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NOTES

LEAVING THE EVERGREENING PROBLEM TO THE PATENT EXPERTS – THE USPTO, THE PTAB, AND THE FEDERAL CIRCUIT

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INTRODUCTION

One of the top ten pharmaceutical companies in the world, AbbVie, Inc., lost its compound patent on the world's best-selling drug in 2016.[1] Adalimumab, also known as Humira®, generates approximately $583 per second for AbbVie.[2] The pharmaceutical company's continued success lies in its manipulation of the patent system.[3] The twenty-year exclusivity restriction in patent law ensures that society receives the benefit of the drug as it enters into the public domain.[4] However, AbbVie has obtained more than 247 patents on Humira® in the United States alone to extend its own exclusivity in the drug's market.[5] Additionally, AbbVie filed eighty-nine percent of Humira® patents after the drug was introduced to the public.[6] AbbVie filed more than fifty percent of the total applications twenty years after initial research began and more than a decade after the drug was initially sold.[7] What should have been a price decrease in the drug in 2014 due to loss of exclusivity could theoretically be a constant increase in pricing until

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1. AbbVie Inc., Annual Report (Form 10-K) (Feb. 19, 2016).

2. *Overpatented, Overpriced: Special Humira Edition*, I-MAK at 7 (Sept. 18, 2018), http://www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_0917.pdf [https://perma.cc/34YJ-7W79].

3. *Id.*

4. *Why Do Patents Expire: Everything You Need to Know*, UPCOUNS., https://www.upcounsel.com/why-do-patents-expire (last visited Oct. 7, 2019) [https://perma.cc/AJ6M-J7ZR].

5. *Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 2.

6. *Id.*

7. *Id.*

2037.[8]

Similarly, Sanofi's original patent on one of its drugs, Lantus®, expired in 2015.[9] Nonetheless, the pharmaceutical company filed an additional seventy-four patent applications in the United States alone[10]; this could extend Sanofi's exclusivity for an additional thirty-seven years.[11] Like AbbVie's impressive revenue with Humira®, Sanofi collects approximately $11,000 per minute on Lantus® alone.[12] Similarly, Sanofi filed ninety-five percent of the Lantus® patents after the drug came to market in 2000.[13] This patenting scheme caused total Medicare and Medicaid spending on Lantus® to increase 132% between 2012 and 2016.[14] During this time, the average annual Medicare spending on Lantus® per person increased eighty-nine percent—from $1,284 to $2,431.[15]

The top twelve selling drugs in 2017 had an average of 125 patent applications filed.[16] Theoretically, these additional patents could block generic competition for an average of thirty-eight years in addition to its initial twenty-year exclusivity period.[17] Without competition on the market, the prices for these drugs increased on average by sixty-eight percent.[18] Additionally, these top-grossing drugs have already been on the market for fifteen years.[19] Over half of the top twelve drugs have more than 100 attempted patents per drug.[20]

Patents play an essential role in the pharmaceutical industry; the process of developing a new drug and bringing it to market is not only long and costly, but also extremely tedious.[21] Specifically, the research and development process can

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8. *Id.* at 4.

9. *Overpatented, Overpriced Special Edition: Lantus (Insulin Glargine)*, I-MAK at 4 (Nov. 1, 2018), http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf [https://perma.cc/9XNH-MKBX].

10. *Id.*

11. *Id.*

12. *Id.* at 7.

13. *Id.* at 4.

14. *Id.* at 2.

15. *Id.* at 7.

16. *Overpatented: (Not so) Average*, I-MAK (Aug. 2, 2018), https://www.i-mak.org/wp-content/uploads/2018/08/imak.100s.patents.totals-2.png [https://perma.cc/62XK-ZBEP] (stating pharmaceutical drugs with the largest number of secondary patents are Humira® with 247, Avastin® with 219, and Rituxan® with 204).

17. *Id.* (stating the "worst offenders" of blocking generic companies are Herceptin® with forty-eight years, Rituxan® with forty-seven years, and Avastin® with forty-three years).

18. *Id.* (stating the largest price hikes over the past six years include Lyrica® with an increase of 163%, Enbrel® with an increase of 155%, and Humira® with an increase of 144%).

19. *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting Is Extending Monopolies and Driving Up Drug Prices*, I-MAK at 2 (Aug. 2, 2018), https://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf [https://perma.cc/9UQF-RCH8] [hereinafter *Excessive Pharmaceutical Patenting*].

20. *Id.*

21. Henry G. Grabowski, Joseph A. DiMasi & Genia Long, *The Roles of Patents and*

take over a decade to complete and cost over a billion dollars.[22] Only one in eight drug candidates survives clinal testing, though this does not necessarily mean it will become a "blockbuster" or even a profitable drug.[23] After the drug patent's expiration, its generic rivals can enter the market with the same drug at a greatly reduced price.[24] Although this greatly benefits the consumer, the resulting competition heavily diminishes the innovator's profits.[25]

The issue of pharmaceutical companies extending a drug's exclusivity—when based on abundant secondary patents with minimal variation from the compound patent—is called "evergreening."[26] This results in the delayed arrival of a generic drug or biosimilar in a given market; consequently, the drug's price will likely not decrease until the launch of the generic or biosimilar drug.[27]

However, not every additional patent application is an example of evergreening, as many pharmaceutical companies continue to perform research and development which may yield promising new uses for the drug.[28] In response to evergreening, recently proposed legislation includes, but is not limited to, the Reforming Evergreening and Manipulation that Extends Drug Years Act (the "REMEDY Act"), the Affordable Prescriptions for Patients Act of 2019 (the "APP Act"), and the Terminating the Extension of Rights Misappropriated Act of 2019 (the "TERM Act").[29] Each of these bills is likely to result in an incorrect treatment of most, if not all, secondary patents as attempts at evergreening;

Research and Development Incentives in Biopharmaceutical Innovation, 34 HEALTH AFF. 302, 302 (2015), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1047 [https://perma.cc/VZA4-9FA2].

22. *Id.* at 303.

23. *Id.*; *see* James Chen, *Blockbuster Drug*, INVESTOPEDIA (Jan. 23, 2018), https://www.investopedia.com/terms/b/blockbuster-drug.asp [https://perma.cc/H2TW-HM2X] (defining blockbuster drug as any popular drug that generates annual sales of at least one billion dollars).

24. Grabowski, DiMasi & Long, *supra* note 21, at 302.

25. *Id.*

26. Roger Collier, *Drug Patents: The Evergreening Problem*, 185(9) CANADIAN MED. ASS'N J. E385, E385 (2013).

27. *How Long Does a Drug Patent Last?*, UPCOUNS., https://www.upcounsel.com/how-long-does-a-drug-patent-last (last visited Aug. 28, 2019) [https://perma.cc/7D5H-WRWX]. For an explanation on biosimilars, see *Biosimilars*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars (last updated Feb. 3, 2020) [https://perma.cc/HFM9-F32G].

28. Frank Bongers & Hugo Carradinha, *How to Increase Patient Access to Generic Medicines in European Healthcare Systems*, MEDS. FOR EUR. at 39 (2009), https://www.medicinesforeurope.com/wp-content/uploads/2016/03/Market_Barriers_Report_FINAL_update_How_to_Increase_Patient_Access_to_Generic_Medicines.pdf [https://perma.cc/ZPG4-WFGK].

29. S. 1209, 116th Cong. § 3 (2019); S. 1416, 116th Cong. (2019); H.R. 3199, 116th Cong. (2019).

therefore, they would be detrimental to the patent system and the pharmaceutical industry.

I. THE EVERGREENING PROBLEM

A. Exclusivity and Secondary Patents

35 U.S.C. § 154 guarantees an inventor twenty years of exclusivity from the filing date of a patent.[30] The exclusivity provides incentives for inventors to present their inventions to the public.[31] This motivation draws many inventors away from the trade secret track, as once a trade secret is public knowledge, there is no recourse that is as strong as patent protection.[32] The patent system incentivizes innovation and disclosure, allowing the public to consistently improve on society's discoveries.[33] In the pharmaceutical industry, the innovator receives an exclusivity term for providing the public with a beneficial drug, while the public gets access to the drug for the exclusivity period.[34] Additionally, after the exclusivity period, the public will likely get access to the drug at a much lower price due to the generic competition entering the market, and the generic company will be able to profit off of the drug while providing it at a lower price than offered by the innovator company.[35]

The ability for the drug developer to obtain secondary patents on the same drug provides drug developers with an important opportunity.[36] While the primary patent protects the active drug, secondary patents can protect ranges of chemicals involved in the active drug, methods of using the drug, formulations, dosages, and methods of manufacturing.[37] Generally, secondary patents are granted in order to encourage further discoveries that can result from additional research and development on a known drug.[38] Notably, these secondary patents

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30. 35 U.S.C. § 154 (1952).

