutory exclusivity scheme created by BPCIA differs from that of the Hatch-Waxman Act in that BPCIA does not incentivize additional clinical research leading to the approval of the same biologic for the treatment of additional medical conditions.

28. U.S. CONST. art. I § 8 cl. 8.

29. *E.g.* novelty, nonobviousness, written description, enablement, and more. *See* 35 U.S.C. §§ 101 *et seq.*

the biological product as approved against generic manufacturers<sup>30</sup> applying for the approval of generic versions of such products (“proposed amendment”).<sup>31</sup>

Importantly, this proposal would strip biological products of any additional period of protection under their primary patents subsequent to the expiration of the market exclusivity under BPCIA. The potential loss of this additional protection under patent law (with all of its shortcomings) is justified because it reflects payment for insurance embodied in the statutory exclusivities afforded under BPCIA. In other words, developers of original biological products would surrender about five to eleven months on average of exclusivity under patent law in return for 12 to 12 ½ years of litigation-free market exclusivity (and 4 to 4 ½ years of data exclusivity).

Further, making it impossible for developers of original biological products to enforce their primary patents against generic applicants filing for generic versions of biological products under BPCIA would prevent developers from “double dipping.” Arguably, the length of the market exclusivity period granted under BPCIA should be sufficient to incentivize R&D in the area of biological pharmaceuticals.<sup>32</sup> There is no justification

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30. Importantly, this amendment is not meant to prevent developers of biological products from enforcing their patents against later applicants seeking approval *not* under BPCIA. Namely, under no circumstances would developers of biological products be unable to sue for infringement of their patents where a competitor might seek FDA approval of the same biological compound for the treatment of the same medical condition by conducting their own clinical trials, i.e. without relying on the approval of the original biological product under BPCIA.

31. One way of achieving this result would be to amend Title 35 of the U.S. Code to limit section 271 so that it would create causes of action against generic applicants under BPCIA only if no statutory exclusivity under BPCIA is in effect with relation to the product covered by the patent whose enforcement is sought. A possible “softer” version of such a sweeping prohibition of enforcement of pertinent patents is to have developers of biological products elect *how* to protect their proprietary interests in their products, namely by choosing to benefit from the statutory exclusivities scheme afforded under BPCIA *or* having the ability to enforce their patents covering the underlying technologies in the approved biological product against generic applicants. To implement this “softer” version of the proposed amendment, BPCIA could be amended to stipulate that the FDA would refrain from taking the actions related to the approval of generic versions of the biological products as prescribed under PPACA § 7002(a) (codified at 42 U.S.C. § 262(k)(7)) only pursuant to a commitment by a BLA applicant to be estopped from enforcing its patents pertaining to the approved biological product against such generic applicants and/or *so long as* developers of biological products do not seek enforcement of their patents covering inventions pertaining to their biological products against parties seeking approval for generic versions of such product in accordance with BPCIA. This “softer” version may circumvent possible challenges of the proposed amendment as an unconstitutional taking of one’s proprietary rights in its patents in violation of the Fifth Amendment of the Constitution.

32. The reoccurrence of a twelve-year period in many of the proposals has not been coincidental. Rather, it was the result of a perception that “the effective patent life for pharmaceuticals—the time remaining following FDA approval—is approximately eleven to twelve years.” See FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON

for “windfalls” in the form of additional monopoly periods conferred by primary patents extending beyond the end of the market exclusivity period in some of the biological products that would further curb public access to these products.<sup>33</sup>

Yet, the proposed amendment is unlikely to discourage continued R&D of approved biological products (which is intended to lead to improvements of approved biological products and, possibly, to the development of new ones). This is because the proposed amendment would only apply to patents that cover biological products as originally approved by the FDA. To avoid unnecessary legal disputes there may also be merit in explicitly limiting the proposed amendment so that it would only apply to primary patents and would not prevent enforcement of secondary patents covering inventions stemming from continued R&D. Such explicit limitation, while potentially opening the door to litigation involving secondary patents (with all of its risks of evergreening and patent abuse), would assist in providing the necessary incentive for continued R&D of already-approved biologics, which is currently missing from BPCIA. An alternative solution to the problem of lack of incentive for continued R&D of already-approved biological products would be to amend BPCIA so as to allow for an additional short period of market exclusivity for the approval of additional medical indications for already-approved biological products.

#### V. WHY (AND WHEN) WE STILL NEED PATENTS TO INCENTIVIZE INNOVATION IN THE AREA OF BIOLOGICAL PHARMACEUTICALS

Despite the clear advantages statutory exclusivities have over patents and their numerous shortcomings as means of incentivizing R&D in the area of biologics, patents still have important functions to fulfill during the period prior to the approval of biological products by the FDA. Thanks to their ability to prevent situations of “races to register,”<sup>34</sup> patents serve an important fundraising function, which enables R&D entities to raise the

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BIOLOGIC DRUG COMPETITION vi-vii (2009) (“[t]he economic model put forth by pioneer drug manufacturers to justify [a twelve to fourteen year exclusivity period] is based on the average time required to recoup the investment to develop and commercialize a typical biologic drug”). Thus, an exclusivity period of about twelve years would presumably provide developers of original biologics with the assurance that the return on their investment would justify the time, money, and effort they expended in developing their products.

33. Importantly, primary patents covering biological products (which would, under the proposal herein, be unenforceable against generic manufacturers seeking approval of their products under BPCIA) would still be enforceable against independent developers of the same biological product and third parties who do not seek to utilize the BPCIA framework and who would therefore not be subject to BPCIA’s statutory exclusivities provisions.

34. A “race to register” occurs when two companies undertake a similar research project and are competing to have their respective products approved by the FDA first.

funds necessary to support their research projects. In this respect patents have a vital function in the development of pharmaceutical products and, even more so, of biological products as they make it possible for developers of such products to raise the funds necessary to traverse the various, numerous expensive steps of clinical development prior to being eligible to benefit from the statutory exclusivities under BPCIA (subsequent to approval of the biological product by the FDA). Accordingly, during the period prior to approval of biological products by the FDA and the onset of statutory exclusivities under BPCIA, patents would actually serve as “insurance policies” that would make the achievement of statutory exclusivities possible further down the road.

In addition, as discussed earlier, follow-on patents would also still have an important role to play in incentivizing continued R&D of biological products past the point of “sufficiency of research” for the purpose of approval by the FDA as such R&D would, presumably, result in patents that would expire subsequent to the expiration of statutory exclusivity periods under BPCIA.

To summarize: there is merit in affording biological products sequential (rather than concurrent) protection from (1) any primary patents pertaining to the underlying technology in such products prior to the onset of statutory exclusivities under BPCIA, (2) statutory exclusivities in the FDA approved products themselves and (3) any secondary patents pertaining to substantial further developments of the originally approved biological product.

## VI. CONCLUSION

The most important function of patents and statutory exclusivities alike is to ensure that those partaking in technological R&D would not only survive to continue their activity, but would also prosper and seek to continue their R&D activities in the future. However, at least in the field of biologics, patents might not serve this purpose as well as statutory exclusivities would. The statutory exclusivities afforded under BPCIA have been tailored to the needs of developers of biological products in the context of generic competition and should thus be held as sufficient for accommodating those needs. Allowing developers of biological products to benefit from the protection of primary patents alongside and concurrent with such statutory exclusivities would cause waste and could lead to abuse of the patent system. A substitution of primary patent enforcement rights against generic competition where statutory exclusivities in FDA-approved biological products are in force is the best means to incentivize continued investment in R&D while guaranteeing sufficient public access to generic versions of biological products.