NOTE

Crossing the Thicket Line

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INTRODUCTION

The pharmaceutical industry is deeply intertwined with the patent system.[1] This creates a dependency, which in turn renders the field difficult to navigate due to the development of patent thickets[2] and gives rise to an anticommons problem.[3] Both patent thickets and potential anticommons issues lead to higher transaction costs,[4] which are ultimately shouldered by the consumer who pays higher drug prices.[5]

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[1] Patent thickets are a dense web of overlapping intellectual property rights. *See "Patent Thickets" Are Anti-Competitive and Lead to Higher Drug Costs*, PCMA (May 17, 2021), https://www.pcmanet.org/patent-thickets-are-anti-competitive-and-lead-to-higher-drug-costs/ [https://perma.cc/7FD9-22S3] (describing patent thickets as "a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology").

[2] *See id.*; *see also* Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 491-92 (2020) (referring specifically to forming patent thickets as a brand-name versus generic strategy). "Under the most simplified definition, evergreening means a strategic accumulation of patents to create a thicket capable of burdening and potentially blocking generic competition . . . . [B]y accumulating multiple probabilistic patents, brand-name manufacturers strategically raise the costs and risks associated with generic entry and maintain monopoly power." *Id.*

[3] The anticommons problem describes the divided entitlements among complements when patents cover different pieces that must then be integrated into a product or when multiple patents cover different steps in the innovation process. *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1624 (2003). Burk and Lemley describe the anticommons problems within the pharmaceutical industry as "emphasiz[ing] the problems of divided entitlements among complements. These problems can occur either horizontally or vertically-horizontally if patents cover different pieces that must be integrated into a product, and vertically if patents cover different steps in a cumulative innovation process." *Id.*

[4] *Speak Up For Access*, ASS'N FOR ACCESS. MEDS., https://accessiblemeds.org/advocacy#patent (last visited Nov. 11, 2022) [https://perma.cc/ZFA9-AHYA] (discussing how patent thickets discourage competitors from entering the drug market because of the high costs of litigating meritless patents).

[5] *See How Big Pharma Plays Games with Drug Patents and How to Combat It*, USA TODAY (July 18, 2019, 6:29 PM ET), https://www.usatoday.com/story/opinion/2019/07/18/big-pharma-plays-games-drug-patents-you-pay-editorials-debates/1769746001/ [https://perma.cc/S2CQ-TAHK] ("But drug companies overcharge in ways that are unique to their industry . . . . The most promising [solution] involve combating the games drug companies play with patents."). Aside from the patent thickets, the availability of insurance, participation of pharmacy benefit managers, and reimbursement rates from government programs impact the price and availability of drugs.

One cannot charge a price unless buyers are willing to pay that amount.[6] However, health care is a unique market, where patients consume medication, but doctors choose it, and insurance pays for part of it.[7] Essentially, the single consumer is split into three entities; the doctor, patient, and insurance provider, which all have different incentives when selecting a drug.[8] Without having informed consumers, with a right to choose their commodity, the market cannot remedy the high prices and perverse incentives that exist within the pharmaceutical industry.[9]

This Note will address the current judicial and legislative shortcomings enabling patent thickets to develop within the pharmaceutical industry well beyond their initial twenty years and discuss potential solutions to the identified problems.[10]

The development of overlapping, and often splintered, intellectual property rights associated with a technology creates patent thickets.[11] There are strong financial incentives for corporations to pursue hundreds of patents on a single, individual drug "'through minor, even cosmetic, tweaks to delivery mechanism, dosages, and formulations"

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[6] *See* Robin Feldman, *Our Patent System Is Broken. And It Could Be Stifling Innovation*, WASH. POST (Aug. 8, 2021, 6:00 AM EDT), https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/ [https://perma.cc/6X5T-2ZFL] [hereinafter *Our Patent System Is Broken*] ("In a perfect world, one might expect purchasers to create a natural brake on the system. In theory, one cannot charge a price unless buyers are willing to pay.").

[7] *See id.*; *see also* Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices — Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 326 (2020) (describing how at numerous levels there are various incentives that play into the drug pricing).

[8] W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 773 (2020) (discussing how there are three main players in the drug selection process and each of the three have different incentives: "patients, doctors, and insurers split the consumer functions of selecting, paying for, and benefiting from goods").

[9] *Id.*

[10] A thorough analysis of all the root causes of the lack of drug affordability is complex and outside the scope of this Note.

[11] *See "Patent Thickets" Are Anti-Competitive and Lead to Higher Drug Costs*, *supra* note 1; *see also* Intell. Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1328 (Fed. Cir. 2016) ("[I]t is virtually impossible to innovate in any technological field without being ensnared by the patent thicket.").

leading to a splintered ownership of pharmaceutical technology.[12] Professor Feldman, a scholar in the field of Pharmaceutical Patent Law, has analogized that "intellectual property [is] a wall, these [minor changes to a drug] either make the wall longer — [by] extend[ing] the length of time for protection. Or they make the wall thicker — [by] add[ing] more patents or other protections that the competitors have to challenge."[13] Ultimately, the incentives within the current patent framework disproportionately reward pursuing patents for well-established, old inventions rather than assuming risk to patent new inventions.[14] This misaligned incentive creates persistent barriers and staves off competition and innovation.[15] Unsurprisingly, the most profitable drugs are also the most patented.[16]

Protecting products through patents is not anti-competitive in itself.[17] There is a fine line companies are toeing by applying for (and being granted) patents in the name of protecting their investment cash cow

[12] Alvin Lee, *Senators Urge Regulators to Block and Clear Patent Thickets*, JD SUPRA (June 23, 2022), https://www.jdsupra.com/legalnews/senators-urge-regulators-to-block-and-1332158/ [https://perma.cc/W78R-S8NP].