31. *Frequently Asked Questions: Patents*, WORLD INTELL. PROP. ORG., https://www.wipo.int/patents/en/faq_patents.html (last visited Oct. 9, 2019) [https://perma.cc/NNY7-GV4W].

32. Orly Lobel, *Filing for a Patent Versus Keeping Your Invention a Trade Secret*, HARV. BUS. REV. (Nov. 21, 2013), https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret [https://perma.cc/7DB7-9BFS].

33. *Patent*, CORNELL L. SCH., https://www.law.cornell.edu/wex/patent (last visited Oct. 17, 2019) [https://perma.cc/PE9T-F2TA].

34. Grabowski, DiMasi & Long, *supra* note 21, at 302.

35. *Id.*

36. Sarah Jane Tribble, *Drugmakers Play the Patent Game to Ward Off Competitors*, NBC NEWS (Oct. 2, 2018), https://www.nbcnews.com/health/health-news/drugmakers-play-patent-game-ward-competitors-n915911 [https://perma.cc/L7FT-6F2Z] [hereinafter Tribble, *Drugmakers Play the Patent Game*].

37. María José Abud Sittler et al., *Study on Pharmaceutical Patents in Chile*, WORLD INTELL. PROP. ORG. at 1 (2015), https://www.wipo.int/edocs/mdocs/mdocs/en/cdip_15/cdip_15_inf_2.docx [https://perma.cc/WU2M-U3NU].

38. Christopher Holman, *Inside Views: Why Follow-on Pharmaceutical Innovations Should*

can extend the pharmaceutical company's exclusivity even beyond the original twenty years.[39] The implication for the public is higher prices for an extended period of time[40]; additionally, this patent scheme could theoretically allow a pharmaceutical company to continuously extend its exclusivity by making insubstantial changes to its subsequent applications on the same drug.[41] In some instances, where the drug is a natural product, only secondary patents are likely to provide any patent exclusivity for the drug.[42]

The initial reasoning behind allowing secondary patents sought to protect genuine innovation.[43] For example, zidovudine (AZT) initially failed as a cancer drug.[44] However, after years of additional research, scientists discovered AZT's potential against acquired immune deficiency syndrome (AIDS).[45] Additional examples of discovered drug uses due to the allowance of secondary patents include Evista® (used for treatment of osteoporosis and breast cancer) and Zyprexa® (used for treatment of schizophrenia).[46]

Nevertheless, instances exist that seem to be distinct cases of pharmaceutical companies evergreening in order to extend their monopolies.[47] Famous examples include making minimal changes to the drug formula, lowering the dosage of the drug, and reformulating the drug to be taken once a day instead of twice a day.[48] Additionally, the number of secondary patents filed on a particular drug can be an indication of whether there was an attempt to evergreen or whether there was genuine further research on the drug.[49]

Be Eligible for Patent Protection, INTELL. PROP. WATCH (Sept. 21, 2018), https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/ [https://perma.cc/S775-UD87].

39. Sittler et al., *supra* note 37, at 4. *But see* Carlos A. Garcia & Jonathan Stroud, *Ships in the Night: Resolving Administrative Conflict Between FDA- and Patent-Related Legislation*, 68 AM. U. L. REV. 1111, 1143–46 (2019) (discussing how pharmaceutical products rarely get to enjoy the full exclusivity their patent offers).

40. Grabowski, DiMasi & Long, *supra* note 21, at 302.

41. Tahir Amin, *The Problem with High Drug Prices Isn't 'Foreign Freeloading,' It's the Patent System*, CNBC (June 27, 2018), https://www.cnbc.com/2018/06/25/high-drug-prices-caused-by-us-patent-system.html [https://perma.cc/UX2F-HR62].

42. *See* Maximilienne Giannelli & Amana Abdulwakeel, *Puzzling Out the Patent-Eligibility of Natural Products*, FINNEGAN (Nov. 9, 2018), https://www.finnegan.com/en/insights/puzzling-out-the-patent-eligibility-of-natural-products.html [https://perma.cc/FH3U-F37D].

43. Sittler et al., *supra* note 37, at 2.

44. Holman, *supra* note 38.

45. *Id.*

46. *Id.*

47. Tribble, *Drugmakers Play the Patent Game*, *supra* note 36.

48. *Id.*

49. *Excessive Pharmaceutical Patenting*, *supra* note 19, at 4.

B. The Effects of Evergreening on Drug Prices

During the exclusivity period, in terms of the primary compound patent, the drug developer generally enjoys a competition-free market in return for its disclosure of the drug to the public.[50] After this period is over, generic companies may produce the same drug at lower prices.[51] However, evergreening not only allows for extended exclusivity, but also increases litigation costs to the challenger which may discourage generic drug developers from entering the market of a particular drug.[52]

The issue with evergreening is not necessarily that pharmaceutical companies are patenting small or trivial distinctions from their primary to secondary patents; rather, it is the massive number of patents a company receives on the drug that could be asserted against a potential infringer.[53] The median cost of a patent litigation case is over $3 million alone.[54] For example, in order to eliminate all of the Humira® secondary patents, a competitor would need to spend over $741 million.[55] Additionally, each patent case can last for two or more years.[56] Not only is it unlikely that a generic company will want to spend this amount of time and money on litigating against the innovator company, but one generic company would rarely agree to do this just so other generic companies can enter the market without spending as much.[57] This means the innovator then has the power to force competitors either to wait until the secondary patents expire to enter the market or to settle with a non-exclusive license that stalls the competitor from entering the market until a predetermined date, and, when it enters, to give the innovator

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50. Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades*, 31 HEALTH AFF. 2286, 2286 (Oct. 2012), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2012.0107 [https://perma.cc/HF4S-DVGT].

51. *Id.*

52. *Id.* at 2287.

53. *Excessive Pharmaceutical Patenting*, *supra* note 19, at 5.

54. Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG L. (Sept. 10, 2019), https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds [https://perma.cc/S22X-L2XX].

55. *See Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 8 (discussing the 247 secondary patents AbbVie has been granted on Humira®). The total of $741 million was calculated by multiplying AbbVie's 247 secondary patents on Humira® by $3 million.

56. Maria Luisa Palmese, *Patent Litigation in the United States: Overview*, THOMSON REUTERS PRAC. L., https://www.wg-law.com/publications/patent-litigation-united-states-overview/ (last updated July 1, 2018) [https://perma.cc/Z3MD-9EMJ].

57. Christopher Rowland, *Why Price of Humira Keeps Rising Despite FDA Approval of Generic Competition*, WASH. POST (Jan. 8, 2020, 7:00 AM), https://www.washingtonpost.com/business/economy/why-humiras-price-keeps-rising-despite-fda-approval-of-generic-competition/2020/01/07/549ed0ce-2e3a-11ea-bcb3-ac6482c4a92f_story.html [https://perma.cc/92HT-55RX].

royalties.[58] Both potential outcomes encourage innovator companies to try to evergreen on their most successful drugs, as they end up with either an extended exclusivity period, royalties from generic companies that will eventually enter the market, or both.[59]

Notably, a secondary patent does not technically extend the exclusivity of the primary patent.[60] For example, the exclusivity associated with a secondary patent on a new dosage or new method of manufacture will be limited to only that improvement.[61] However, excessive secondary patents on a drug not only aim to extend the company's exclusivity, but also aspire to deter generic companies from engaging in expensive litigation and to keep the prices high for consumers.[62]

In order to solve this issue, legislation has been recently proposed including, but not limited to, the REMEDY Act, the APP Act, and the TERM Act.[63] However, deciding which secondary patents are an attempt to evergreen and which protect genuine innovation is very difficult.[64] As a result, blanket legislation aimed at preventing evergreening would likely impede goals of research and development of many drugs.[65] The following proposed legislation would not only discourage innovator companies from performing any further research and development on known drugs, but would also likely not solve the evergreening issue that is preventing decreases in drug prices.

