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I. INTRODUCTION

There is a widespread perception that drug prices in the U.S. are much higher than they should be, and that the problem is only getting worse. Critics argue that the pharmaceutical industry is improperly gaming the system in a manner that takes advantage of legal loopholes and administrative limitations to the detriment of patients and third-party payers.[1] Both houses of Congress responded in 2019 with a slew of hearings focused on pharmaceutical pricing, and dozens of bills have been introduced that would attempt to bring down the cost of drugs.[2]

The hearings and proposed legislation have focused on a variety of practices thought to contribute to excessive drug prices, including, to name just a few, so-called "pay-for-delay agreements" or "reverse payment settlements" between branded and generic pharmaceutical companies, alleged abuse of the U.S. Food and Drug Administration ("FDA") citizen's petition process, and the alleged withholding of equivalent drug samples from potential generic competitors.[3] Much of the discussion, and some of the proposed legislation, is aimed particularly at the oft-stated claim that drug companies are "evergreening" the patent protection on their products, thereby delaying generic market entry and the lowering of prices

1. *See, e.g.*, Robin Feldman, *May Your Drug Price be Evergreen*, 5 J.L. & BIOSCIENCES 590 (2018); Douglas L. Rogers, *Double Patenting: Follow-on Pharmaceutical Patents that Suppress Competition,* 14 NW. J. TECH. & INTELL. PROP. 317 (2017) ("Prices for pharmaceutical products over the last 10 years have skyrocketed, increasing far more rapidly than the general cost of living."); Thom Tillis, Senator, Prepared Opening Remarks for a Hearing Entitled "Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition" (May 7, 2019), https://www.judiciary.senate.gov/imo/media/doc/05-07-2019%20Tillis%20Statement.pdf (on file with *The University of the Pacific Law Review*) (noting that "pharmaceutical prices are too high").

2. *See, e.g.*, *Drug Pricing in America: A Prescription for Change, Part I Before the S. Comm. on Fin.*, 116th Cong. (Jan. 29, 2019), https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i (on file with *The University of the Pacific Law Review*); *Drug Pricing in America: A Prescription for Change, Part II Before the S. Comm. on Fin.*, 116th Cong. (Feb. 26, 2019), https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-ii (on file with *The University of the Pacific Law Review*); *Drug Pricing in America: A Prescription for Change, Part III Before the S. Comm. on Fin.*, 116th Cong. (Apr. 9, 2019), https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-iii (on file with *The University of the Pacific Law Review*); *Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition Before the H. Comm. on Energy and Commerce*, 116th Cong. (Mar. 13, 2019), https://energycommerce.house.gov/committee-activity/hearings/hearing-on-lowering-the-cost-of-prescription-drugs-reducing-barriers-to (on file with *The University of the Pacific Law Review*); *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition Before the S. Comm. on the Judiciary*, 116th Cong. (May 7, 2019), https://www.judiciary.senate.gov/meetings/intellectual-property-and-the-price-of-prescription-drugs-balancing-innovation-and-competition (on file with *The University of the Pacific Law Review*).

3. *See, e.g.*, Competitive DRUGS Act of 2019, H.R. 1344, 116th Cong. (2019) (reverse payment settlements); Preserve Access to Affordable Generics and Biosimilars Act, H.R. 2375, 116th Cong. (2019) (reverse payment settlements); Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019, S. 340/ H.R. 965, 116th Cong. (2019) (access to equivalent samples); FAST Generics Act of 2019, H.R. 985, 116th Cong. (2019) (access to equivalent samples); Efficiency and Transparency in Petitions Act, S. 660, 116th Cong. (2019) (curbing citizen's petition abuse).

assumed to flow from generic competition.[4] Hemphill and Savat have defined "evergreening" as the "acquisition of additional patents by brand-name drug makers, often of doubtful validity or applicability, in order to delay generic competition."[5] They argue that these "additional" patents are generally of a lower quality than the initial patent on a drug's active ingredient, and, in many cases, should not have been allowed to issue from the U.S. Patent and Trademark Office (USPTO) in the first place.[6]

In 2018, Professor Robin Feldman published what she described as "the first comprehensive study of evergreening," in which she "analyse[d] all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity."[7] She found that "almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added on to them," and that "[a]dding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% had their protection extended at least once, with almost 50% having the protection cliff extended more than once." She further found that "[r]ather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs." She also reported that the "problem is growing across time. The number of drugs that had a patent added on to them almost doubled during the time period. The addition of certain other types of barriers increased at an even greater rate, with some tripling." In 2016, Professor Feldman provided testimony to a Senate Judiciary committee regarding her views on evergreening and the pharmaceutical industry's patenting practices.[8]

The present Article examines some recent legislative proposals aimed specifically at the perceived problem of pharmaceutical evergreening. To provide context, the Article begins by reviewing some of the academic literature and other commentary that would lend support to these efforts. The Article also provides this author's own analysis and commentary of the proposed legislation, which

4. *See, e.g.*, Feldman, *supra* note 1, at 596 (defining "evergreening" as "artificially extending the life of the patent or other exclusivity by obtaining additional protections to extend the monopoly period."); Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?*, 41 IDEA 227, 233 (2001); Christine S. Paine, *Brand Name Drug Manufacturers Risk Antitrust Violations By Slowing Generic Production Through Patent Layering*, 33 SETON HALL L. REV. 479, 506 (2002); Frederick Tong, *Widening the Bottleneck of Pharmaceutical Patent Exclusivity*, 24 WHITTIER L. REV. 775, 787-88 (2003).

5. C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. OF HEALTH ECON., 327, 327–28 (2012).

6. *Id.* at 328–29.

7. Feldman, *supra* note 1.

8. *The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition Before S. Subcomm. on Antitrust, Competition Policy and Consumer Rights*, 114th Cong. (2016) (written submission of Professor Robin Feldman, Director of the Institute for Innovation Law, University of California Hastings College of the Law).

generally concludes that the legislative proposals are largely misguided, and, if enacted, would be likely to cause more harm than good by discouraging innovation in pharmaceuticals without effectively addressing the core concerns. Instead, any legislative measures taken to address evergreening should focus directly on the misuse of patents, rather than impairing the ability of innovators to patent pharmaceutical inventions irrespective of their merit and their potential to improve the human condition.

II. CONCEPTS AND DOCTRINES PERTINENT TO THE EVERGREENING DEBATE

This section of the Article reviews a sampling of the commentary and academic literature relating to some core concepts in the debate over evergreening. These concepts include so-called "product hopping" and "product thicketing," pejorative terminology of relatively recent origin that is aimed at, respectively, pharmaceutical companies' efforts to develop follow-on products and to switch patients to these products from an earlier version of the drug, and companies obtaining multiple patents covering a single pharmaceutical product. This section also discusses the concept of "secondary patents," which I prefer to refer to as "follow-on patents," a classification of pharmaceutical patents that has come under particular scrutiny for its alleged role in facilitating evergreening. Finally, two doctrines of patent law that have been implicated in the evergreening debate, double patenting and continuation practice, are addressed.

III. PRODUCT HOPPING

When critics of the pharmaceutical industry initially began talking about "evergreening," the discussion often seemed to imply that pharmaceutical companies were literally re-patenting the same product. However, those more familiar with patent law have responded by pointing out that, as a general matter, pharmaceutical companies are not simply re-patenting a product, and that various doctrines of patent law work in conjunction to prevent a company from obtaining new patents on a product that is already on the market. For example, at a May 7 Congressional Hearing entitled Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition, Professor David Olson of the Boston College Law School explained to lawmakers that:

> It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong. . . . New patents can be filed on different formulations of a previous

> drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.
>
> If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, the new patent is either invalid or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing.[9]

In recognition of the fact that literal evergreening generally does not occur, critics of pharmaceutical patenting practices have moved the debate to so-called "product hopping," which Professor Feldman has described as a variant of evergreening.[10] As she explains it, a product hop occurs when a brand-name drug company makes a "small change" to an existing patented drug, such as a new form, formulation, or dosage of the drug, patents that change, and then just as the patent on the original drug is set to expire, the drug company "forces a market shift away from the old drug" by convincing doctors to prescribe the new version, patients to use it, and insurers to pay for it.[11] This "forced" market shift is accomplished, according to Professor Feldman and others who share her views, by the branded company advertising and promoting the new product, convincing doctors to prescribe it, providing significant rebates and discounts to patients and third-party payers, and in some cases discontinuing the previous version of the drug.