[13] Shanoor Seervai, *It's the Patents, Stupid — Why Drugs Cost So Much in the U.S.*, THE COMMONWEALTH FUND (Feb. 25, 2022), https://www.commonwealthfund.org/publications/podcast/2022/feb/its-the-patents-stupid-why-drugs-cost-so-much-in-us [https://perma.cc/26JW-YVRB].

[14] *See* Hacohen, *supra* note 2, at 486 ("In the pharmaceutical industry, incentives to pursue new patents are dictated not by the expected value of the new inventions, but by the well-established market value of old inventions that should no longer be legally protected.").

[15] *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCI. 590, 596 (2018) [hereinafter *May Your Drug Price Be Evergreen*] ("The data demonstrate that throughout the industry, companies create serial barriers to hold off the type of competitive entry that is fundamental to our innovative system.").

[16] *See* Hacohen, *supra* note 2, at 486-87 ("The market value for the anti-inflammatory biologic drug Humira, for example, is worth close to $40 million a day to AbbVie, its brand-name manufacturer. As of 2017, AbbVie filed 247 patent applications related to Humira, over 100 of which have already been issued. If unchallenged, the combined legal protection provided by these patents would reach 2034, over three decades since the drug was launched and nearly two decades after the lead patent for the drug has expired.").

[17] *See* Bryan Koenig, *7th Circ. To Crawl Into Humira "Patent Thicket" Dispute*, LAW360 (Feb. 23, 2021, 6:58 PM EST), https://www.law360.com/articles/1351485/7th-circ-to-crawl-into-humira-patent-thicket-dispute [https://perma.cc/3DK7-7QRX].

pharmaceutical innovations.[18] The current intellectual property model fosters competition and innovation through incentivizing exclusivity.[19] The focus on exclusivity is used to justify high costs of drugs over long periods of time.[20] Ultimately, the consumer shoulders the consequences of the pharmaceutical industry's patent practices, like the development of thickets, or the effects of evergreening techniques.[21] The most salient example of consumers shouldering these outrageous prices is the cost of Gilead's hepatitis C treatment, which costs $84,000 to treat a single patient.[22]

Additionally, an anticommons problem can arise when the number of patents impedes the development and marketing of new products.[23] Independently owned patent holders can exclude one another from accessing their patented technology — leading to the underuse of scarce resources and technologies.[24] This results in increased transaction costs

[18] *Id.*

[19] *See* Feldman, *supra* note 15, at 593 (explaining that the federal government offers ten other forms of exclusivity, other than the traditional patent, that can be granted to stave off competitors). Pharmaceutical companies can have exclusivity for developing drugs for small groups, or for pediatric purposes. *See id.*; *see also* 21 U.S.C. §§ 360bb-360cc (these sections contain the Orphan Drug Act information); *id.* § 355a(b) (this section contains information on exclusivity granted for pediatric studies of a drug).

[20] *See* Feldman, *supra* note 15, at 595. Feldman discusses the characteristics of a normal market, where a competitor would step in and drive down the sky-high drug prices. *Id.* However, in the pharmaceutical industry exclusivity, patents, and intellectual property rights prevent competitors from entering the market and reducing costs as easily as in a free market. *Id.*

[21] *See How Big Pharma Plays Games with Drug Patents and How to Combat It*, *supra* note 5 ("But drug companies overcharge in ways that are unique to their industry . . . . The most promising [solutions] involve combating the games drug companies play with patents.").

[22] Carolyn Y. Johnson & Brady Dennis, *How an $84,000 Drug Got Its Price: "Let's Hold Our Position . . . Whatever the Headlines"*, WASH. POST. (Dec. 1, 2015, 2:27 PM EST), https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/ [https://perma.cc/K5HV-2CRZ].

[23] *See* Burk & Lemley, *supra* note 3, at 1624 ("Anticommons theorists point to the risk of a bargaining breakdown whenever the development of a product requires permission from the owners of two or more inputs."). One solution to this identified problem is to consolidate ownership into a single owner or to preclude patent protection all together. *Id.*

[24] Michael Heller, *The Tragedy of the Anticommons: A Concise Introduction and Lexicon*, 76 MOD. L. REV. 7 (2013) ("The anticommons thesis is that simple: when too many people

as the required patents are held by multiple entities, which may be challenging to coordinate with as a downstream inventor.[25]

Pharmaceutical drugs are unique because of the interface with the public.[26] The public relies on few other patented commodities in the same way it relies on pharmaceutical drugs: for livelihood and health.[27] For this reason, it is important for the legal framework surrounding pharmaceutical patents to be updated to realign the incentives surrounding patents to meet the heavy burden it carries.

This Note will argue for the realignment of patent incentives within the pharmaceutical field to help address the patent thicket problem in an effort to reduce transaction costs. Part I of this Note establishes a background of patents and the role they play in the pharmaceutical industry. Part II argues courts should intervene and prevent the development of patent thickets by limiting the number of patents on a single drug in order to better align patent portfolios with the spirit of the law. Additionally, Part II identifies and argues for reforms within the current patent legislation that is being stretched beyond the intended purpose to contribute to patent thickets. Finally, Part III builds on those arguments to identify proposed solutions of ways this realignment can be achieved. This includes proposing that the USPTO and FDA coordinate early on in the patent process for applications requesting a patent on an already existing pharmaceutical drug.

own pieces of one thing, nobody can use it. . . . But too much ownership has the opposite effect — it leads to resource underuse in an anticommons. . . . If too many owners control a single resource, cooperation breaks down, wealth disappears, and everybody loses.").

[25] *See* Burk & Lemley, *supra* note 3, at 1611.

[26] *Speak Up For Access*, *supra* note 4 ("Health care is an issue we all care about, and all of us — and those we love — will need medicine one day.").