II. ADDRESSING THE PROPOSED LEGISLATION

A. The REMEDY Act

The REMEDY Act is a bipartisan bill that legislators introduced to "tackle the pharmaceutical industry's practice of gaming the patent system to extend monopolies on lifesaving drugs."[66] According to Senators Dick Durbin and Bill

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58. Manogna Maddipatla & Saumya Sibi Joseph, *Abbvie Settles Humira Patent Disputes with Novartis Unit*, REUTERS (Oct. 11, 2018), https://www.reuters.com/article/us-abbvie-novartis-humira/abbvie-settles-humira-patent-disputes-with-novartis-unit-idUSKCN1ML31B [https://perma.cc/P8NX-H22A].

59. *Id.*

60. Holman, *supra* note 38.

61. *Id.*

62. Adam Houldsworth, *Pressure Piles on US Pharma and Biotech IP Owners*, IAM MEDIA (Jan. 31, 2019), https://www.iam-media.com/law-policy/why-evergreening-not-dirty-word [https://perma.cc/XVZ2-DCN4].

63. S. 1209, 116th Cong. (2019); S. 1416, 116th Cong. § 3 (2019); H.R. 3199 § 2 (2019).

64. *See* Sittler et al., *supra* note 37, at 4.

65. Holman, *supra* note 38.

66. *Durbin, Cassidy Introduce REMEDY Act to Lower Drug Prices by Curbing Patent Manipulation, Promoting Generic Competition*, DICK DURBIN, U. S. SENATOR ILL. (Apr. 11, 2019), https://www.durbin.senate.gov/newsroom/press-releases/durbin-cassidy-introduce-remedy-act-to-lower-drug-prices-by-curbing-patent-manipulation-promoting-generic-competition

Cassidy, the Act would lower drug prices and promote competition by removing barriers to Food and Drug Administration (FDA) approval for lower-cost generic drugs.[67] Particularly, the Senators allege that the Act would "crack down on [] abusive pharmaceutical monopolies" that are attempts to evergreen.[68]

The Senators maintain that incentives for drug manufacturers to file excessive patents would be removed by amending FDA statutes as well as by lifting "barriers that delay generic market entry."[69] The Senators declare that "once the substance patent and all exclusivities expire, generic manufacturers would be allowed to enter the market more easily."[70] Additionally, the Act would attempt to increase transparency by updating FDA listings once a patent is invalidated by the United States Patent and Trademark Office (USPTO).[71]

Although the Act has gained momentum from endorsements like the Campaign for Sustainable Rx Pricing and American Association of Retired Persons (AARP),[72] some patent experts view the bill as "ill conceived and unlikely to have anything more than a cosmetic effect."[73] Particularly, critics of the Act point out that if this proposal became law, an innovator company "would only be able to have the benefit of the 30-month stay enshrined in these provisions of the Hatch-Waxman Act for patents claiming a drug substance itself, but not formulations or methods of treatment using a patented, branded drug under an NDA."[74] A generic company would be in a "launch at risk" scenario, and the company would risk both an injunction and treble damages for willful infringement.[75] Many attorneys believe this is not as attractive to generic companies as the Senators assert.[76]

Additionally, critics of the bill note that it is unclear whether any of the proposed changes will remedy any actual issues in patent law, including the issue

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[https://perma.cc/QV7J-FZ6T].

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. Jon Conradi, *CSRXP Applauds Introduction of Cassidy-Durbin "Remedy Act"*, CAMPAIGN FOR SUSTAINABLE RX PRICING, https://www.csrxp.org/csrxp-applauds-introduction-of-cassidy-durbin-remedy-act/ (last visited Nov. 28, 2019) [https://perma.cc/SW65-QCVH]; *see also* Letter from David Certner, Legislative Counsel & Legislative Policy Director, Governmental Affairs, to Bill Cassidy & Richard J. Durbin, Senators (June 25, 2019), https://www.aarp.org/content/dam/aarp/politics/advocacy/2019/06/062519-endorsement-letter-for-remedy-act-final.pdf [https://perma.cc/E2HQ-JA3R].

73. Kevin E. Noonan, *More Ill-conceived Remedies from Congress Regarding Prescription Drug Costs*, PAT. DOCS (Apr. 21, 2019), https://www.patentdocs.org/2019/04/more-ill-conceived-remedies-from-congress-regarding-prescription-drug-costs.html [https://perma.cc/4GQQ-WQKD].

74. *Id.*

75. *Id.*

76. *Id.*

of evergreening.[77] Further, these critics note that the answer to systematic problems, such as evergreening in patent law, is not through quick or simple changes in the law, as this bill is attempting to make.[78] Others note that targeting the pharmaceutical industry because of its products discriminates against the industry and could impede "innovation and new product development."[79] Labeling patent extensions as either anticompetitive or unethical will likely cause innovator companies to discontinue research on a known drug.[80] Failure to investigate new applications of existing drugs will inevitably lead to patients "los[ing] out on potentially life-saving treatments."[81]

B. The APP Act

The APP Act would prevent innovator companies from their "anti-competitive use of patents to protect their prescription drugs and prevent generic and biosimilar competition from coming to market."[82] The purpose of the bill is to encourage competition and to give patients access to prescriptions at lower prices "without stifling innovation or infringing on patent rights."[83] Specifically, the Act would change the definitions of product hopping and patent thicketing, which are other names for evergreening, within the Federal Trade Commission ("FTC").[84] The FTC would then be able to challenge the pharmaceutical companies as anti-competitive and bring antitrust suits against the companies who are capitalizing on their "abuse of the system."[85] Additionally, the bill would limit the number of patents that can be litigated under the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") and would impose a private sector mandate limiting the number of patents that could be asserted for biological

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77. *Id.*

78. *Id.*

79. *Should Pharmaceutical Companies Be Prohibited from 'Patent Evergreening'?*, COUNTABLE, https://www.countable.us/bills/s1209-116-reforming-evergreening-and-manipulation-that-extends-drug-years-act (last visited Oct. 12, 2020) [https://perma.cc/67A5-WJF7].

80. *Id.*

81. *Id.*

82. *Cornyn, Blumenthal Introduce Bill to Prevent Drug Companies from Abusing Patent System*, JOHN CORNYN U.S. SEN. FOR TEXAS. (May 9, 2019), https://www.cornyn.senate.gov/content/news/cornyn-blumenthal-introduce-bill-prevent-drug-companies-abusing-patent-system [https://perma.cc/UL77-AKLG] [hereinafter *Cornyn, Blumenthal Introduce Bill*].

83. *Id.*

84. *Id.*; *Affordable Prescriptions for Patients Act Introduced in the Senate*, GOODWIN (May 15, 2019), https://www.bigmoleculewatch.com/2019/05/15/affordable-prescriptions-for-patients-act-introduced-in-the-senate/ [https://perma.cc/K5FS-PBHS] (defining "product hopping" as "producing iterative minor reformulations of a drug" and "patent thicketing" as "generating many patents on a single product").

85. *Cornyn, Blumenthal Introduce Bill*, *supra* note 82.

products in infringement claims.[86]

However, whether a pharmaceutical company is evergreening is rarely obvious.[87] The repercussion of blanket legislation such as the APP Act would "impact the enforcement of pharmaceutical patents, the prosecution of those patents, and the desire of companies to improve known drugs."[88] The bill would allow manufacturers to rebut FTC determinations based on the following four criteria: (1) clinically meaningful and significant therapeutic or safety benefits; (2) significantly improved purity or potency of the drug; (3) significant gains in efficiencies of manufacturing; or (4) any other improved attributes that could produce substantial benefits for consumers and patients.[89] This creates a risk that one type of litigation, alleging patent infringement, would essentially be replaced by litigation between the alleged malefactor drug company and the FTC.[90] In addition, manufacturers can rebut evergreening allegations by exhibiting evidence of the recent discovery providing a significant health benefit, by showing that it is the least likely route to reduce potential competition, and by showing that the manufacturer had financial motivation besides reducing competition to patent the recent discovery.[91] However, disclosures like these are usually made at the USPTO to prove that the recent discovery is non-obvious and novel.[92] Because similar information could be used by innovation companies for both patent prosecution and against an antitrust suit, pharmaceutical companies are more likely to be careful with their disclosures so as not to harm themselves in an antitrust suit.[93]

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.[94] A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as

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86. *S. 1416, Affordable Prescriptions for Patients Act of 2019*, CONG. BUDGET OFF. (July 19, 2019), https://www.cbo.gov/publication/55472 [https://perma.cc/NP4J-TARD].