When presented with allegations that product hopping constitutes an antitrust violation, courts have generally found that bringing a new pharmaceutical product to market, in and of itself, will not create antitrust liability, nor do the antitrust laws require a pharmaceutical company to show that a new product is somehow superior to earlier versions of the drug.[12] However, courts have found that bringing a new

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9. *Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition Before S. Comm. of the Judiciary*, 116th Cong. (2019) (statement of David Olson), *available at* https://www.judiciary.senate.gov/imo/media/doc/Olson%20Testimony1.pdf (on file with *The University of the Pacific Law Review*).

10. Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 500 (2016).

11. *Id.*

12. Michael Gallagher et al., *United States: Pharmaceutical Antitrust*, WHITE & CASE LLP (2019), *available at* https://www.whitecase.com/sites/whitecase/files/files/download/publications/us-pharmaceutical-

product to market, when combined with other actions intended to improperly coerce patients to switch to the new product, can constitute an antitrust violation. Examples have included withdrawing the earlier product from the market for no apparent reason other than to stymie competition, buying back supplies of the old formulation combined with changing product codes for the old product to "obsolete" to prevent pharmacies from filling prescriptions with generic versions of the old formulation, or fabricating safety concerns about the earlier product.[13]

IV. PATENT THICKETS

The term "patent thicket" was originally popularized by Carl Shapiro in a 2001 article that used it to describe a scenario in which multiple patents on complementary inputs for a given product, owned by multiple independent patent owners, creates a dense "thicket" of intellectual property rights that could potentially render it difficult, if not practically impossible, to develop and/or bring that product to market. Under this conceptualization of the patent thicket, the primary concern is the dispersion of patent ownership, resulting in overwhelming transactional costs for a firm needing to negotiate and pay a royalty to each of the patent owners to secure the necessary rights.[14] Shapiro's work harkens back to Heller and Eisenberg's seminal 1998 article, which referred to the same phenomenon as a patent anticommons, and postulated that it could be particularly problematic for research and development in the life science owing to the large number of patents on biotechnology research tools.[15] In the early years of the 21st century, there was in fact a particular concern that a host of gene patents had created a patent thicket that would impede the development of technologies implicating multiple genes, such as DNA microarrays and multiplex genetic testing.[16]

Subsequent to Shapiro's article, the term patent thicket has taken on a life of its own, and a host of commentators have used it to describe a variety of scenarios that differ substantially from that originally conceptualized by Shapiro, Heller, and Eisenberg. A recent article by Egan and Teece reviewed the patent thicket literature and identified four very different definitions for the term, used by different authors, each implicating a different set of economic issues. While differing substantially

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antitrust-2019.pdf (on file with *The University of the Pacific Law Review*).

13. *Id.*

14. Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (March 2001), *available at* https://ssrn.com/abstract=273550 (on file with *The University of the Pacific Law Review*) ("In order to produce [its product] as designed, the company needs to obtain licenses.").

15. Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) ("The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to multiple patented inputs to create a single useful product.").

16. *See, e.g.*, Chris Holman, *Clearing a Path through the Patent Thicket*, CELL 125, at 629–633 (2006); Christopher M. Holman, *Will Gene Patents Derail the Next-Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563 (2012).

in substance, the various conceptions of the patent thicket all share the common notion that "too many patents" can be a problem.[17] Egan and Teece note that over the last decade, patent thicket arguments have become a routine fixture in intellectual property court cases, as well as a "staggering barrage of policy reports and recommendations" commissioned by wide variety of public bodies.[18] They go on to report a "sizable, fractious, and collectively incoherent" economic literature on patent thickets, that has failed to reach much in the way of firm conclusions and "is not so much contentious as confused."[19]

Today, pharmaceutical companies are being charged with anticompetitive behavior based on their creation of what are being referred to as patent thickets around their products.[20] Most notably, AbbVie has been the subject of multiple antitrust lawsuits claiming that the company has illegally created a patent thicket around its blockbuster product Humira, based largely on the company's own representations that it has in the neighborhood of 100 patents that could be infringed by a competing biosimilar product.[21] More broadly, pharmaceutical companies in general have been criticized for procuring too many patents around their products, thereby creating patent thickets that unduly deter and delay generic and biosimilar competition. Note that this is not the sort of patent thicket envisioned by Shapiro, Heller, and Eisenberg, since generally the patents are owned by a single firm, and thus there is not the transactional problem associated with a need to license multiple patents from a multiplicity of patent owners. Still, the concern for critics of pharmaceutical patent practices is that the sheer number of patents creates an overwhelming obstacle for any competing company seeking to come to market with a generic or biosimilar version of the product.

V. FOLLOW-ON/SECONDARY PATENTS

As a general matter, even the harshest critics of the patenting practices of pharmaceutical companies will acknowledge that some period of exclusivity is appropriate for innovative drugs. They do have a problem, however, with the number of patents pharmaceutical companies are obtaining, and the nature of these patents. These critics will often distinguish between patents on drug active

17. Edward J. Egan & David J. Teece, *Untangling the Patent Thicket Literature* (Tusher Center for Management of Intellectual Capital, Working Paper, 2015), https://pdfs.semanticscholar.org/e878/1ac8512559730ad43381f0e28d6a75d80d0d.pdf (on file with *The University of the Pacific Law Review*).

18. *Id.*

19. *Id.*

20. *Id.*

21. Max Mitchell, *AbbVie Sued for Alleged Antitrust Violations Over Blockbuster Med Humira*, LAW.COM (Mar. 19, 2019), https://www.law.com/newyorklawjournal/2019/03/19/abbvie-sued-for-alleged-antitrust-violations-over-blockbuster-med-humira/?slreturn=20190709201413 (on file with *The University of the Pacific Law Review*); Eric Sagonowsky, *AbbVie's Humira Antitrust Woes Snowball as Class-Action Plaintiffs Pile In*, FIERCE PHARMA (Apr. 3, 2019), https://www.fiercepharma.com/pharma/police-miami-city-officials-baltimore-and-trade-workers-minnesota-join-class-action-over (on file with *The University of the Pacific Law Review*).

ingredients, i.e., the chemical compounds responsible for the pharmaceutical effect of drugs and biological products, versus patents that claim other pharmaceutical inventions, which they often refer to as to as "secondary patents."[22] Examples would include patents claiming new formulations or dosages of an active ingredient, new combinations of active ingredients, new forms of the active ingredient, such as prodrugs, polymorphs, salts, ethers and esters, drug metabolites, or intermediates used in the production of drugs, as well as methods of manufacturing and using drugs. Since these inventions generally arise subsequent to the initial invention of the active ingredient, I generally refer to these patents as "follow-on patents," as opposed to "secondary patents," a term that seems to suggest that follow-on innovation is of lesser merit and less worthy of patent protection, a notion that I have argued against in earlier articles.[23]

A 2012 empirical study looked at the claims of the 1304 Orange Book-listed patents on all new molecular entities approved in the U.S. between 1988 and 2005, found that secondary patents (i.e., patents with only claims directed to a follow-on invention and no claims covering the active molecule itself) tend to be filed and issued later than chemical compound patents, and are also more likely to be filed after the drug is approved.[24] The authors of the study reported that, when present, independent formulation patents add an average of 6.5 years of patent life to an approved drug, independent method of use patents add 7.4 years, independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years. Furthermore, they found "evidence that late-filed independent secondary patents are more common for higher sales drugs."[25] It has also been reported that when the lawsuits are pursued to completion, rather than settled, brand companies are less likely to win with secondary patents than with the active-ingredient patents, with comparative win rates of 32% and 92%, respectively.[26]

Many critics of pharmaceutical patenting seem to believe that a drug is a single product and thus should only be subject to the protection of a single patent. They argue that pharmaceutical companies use follow-on patents that expire subsequent to the expiration of a patent on the drug's active ingredient to improperly extend

22. Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents*, 7 PLOS ONE 1, 1 (2012).

23. Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759 (2017); Christopher M. Holman, Timo Minssen & Eric Solovy, *Patentability Standards for Follow-on Pharmaceutical Innovation*, 37 BIOTECHNOLOGY L. REP. 131 (2018).