[27] Sandro Galea, *The Cost of Pharmaceuticals, The Role of Public* Health, BOS. UNIV. SCH. PUB. HEALTH (June 5, 2016), https://www.bu.edu/sph/news/articles/2016/the-cost-of-pharmaceuticals-the-role-of-public-health/ [https://perma.cc/K35P-KUJ2] ("Hidden in the political rancor around drug pricing is an implicit acceptance of our fundamental reliance on drugs and medical curative strategies as the cornerstone to our approach to health.").

I. HISTORY OF PATENT LAW

A. Historical Framework of Patent Law Development

The overarching goal of the patent system has remained constant since its inception: to promote scientific progress in furtherance of the public good.[28] Overtime, the patent infrastructure has changed.[29] Understanding the ways the patent system has evolved through the years is relevant to understanding the ways the pharmaceutical sector has outgrown the current patent system and potential modifications that can bring the two in better alignment.[30]

The earliest recorded grant of a patent application in the present-day United States depended on the English Statute of Monopolies of 1623 which granted exclusive rights for fourteen year terms and applied to any "manner of new manufacture."[31] By the time the U.S. Constitution was ratified, the Framers upheld the precedent laid by the English Statute of Monopolies.[32] The Constitution provides the foundation for federal patent systems. Article 1, Section 8, clause 8 states that "Congress shall have power to . . . promote the progress of science and useful arts, by securing for a limited times to authors and inventors the exclusive right to their respective writings and discoveries."[33] Though eventually repealed and replaced, the first United States Patent Act of 1790 laid the foundation for a centralized system for patent issuance.[34] The Act of 1790 required the approval of any two of the Secretary of

[28] *See* U.S. CONST. art. I, § 8, cl. 8; *see also* Motion Picture Pats. Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917).

[29] *See A Brief History of the Patent Law of the United States*, LADAS & PERRY EDUC. CTR. (May 7, 2014), https://ladas.com/education-center/a-brief-history-of-the-patent-law-of-the-united-states-2/ [https://perma.cc/9TU2-2ZD7].

[30] See *infra* Parts II.A and II.B for a discussion of the ways patent law has outgrown its current framework and reforms needed to bring it back into alignment.

[31] Statute of Monopolies 1623, 21 Jac. c. 3 (Eng.).

[32] *Origins and Scope of the Power*, JUSTIA, https://law.justia.com/constitution/us/article-1/50-copyrights-and-patents.html (last visited Jan. 10, 2023) [https://perma.cc/QW8M-FRJZ] ("Informed by these precedents and colonial practice, the Framers restricted the power to confer monopolies over the use of intellectual property through the Copyright and Patent Clause.").

[33] U.S. CONST. art. I, § 8, cl. 8.

[34] Patent Act of 1790, ch. 7, 1 Stat. 109-12 (repealed 1793).

State, Secretary of War, and Attorney General to issue a patent for a period of up to fourteen years.[35] Under the Act, patents were granted for the invention or discovery of "any useful art, manufacture, engine, machine, or device, or any improvement therein not before known."[36]

The 1790 Act was replaced by a new version in 1793, which provided the first working definition resembling the current-day form,[37] and provided only the Secretary of State as the regulatory arm in charge of the process.[38] In relevant part, the 1793 version of the Act stated that a patent can be granted to a person who "shall allege that [they] have invented any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter."[39] The next major revision to the Act was in 1836, which created the modern Patent Office.[40]

The 1836 revision was carried out in response to concerns about the grant of patents for inventions that lacked proper vetting and novelty.[41] It is under this revision that the current framework of the Patent Office was set up to examine the novelty of patents before a patent could be granted.[42] The Patent Office was established as part of the State Department.[43] Another notable feature of the 1836 revision was the allowance of a patent extension beyond the initial fourteen year issuance if there was a finding that "the patentee, without neglect or fault on [their] part, having failed to obtain, from the use and sale of [their invention] a reasonable renumeration for the time, ingenuity, and

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[35] *Id.* § 1.

[36] *Id.*

[37] Patent Act of 1793, ch. 11, § 1, § 3, 1 Stat. 318, 318-22 (repealed 1836) (requiring a short description be filled with the application along with a well written description of the invention, and the manner of using the invention in full, clear, exact terms to distinguish it from everything that came before).

[38] *See id.* § 1.

[39] *Id.*

[40] *See A Brief History of the Patent Law of the United States*, *supra* note 29.

[41] *Id.* (noting "a major review of the law was undertaken in 1836 in response to complaints about the grant of patents for things that lacked novelty").

[42] *Id.*

[43] *Records of the Patent and Trademark Office: 241.1 Administrative History*, NAT'L ARCHIVES, https://www.archives.gov/research/guide-fed-records/groups/241.html (last visited Feb. 9, 2024) [https://perma.cc/B5WD-3ELT].

expense bestowed upon the same, and the introduction thereof into use."[44]

The contours of the current patent landscape were further defined through the 1952 adoption of the Patent Act.[45] Most significantly, the Patent Act of 1952 provided stability to patent infringement common law jurisprudence by "distinguishing between the theories of inducement infringement and contributory infringement in their codification of Section 271(b) and Section 271(c), respectively."[46] Another significant change was the replacement of the Act's 1793 language of the word "art" with "process."[47] The 1952 Patent Act defines the four classes of statutory subject matter as "process, machine, manufacture, or composition of matter," which has been adopted by the current language in 35 U.S.C. § 101.[48]

B. Modern Analysis of Patent Law

Presently, patent law is governed by Title 35 of the United States Code, which outlines the requirements an invention must meet to be deemed patentable.[49] It also establishes the United States Patent and Trademark Office ("USPTO") as the entity responsible for the issuance of patents.[50]

The main goal of the patent system is to promote the progress of science for public benefit.[51] At its core, it is a tool to serve the public need. The Supreme Court reinforced this proposition by writing "the primary purpose of our patent laws is not the creation of private

[44] Patent Act of 1836, ch. 357, § 18, 5 Stat. 117, 124 (repealed 1952).