87. *See* Sittler et al., *supra* note 37; *see also* Anna Edney, *Senate Targets Hoarding of Drug Patents to Deter Competition*, BLOOMBERG (May 9, 2019, 2:42 PM), https://www.bloomberg.com/news/articles/2019-05-09/hoarding-drug-patents-to-deter-competition-is-targeted-by-senate [https://perma.cc/L4FC-ZNXS].

88. Steve Brachmann, *Affordable Prescriptions for Patients Act Would Allow FTC to Prosecute Pharma Patent Thickets, Product Hopping*, IPWATCHDOG (May 20, 2019), https://www.ipwatchdog.com/2019/05/20/affordable-prescriptions-patients-act-allow-ftc-prosecute-pharmaceutical-patent-thickets-product-hopping/id=109384/ [https://perma.cc/XL3X-EJNV] [hereinafter Brachmann, *Affordable Prescriptions for Patients Act*] (discussing the opinion of a patent attorney that has represented both branded pharmaceutical companies and generic manufacturers).

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

"one-and-dones."[95] Patents are meant to be issued for innovations, not for products.[96] Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research "new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents."[97] The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society.[98] Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.[99] Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug.[100] If enacted, the legislation could also "erode[] incentives and threaten[] innovation," which is what the patent system was created to protect.[101]

C. The TERM Act

The proposed TERM Act aims to lower drug prices and reduce the evergreening problem by shifting the burden of proving why a new patent on a known drug should be granted.[102] Specifically, the Act aims to prevent innovator companies from evergreening.[103] This bipartisan legislation would create a presumption that "a patentee has disclaimed the portion of any patent term that extends beyond the term of the earliest-expiring patent."[104] Currently, generic

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95. *Id.*

96. Tom Giovanetti et al., *Coalition Letter Expressing Concerns with S.1416, the "Affordable Prescriptions for Patients Act of 2019"*, INST. FOR POL'Y INNOVATION (June 25, 2019), https://www.ipi.org/ipi_issues/detail/coalition-letter-expressing-concerns-with-s1416-the-affordable-prescriptions-for-patients-act-of-2019 [https://perma.cc/L4U9-MAVP].

97. *See id.*; Brachmann, *Affordable Prescriptions for Patients Act*, *supra* note 88.

98. Brachmann, *Affordable Prescriptions for Patients Act*, *supra* note 88.

99. Giovanetti et al., *supra* note 96.

100. *See* Brachmann, *Affordable Prescriptions for Patients Act*, *supra* note 88.

101. Giovanetti et al., *supra* note 96.

102. *Rep. Jeffries Introduces Bipartisan Legislation to Lower Skyrocketing Cost of Prescription Drugs*, U.S. CONGRESSMAN HAKEEM JEFFRIES FOR 8TH DISTRICT N.Y. (June 12, 2019), https://jeffries.house.gov/media-center/press-releases/reps-jeffries-collins-introduce-bipartisan-legislation-to-lower [https://perma.cc/HY5W-BPCG] [hereinafter *Bipartisan Legislation*].

103. *Id.*; Todd S. Werner, *TERM Act Would Presume All Patents Covering a Branded Pharmaceutical Product Are Not Patentably Distinct*, CARLSON CASPERS (June 29, 2019), https://www.carlsoncaspers.com/term-act-would-presume-all-patents-covering-a-branded-pharmaceutical-product-are-not-patentably-distinct/ [https://perma.cc/B6PC-NYYD].

104. Jonathan Bachand & Cassie Gourash, *"Term Act of 2019" Proposes Shifting Patent Challenge Burdens to Branded Companies*, KNOBBE MARTENS (June 18, 2019), https://www.knobbe.com/news/2019/06/%E2%80%9Cterm-act-2019%E2%80%9D-proposes-shifting-patent-

drug manufacturers bear the burden and generally aim to prove why a new patent should not be granted.[105] Finally, the bill would instruct the USPTO to reevaluate its examination procedures for patents relating to the same drug or biological product and "determine whether improvements can be made to reduce instances of double patenting."[106] The apparent purpose of the TERM Act is to reduce "patent abuses in order to expedite the entrance of lower cost generic drugs to market."[107]

Like the APP Act, if enacted, the TERM Act would impair innovation on known medicines.[108] Procedurally, the Act would create "a default forfeiture of serial patent terms" and would presume that obviousness-type double patenting exists unless the patentee proves otherwise, even though current patent law places the burden of proof of obviousness-type double patenting on the examiner or challenger of the patent.[109] Additionally, the bill presumes that the USPTO and its examiners are neglecting their duties to present obviousness rejections to patentees.[110] Further, many pharmaceutical companies already settle for terminal disclaimers when given obviousness-type double patenting rejections.[111] The Act shows how pharmaceutical companies receive scrutiny in terms of their patent strategies for the high costs of medicines, but other fields such as pharmacy benefit managers and insurance companies do not.[112]

Further, placing the burden of proof on the generic company is necessary since not every patent on a drug is called to be invalidated; generic manufacturers generally try to invalidate a patent if (1) they want to enter the particular market before the patent in question expires, and (2) it is impossible to sell the drug without infringing the patent.[113] Additionally, the TERM Act would apply in proceedings challenging the validity of the patent, but generic manufacturers are

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challenge-burdens-branded-companies [https://perma.cc/TV2D-SRCY].

105. *Bipartisan Legislation*, *supra* note 102.

106. Bachand & Gourash, *supra* note 104.

107. *Bipartisan Legislation*, *supra* note 102.

108. *See* Steve Brachmann, *Congress Adds TERM Act and No Combination Drug Patents Act to List of Drug Patent Bills Being Considered*, IPWATCHDOG (June 20, 2019), https://www.ipwatchdog.com/2019/06/20/congress-term-act-no-combination-drug-patents-act-added-list-drug-patent-bills-considered/id=110525/ [https://perma.cc/964L-5R54] [hereinafter Brachmann, *Congress Adds TERM Act*].

109. Werner, *supra* note 103; MPEP § 1504.06 (9th ed. Rev. 10.2019, June 2020). For a definition and discussion of obviousness-type double patenting, see Aaron Reinhardt, *Obviousness-Type Double Patenting Considerations*, IPWATCHDOG (July 19, 2017), https://www.ipwatchdog.com/2017/07/19/obviousness-type-double-patenting-considerations/id=85791/ [https://perma.cc/R26C-N55X].

110. Werner, *supra* note 103; *see also* Courtenay C. Brinckerhoff, *Why the TERM Act Is a Misguided Solution to a Different Problem*, JD SUPRA (June 18, 2019), https://www.jdsupra.com/legalnews/why-the-term-act-is-a-misguided-56742/ [https://perma.cc/7RBX-XF8G].

111. Werner, *supra* note 103.

112. *Id.*

113. Brinckerhoff, *supra* note 110.

already able to raise questions of obviousness-type double patenting in these proceedings.[114] Although it is clear that the Act would decrease further innovation on already-known drugs, it is not clear if this Act would realistically be effective against the evergreening issue.[115]

III. LEAVING THE EVERGREENING ISSUE TO THE USPTO, THE PTAB, AND THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT

A. Implement a Balancing Test to Determine if Evergreening Exists

Although evergreening is an issue that should be addressed, the legislature is not the branch that should address it. This problem should be left to the patent examiners and administrative judges at the USPTO, the Patent Trial and Appeal Board (the "PTAB"), and the Court of Appeals for the Federal Circuit (the "Federal Circuit").[116] The examiners and administrative judges have qualifications to examine the evergreen problem; this is because they carry the necessary science background to become examiners and are highly experienced in the area of patent law.[117] Particularly, the Federal Circuit is a specialized court that has exclusive jurisdiction for patent cases.[118] Currently, the Federal Circuit is comprised of six judges that are former patent attorneys, at least two of whom have degrees in chemistry.[119] Both the examiners and the Federal Circuit have the most experience not only with patent law in general, but also in terms of obviousness and double patenting rejections.[120]

However, the evergreening issue should not be left to the USPTO, the PTAB, and the Federal Circuit without any adjustments, as there have been many

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114. *Id.*

115. *See id.*

116. *See* Giovanetti et al., *supra* note 96 (noting the baseless and inaccurate criticisms of the patent system in terms of evergreening); *see also* Steven Globerman & Kristina M. Lybecker, *The Benefits of Incremental Innovation: Focus on the Pharmaceutical Industry*, FRASER INST. (June 2014), https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf [https://perma.cc/7B23-9EUH]; Kevin Madigan & Sean O'Connor, *"No Combination Drug Patents Act" Stalls, but Threats to Innovation Remain*, CTR. FOR PROTECTION INTELL. PROP. (June 27, 2019), https://cpip.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/ [https://perma.cc/7M39-GCC7].