24. Kapczynski et al., *supra* note 22; The Orange Book, more formally the "Approved Drug Products with Therapeutic Equivalence Evaluations," is a list of drugs that the FDA has approved as both safe and effective, which includes for each drug a list of patents claiming forms and formulations of the drug, as well as methods of using the drug. *See, e.g.*, Christopher M. Holman, *Do Reverse Payment Settlements Violate The Antitrust Laws?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 489 (2007) (explaining the Orange Book).

25. Kapczynski et al., *supra* note 22.

26. Feldman, *supra* note 1 (*citing* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 138 (Mar. 22, 2013)).

the patent term, while creating a thicket of patents that is more difficult for a potential generic or biosimilar competitor to circumvent than a single patent. They also claim that the inventions claimed in secondary patents often provide little if any improvement in drug efficacy.

VI. DOUBLE PATENTING

Some critics of pharmaceutical patenting have gone so far as to argue that not only are pharmaceutical companies patenting trivial "secondary" pharmaceutical innovations, but that they are actually obtaining multiple patents on the same invention, or at least on patentability indistinct, obvious variations of an already patented invention.[27] Of course, patent law already has doctrines that, at least formally, preclude this sort of activity: "same invention-type" double patenting, which is based on the language of 35 U.S.C. § 101 that "[w]hoever invents or discovers any new and useful [invention] may obtain *a* patent therefor . . ." (emphasis added), and which precludes a patent applicant from obtaining two or more patents on an identical invention; and "obviousness-type" double patenting, which prevents a patent applicant from receiving a second patent on a non-identical but still merely obvious variant of a patented invention.[28] This second form of double patenting, while firmly established in U.S. case law, lacks any explicit basis in the patent statute, and for that reason is often referred to as "nonstatutory" double patenting.

In a 2017 article, Rogers attributes the skyrocketing prices of pharmaceutical products, at least in part, on a weakened prohibition against double patenting, and argues that the double patenting prohibition should be strengthened to increase competition for the production of follow-on drugs.[29] He contends that pharmaceutical companies are "extending [their] exclusive right to market a drug beyond the original patent term by dressing up part of that invention as a new one," and "argues that when the same inventor holds a genus patent for a pharmaceutical product, it should be estopped from obtaining a patent on a species within the scope of the genus, whether or not the genus patent constitute prior art."[30] Note that, as is typical in this genre of article, the focus is entirely on pharmaceutical products, and the normative suggestion would seek to strengthen the double patenting prohibition with respect to pharmaceutical products in particular, as opposed to inventions in general.

Lemley and Moore have likewise argued that "[w]hile the doctrine of obviousness-type double patenting solves the worst problem with obtaining

27. *See, e.g.*, JANICE M. MUELLER, PATENT LAW 79 (Fifth Edition, 2016) (citing Rebecca S Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 354 (2007)) (commenting that "[i]n recent years drug innovators have sought to prolong their effective periods of patent protection through various 'evergreening' strategies that add new patents to their quivers as old ones expire").

28. *Id.*

29. Rogers, *supra* note 1.

30. *Id.* at 318 (Abstract).

multiple patents, double patenting still has pernicious consequences in the pharmaceutical industry," i.e., by facilitating "evergreening."[31]

VII. CONTINUATIONS AND DIVISIONALS

Some commentators contend that pharmaceutical companies have used continuation (also referred to as "continuing application") practice to facilitate evergreening. Sections 120 and 121 of the Patent Act provide the statutory basis for continuation practice, which allows a patent applicant to file continuing patent applications that are entitled to the benefit of the filing date of an earlier-filed patent application.[32] For purposes of defining the available prior art, which is used in assessing whether a patent claim is invalid for anticipation or obviousness under Sections 102 or 103, respectively, the "effective filing date" of a continuing application is the filing date of the earlier-filed patent application, often referred to as the parent application.

A continuing application must satisfy certain statutory requirements: (1) it must contain some or all of the disclosure of that applicant's earlier-filed application; (2) the continuing and parent application must name at least one common inventor; (3) the continuing application must be filed while the parent application is still pending; and, (4) at the time of filing the continuing application must specifically claim priority to the parent application.[33] Claims in the continuing application will only be afforded the benefit of the earlier filing date if the subject matter of those claims is fully supported by the disclosure set forth in the parent specification in accordance with the requirements of 35 U.S.C. § 112, i.e., the disclosure in the parent application must satisfy the enablement and written description requirements with respect to the claims in the continuing application.[34]

Continuation practice allows a patent applicant to continue prosecuting a patent application even after receiving a "final" rejection, and this can go on indefinitely by the filing of multiple continuations, subject in some cases to prosecution history laches.[35] During this process, the patent applicant is permitted to amend the claims, or add new claims, directed to subject matter entirely distinct from subject matter originally claimed in the parent application, so long as the newly claimed matter is supported by the parent specification as filed.[36] Furthermore, an unlimited number of divisional applications (a type of continuing application) can be filed, all claiming the benefit of the filing date of a single parent

31. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63 (2004).

32. 35 U.S.C. §§ 120–21 (2015).

33. *Id.*

34. *Id.*

35. Lemley & Moore, *supra* note 31, at 68, 111.

36. *Id.* at 77.

application, with each divisional claiming a distinct invention, which might or might not have been claimed in the parent application as filed.

For example, it is possible for a patent applicant to file an application claiming an isolated human gene, and then years later to file divisional applications claiming other inventions such as a recombinant cell transformed with the gene, processes for manufacturing that recombinant cell, processes for using the recombinant cell to express a therapeutic protein encoded by the gene, the therapeutic protein itself, formulations comprising the therapeutic protein, use of the therapeutic protein as a pharmaceutical, etc. So long as the inventions claimed in the divisional applications were adequately disclosed in the parent, and the divisional applications meet the various requirements for continuing applications, each of these divisional applications can result in a patent. Divisional applications are often filed as a result of a restriction requirement imposed during prosecution before the USPTO,[37] but patent applicants can and often do file divisional applications directed towards inventions that were not claimed in the parent application is filed, and perhaps were not even recognized as inventions at the time of initial filing.

In an empirical study of continuation practice, Hegde et al. found that pharmaceutical companies are particularly likely to make use of continuation practice.[38] They also concluded that "patentees file continuing applications to acquire patents with weak claims of dubious quality that were rejected by the examiner during initial prosecution. These lower-quality patents can be valuable to patent holders seeking to accumulate a thicket."[39] Note that this conclusion relates to patentees in general, not pharmaceutical companies in particular.

Lemley and Moore have argued that pharmaceutical "[e]vergreening is facilitated by the existence of continuation applications," and that pharmaceutical patent owners "have used the continuation process to obtain multiple patents covering obvious variants of the same drug."[40] These authors found that "[c]ontinuation applications have led to abuse of the patent prosecution process[,] serve very little useful purpose, and . . . [t]he world would probably be a better place if they were abolished."[41]

It is important to note that Congress has already successfully addressed some of the problems that have been attributed to continuation practice. For example, Lemley and Moore's conclusion that continuation practice facilitates evergreening was largely premised on their assertion that it was being used to list multiple patents on obvious variants of the same drug in the Orange Book, and to use these patents to obtain "not one, but many sequential 30-month stays [in the FDA's

37. *See* 35 U.S.C. § 121 (providing that "[i]f two or more independent and distinct inventions claimed in one application, the Director may require the application to be restricted to one of the inventions").

38. Deepak Hegde, David C. Mowery & Stuart J.H. Graham, *Pioneering Inventors or Thicket-Builders: Which Firms Use Continuations in Patenting?*, 55 MGMT. Sci 1214, 1214–15 (2009), *available at* https://ssrn.com/abstract=1807073 (on file with *The University of the Pacific Law Review*).