[45] *See A Brief History of the Patent Law of the United States*, *supra* note 29.

[46] *See* Spencer K. Lickteig, *A Madness to the Method: Fixing the Joint Infringement System for Method Patents After* Akamai Technologies, Inc. v. Limelight Networks, Inc., 2015 U. ILL. J.L., TECH. & POL'Y 39, 50; *see also* Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 761 (2011) ("Before 1952, both the conduct now covered by § 271(b) (induced infringement) and the conduct now addressed by § 271(c) (sale of a component of patented invention) were viewed as falling within the overarching concept of "contributory infringement."); 35 U.S.C. § 271.

[47] *See* Act of July 19, 1952, ch. 950, Pub. L. No. 593, 66 Stat. 792, 797.

[48] *See id.*; 35 U.S.C. § 101.

[49] *See* 35 U.S.C. §§ 101-03, 112.

[50] 35 U.S.C. § 1.

[51] *See* U.S. CONST. art. I, § 8, cl. 8.

fortunes for the owners of patents but is 'to promote the progress of science and the useful arts.'"[52] The USPTO receives about 650,000 patent applications annually and issues grants to about 390,000.[53] To obtain a patent, an inventor files an application with the USPTO, which examines the application for its substantive quality.[54] Among other things, the patent application must be of patentable subject matter,[55] useful,[56] novel,[57] nonobvious,[58] and adequately described.[59] Once issued, the patent holder has the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . ." for a period of twenty years.[60] Typically, patents in the pharmaceutical industry are "composition-of-matter" patents,[61] which cover specific molecules, or combinations of molecules.[62] A patent can

[52] Motion Picture Pats. Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917).

[53] *See U.S. Patent Statistics Chart Calendar Years 1963–2020*, PAT. TECH. MONITORING TEAM, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last updated Nov. 8, 2022, 2:46 PM PST) [https://perma.cc/QA6E-SEAV] (the U.S. Patent Statistics Chart shows a total of 646,244 total patent applications and 388,900 total patent grants for in 2020).

[54] *See* 35 U.S.C. §§ 101-03, 112.

[55] *See id.* § 101.

[56] *See id.*

[57] *See id.* § 102.

[58] *See id.* § 103.

[59] *See id.* § 112.

[60] 35 U.S.C. § 154(a)(1); *see, e.g.*, *What Is a Patent?*, FINDLAW, https://www.findlaw.com/smallbusiness/intellectual-property/what-is-a-patent.html (last updated July 2, 2019) [https://perma.cc/RMV9-VCVA].

[61] Composition-of-matter patents list the chemical ingredients (compounds, elements, or radicals) that make up the compound. These can be listed narrowly, with intermediate scope, or broadly. Narrow listing names the specific components, while the intermediate scope patent lists groups of similar elements that are functionally equivalent, and broad patents list the function performed. *See Composition of Matter*, SMITH & HOPEN, https://smithhopen.com/glossary/composition-of-matter/ (last visited Nov. 1, 2022) [https://perma.cc/D7S2-3B6F].

[62] Veronica Salib, *How Pharmaceutical Patents Contribute to Increased Drug Costs*, PHARMA NEWS INTEL. (Aug. 16, 2022), https://pharmanewsintel.com/features/how-pharmaceutical-patents-contribute-to-increased-drug-costs [https://perma.cc/YHS8-H7Q3].

cover the actual drug itself, or it can cover the production process.[63] A new patent is valid for twenty years from the time the patent is filed.[64]

Patent law requires novelty,[65] which means the invention is "bestowed for the first time upon the public by the patentee."[66] However, it is common practice for companies to pursue additional patents on existing drugs for marginal improvements to lengthen the time an existing patent is enforceable past the initial twenty-year exclusivity granted from the first patent.[67]

There are several different approaches pharmaceutical companies take to patenting the same biopharma. Two examples are evergreening and product hopping.[68]

Evergreening is the practice of pharmaceutical companies patenting new inventions with slight modifications of old drugs.[69] These incremental modifications that get patented can include new

[63] *Id.*

[64] 35 U.S.C. § 154(a)(2) (granting patent term of twenty years).

[65] *See id.* § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent . . . ."); *see also* Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985) (interpreting § 101 novelty requirement as being a "fundamental conditions for patentability").

[66] *See* Sean B. Seymore, *Patenting New Uses for Old Inventions*, 73 VAND. L. REV. 479, 481 (2020).

[67] *Patent Database Exposes Pharma's Pricey "Evergreen" Strategy*, UC COLLEGE OF THE L., S.F. (Sept. 24, 2020), https://www.uclawsf.edu/2020/09/24/patent-drug-database/#:~:text=AstraZeneca%2C%20Johnson%20%26%20Johnson%20and%20Gilead,driver%20of%20high%20drug%20prices. [https://perma.cc/BS4N-5MBQ] (discussing how drug makers excessively extend patent protections to limit the market entry of competing products in an anti-competitive practice).

[68] *See* Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CMAJ E385, E385 (2013); *see also* Phebe Hong, *Stopping the Pharmaceutical "Product Hop,"* HARVARD L. BILL OF HEALTH (Oct. 11, 2019), https://blog.petrieflom.law.harvard.edu/2019/10/11/stopping-the-pharmaceutical-product-hop/#:~:text=%E2%80%9CProduct%20hopping%E2%80%9D%20in%20the%20drug,%E2%80%93%20and%20newly%20patented%20%E2%80%93%20formulation [https://perma.cc/RS9U-QRBW] ("'Product hopping' in the drug industry occurs when a pharmaceutical manufacturer winds down production of an old drug formulation whose patent expiration date has passed or is approaching. The company then forces or persuades patients to switch prescriptions to the drug's new — and newly patented — formulation. A successful 'product hop' extends a pharmaceutical manufacturer's monopoly and therefore its ability to charge high prices.").