117. *Patent Examiner: Everything You Need to Know*, UPCOUNS., https://www.upcounsel.com/patent-examiner (last visited Oct. 14, 2019) [https://perma.cc/C46L-5AJH].

118. *Court Jurisdiction*, U.S. CT. APPEALS FOR FED. CIR., http://www.cafc.uscourts.gov/the-court/court-jurisdiction (last visited Oct. 16, 2019) [https://perma.cc/4EPM-K2FE].

119. *Judges*, U.S. CT. APPEALS FOR FED. CIR., http://www.cafc.uscourts.gov/judges/s-jay-plager-circuit-judge.html (last visited Oct. 16, 2019) [https://perma.cc/HTM5-6RQF] (further noting a few judges that were not patent attorneys but were instrumental in patent treatises, casebooks, and seminars).

120. 35 U.S.C. § 103 (1952); MPEP § 804 (9th ed. Rev. 10.2019, June 2020).

examples of evergreening that have escaped the USPTO and the Federal Circuit.[121] Therefore, the USPTO, the PTAB, and the Federal Circuit should implement a balancing test that "delicately balances innovation and competition."[122] Ideally, the balancing test would include examining the following factors:

(1) the number of secondary patents on the drug[123];
(2) whether members of the patent family have been challenged and invalidated at the USPTO, PTAB, or Federal Circuit;
(3) when the bulk of the patents were filed in relation to the approval date for the drug;
(4) whether the patent owner is attempting to protect a legacy patent (i.e. a product with approved generics or biosimilars on the market);
(5) the innovation between the initial patent and secondary patent[124];
(6) the amount of research and development initiated in order to find the innovation[125];
(7) whether the patent relates to a new and improved treatment in the disease area or whether it relates to an alternative treatment;
(8) the number of patents granted in other countries in comparison to the expiration date in those countries[126];
(9) whether the secondary patent was related to innovation that the applicant suppressed or concealed for a significant period of time or whether the applicant was not reasonably diligent in filing the patent application(s);
(10) whether the patent was not listed in the Orange Book[127]; and
(11) any other information that may be relevant.

This test could be applied when determining whether to grant a patent during an inter partes review ("IPR") or post-grant review ("PGR") validity proceeding or during Hatch-Waxman or BPCIA litigation.[128] Additionally, because other

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121. *See Overpatented, Overpriced: Special Humira Edition*, *supra* note 2; *Overpatented, Overpriced Special Edition: Lantus*, *supra* note 9.

122. Robin Feldman, *May Your Drug Prices Be Evergreen*, 5 J.L. & BIOSCI. 590, 639 (2018), https://academic.oup.com/jlb/article/5/3/590/5232981 [https://perma.cc/69YH-2SBV].

123. *See Overpatented: (Not so) Average*, *supra* note 16.

124. Sarah Jane Tribble, *'Evergreening' and Other Ways Pharma Companies Manipulate Patents*, BENEFITSPRO (Oct. 4, 2018, 10:36 AM), https://www.benefitspro.com/2018/10/04/evergreening-and-other-ways-pharma-companies-manip/?slreturn=20190916190529 [https://perma.cc/7NLA-6UPQ].

125. *See* Collier, *supra* note 26.

126. *Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 5.

127. *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last updated Sept. 11, 2020) [https://perma.cc/9YAV-AYQU].

128. For a discussion on IPR and PGR, see Ryan Kenny, *Which Invalidity Avenue to Take: Inter Partes Review Verses Post-Grant Review*, IPWATCHDOG (July 31, 2018), https://www.ipwatchdog.com/2018/07/31/which-invalidity-avenue-ipr-verses-post-grant-review/id=99460/

federal courts have jurisdiction to hear patent cases,[129] they are encouraged to implement the test as well. However, as with most patent cases, the Court of Appeals for the Federal Circuit is usually the last court to hear a case[130]; it is therefore crucial that the test is implemented there as well as at the USPTO.

B. Explanation of the Balancing Test

The balancing test above contains eleven relevant factors that may help the USPTO, the PTAB, or the Federal Circuit determine whether or not a pharmaceutical company is attempting to evergreen on one of its products. However, not every factor should be given equal weight; additionally, not every factor would need to be found to draw the conclusion of evergreening.

The first factor—the number of secondary patents on a drug—should be given substantial weight, considering the issue of evergreening is the abundance of secondary patents on slight modifications.[131] A substantial number of secondary patents could be a clear indication of a pharmaceutical company's intent to evergreen.[132] However, the secondary patents could be genuine discoveries[133]; therefore, factor one would likely be examined alongside factor five—the innovation between the initial patent and the secondary patent. Ideally, whichever entity implements the balancing test would heavily rely on not only their own expertise with their patent and science background,[134] but also on that of other scientists and pharmaceutical researchers.

The purpose of the second factor—whether members of the patent family

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[https://perma.cc/9D8R-7XZ8]. For a discussion on Hatch-Waxman and BPCIA litigation, see What Are the Patent Litigation Differences Between the BPCIA and Hatch-Waxman Act?, WINSTON & STRAWN LLP, https://www.winston.com/en/legal-glossary/BPCIA-Hatch-Waxman-Act-differences.html (last visited Nov. 28, 2019) [https://perma.cc/VYR8-2CNH].

129. *State and Federal Court Adjudication of Federal Patent Issues*, BRINKS GILSON & LIONE, https://www.brinksgilson.com/state-federal-court-adjudication-federal-patent-issues (last visited Nov. 29, 2019) [https://perma.cc/R4H9-C963].

130. *Id.*

131. Collier, *supra* note 26, at E385.

132. *See* Erik Komendant, *Anti-Competitive Evergreening Delays Patient Access to More Affordable Generics and Biosimilars*, ASS'N FOR ACCESSIBLE MEDS., https://accessiblemeds.org/resources/blog/anti-competitive-evergreening-delays-patient-access-more-affordable-generics (last visited Jan. 18, 2020) [https://perma.cc/5YSZ-V6PR] (discussing AbbVie's strategy of filing more than 100 late-stage patents to protect its annual revenues of more than $16 billion).

133. *See* Holman, *supra* note 38 (discussing how secondary patents can be protecting follow-on innovation that can play a critical role in transforming a drug to a more effective and safe treatment).

134. *See Patent Examiner: Everything You Need to Know*, *supra* note 117 (discussing a degree in the relevant science is necessary to be a patent examiner in a particular field); *see also Judges*, *supra* note 119 (discussing that many judges on the Federal Circuit have a science background, and further noting a few judges that have contributed to patent treatises, casebooks, and seminars).

have been challenged and invalidated at the USPTO, the PTAB, or at the Federal Circuit—could be a sign to the examining entity that evergreening is taking place if multiple members of the patent family were invalidated. On the other hand, if members of the family had been challenged previously and were found valid for true innovation, this could be a signal that evergreening is absent. However, when looking to invalidated family members, it would be important that the USPTO, the PTAB, and the Federal Circuit give weight to why the members were held invalid, as it could be invalidated for reasons other than lack of novelty or obviousness.[135]

As the Humira® facts demonstrated,[136] the third factor—when the bulk of the patents were filed in relation to the approval date for the drug—can be evidence of evergreening; a pharmaceutical company that files a multitude of secondary patents at the end of the life of the compound patent and not throughout the life of the drug can indicate that the company was not focused on innovation, but instead on holding its exclusivity on the drug.[137] However, the inspecting authority should be mindful that innovations can be very time-consuming[138]; therefore, the authority should compare the timeline of the applications filed to the time the research was started and the innovations were recognized. Additionally, the sixth factor—the amount of research and development initiated in order to find the drug—could be examined along with the third, as a minimal adjustment is not likely to yield from a large amount of research and development.

Further, the examining authority should give heavy weight to the ninth factor—whether the secondary patent was related to innovation that the applicant suppressed or concealed for a significant period of time or whether the applicant was not reasonably diligent in filing the patent application(s). This factor can be determinative of whether or not a company is evergreening; a delay in the application process is likely due to a company wanting to file its application later during the life of the compound patent in order to extend exclusivity. However, the examining authority should consider whether there were other reasons as to

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135. *What Are the Grounds for Patent Invalidity*, TRADEMARKS & PATS. (Feb. 26, 2018), http://trademarkspatentslawyer.com/what-are-the-grounds-for-patent-invalidity/ [https://perma.cc/L6XK-AULK].

136. Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG BUSINESSWK. (Sept. 7, 2017, 6:00 AM), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug [https://perma.cc/9SV9-LGCH] (noting that many of the secondary patents on Humira® were issued as the expiration date of the compound patent grew closer).

137. *See Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 2 (noting that "89% of the total patent applications on Humira in the U.S. were filed *after* the drug was first approved and on the market").

138. *See* Emily Saadi & Greg White, *Rewarding Innovation in Drug Development*, 7(7) AM. HEALTH & DRUG BENEFITS 373, 373 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4268767/ [https://perma.cc/Q9UL-DF98] (discussing how the entire cycle from initial research and development to a drug's regulatory approval can take between ten and fifteen years).

why the pharmaceutical company decided to delay the application process.[139]

The fourth factor—whether the patent owner is attempting to protect a legacy patent—should be given substantial weight by the examining entity. Under the BPCIA, a biosimilar applicant is expected to provide the innovation company with a copy of its abbreviated Biologics License Application ("aBLA").[140] The purpose of the aBLA is for the biosimilar applicant to show that the product is "highly similar" to the branded drug and that there are no existing "meaningful differences between the biological product and the reference product in terms of safety, purity and potency."[141] The innovator company can then use the confidential disclosure provided by the generic company to determine which patents it may assert to block the biosimilar applicant.[142] If there are approved biosimilars, the secondary patents a pharmaceutical company is granted are likely to impede biosimilar launches. Therefore, factors indicating an innovator company is attempting to protect its legacy patent by keeping the biosimilar products at bay, including the timing of the filing of the secondary patents, can be evidence of the intent to evergreen.

The fifth factor—the innovation between the initial patent and secondary patent—should also be heavily considered; however, the examining authority should be sure to include experts and scientists in the determination of whether or not there was substantial innovation. As noted by a number of patent experts, there is a flawed premise that follow-on innovation is of little value and is less deserving than the innovation that resulted in the primary patent.[143] On the contrary, the innovation that leads to the secondary patent can be more beneficial to society than the innovation that led to the first.[144] However, innovator companies do have the ability to make small changes to the branded drug—including changes to the mode of administration, new dosages, or even a change in color to the drug itself—in order to obtain the secondary patent.[145] Though, based on the patentability standards enforced at the USPTO,[146] any

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139. *See* Michael Henry, *How to Slow Down Patent Prosecution with the USPTO*, HENRY PAT. L. FIRM (May 10, 2018), https://www.henrypatentfirm.com/blog/slow-down-patent-prosecution [https://perma.cc/4HHJ-H49C] (discussing reasons to delay the patent prosecution process).

140. Claire Laporte, *Manufacturers of Biosimilar Drugs Sit Out the 'Patent Dance'*, HEALTH AFF. (Mar. 10, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170310.059143/full/ [https://perma.cc/Q3DU-LRKL].

141. *Id.*

142. *Id.*

143. Holman, *supra* note 38.

144. *See id.* (discussing how AZT was initially a failed cancer drug until its application to the fight against AIDS was discovered).

145. Allie Nawrat, *From Evergreening to Thicketing: Exploring Manipulation of the Pharma Patent System*, PHARMA TECH. FOCUS, https://pharma.nridigital.com/pharma_nov19/from_evergreening_to_thicketing_exploring_manipulation_of_the_pharma_patent_sys# (last visited Jan. 24, 2020) [https://perma.cc/L5DG-KLGS].

146. *See* MPEP § 1504 (9th ed. Rev. 10.2019, June 2020) (discussing the standards of novelty

innovation that is minimal is unlikely to be granted. On the other hand, the possibility of patentability still exists; therefore, scientists and experts should be used to determine if there is genuine innovation.

Next, the seventh factor—whether the patent relates to a new and improved treatment in the disease area or whether it relates to an alternative treatment—should be given weight, but it is important to consider this factor in light of not only the disease or condition being treated, but also the treatment already in existence. For example, if the drug is deemed ineffective for the disease it was originally in pursuance of, but is discovered to be effective against another disease, this could be an indication of true innovation. However, if the claimed innovation seems to be minor, such as requiring a patient to take three pills a day instead of four, this may be an indication of evergreening. Because the facts of each case will vary depending on the drug and the claimed innovation, the examining authority should recognize what seems like a minor improvement in one case could be the result of genuine innovation in another.

The eighth factor—the number of patents granted in other countries in comparison to the expiration date in those countries—should be considered but should not be determinative of a conclusion of evergreening on its own. This factor could be indicative of evergreening because a blockbuster drug in one country is likely to be a blockbuster drug in many countries.[147] However, because different countries regulate the patenting process differently for the prevention of evergreening,[148] a large number of patents in other countries in comparison to their expiration date should not necessarily cause the examining entity to find a result of evergreening. On the other hand, the examining entity should take notice of the innovator company's efforts of applying for secondary patents later in the life of the compound patent in other countries as it would in the United States (see factor three above); the display of secondary patents only later in the compound patent's life, and not throughout, could be a signal that the innovator was intending to evergreen in another country.

With regard to the tenth factor, once approved, every drug is to be listed in the Orange Book in order to serve as a reference for generic companies who want to launch their generic products at the end of the patent term.[149] Additional patents

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and non-obviousness).

147. *See* WORLD HEALTH ORGANIZATION MODEL LIST OF ESSENTIAL MEDICINES, 21ST LIST, WORLD HEALTH ORG. (2019), https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1 [https://perma.cc/EMT4-QJQJ] (discussing essential medicines of the world).

148. *See* Arun Kumar & Arun Nanda, *Ever-greening in Pharmaceuticals: Strategies, Consequences and Provisions in the USA, EU, India and Other Countries*, 6 PHARM. REG. AFF.: OPEN ACCESS (Apr. 18, 2017), https://www.hilarispublisher.com/open-access/evergreening-in-pharmaceuticals-strategies-consequences-and-provisions-for-prevention-in-usa-eu-india-and-other-countries-2167-7689-1000185.pdf [https://perma.cc/CE4H-M3BE].

149. *Id.*; *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, *supra* note 127 (discussing how the purpose of the Orange Book is to identify drug products approved on the basis of safety and effectiveness by the FDA as well as identify related patent and

that are tied to the primary patent, including secondary patents, should be listed as well.[150] In order for a generic drug to get approved, it must file an Abbreviated New Drug Application ("ANDA") and must certify one of the following: (1) "[t]he drug is not patented"; (2) "[t]he drug patent has already expired"; (3) "[t]he generic will enter the market only when the patent has expired"; or (4) "[t]he patent is invalid or will not be infringed by the generic."[151] Additionally, the generic company must show that its version is comparable to the innovator drug in bio-equivalence.[152] However, an innovator can work to de-list its drug in order to significantly delay the entry of generics.[153] Additionally, under the Hatch-Waxman Amendments,[154] manufacturing patents are not allowed to be listed. Therefore, if a secondary patent is not listed, it is conclusively either a manufacturing patent or a patent that the innovator company decided not to list in the Orange Book.[155] The strategy to obtain secondary patents on manufacturing patents can delay the release of the generic products, and therefore should be scrutinized.

The final factor—any other information that may be relevant—is necessary considering that evergreening is an evolving problem in the United States, and it is expected that pharmaceutical companies will continue to search for technicalities in the patent system in order to extend the exclusivity on a blockbuster drug. It is also possible that there will be evidence unearthed during discovery or after the USPTO requests additional information that may prove evergreening and is not one of the factors described above. Therefore, the examining entity could consider including additional factors it believes to be necessary in the determination of whether or not evergreening exists in a particular case.

C. Application of the Balancing Test to the Best-Known Example of Evergreening

The balancing test can be applied to AbbVie's patent strategy on its blockbuster drug Humira®, as it is conceivably the best example of evergreening. However, not all factors will be considered, as some of the factors listed above would be scrutinized only after (1) a competitor completed discovery, or (2) the

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exclusivity information).

150. Kumar & Nanda, *supra* note 148, at 2.

151. *Id.*

152. *Id.* at 3.

153. *Id.*

154. For an overview of the Hatch-Waxman Amendments, see *Hatch-Waxman Letters*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/hatch-waxman-letters (last modified July 19, 2018) [https://perma.cc/7HNM-NHA3].