39. *Id.*

40. Lemley & Moore, *supra* note 31, at 71.

41. *Id.* at 118.

approval of a generic version of the drug]." Congress amended the Hatch-Waxman Act[42] in 2004 so that now a pharmaceutical company can generally only obtain one 30-month stay for an Orange Book-listed drug, regardless of how many listed patents are asserted, obviating this particular concern.[43]

Lemley and Moore also suggest that continuation practice facilitates evergreening by making it easier (albeit not impossible) for a patent applicant to file one or more divisional applications and "draw one prosecution out much longer than another."[44] Prior to statutory reform in 1995, this practice could result in multiple divisional patents arising from a single parent application, each with a different expiration date. In one well-known and much-litigated example, Amgen filed a patent application in 1983 that served as the parent application for seven divisional applications that eventually turned into patents.[45] The first patent, essentially claiming the isolated human erythropoietin gene, U.S. Patent Number 4,703,008, issued in 1987.[46] The last of the divisional patents, U.S. Patent Number 5,955,422, which essentially claimed a pharmaceutical composition comprising the erythropoietin protein, issued 12 years later, in 1999.[47] Between 1987 and 1999, five other divisional patents issued, claiming a process for making recombinant erythropoietin (U.S. Patent Number 5,441,868), recombinant erythropoietin protein (U.S. Patent Number 5,547,933), a process for making the protein (U.S. Patent Number 5,618,698), a different embodiment of the protein (U.S. Patent Number 5,621,080), and vertebrate cells transformed with the gene (U.S. Patent Number 5,756,349).[48]

Under then-applicable law, each of these patents was entitled to a 17 year term from the date of issuance, so continuation practice did allow Amgen a total of 29 years (17 plus the additional 12 before the expiration of the last divisional) for patents arising from a single parent application. All of the patents are directed towards different inventions (if that were not the case, the divisional patents would be invalid for double patenting), but it could be that a biosimilar version of this important biologic drug could not be brought to market without infringing more than one of the patents, which would effectively result in the period of exclusivity extending beyond the initial 17-year term.

But this concern about extending effective patent term through continuation practice was addressed by Congress in 1994, and for patent applications filed on

42. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

43. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-73 § 1101, 117 Stat. 2066.

44. Lemley & Moore, *supra* note 31, at 83.

45. Amgen, Inc. v. F. Hoffman-La Roche Ltd., 581 F. Supp. 2d 160 (D. Mass. 2008).

46. U.S. Patent No. 4,703,008 (filed Nov. 30, 1984).

47. U.S. Patent No. 5,955,422 (filed Aug. 2, 1993).

48. U.S. Patent No. 5,441,868 (filed Oct. 23, 1987); U.S. Patent No. 5,547,933 (filed Jun. 7, 1995); U.S. Patent No. 5,618,698 (filed Jun. 6, 1995); U.S. Patent No. 5,621,080 (filed Jun. 6, 1995); U.S. Patent No. 5,756,349 (filed Jun. 6, 1995).

or after June 8, 1995 the term of a continuation (e.g., divisional) application is 20 years from the filing date of the earliest filed parent application to which claims priority.[49] All of Amgen's divisional applications were filed prior to June 8, 1995, but if they had been filed after that date, they would have expired on the same date as the first patent to issue.[50] In other words, while a patent applicant is still able to obtain multiple patents claiming priority to a single parent application, continuation practice cannot be used to extend the duration of patent protection, because they will all expire on the same date.

Critics might argue that continuation practice can still facilitate "patent thicketing," by allowing a patent applicant to introduce new claims years after the initial filing of the parent application, perhaps directed towards an invention that it was not even possible to imagine at the time the parent was initially filed.[51] In an earlier article, for example, this author explained how Amgen used such tactics to obtain a patent that was found to encompass production of recombinant erythropoietin using gene activation, a technology that was unknown at the time the parent application was filed, and that most likely would not have been found to infringe the claims as they appeared in the parent application as filed.[52]

In 2007, the USPTO promulgated its infamous "Rule 78," which would have limited applicants to two continuation applications per application family absent a petition and showing.[53] A panel of the Federal Circuit struck down Rule 78, finding it to be inconsistent with 35 U.S.C. § 120.[54] The panel's opinion was vacated by the en banc court and rehearing granted, but ultimately the issue was rendered moot and left undecided when the USPTO voluntarily withdrew the rule.[55]

VIII. PROPOSED LEGISLATION TO ADDRESS EVERGREENING

This section of the Article describes and provides some commentary on three bills that have been proposed by members of Congress in 2019 and are specifically aimed at curbing evergreening by pharmaceutical innovators. The analysis focuses on the concepts and doctrine discussed in the previous section.

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49. Uruguay Round Agreements Act, Pub. L. No. 103-465 § 532(a)(1), 108 Stat. 4809 (1994).

50. '008 Patent; '422 Patent; '868 Patent; '933 Patent; '698 Patent; '080 Patent; '349 Patent.

51. Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 328 (2007).

52. *Id.* at 326–27.

53. Tafas v. Doll, 559 F.3d 1345, 1349 (Fed. Cir. 2009), *reh'g en banc granted, opinion vacated, reh'g dismissed as moot,* 328 F. App'x 658 (Fed. Cir. 2009).

54. *Id.*

55. Gene Quinn, *Kappos Rescinds Claims & Continuations Rules, What Next?*, IPWATCHDOG (Oct. 9, 2009), *available at* https://www.ipwatchdog.com/2009/10/09/kappos-rescinds-claims-continuations-rules-what-next/id=6495/ (on file with *The University of the Pacific Law Review*).

IX. PRODUCT HOPPING

On May 9, 2019, Senators John Cornyn and Richard Blumenthal introduced the Affordable Prescriptions for Patients Act of 2019, which would seek to address product hopping.[56] A background document provided by the bill's sponsors states:

> Product Hopping takes advantage of our current FDA approval system to get around pharmacy-level generic substitution laws. When making a new version of a drug, like a minor reformulation, that new drug can't be substituted for the generic, because the generic is tied to the old version. Sometimes the manufacturer will go so far as to remove the old version from the market completely. This leaves the generic with nowhere to go, as patients are forcibly switched to the new version.[57]

The Affordable Prescriptions for Patients Act would make it a prima facie antitrust violation (more particularly, an "unfair method of competition in or affecting commerce in violation of section 5(a)") for a manufacturer of a reference product (on which a biosimilar biologics license application ("BLA") under 24 USC §262 is based) or an Orange Book-listed drug to take one of the following two actions during the relevant time frames:

> (1) cause FDA to discontinue or withdraw the "reference drug's"[58] application (or announce discontinuance of or withdrawal of the application) during the period beginning on the date on which the manufacturer of the reference drug receives notice that an applicant has submitted an abbreviated new drug application ("ANDA") or biosimilar BLA and ending on the date that is 180 days after the date on which that generic drug or biosimilar product first enters, or could enter, the market, or is denied; or
>
> (2) market or sell a follow-on product during a period of time referred to as the "competition window."[59]

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56. Affordable Prescriptions for Patients Act of 2019, S. 1416, 116th Cong. (2019).

57. Steve Brachmann, *Affordable Prescriptions for Patients Act Would Allow FTC to Prosecute Pharma Patent Thickets, Product Hopping*, IP WATCHDOG (May 20, 2019), *available at.* https://www.ipwatchdog.com/2019/05/20/affordable-prescriptions-patients-act-allow-ftc-prosecute-pharmaceutical-patent-thickets-product-hopping/id=109384/ (on file with *The University of the Pacific Law Review*).

58. The bill does not define the term "reference drug," but its usage indicates that it refers to a listed drug or reference product. See, *e.g.*, S. 1416, *supra* note 56.

59. *Id.*

With respect to an Orange Book-listed drug, the term 'competition window' is defined as the period between:

> (1) the date that is the earlier of (a) 8 years before any patent or marketing exclusivity granted with respect to such listed drug expires; and (b) the date on which the first ANDA that references such listed drug is filed; and
>
> (2) the date that is the later of (a) 180 days after the ANDA that references such listed drug is filed; and (b) 1 year after the date on which the generic drug that is the subject of the ANDA enters the marketplace.