[69] Collier, *supra* note 68.

formulations, preparations, delivery, or uses. Some of the incremental changes have important clinical outcomes, while the rest are purely cosmetic.[70] Companies do so to continue benefiting from the handsome profits their product garners in an exclusive market.[71]

Evergreening allows the brand name manufacturer to maintain patent power over the drug for longer periods of time.[72] An example is drug manufacturer AbbVie's strategy with Humira.[73] Humira is approved by the Food and Drug Administration ("FDA") to treat rheumatoid arthritis.[74] The original patent for Humira's active ingredient expired in 2016.[75] There are four generic competitors to Humira that have also already received approval by the FDA.[76] Yet, there is currently no generic competitor in the market.[77] This is due to AbbVie's two-prong approach of aggressively patenting and litigating to protect Humira from competition for as long as possible.[78] Through this strategy, AbbVie has filed more than 200 patent applications, receiving 132 of those patents.[79] Additionally, AbbVie aggressively litigated against competitor drug manufacturers to prevent them from entering the market.[80] As a result of the 132 patents issued to AbbVie, no competitors could enter the

[70] *Id.* (discussing how drug makers excessively extend patent protections to limit the market entry of competing products in an anti-competitive practice).

[71] *See In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 824 (N.D. Ill. 2020). The earliest possible competitor to Humira is Amjevita, which was approved by the FDA in 2016. *Id.* However, due to a patent infringement lawsuit by AbbVie, the earliest that Amjevita can enter the market is 2023. *Id.*

[72] Hong, *supra* note 68.

[73] *See* Sy Mukherjee, *Protect at All Costs: How the Maker of the World's Bestselling Drug Keeps Prices Sky-High*, FORTUNE (July 18, 2019, 3:30 AM PDT), https://fortune.com/longform/abbvie-humira-drug-costs-innovation/ [https://perma.cc/W9BL-5TQF] ("Humira isn't just AbbVie's bestselling drug, it is its everything-drug.").

[74] Emily Miller, *Humira*, DRUGWATCH, https://www.drugwatch.com/humira/ (last updated Sept. 5, 2023) [https://perma.cc/5DY7-9979].

[75] *In re Humira*, 465 F. Supp. 3d at 820 (noting that the patent on Humira's active ingredient, Adalimumab, expired on December 31, 2016).

[76] *Id.* at 825.

[77] *Id.* at 824-25.

[78] *See* Mukherjee, *supra* note 73 (discussing how "AbbVie [is] a pioneer — not just in medical treatments but also in legal protections").

[79] *In re Humira*, 465 F. Supp. 3d at 822.

[80] *Id.* at 824.

market until at least 2023.[81] One of the reasons AbbVie was able to build such a formidable patent thicket was because Humira is a biologic, rather than a synthesized drug.[82] There are two classes of drugs that can be patented, biologics and small molecules.[83] Biologics are derived from living organisms[84] while small molecules are the end products of a chemical synthesis.[85] Having a biologic drug allowed AbbVie to leverage their patent and apply for follow-up patents on obscure steps in the production related to manufacturing or dosing.[86]

Another example of evergreening is AstraZeneca, which leads the pharmaceutical market in filings for continued patent protections, and the associated time extensions.[87] Six of its drugs rank among the top twenty for patent protections received.[88] Through continuing the clock, AstraZeneca secured more than ninety years of extensions on its drugs.[89] AstraZeneca is not unique in the pharmaceutical industry in engaging in this behavior.[90] Many other companies do so as well.[91] As a

[81] *Id.*

[82] *See* Mukherjee, *supra* note 73 ("Unlike chemically synthesized drugs, biologics derive from actual biological material, making them significantly more complex than standard chemical medicines.").

[83] *Biologics vs. Small Molecule Drugs: Which are Better?*, ASCENDIA PHARMA (Oct. 27, 2021), *https:*//ascendiapharma.com/newsroom/2021/10/27/biologics-vs-small-molecule-drugs [https://perma.cc/K4E8-4G98].

[84] *Id.*

[85] *Id.*

[86] *See* Mukherjee, *supra* note 73 ("And therein lies the key to AbbVie's IP strategy, explains Feldman. For instance, a company may be able to file patents on obscure steps in the production and manufacturing process, or adjustments in dosing.").

[87] *Patent Database Exposes Pharma's Pricey "Evergreen" Strategy*, *supra* note 67.

[88] *Id.*

[89] *Id.* Some of the drugs AstraZeneca develops treats common, prevalent diseases including diabetes. *See id.*

[90] In the pharmaceutical trade, when brand-name companies patent "new inventions" that are really just slight modifications of old drugs, it's called "evergreening." Collier, *supra* note 68, at E385 ("Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company's economic advantage.").