155. For a discussion on which patents can be listed in the Orange Book, see *Orange Book Listed Patents: Everything You Need to Know*, UPCOUNS., https://www.upcounsel.com/orange-book-listed-patents (last visited Jan. 26, 2020) [https://perma.cc/KQZ5-YPP2].

USPTO requested additional information regarding certain factors; and not all of the information that would be found during such discovery or request from the USPTO is available now.

In examining the first factor (the number of secondary patents on a drug), there are 247 secondary patents on Humira® in the United States alone.[156] Eighty-nine percent of the applications were filed after Humira® was on the market in 2002.[157] AbbVie filed the primary patent for Humira® in 1994, so AbbVie's exclusivity for this drug should have expired in 2014[158]; however, if its secondary patents are enforced, its exclusivity could be protected until 2037.[159] In relation to the third factor (when the bulk of the patents were filed in relation to the approval date for the drug), forty-nine percent of all applications were filed after the first patent expired in 2014.[160] These facts make it clear that, with regard to the first factor, AbbVie was likely attempting to evergreen.

Similarly, considering the eighth factor (the number of patents granted in other countries in comparison to the expiration date in those countries), AbbVie has filed an additional seventy-six patent applications in Europe after its primary patent.[161] However, secondary patents filed after 2002 that would have significantly extended AbbVie's exclusivity in the market were either withdrawn, refused, or revoked after patent challenges.[162] The reluctance of the European Patent Office is an indication of the Office's awareness of AbbVie's intentions. AbbVie likewise filed sixty-three additional patents in Japan[163]; while Japan's reaction to the abundant filings is not readily apparent, it is known that the original expiration of the primary patent was supposed to be in 2017 but has been extended to August of 2021.[164]

When applying the second factor (whether members of the patent family have been challenged and invalidated by the USPTO, PTAB, or Federal Circuit) to Humira®, it is crucial not only to look at the number of patents that have been invalidated, but to also consider any reasoning as to why all were not challenged. On June 9, 2017, the PTAB found three of the Humira® patents invalid based on a finding of obviousness.[165] On July 6, 2017, the PTAB found one additional

156. *Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 2.

157. *Id.*

158. *Id.* at 4.

159. *Id.*

160. *Id.*

161. *Id.* at 5.

162. *Id.*

163. *Id.*

164. *See* William Han, *The Benefits of Japanese Patent Law System over Those of the US in the Pharmaceutical Area*, JAPAN PAT. ATT'YS ASS'N 7, https://www.jpaa.or.jp/discoveripjapan/pdf/Plenary_Session.pdf (last visited Mar. 11, 2020) [https://perma.cc/6RLV-A9QY].

165. Christopher J. Betti & Maria E. Doukas, *Humira Patents Invalidated in Inter Partes Reviews*, MORGAN LEWIS (June 14, 2017), https://www.morganlewis.com/pubs/humira-patents-invalidated-in-inter-partes-reviews [https://perma.cc/5CDW-NL6X].

patent invalid on another finding of obviousness.[166] More recently, on January 7, 2020, the Federal Circuit found three Humira® patents invalid based on obviousness.[167]

As of May 2017, it had been estimated that only fourteen of AbbVie's patents had been challenged.[168] Considering the premeditated patent strategy employed by AbbVie, it may come as a surprise, or even as an indication of non-evergreening, that so few of the 246 secondary patents have been invalidated. However, when the median cost of a patent litigation case is over three million dollars alone,[169] it is unlikely that generic companies are willing to spend that much to invalidate such patents. As such, the invalidated cases themselves should hold heavy weight; however, the number of unchallenged cases should not.

Given the available patent history and the known generics that are ready for launch, it would be easy for the USPTO, PTAB, or Federal Circuit to find factor four in favor of evergreening. There are multiple generic drugs available that are ready for launch, including Hyrimoz,[170] Amjevita,[171] and Hadlima.[172] In actuality, at least five different generics that could be launched now might make the medicine more affordable for consumers.[173] However, the 120 patents filed after the primary patent expired could theoretically protect AbbVie's exclusivity until 2037.[174] Therefore, the examination of this factor would likely lead the examining entity to believe AbbVie was evergreening.

The fifth factor, too, would likely weigh in favor of a finding of evergreening. AbbVie's admitted patent portfolio tends to protect every aspect of the drug's life, from its origins to the diseases it's approved for,[175] which, in general, is not considered unfair. However, many of the secondary patents on Humira® were

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166. Jan Wolfe, *PTAB Sides with Boehringer in Challenge to Humira Patent*, REUTERS (July 7, 2017), https://www.reuters.com/article/ip-patent-boehringer/ptab-sides-with-boehringer-in-challenge-to-humira-patent-idUSL1N1JY1U8 [https://perma.cc/7N5N-QK5F].

167. Jan Wolfe, *IN BRIEF: Appeals Court Chips Away at Abbvie's Humira Patent Fortress*, REUTERS (Jan. 7, 2020), https://www.reuters.com/article/ip-patent-humira-idUSL1N29D008 [https://perma.cc/U9RB-5NZQ].

168. Peter Norman, *Humira®: Recent Developments*, FUTURE SCI. (May 9, 2017), https://www.future-science.com/doi/full/10.4155/ppa-2017-0012 [https://perma.cc/6MDH-C3HM].

169. Nayak, *supra* note 54.

170. Alex Keown, *FDA Approves Humira Biosimilar That Won't Be Available Until 2023*, BIOSPACE (Nov. 1, 2018), https://www.biospace.com/article/fda-approves-humira-biosimilar-that-won-t-be-available-until-2023/ [https://perma.cc/2EJJ-HZ5H].

171. Roni Shye, *New Biosimilar Approved for Humira*, GOODRX (Sept. 28, 2016), https://www.goodrx.com/blog/new-biosimilar-approved-for-humira/ [https://perma.cc/4SJ5-MFVM].

172. *FDA Approves Adalimumab Biosimilar Hadlima*, GENERICS & BIOSIMILARS INITIATIVE (Aug. 16, 2019), http://www.gabionline.net/Biosimilars/News/FDA-approves-adalimumab-biosimilar-Hadlima [https://perma.cc/HJQ6-NS2J].

173. Rowland, *supra* note 57.

174. *Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 4.

175. Koons, *supra* note 136.

granted based on changing the drug in superficial, non-innovative ways.[176] Additionally, regarding the sixth factor (the amount of research and development initiated to find the innovation), an examining authority would more than likely find in favor of evergreening. Humira®, as opposed to other drugs made through chemical synthesis, is typically made in living cells.[177] This process involves more steps and more complexity, which allows AbbVie to file more applications.[178] AbbVie's patents on Humira® contain such slight improvements that the company has been accused of wrongful use of the patent system to delay competition.[179] Not only does AbbVie have a large number of patents protecting Humira®, but some generic companies claim that many of the patents cover the same alteration.[180]

More specifically, Boehringer Ingelheim claims that the original patent not only covered the protein itself, but also included formulations and methods of making and using it.[181] Boehringer alleges that AbbVie "engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a 'patent thicket.'"[182] Finally, Boehringer claims that many of the patents share the same disclosure and cover the same inventions.[183] Given the fact that a drug covered by twenty patents in the Orange Book is generally considered excessive,[184] it is not likely that Boehringer's claims are unfounded.

Additionally, this evidence can support a finding for evergreening in terms of the seventh factor (whether the patent relates to a new and improved treatment in a disease area or whether it relates to an alternative treatment). Humira® is "a fully human monoclonal antibody that binds to tumor necrosis factor-alpha" ("TNF-α"), a signaling protein involved in inflammation.[185] Therefore, Humira® reduces the inflammatory response of autoimmune diseases.[186] Looking to the claims of the various Humira® patents,[187] an examining authority would probably find that past the initial discovery of Humira®, not much innovation continued

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176. Joe Cahill, *Humira Patent Strategy Makes the Case for Reform*, CRAIN'S CHI. BUS. (May 15, 2019), https://www.chicagobusiness.com/joe-cahill-business/humira-patent-strategy-makes-case-reform [https://perma.cc/YP98-KBK3].

177. Koons, *supra* note 136.

178. *Id.*

179. Zachary Silbersher, *Did AbbVie Create a Wrongful "Patent Thicket" Around Humira®?*, MARKMAN ADVISORS (Aug. 27, 2018), https://www.markmanadvisors.com/blog/2018/8/27/did-abbvie-create-a-wrongful-patent-thicket-around-humira [https://perma.cc/JFC7-UX8Q].