Similarly, with respect to a biological reference product the term 'competition window' is defined as the period between:

> (1) the date that is the earlier of (a) 6 years before any patent or marketing exclusivity granted with respect to such reference product expires; and (b) the date on which the first biosimilar BLA that references such reference product is filed; and
>
> (2) the later that is the later of (a) 180 days after the date on which the first biosimilar BLA that references such reference product enters the marketplace; and (b) 1 year after the date on which the biosimilar biological product that is the subject of the biosimilar BLA enters the marketplace.[60]

The term 'follow-on product' is defined as an approved drug or biological product that represents a "change, modification, or reformulation" to the same manufacturer's previously approved drug or biological product.[61]

A manufacturer can rebut the prima facie case of unfair competition arising from the discontinuance or withdrawal of a reference product's application by demonstrating the drug was removed from the market for "significant and documented safety reasons."[62] In a case in which a manufacturer has brought a follow-on product to market during the competition window, the prima facie case of unfair competition can be rebutted by demonstrating that:

> (1) the follow-on product provides a clinically meaningful and significant additional health benefit to the target population beyond that provided by the previously approved drug or

60. *Id.*
61. *Id.*
62. *Id.*

> biological product;
>
> (2) the follow-on product was the available means that was least likely to reduce competition; and
>
> (3) the manufacturer had substantive financial reasons, apart from the financial effects of reduced competition, to introduce the follow-on product to the market.[63]

In making this demonstration, the manufacturer must provide to the Federal Trade Commission ("FTC"):

> (1) all research and development, manufacturing, marketing, and other related costs associated with the previously approved drug or biological product, including all documents, memos, or other business documents that explain, mention, or otherwise justify the decision of the manufacturer to develop and manufacture the follow-on product; and
>
> (2) the revenue obtained by the manufacturer with respect to the previously approved drug or biological product drug and the "expected revenue" of the manufacturer with respect to the previously approved drug or biological product and the follow-on product.[64]

The term 'expected revenue', with respect to a follow-on product, means the financial value represented by the number of individuals in the target population multiplied by the financial revenue generated by each member of the target population over the 3-year period beginning[:]

> (1) on the day that 3 generic drugs referencing the same listed drug or 2 or more biosimilar biological products referencing the same reference product would have been widely available in the market; or
>
> (2) if 3 or more generic drugs referencing the same listed drug or 2 or more biosimilar biological products referencing the same reference product are already widely available in the market, the day that the follow-on product enters the market.[65]

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63. S. 1416, *supra* note 56.

64. *Id.*

65. *Id.*

> The term 'target population' means the population of individuals that:
>
> (1) would experience a significant health improvement from a follow-on product; and
>
> (2) would have bought the follow-on product solely because of the significant health improvement that those individuals would experience.[66]

Unfortunately, the ultimate effect of such legislation, if enacted, would be to discourage pharmaceutical innovators from improving existing products. Senator Thom Tillis warned of this in his opening remarks for the May 7, 2019, Judiciary Committee hearing on IP and drug pricing, pointing out that "[t]he newest iPhone is better is because Apple continued to develop new technology to incorporate into the iPhone. We want to encourage this research and innovation, not penalize it . . . In the same way, we don't want to penalize drug companies for improving the first version of a drug, we want to encourage that innovation and research."[67]

X. PATENT THICKETS

The Affordable Prescriptions for Patients Act of 2019 would also turn pharmaceutical "patent thicketing" into a presumptive antitrust violation subject to enforcement action by the FTC. In the background document referenced in the previous subsection of this Article, the bill's sponsors state their concern:

> Some manufacturers have taken advantage of the complex interplay of the different kinds of patents that inhere to one drug—methods of manufacture, formulations, devices, uses, as well as the underlying composition of matter patents—to deploy these patents strategically in order to prevent competition. This is a patent thicket. Would-be competitors, known as generic or biosimilar manufacturers, have to fight through these patents before they can get their drug approved, or they risk losing their chance to sell their drug.[68]

The proposed legislation would render "patent thicketing" a prima facie unfair

66. *Id.*

67. Tillis, *supra* note 1 ("I'm worried that they're trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel.").

68. Brachmann, *supra* note 57; IP WATCHDOG, *Affordable Prescriptions for Patients Act*, *available at* http://www.ipwatchdog.com/wp-content/uploads/2019/05/Affordable-Prescriptions-for-Patients-Act.docx (on file with *The University of the Pacific Law Review*).

method of competition under section 5(a) of the Federal Trade Commission Act.[69] The Act defines "patent thicketing" as encompassing any action taken to limit competition by a patentee with respect to an approved drug in which the following three conditions are met:

(1) the patentee obtains "additional" patents with respect to which either

(a) the effective filing date does not precede the date on which a New Drug Application ("NDA") or BLA was filed, or

(b) the underlying composition of matter patent is found invalid;

(2) an abbreviated ANDA (or biosimilar BLA) referencing the approved drug could not be marketed without practicing one or more of the inventions claimed in the additional patents; and

(3) the FTC determines that the patentee improperly limited competition by obtaining the additional patents.[70]

The bill would define "additional patents" as patents in the same "patent family or patent portfolio" that claim the drug (or biological product), a form of the drug (or biological product), or a method of using or manufacturing the drug (or biological product). The term "patent family" is defined as a group of related patents that "continue the priority date of the underlying composition of matter patent, all of which claim the same drug or biological product or a use of the same drug or biological product."[71] The term "patent portfolio" is defined as a group of "related patents covering the same or similar technical content."[72]

In assessing whether a patentee has improperly limited competition through patent thicketing, the legislation directs the FTC to consider the following factors as evidence demonstrating anticompetitive intent:

(1) the additional patents stem from few patent families,

(2) the additional patents have common specifications,

69. S. 1416, *supra* note 56.

70. *Id.*

71. *Id.*

72. *Id.*

(3) the additional patents did not result from a restriction requirement under 35 U.S.C. § 121,

(4) the additional patents have "overlapping or identical claims,"

(5) the additional patents are directed to formulations or composition to the product and not used,

(6) one or more of the additional patents have been invalidated in an inter partes review (IPR) or post-grant proceeding under 35 U.S.C. § 32,

(7) litigation with applicants under the patent enforcement provision of the Biologics Price Competition and Innovation Act of 2009 (BPCIA) has been extended based on the additional patents,

(8) the applications with respect to the additional patents are submitted not more than 36 months before the expiration of the underlying composition of matter patent,

(9) any evidence demonstrating that the patentee intended to use the number of patents or length of extended patent protection in order to unduly limit competition, such as a public or internal statement, or a shareholder call.[73]

The bill provides that the presumption of unfair competition based on patent thicketing can be rebutted if the drug manufacturer can demonstrate by a preponderance of the evidence that the anticompetitive effects of the action do not outweigh its pro-competitive effects.[74] In making such a demonstration, a manufacturer may present evidence that:

(1) the inventions claimed in the additional patents resulted in:

(a) clinically meaningful and significant therapeutic or safety benefits,

(b) significantly improved product purity or potency,

(c) significant gained efficiencies in manufacturing, or

(d) other improved product attributes having substantial

73. *Id.*

74. *Id.*

benefits for consumers or patients;

(2) a generic drug or biosimilar biological product could be marketed commercially without incorporating the improvements claimed in the additional patents; or

(3) for each of the later filed patents, the manufacturer had substantial financial reason, apart from the financial effects of reduced competition, to file each of the patents.[75]

In making a demonstration to rebut the presumption of an antitrust violation, the bill would require a pharmaceutical manufacture to submit to the FTC, or the court, as applicable, all research and development, manufacturing, marketing, and other costs associated with approval of the original drug or biological product.[76] This disclosure is to include any documents relating to the costs and benefits of the later filed patents with respect to patients who use the drug; as well as any applications for patents that were filed and rejected. The bill further specifies that the FTC may rebut the drug manufacturers evidence by establishing by a preponderance of the evidence that the harm to consumers from the action that is the subject of that presentation is greater than the benefits to consumers from that action.[77]

It should be noted that "patent thicketing" is by no means unique to pharmaceuticals, nor inherently nefarious or anticompetitive.[78] In a 2009 paper addressing patents and competition in pharmaceuticals, Sir Robin Jacob, a Judge of the Court of Appeal of England and Wales who is in charge of that court's Intellectual Property List, pointed out that "[e]very patentee of a major invention is likely to come up with improvements and alleged improvements to his invention. By the time his main patent has expired there will be a thicket of patents intended to extend his monopoly."[79]

It is generally recognized that an advanced smart phone, such as Apple's iPhone, is covered by literally thousands of patents.[80] In his opening remarks

75. *Id.*

76. *Id.*

77. *Id.*

78. *See* Gavin Clarkson & Joshua Newberg, *Blunt Machetes in the Patent Thicket: Modern Lessons from the History of Patent Pool Litigation in the United States Between 1900 and 1970*, 22 J. Tech. L. & Policy 1, 9 (2018) (explaining that "few technological spaces have had more concern about patent thickets than biomedical research, despite the fact that the patent thickets in medicine and the life sciences are just as dense if not denser as those in standards-based industries such as telecommunications and consumer electronics").