[91] *See Patent Database Exposes Pharma's Pricey "Evergreen" Strategy*, *supra* note 67. Feldman describes Johnson & Johnson's HIV drug, which ranked second in number of protections, having received 167 protections from 14 unique patents and delayed

whole, the top twelve brand drugs on the market were protected by a total of 848 patents.[92] In total, these patents provide an additional thirty-eight years on average, without competition.[93]

The second method pharmaceutical companies can use to patent the same biopharma is product hopping; where pharmaceutical manufacturers wind down production of a drug formulation whose patent has already expired or is expiring soon.[94] The company then utilizes a patient's healthcare team to switch patient's prescriptions to the drug's newly patented formulation.[95] In essence, the product hops from one formulation to another. The effect of which extends the manufacturer's monopoly and enables them to continue charging market-exclusive, high prices.[96]

In 2019, the pharmaceutical industry spent $83 billion on research and development.[97] Adjusted for inflation, that is ten times higher than what the industry spent per year in the 1980s.[98] These costs encompass the discovery and testing of the potential active drug, testing, and marketing.[99] This high up-front financial investment[100] in the research and development of drugs incentivizes the process to remain heavily

competitor entry for 16 years. *Id.* Another example is Gilead's HIV drug, Truvada, which extended its HIV drug, Viread, for more than 17 years through 120 protections. *Id.*

[92] Erik Komendant, *Pharmaceutical Patent Abuse: To Infinity and Beyond!*, ASS'N FOR ACCESS. MEDS., https://accessiblemeds.org/resources/blog/pharmaceutical-patent-abuse-infinity-and-beyond (last visited Nov. 10, 2022) [https://perma.cc/7SGD-UU3R] ("In a recent report from I-MAK, the top 12 brand drugs on the market last year are protected by a total of 848 patents (71 per drug) providing an average of 38 years without generic competition.").

[93] *Id.*

[94] Collier, *supra* note 68, at E385.

[95] *Id.*

[96] *See* Collier, *supra* note 68, at E385.

[97] CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 1 (2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf [https://perma.cc/Y2D3-X3F7].

[98] *Id.*

[99] *See id.*

[100] Feldman, *May Your Drug Price Be Evergreen*, *supra* note 15, at 592 ("The processes of developing new drugs, conducting the clinical trials, obtaining FDA approval, and bringing the drugs to market are extraordinarily expensive.").

secretive.[101] The costs associated with drug development, marketing, and manufacturing are some of the reasons why the pharmaceutical industry relies so heavily on patents as the most effective manner to extract profit from their inventions.[102]

II. REALIGNING INCENTIVES WITHIN THE PHARMACEUTICAL INDUSTRY

As discussed in Part I, many private pharmaceutical companies have significant monetary incentives to develop and preserve their patent portfolios as a financial strategy.[103] Therefore, in order to effectively make a change to the patent thicket landscape, patent law itself needs to be modernized. There is a growing push from legislators for the USPTO to take action regarding the continuation patent problem that is rampant in the pharmaceutical industry.[104]

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[101] *Id.* at 596 (describing how transparency is not in the industry's best interests, and how companies go to great lengths to hide their strategic behavior to prevent competitors from mimicking their "clever strategies").

[102] *See* OLIVER GASSMANN, GERRIT REEPMEYER & MAXIMILIAN VON ZEDTWITZ, LEADING PHARMACEUTICAL INNOVATION: TRENDS AND DRIVERS FOR GROWTH IN THE PHARMACEUTICAL INDUSTRY 133-34 (2d ed. 2008) ("[Patent] protection is crucial in the pharmaceutical industry as otherwise nobody would invest in expensive and long-term drug development.").

[103] *See supra* notes 12–16 and accompanying text for a more detailed discussion of the financial considerations in the current pharmaceutical patent structure.

[104] *See* Steve Brachmann, *Drug Patent Thicket Letter from U.S. Senators to Vidal Seeks Reforms on Continuation Patent Filings*, IPWATCHDOG (June 15, 2022, 4:15 PM), https://ipwatchdog.com/2022/06/15/drug-patent-thicket-letter-u-s-senators-vidal-seeks-reforms-continuation-patent-filings/id=149639/ [https://perma.cc/WC3P-JA9G]. Brachmann reports that, on June 8, 2022 bipartisan U.S. Senators sent a letter to the USPTO Director to voice their concerns about the practice of patent thickets in the pharmaceutical industry. *Id.* They were especially frustrated over the "large numbers of patents granted to cover various aspects of a single pharmaceutical treatment, 'primarily made up of continuation patents.'" *Id.* This is not the first attempt members of Congress have made to address the patent thicket landscape in the pharmaceutical industry. *See* Affordable Prescriptions for Patients Act of 2019, S. 1416, 116th Cong. (seeking to amend the Federal Trade Commission ("FTC") Act to prohibit anticompetitive behaviors by drug product manufacturers. The language of the proposed bill would have allowed the FTC to define patent thickets as an unfair method of competition, thus violating § 5(a) of the FTC Act). The bill was introduced to the Senate floor again in 2021, however the language was more generalized to target product hopping, the practice of switching the drug formulation covered by new patents in an existing product because generic drug

The statutory frameworks currently in place provide companies with opportunities to exploit statutory grey-areas to their own financial advantage at the cost of losing sight of the purpose of patents in the first place, which as discussed above, is to further scientific innovation for the public benefit.[105] Patents offer powerful rights to the holder. However, there needs to be a mechanism to prevent duplicative issuance of patents. When an existing drug is modified, there is generally no threshold determination needed to show clinical improvement or distinctiveness in order to obtain a new patent.[106]

A. *Courts Should Intervene to Prevent the Development of Patent Thickets to Better Align Patent Portfolios with the Spirit of the Law*

Under the current patent framework, litigation can be utilized to help cut through patent thickets.[107] At present, courts and judges do not have an accurate gauge of a patent's utility when it reaches their courtroom. More specifically, judges detrimentally rely on the fact that a patent was issued, rather than diving deeper into the quality of the patent.[108] Judges should rest more of their determination on whether a patent at issue is clinically significant and not rely detrimentally on the mere fact that a patent was issued in the first place.[109] Courts have some power to help realign the economic and patent incentives within the pharmaceutical industry. As discussed earlier, the pharmaceutical sector is a unique

manufacturers entering into the space. *See* Affordable Prescriptions for Patients Act of 2021, S. 1435, 117th Cong. §§ 2, 27 (seeking to amend the FTC Act to prohibit product hopping).