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. Paul Moradian, *AbbVie's Humira Patent Portfolio*, BIOPHARMAPAT. (Sept. 29, 2016, 3:21 PM), http://biopharmapatent.blogspot.com/2016/09/abbvies-humira-patent-portfolio.html [https://perma.cc/A66Y-EE2R].

186. *Id.*

187. *Id.*

based on the seemingly slight changes described. Although multiple patents describe different diseases to be treated, and in general treatments for different diseases should weigh against a finding of evergreening, an examining authority would likely find the opposite here; the inhibition of TNF-α would be expected by one having ordinary skill in the art to treat autoimmune diseases, as many of these diseases are exacerbated by signaling proteins like TNF-α.[188] This is not the same as finding vital uses for previously failed drugs after further research and development.[189]

The examination of the ninth factor would depend heavily on information requested by the examining entity or information that is revealed during discovery. Based on the current information available, it is not clear whether there was calculated suppression or concealment for a significant period of time. However, it does seem that AbbVie was not diligent in filing patent applications. Out of the 246 secondary patents, only twenty-seven patents were filed by the launch of the drug in 2002.[190] Additionally, not only were forty-nine percent of the applications filed after the first patent expired in 2014,[191] but also an examination of the claims of these later-filed applications does not display any ground-breaking innovation that was not disclosed during the early years of the primary patent's life.[192] Therefore, it is likely that the examining authority would find AbbVie to be evergreening when examining this factor.

D. Proposed Bill to Assist the USPTO and Federal Circuit

Separately, if Congress is pressured to enact legislation addressing the evergreening issue, they may be able to do so without supplementing their own novice ideas for that of the USPTO and the Federal Circuit or by changing established procedures in the USPTO. The legislature can enact a statute that if one patent in the family is found to be double patenting and is found by the USPTO, the PTAB, or the Federal Circuit to be the innovator's attempt to evergreen, then the reference patent is also unenforceable for double patenting.[193] This law would discourage innovators from evergreening because applying for non-innovative secondary patents would put the active drug patent at risk. On the other hand, if the innovators are confident that the new patent application covers

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188. K. Chatzantoni & A. Mouzaki, *Anti-TNF-alpha Antibody Therapies in Autoimmune Diseases*, PUBMED (2006), https://www.ncbi.nlm.nih.gov/pubmed/17017952 [https://perma.cc/K9P3-4Y2E].

189. *See* Holman, *supra* note 38.

190. Alex Berezow, *How Big Pharma Uses Logically Impossible Patents to Block Innovation*, AM. COUNCIL ON SCI. & HEALTH (Aug. 7, 2019), https://www.acsh.org/news/2019/08/07/how-big-pharma-uses-logically-impossible-patents-block-innovation-14207 [https://perma.cc/ARA9-KZJE].

191. *Overpatented, Overpriced: Special Humira Edition*, *supra* note 2, at 4.

192. To view the claims of the Humira® patents, *see* Moradian, *supra* note 185.

193. *See* MPEP § 1504.06 (9th ed. Rev. 10.2019, June 2020) (discussing current practices in terms of double patenting rejections).

meaningful innovation, they are likely to seek protection for it. Ideally, since double patenting rejections are not unusual, the USPTO would take into consideration not only the rejection but also the balancing test above.[194]

E. Effect of the Proposed Bill on Evergreening Ploys Similar to Humira®

The primary consequence of enacting the proposed bill in addition to the balancing test is that innovator companies will not risk the loss of the primary patent in order to potentially extend its twenty-year exclusivity. Additionally, the bill would prevent the loss of the USPTO, the PTAB, and the Federal Circuit's influence over pharmaceutical patent law into the hands of the legislature while still allowing the legislature to act in the prevention of evergreening to decrease drug prices.

Moreover, if innovator companies continue to evergreen, less generic companies will be hesitant to litigate due to an abundance of patents—an issue that exists with the current Humira® patent landscape. What is now an impossible feat would become possible for generic companies if the knock-down of one patent could become the knock-down of all patents. However, the USPTO, the PTAB, and the Federal Circuit should be cautious in implementing this strategy in only the cases of blatant evergreening, as over-implementation can result in a decrease of further research and development on known drugs.

In addition to the increased incentive for generic companies to litigate, innovator companies would not be able to settle with generic companies to delay them from entering the market. For example, AbbVie has settled patent disputes with multiple generic companies over Humira®.[195] AbbVie granted Novartis a non-exclusive license to manufacture and sell a copycat version of the drug beginning on September 30, 2023.[196] AbbVie reached a similar agreement with Amgen, allowing the company to release its version of the drug on January 31, 2023.[197] The implementation of this bill would incentivize generic companies to litigate against patents they believe are attempts to evergreen instead of settling for a non-exclusive license that would not be necessary in the absence of evergreening.

CONCLUSION

The use of a loophole in the patent system that allows pharmaceutical companies to evergreen is a continuing issue that likely will not be resolved until there is an active push against the practice.[198] The continued use of evergreening

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194. *See* Qiang Lu et al., *USPTO Patent Prosecution Research Data: Unlocking Office Action Traits*, U.S. PAT. & TRADEMARK OFF. (Nov. 2017), https://patentlyo.com/media/2017/11/USPTO-Patent-Prosecution-Research-Data_Unlocking-Office-Action-Traits-1.pdf [https://perma.cc/NWH8-U33L] (discussing frequency of non-statutory double patenting).

195. Maddipatla & Joseph, *supra* note 58.

196. *Id.*

197. *Id.*

198. *How Big Pharma Plays Games with Drug Patents and How to Combat It*, USA TODAY

will prevent the reduction of a drug's cost and can even contribute to a rising price of the drug.[199] Although many members of Congress are pushing for bipartisan lawmaking to solve this issue,[200] proposed legislation would treat the evergreening problem as a black-and-white issue. Legislation, such as the REMEDY Act, the APP Act, or the TERM Act, might address the evergreening problem but would also impair innovation on known drugs.[201] Additionally, legislation like the REMEDY Act provides no actual substantive answer to a systematic issue in patent law, but only acts to give the "cosmetic effect" of a solution to the evergreening issue.[202]

The best avenue for correcting this issue is to leave the dilemma to the branches of government that have the most experience with patent law—the judicial and executive branches. Specifically, the matter should be left to the USPTO, the PTAB, and the Court of Appeals for the Federal Circuit, as not only are they the most competent in terms of patent law, but they are also composed of scientists and former patent attorneys.[203] However, this does not mean there should be a straight-line rule, as this too could impair innovation. An observation of a multitude of secondary patents does not automatically mean that the pharmaceutical company is evergreening. Therefore, a balancing test that examines the most likely factors that would convince the USPTO or the Court of Appeals that the pharmaceutical company is evergreening would be beneficial.

Additionally, a statute can be enacted that proposes if one patent in the family is found to be double patenting and is thought to be the innovator's form of evergreening, then the reference patent is also unenforceable for double patenting.[204] This allows the risk of a finding of evergreening to be on the pharmaceutical company, and it would likely decrease efforts of evergreening because of the endangerment of the reference patent. Additionally, this statute would prevent placing the power of regulating a patent law issue on the legislature when it should remain with the USPTO, the PTAB, and the Federal Circuit. However, it would allow the legislature to still alleviate the evergreening issue and help decrease the costs of drug prices.

(Jul. 18, 2019, 6:29 PM), https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/ [https://perma.cc/P4ZR-QUDC].

199. Robert King, *Senators Want to Clamp Down on Drugmakers' Patent Protections*, WASH. EXAMINER (Dec. 12, 2017, 3:33 PM), https://www.washingtonexaminer.com/senators-want-to-clamp-down-on-drugmakers-patent-protections [https://perma.cc/DS96-CFXG].

200. *Id.*

201. *See* Brachmann, *Congress Adds TERM Act*, *supra* note 108.

202. Noonan, *supra* note 73.

203. *Patent Examiner: Everything You Need to Know*, *supra* note 117; *Court Jurisdiction*, *supra* note 118; *Judges*, *supra* note 119.

204. *See* MPEP § 1504.06 (9th ed. Rev. 10.2019, June 2020).

The balancing test alone or both the balancing test and the statute enacted can eliminate the evergreening issue without impeding further research and development. As a result, drug prices will not only decrease due to the allowance of generic drugs on the market at the end of an innovator's exclusivity period, but it would also work to protect legitimate innovation on a known drug.