79. Robin Jacob, *Patents and Pharmaceuticals – a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry*, EUROPEAN COMMISSION (2009), *available at* https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/jacob.pdf (on file with *The University of the Pacific Law Review*).

80. Olson, *supra* note 9 ("Estimates of the number of patents that cover a smartphone, for instance, range

before the May 7, 2019, Senate Judiciary hearing Senator Thom Tillis noted this fact, pointing out that "[j]ust like an iPhone has thousands of patents, so does a complex pharmaceutical product."[81] In his written testimony prepared for that same hearing, Professor Olson pointed out that while some might expect the large number of patents on smart phones to create a "significant drag on innovation," in fact "there is no conclusive evidence that smartphone or other high-tech innovation is being retarded by the large numbers of patents that may cover these devices."[82] He goes on to point out that "[t]he number of patents that cover any particular drug or biologic, in comparison, are quite low, ranging from the single digits to perhaps one hundred. This is not enough patents to constitute a substantial patent thicket that will deter innovation."[83]

Similarly, in recent testimony before the House Judiciary Committee, USPTO Director Andrei Iancu was asked about the issues of "evergreening" and "patent thicketing" in the context of pharmaceutical drugs, and he defended his office's practice of issuing multiple patents to the same drug, stating that each application is evaluated for whether the claimed invention "actually presents novel and nonobvious innovation vis-à-vis what's come beforehand."[84]

XI. RAISING THE NONOBVIOUSNESS BAR FOR FOLLOW-ON/SECONDARY PATENTS

In June 2019, Senator Lindsay Graham released a proposed bill, entitled the "No Combination Drug Patents Act," which would amend Section 103 of the Patent Act (the statutory basis for the obviousness requirement) in a manner creating a rebuttable presumption that most follow-on pharmaceutical innovations are legally obvious.[85] As of the date this is being written, the bill has not been formally introduced in Congress,[86] but it is still worth discussing since its substance could, at some point, appear in an introduced bill.

Senator Graham's proposed legislation would amend 35 U.S.C. § 103, the statutory basis of the nonobviousness requirement, by adding a new subsection (c)

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from the thousands to the tens of thousands to even the hundreds of thousands.").

81. Tillis, *supra* note 1 ("I'm worried that they're trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel.").

82. Olson, *supra* note 9 ("Estimates of the number of patents that cover a smartphone, for instance, range from the thousands to the tens of thousands to even the hundreds of thousands.").

83. *Id.*

84. *Oversight of the U.S. Patent and Trademark Office: Hearing Before H. Comm. on the Judiciary*, 116th. Cong. (2019), https://judiciary.house.gov/calendar/eventsingle.aspx?EventID=1816 (on file with *The University of the Pacific Law Review*).

85. No Combination Drug Patents Act, S., 116th Cong. (as drafted, 2019) [hereinafter *Graham Bill*] (on file with *The University of the Pacific Law Review*).

86. Kevin Madigan & Sean O'Connor, "*No Combination Drug Patents Act" Stalls, but Threats to Innovation Remain*, CENTER FOR THE PROTECTION OF INTELLECTUAL PROPERTY (June 27, 2019), https://cpip.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/ (on file with *The University of the Pacific Law Review*).

entitled "Presumption with Respect to Certain Changes to Drugs and Biological Products."[87] The titles of this subsection and of the bill itself are somewhat misdescriptive, in that they seem to suggest that the target of the legislation is limited to inventions that involve "changes" to a drug, or drug combination inventions, respectively.[88] If enacted, the bill would create a presumption of obviousness with respect to any "covered claimed invention," which is any claimed invention that "contains or uses a drug or biological product that is prior art," and which is different from the prior art only with respect to one or more of four enumerated criteria.[89] The enumerated criteria are:

> (1) a dosing regimen for the drug or biological product,
>
> (2) a method of administration or delivery of the drug or biological product,
>
> (3) a method of treatment using the drug or biological product, or
>
> (4) a pharmaceutical formulation including the drug or biological product.

Apparently excluded from the categories are some of the more controversial follow-on pharmaceutical inventions, including patents on polymorphs, enantiomers, salts, ethers and esters, prodrugs, and metabolites. Although the proposed subsection purports to be directed towards inventions involving changes to drugs, the sorts of secondary pharmaceutical innovation that are most akin to a change to a drug—such as prodrugs, metabolites, polymorphs, and enantiomers—would not appear to be covered by the language of the bill. It seems that this might have been an oversight by whoever drafted the bill, and would likely be caught and rectified were the bill to move forward.

Under the proposed legislation, the statutory presumption of obviousness with respect to covered claimed inventions may be rebutted if the applicant demonstrates that the invention either (1) is a new treatment for a new indication, or (2) results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.

The proposed amendment includes the following "Rule of Construction":

> Nothing in this subsection may be construed to affect the conditions for patentability with respect to any claimed invention that is a drug, a biological product, a dosing regimen or method of

87. *Graham Bill*, *supra* note 85.

88. *Id.*

89. *Id.*

> administration for a drug or biological product, a method of treatment using a drug or biological product, or a pharmaceutical formulation including a drug or biological product if the patent application with respect to the claimed invention claims only that drug, biological product, regimen or method of administration, method of treatment, or formulation, as applicable.[90]

In other words, the presumption of nonobviousness would not apply with respect to any claimed invention that is a drug, if the "patent application with respect to the claimed invention" claims only that drug. Likewise, the presumption does not apply when the claimed invention is a dosing regimen, if the patent application "with respect to the claimed invention" claims only that regimen. The same goes for the other categories of invention to which the presumption would otherwise apply, i.e., methods of treatment, methods of administration, or pharmaceutical formulations.

This exemption could largely eviscerate the bill's effect, depending on how one interprets the phrase "patent application with respect to the claimed invention."[91] If it encompasses the patent application that the USPTO allowed to issue as a patent, then it will generally be the case that this application will only claim one of these categories of invention. To the extent that the drug and a method of using the drug, for example, are discrete inventions, then the double patenting doctrines discussed above require that they be divided into separate patent applications and patents. In any event, a pharmaceutical company aware of this exemption would apparently be able to easily qualify for it by making sure that it files divisional applications in order to have separate applications for each of these categories of invention. But is this really what the authors of this legislation intended? With so many complaining that there are too many patents, and continuation practice, why amend the Section 103 in a way that encourages more divisional patents? One suspects that the authors of the legislation had something else in mind.

Another possibility could be that "patent application with respect to the claimed invention" is intended to refer to a patent application as originally filed.[92] Under this interpretation, the exemption would be inapplicable if the patent application as filed was directed towards one category of invention, for example the drug active ingredient per se, and through amendment the claims were changed to cover a formulation of the drug, or method of using it. This would seem to be an unwarranted restriction on the ability of patent applicants to amend their claims, since as a general matter patent applicants are free to amend claims, cancel claims, and add claims directed towards entirely new inventions during the prosecution of a patent application. It could also, in many instances, be easily circumvented. For

90. *Id.*
91. *Id.*
92. *Id.*

example, if a patent application as filed includes claims directed towards a drug, and the applicant wants to instead pursue claims directed towards a method of using the drug, then instead of amending the claims (and losing advantage of the exemption), the applicant could simply file a divisional application including claims directed towards the method of using the drug.

Yet another possibility could be that "patent application with respect to the claimed invention"[93] is meant to encompass a parent application to which any continuing application claims priority. As discussed above, there is literature suggesting that continuation practice is problematic and has been abused by pharmaceutical companies, so it could be that the exemption is intended to discourage the filing of divisional application. As noted, it is common for an initially filed patent application to disclose multiple inventions, and to serve as the parent application for divisional applications that result in multiple patents directed towards distinct inventions, all claiming priority to that parent. Consider, for example, the single patent application filed by Amgen that resulted in seven patents claiming distinct inventions relating to the making and using of erythropoietin as a human therapeutic.[94]

Under this interpretation of the bill, pharmaceutical companies would be motivated to dramatically change their patent filing practices. Instead of filing an application with claims that might be found to be directed towards two or more distinct inventions—and thus subject to a restriction requirement—the pharmaceutical company would need to file many patent applications simultaneously, each with claims directed towards the different inventions. For example, if this was the law at the time Amgen filed its initial patent application in 1983, it would have likely responded by filing at least seven applications with claims directed towards various methods, reagents, and products, rather than filing a single application that ultimately resulted in seven patents.