[105] *See* Motion Picture Pats. Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917).

[106] *See In re* Sichert, 566 F.2d 1154, 1159-61 (C.C.P.A. 1977) (discussing the low threshold that needs to be established for patent utility).

[107] *Cf.* Lisa Orucevic, Note, *A Machete for the Patent Thicket: Using* Noerr-Pennington *Doctrine's Sham Exception to Challenge Abusive Patent Tactics by Pharmaceutical Companies*, 75 VAND. L. REV. 277, 277 (2022) ("Patent kelaw's weapons in the fight against patent thickets, namely litigation and inter partes reviews (an abbreviated process for challenging patent validity), have proven to be inadequate . . . .").

[108] *See* Mayor of Baltimore v. AbbVie Inc., 42 F.4th 709, 713 (7th Cir. 2022) (discussing how weak patents aren't invalid because they were issued and vetted, nonetheless). The party challenging AbbVie argued that some of the patents were too marginal to justify the legal protection that patents had to offer. *See id.*

[109] *See id.*

market operating in a vacuum of true consumer pressure.[110] This is all the more reason for courts to become more active in helping shut down the patent thicket practice. The judiciary can do so by peeling back the curtain on standard industry practices of freezing out competitors by developing patent thickets.[111]

Two recent cases are particularly relevant to highlight the court's reliance on the fact that all patents are created equal[112] in guiding their decisions to uphold the patent thickets. These two cases involve alleged patent thickets of the top two most profitable drugs of all time.[113] The analysis of the cases will demonstrate how pharmaceutical corporations are able to obtain patents with perverse incentives, like patent thickets, and have these patents upheld in court because of the judge's do not have the resources to properly vet innovative patents from clinically insignificant ones.[114] The lack of judicial emphasis on the clinical significance of patents in a dispute can lead to the empowerment of patent thickets for the companies that hold the portfolio.[115]

The first case concerns the drug Humira, and its manufacturer AbbVie's patent portfolio. In *Mayor of Balt. v. Abbvie Inc.*, welfare patients who were prescribed Humira brought a case against AbbVie for obtaining 132 additional patents after the basic patent covering the drug had expired.[116] The case was initially dismissed at the district court level but brought up on appeal to the Seventh Circuit.[117] The Seventh Circuit upheld the dismissal of the case against AbbVie for building a patent portfolio around Humira that created an allegedly illegal monopoly in

[110] *See* Feldman, *Our Patent System Is Broken*, *supra* note 6 ("In a perfect world, one might expect purchasers to create a natural brake on the system. In theory, one cannot charge a price unless buyers are willing to pay."); *supra* notes 6–9.

[111] *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 824 (N.D. Ill. 2020).

[112] *See Mayor of Baltimore*, 42 F.4th at 711-12; Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1068 (Fed. Cir. 2020).

[113] *See Mayor of Baltimore*, 42 F.4th at 712; *Immunex Corp.*, 964 F.3d at 1053.

[114] *See Mayor of Baltimore*, 42 F.4th at 712.

[115] *See id.*

[116] *Id.* at 711-15.

[117] *Id.*; *see also In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 853 (N.D. Ill. 2020).

an effort to stave off competition.[118] As previously mentioned, Humira's original patent expired in 2016,[119] but through its patent portfolio and litigious strategy, competitors were frozen out of the market until 2023.[120] In 2023, competitors introduced fourteen biosimilar[121] drugs into the market.[122] Humira is a major profit center for AbbVie, generating over $19 billion in sales in 2020 alone.[123] This has been one of the incentives for AbbVie to continue obtaining patents in an effort to protect this revenue stream. In the Humira case, the Court focused on the fact that patents come with a presumption of validity.[124] Even though there were 132 patents continuing off of twenty root patents, the Court viewed this as "neither here nor there" and elected to uphold AbbVie's patents on Humira.[125] Ultimately, the Court's decision to dismiss this case was based on a flawed understanding of the patent process: that every change in a process, design, etc. warrants the issuance of a patent and all the protections that come along with it.[126] This illustrates the

[118] *See Mayor of Baltimore*, 42 F.4th at 716.

[119] *In re Humira*, 465 F. Supp. 3d at 820.

[120] *Id.* at 824.

[121] Alyssa Billingsley & Joshua Murdock, *Is There a Biosimilar for Humira? Yes, Here Are 9 Humira Biosimilars Launching in 2023*, GOODRX HEALTH (last updated July 12, 2023), https://www.goodrx.com/humira/biosimilars [https://perma.cc/GD7Y-QZAD]. Humira is a biologic, meaning it comes from living sources like plant and animal cells. *Id.* The equivalent of a generic for a biologic drug is a biosimilar. *Id.*

[122] Adam J. Fein, *The Big Three PBMs' 2024 Formulary Exclusions: Biosimilar Humira Battles, CVS Health's Weird Strategy, and the Insulin Shakeup*, DRUG CHANNELS (Jan. 9, 2024), https://www.drugchannels.net/2024/01/the-big-three-pbms-2024-formulary.html [https://perma.cc/QC9G-7ZPM] (discussing how there are 14 biosimilar versions of Adalimumab where the collective market share barely cracked 1% in 2023).

[123] *See* Ethan E. Litwin, *Seventh Circuit to Determine Whether the Sherman Act Can Mow Down Drug "Patent Thickets,"* CONSTANTINE CANNON (Aug. 9, 2021), https://constantinecannon.com/antitrust-group/antitrust-today-blog/seventh-circuit-to-determine-whether-the-sherman-act-can-mow-down-drug-patent-thickets/ [https://perma.cc/N4XE-CCFY].