In effect, under this interpretation a patent applicant would need to figure out what the inventions are at the time of filing, and claim them, as opposed to the current state of affairs, in which it is enough to disclose inventions, which can then be claimed at the later time. This would be a significant change in the law for pharmaceutical companies, who do sometimes take advantage of continuation practice to secure patent claims directed towards inventions that were not envisioned at the time the parent application was filed. For example, in an earlier article, this author described how Amgen employed continuation practice to obtain new patent claims that encompassed production of erythropoietin by gene activation, a technology that was unknown at the time they filed the original patent application.[95]

Another puzzling aspect of the bill is its "finding" of Congress that "[i]n

93. *Graham Bill*, *supra* note 85.

94. *See supra*, Part II; *see also supra* Part VII.

95. Holman, *supra* note 51, at 326.

Neptune Generics, LLC v. Eli Lilly & Co., 921 F.3d 1372 (Fed. Cir. 2019), the United States Court of Appeals for the Federal Circuit correctly determined the limited occasions in which a combination patent would not be considered unpatentable as obvious."[96] Normally, the term "combination patent" is used to refer to a patent on a product that combines two or more active ingredients. *Neptune Generics*, on the other hand, involves patent claims reciting a method of pretreating a patient with folic acid and a methylmalonic acid ("MMA") lowering agent (such as vitamin B12) before administering pemetrexed disodium (a chemotherapy agent), in order to reduce the toxic effects of pemetrexed. The Federal Circuit unanimously affirmed the Patent Trial and Appeals Board's ("PTAB's") determination that the claims are not obvious, based on substantial evidence supporting the PTAB's finding that the art did not provide a motivation for a skilled artisan to administer an MMA lowering agent in combination with folic acid, and evidence of industry skepticism. The relevance of a lack of motivation to make an invention and industry skepticism are well-established principles of patent law, and there does not appear to be anything particularly noteworthy about the Federal Circuit's decision in *Neptune Generics*. Furthermore, the decision does not appear to have anything to say about "the limited occasions in which a combination patent would not be considered unpatentable as obvious." Perhaps this "Congressional finding," while a bit off the mark, was simply meant to clarify that the intent of the bill is not to render all follow-on pharmaceutical inventions unpatentable as obvious.

The idea of raising the nonobviousness bar specifically for follow-on pharmaceutical inventions is not a new one. In 2015, for example, the United Nations Development Programme issued a document entitled *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective* (the "*Guidelines*").[97] The *Guidelines* represent a follow-up to an earlier document, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective – Working Paper (the "Working Paper")*, which was published in 2007 by the International Centre for Trade and Sustainable Development ("ICTSD"), the United Nations Conference on Trade and Development ("UNCTAD") and the World Health Organization ("WHO").[98] The *Guidelines* provide "recommendations" as to how patent examiners should examine secondary pharmaceutical patent claims in a manner that would, according to its author, "protect public health and promote access to medicines."[99]

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96. *Graham Bill*, *supra* note 85.

97. Carlos Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, UNITED NATIONS DEVELOPMENT PROGRAMME, https://www.undp.org/content/dam/undp/library/HIV-AIDS/UNDP_patents_final_web_2.pdf (on file with *The University of the Pacific Law Review*).

98. Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* (Int'l Ctr. For Trade and Sustainable Dev., World Health Org., & United Nations Conference on Trade and Dev., Working Paper, 2006) (on file with *The University of the Pacific Law Review*).

99. *Id.*

These recommendations generally call for heightening the patentability requirements for follow-on pharmaceutical inventions, largely through a more rigorous application of the nonobviousness standard. In particular, the *Guidelines* postulate that many forms of pharmaceutical innovation are inherently routine and should be found unpatentable due to obviousness absent some sort of exceptional circumstance.

In response to the *Guidelines*, I co-authored an article challenging the assumption that many types of pharmaceutical inventions are inherently obvious and undeserving of patent protection, finding it to be based on an oversimplified view of how these inventions come about and a failure to appreciate the value that they provide for patients.[100] The article reviews numerous decisions from courts and patent offices throughout the world, including in developing countries, which have upheld the validity of follow-on pharmaceutical patents. In these decisions, the courts and patent office officials are generally struck by the amount of work and ingenuity involved in the invention of many follow-on pharmaceutical products and methods, and by the impact they can have on patient's lives.

One of the examples provided in the article is AZT, used in the treatment AIDS.[101] AZT started out as a failed cancer drug, and for that reason patent protection for the composition of matter itself was out of the question. Thankfully, the pharmaceutical company Burroughs-Wellcome was able to secure a patent on a method of using AZT to treat AIDS—without this "secondary" patent, the company would have likely been unable to secure the necessary investment to bring this life-saving drug to patients. At a recent USPTO oversight hearing, USPTO Director Andrei Iancu, when asked about the perceived problem of evergreening and patent thickets, specifically pointed to AZT as an example of the importance of allowing the patenting of follow-on inventions, and the potential danger of legislation that seeks to deny patent protection to such inventions.[102]

Some of the complaints about follow-on pharmaceutical patents, although no doubt well-intentioned and based on sincere belief, do not stand up well to logical scrutiny. For example, a witness at a Senate Judiciary Hearing on May 7, 2019, identified as the Director of the South Carolina Department of Health and Human Services, provided the following written testimony:

> Patents and market exclusivity can be blunt policy instruments. As applied to the pharmaceutical market in their current form, they do not adequately consider the underlying value of a product being protected, nor do they capture the true novelty of a product. Consequently, a medication that combines an over-the-counter pain reliever with an over-the-counter antacid is permitted to

100. Holman et al, *supra* note 23, at 136–137; *see also* Holman, *supra* note 23.

101. *Id.*

102. *Oversight of the U.S. Patent and Trademark Office*, *supra* note 84.

> pursue market exclusivity and come to market with a price tag of several thousand dollars per month. In another instance, an over-the-counter antihistamine was combined with a vitamin to create a treatment for nausea in pregnant women. The price tag for this medication is $600 per month. These examples demonstrate the ability of medications that offer relatively low marginal benefits to come to market with the same protections as the next potential cancer cure.[103]

The witness did not identify the specific combination products he was referring to, but his assertion begs the question—why are patients paying several thousand dollars per month for a medication that does nothing more than combine two over-the-counter ingredients? Taking him at his word, one has to wonder why it is that patients do not simply buy the two ingredients over-the-counter and take them together? If they are willing to pay thousands of dollars a month for this combination product, the benefits of combining the two products must be enormous, and any patent covering the combination product could not be used to prevent someone from simply buying the two drug separately. If patients are really paying thousands of dollars a month for a simple combination of two over-the-counter ingredients, rather than simply buying the two ingredients separately, then that reflects a problem in the market for pharmaceuticals, not a problem with the patent system. In any rational market, such a patent would only provide benefits to patients, by publicly disclosing what must be an enormously beneficial combination of antacid and pain reliever, and without in any way interfering with the ability of patients to buy the components separately and take them in combination.

XII. DOUBLE PATENTING

On June 11, 2019, Congressman Hakeem Jefferies introduced a bill entitled the 'Terminating the Extension of Rights Misappropriated Act of 2019,'' or the ''Term Act of 2019',' H.R. 3199.[104] While language in the bill states that it is intended to prevent "double patenting," the substance of the bill would only apply to patents relating to innovative drugs and biological products. In particular, the Term Act would amend 35 U.S.C. § 253 by adding a subsection creating a presumption that in any patent enforcement action brought with respect to an ANDA under the Hatch-Waxman Act, or a biosimilar BLA under the BPCIA, wherein the validity of a patent is challenged, "the patentee shall be presumed to

103. Joshua D. Baker, Director, S.C. Dept. of Health and Human Servs., Statement for the Record Before the U.S. Senate Judiciary Committee 3 (May 7, 2019) https://www.judiciary.senate.gov/imo/media/doc/Baker%20Testimony1.pdf (on file with *The University of the Pacific Law Review*).

104. Terminating the Extension of Rights Misappropriated Act, H.R. 3199, 116th Cong. (2019).

have disclaimed the patent term for each of the listed patents after the date on which the term the first patent expires."[105]

The term "listed patents" is not defined, but with respect to actions brought under Hatch-Waxman it presumably refers to Orange Book-listed patents. With respect to biosimilar litigation, the meaning is less clear. It could perhaps be applied to the list of patents a reference product sponsor is required to provide to an applicant for biosimilar approval as part of the BPCIA's "patent dance," i.e., patents that could "reasonably be asserted" against a party manufacturing or marketing a biosimilar version of the innovative product.[106] It could also be interpreted as pertaining to the FDA's "Purple Book," which is applicable to biological products and functions as something of an analog to the Orange Book.[107] The Purple Book is currently not mandated by statute, but there is proposed legislation pending that would create a statutory basis for it.[108]

It is significant that the TERM Act would not render these presumptively patentability indistinct patents unenforceable, but would only require disclaimer of any term extending beyond that of an earlier patent. This is essentially the same remedy that the USPTO has long used to address obviousness-type double patenting. In particular, an obviousness-type double patenting rejection can be overcome by the filing of a terminal disclaimer, as authorized by 35 U.S.C. § 253. A terminal disclaimer is a document by which the applicant agrees to disclaim any patent term extending beyond the expiration of the applicant's first patent on which the double patenting rejection was based. The terminal disclaimer alleviates the concern that the second patent will unduly extend patent protection on obvious variations of the initially patented invention, while maintaining some incentive for a patentee to improve upon his original invention.

The bill specifies that its presumption can be overcome if the patentee can demonstrate by a preponderance of the evidence that the patents cover patently distinct inventions.[109] It also specifies that all patent term extensions granted by the USPTO shall be respected. In short, the bill would not alter the standard for

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105. *Id.*

106. CONG. RESEARCH SERV., R45666, DRUG PRICING AND INTELLECTUAL PROPERTY LAW: A LEGAL OVERVIEW FOR THE 116TH CONGRESS 31-33 (2019); *see also* 42 U.S.C. § 262 (a)(1) (describing the requirements for introducing biological products into the interstate market); Christopher M. Holman, *Status Update: Implementation of the Patent Dispute Resolution Provisions of the Biologics Price Competition and Innovation Act*, 34 BIOTECH. L. REP. 247, 247–248 (2015) (describing the BPCIA'a "patent dance").

107. *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or (last visited Jan. 22, 2020) (on file with *The University of the Pacific Law Review*).

108. *See* Christopher M. Holman, *Congress Considering Legislation Aimed at Increasing Competition in Pharmaceuticals*, 38 BIOTECHNOLOGY L. REP. 144, 147 (2019) (discussing the Purple Book Continuity Act of 2019, H.R. 1520, and Biologic Patent Transparency Act, S. 659).

109. H.R. 3199, *supra* note 104.

determining obviousness-type double patenting, nor the remedy, but would shift the burden of proof, requiring a patent applicant to prove that listed patents are patently distinct from one another, as opposed to the current burden on the USPTO to establish that the two patents claim obvious variations of the same invention. The rationale behind the bill is presumably that, since the patentee has chosen to list the patents with respect to the same drug, it has effectively represented that the patents cover the same drug, and thus it is not unreasonable to require the patentee to explain how it is that patents covering the same drug are directed towards patentably distinct inventions.

The bill also would require the Director of the USPTO to conduct a comprehensive review of the Office's patent examination procedures to determine whether it is using best examination practices, guidance, and procedures to avoid the issuance of patents relating to the same drug, or biological product, that are not patentably distinct from one another, and not subject to an appropriate disclaimer of patent term. Furthermore, the bill would require the Director to determine whether the Office should develop and implement new practices, guidance, or procedures to improve examination of patent applications relating to the same drug or biological product, and reduce the improper issuance of patents that improperly extend the term of exclusivity afforded a new drug or biological product. The Director would be required to submit to the Committee on the Judiciary of the House of Representatives a report that contains the findings of the review and any recommendation of the Director with respect to the review.[110]

XIII. CONTINUATIONS AND DIVISIONALS

As far as I am aware, there is no pending legislation that would directly limit continuation practice along the lines of the USPTO's aborted Rule 78 discussed above.[111] However, some of the provisions of bills that have been discussed in this Article would at least indirectly discourage the use of continuation practice, most particularly the filing of divisional applications, by pharmaceutical companies.

In particular, the Affordable Prescriptions for Patients Act defines one of the categories of "additional patents" that could result in liability for patent thicketing as comprised of drug patents in the same "patent family," which are a group of patents that continue the priority date of the underlying composition of matter patent, i.e., divisional patents. If enacted, the bill could encourage pharmaceutical companies to file a large number of patent applications on the same day as, or shortly after, the filing of an initial application disclosing a new active ingredient. These applications would be directed towards the types of inventions targeted by the Act, i.e., forms and formulations of the drug, and methods of making and using it. By doing so, they would be able to avoid the use of continuation practice, and perhaps liability for patent thicketing given that the resulting patents would not

110. *Id.*

111. *See supra*, Part II; *see also supra* Part VII.

reside in the same patent family.

Depending upon how it is interpreted, the "No Combination Drug Patents Act" might also penalize pharmaceutical companies for using continuation practice. As discussed above, the "Rule of Construction" that exempts any claimed invention from the bill's presumption if the patent application with respect to that invention claims only that invention could be interpreted as inapplicable to patents resulting from continuation or divisional applications whose claims differ from those found in the parent application. As with the provision in the Affordable Prescriptions for Patients Act discussed above, this interpretation of the No Combination Drug Patents Act would seem to encourage pharmaceutical companies to file, early on, a large number of independent applications directed towards forms and formulations of the drug, and methods of making or using the drug, in order to avoid the disfavored treatment to be afforded pharmaceutical patents arising out of continuation practice.

XIV. CONCLUSION

Senator Thom Tillis, in his opening remarks prepared for one of the Senate's hearings on drug pricing and intellectual property, expressed his concern that "[some members of Congress are] trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel[, and that] by just focusing on patent protections, and the number of patent protections available to a single product, [Congress] may be doing more harm than good to our nation's innovation economy."[112] Instead, he would support legislation that will "promote innovation and competition, allow the United States to continue to be the leader in medical and pharmaceutical research, and will ultimately lower drug prices for consumers."[113]

It is important to bear in mind that the reason there has been such an uproar over the price of drugs is that these drugs provide huge benefits for society, far exceeding most other patentable innovation, and were it not for the patent incentive, it is very unlikely these products would have been made available to patients in the first place. In his testimony prepared for the same Senate hearing, Professor Olson reminded the Judiciary Committee that "even studies casting doubt on patent law's efficacy generally tend to find that in the area of pharmaceuticals, patent law has a large, positive effect on social welfare by providing incentive for significant levels of drug development that otherwise simply would not occur."[114] By impairing the ability of pharmaceutical companies

112. Tillis, *supra* note 1.

113. *Id.* ("I'm worried that they're trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel.").

114. *See* Olson, *supra* note 9 ("Estimates of the number of patents that cover a smartphone, for instance, range from the thousands to the tens of thousands to even the hundreds of thousands.").

to obtain patents on their inventions, the legislation discussed in this Article could discourage the investment necessary to bring the next generation of pharmaceutical innovation to patients.

If pharmaceutical companies are deemed to be misusing patents to the detriment of patients and third-party payers, then it is that misuse of patents that should be targeted by legislation, not the patents themselves. For example, if the allegations regarding product hopping are true, and doctors are prescribing and patients using far more expensive follow-on products that provide little if any benefit to the patient, then that is a problem with the market that should be addressed, rather than denying patent protection for truly worthwhile product improvements. If pharmaceutical companies are using anticompetitive means to coerce patients and doctors into switching drugs, then antitrust laws can provide the remedy, as discussed above.[115] Likewise, if the sheer number of patents that could be infringed by a single generic or biosimilar product exceeds the litigation capacity of any company attempting to bring such a product to market, then courts have it within their means to require the patent owner to limit infringement litigation to some reasonable number of patents and patent claims, and Congress could pass legislation that would encourage courts to do so, if such a reform is deemed necessary.

By targeting misuse of patents by pharmaceutical companies, rather than pharmaceutical patents per se, it should be possible to address any valid concerns with the way pharmaceutical companies are using the patent system, while maintaining adequate incentives for the next generation of innovation.

115. *See supra* notes 12–13 and accompanying text.