[124] Mayor of Baltimore v. AbbVie Inc., 42 F.4th 709, 713 (7th Cir. 2022).

[125] *Id.*

[126] *Id.* at 712-15 (Judge Easterbrook supporting his opinion by reasoning that "weak patents are valid" and if AbbVie made 132 inventions, it should hold 132 patents).

need for a better system to regulate the issuance of incremental patents.[127]

The second case, *Immuenex Corp. v. Sandoz*, looks at Amgen's multi-billion dollar drug, Enbrel.[128] Enbrel is used to treat rheumatoid arthritis in over a hundred thousand patients, both domestically and world-wide.[129] Another drug manufacturer, Sandoz, applied to market their own biosimilar version of Enbrel and was sued by Amgen, which acquired Immunex, for patent infringement pursuant to the Biologics Price Competition and Innovation Act ("BPCIA").[130]

The primary patent on Enbrel was granted in 1990 and expired in 2010.[131] There are at least nineteen active patent applications which protect its commercial exclusivity until 2029.[132] Amgen has filed a total of fifty-seven patent applications on Enbrel in the United States, which has delayed any competition in the market by thirty-nine years.[133] Patenting with the aim to delay competition is difficult to prove. However, what is clear is that the vast majority of the total patent applications on Enbrel were filed *after* the drug was already approved to be on the market, thus delaying competitor entry into the field.[134] In this

[127] *See generally* Kate S. Guadry, *Evergreening: A Common Practice to Protect New Drugs*, 29 NATURE BIOTECH. 876, 876 (2011) (discussing how evergreening is used within the pharmaceutical industry to extend periods of exclusivity and monopolies associated with the associated product).

[128] Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1068 (Fed. Cir. 2020); *Amgen Defeats Novartis Appeal over Arthritis Drug Enbrel's Patents*, REUTERS (July 1, 2020, 8:12 AM PDT), https://www.reuters.com/article/us-amgen-novartis-enbrel/amgen-defeats-novartis-appeal-over-arthritis-drug-enbrels-patents-idUSKBN2426EG [https://perma.cc/AJC6-TB8Y].

[129] Press Release, Amgen, Enbrel is First Biologic to Receive FDA Approval for the Treatment of Ankylosing Spondylitis (July 24, 2003), https://www.amgen.com/newsroom/press-releases/2003/07/enbrel-is-first-biologic-to-receive-fda-approval-for-the--treatment-of-ankylosing-spondylitis [https://perma.cc/KC69-G4TV].

[130] *See Immunex Corp.*, 964 F.3d at 1053.

[131] I-MAK, OVERPATENTED, OVERPRICED SPECIAL EDITION: ENBREL 1, 3 (2018), https://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf [https://perma.cc/KN8L-JL4M].

[132] *Id.*

[133] *Id.*

[134] *Id.* (discussing how 72% of the total patent applications on Enbrel were filed *after* the drug was approved and on the market).

case, the court rejected Sandoz's argument that the drug patents should be invalidated because the patents at issue described concepts in previous patents and were therefore "obvious"[135] per Section 101.[136] The *Immunex* holding further highlights how the deferential role of the judiciary enables patents beyond the initial twenty-year time period.[137] Amgen had in fact already enjoyed its twenty-year exclusivity period on Enbrel, and will continue to enjoy another nineteen years of exclusivity through to 2029.[138]

Courts are upholding patent thickets regardless of whether the patent may be a continuation patent, clinically insignificant, or intended as a defensive patent to add to a portfolio.[139] In sum, the judiciary is failing to account for the misaligned incentives the patent industry empowers within the pharmaceutical industry.[140] Evergreening undermines the purpose of the patent system and pushes the cost of drugs synthetically higher.[141] If courts are going to continue to base their reasoning on the simple fact that a patent was issued when deciding on patent thicket cases, then the patent process should do a better job at vetting the patents to prevent patent thickets before they get to the judge's bench.[142]

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[135] *Immunex Corp.*, 964 F.3d at 1068.

[136] 35 U.S.C. § 101.

[137] *Immunex Corp.*, 964 F.3d at 1068.

[138] *Id.*

[139] *See* Mayor of Baltimore v. AbbVie Inc., 42 F.4th 709, 713 (7th Cir. 2022).

[140] *See* Robin C. Feldman, David A. Hyman, W. Nicholson Price II & Mark J. Ratain, *Negative Innovation: When Patents Are Bad for Patients*, 39 NATURE BIOTECH. 914, 914-15 (2021) ("The patent examiner evaluating Pharmacyclics' method of treatment patents found lower doses obvious on the basis of the 2009 and 2010 conference and press release disclosures, which occurred more than a year before the relevant patent was filed. Only the highest doses — 420 mg and higher — were granted in the issued method of treatment patent.").

[141] *See id.*

[142] *Mayor of Baltimore*, 42 F.4th at 712-15 (Judge Easterbrook supporting his opinion by reasoning that "weak patents are valid" and if AbbVie made 132 inventions, it should hold 132 patents).

B. Current Patent Legislation Should Be Reformed Because It Is Contributing to Patent Thickets

This Section focuses on whether the claimed invention shows a significant cognitive leap over what is in the existing public knowledge pool.[143] Pharmaceutical companies push the boundaries of the utility[144] and obviousness[145] requirements to "game" the system and obtain patents that contribute to patent thickets.[146] To be granted a patent, the application must be of patentable subject matter,[147] useful,[148] novel,[149] nonobvious,[150] and adequately described.[151] Two sections of the Patent Act that contribute to the development of patent thickets are the utility and nonobvious requirements, Section 101 and Section 103 respectively.[152] These sections outline two of the requirements a patent applicant must meet before a patent can be issued.[153] Section 101 addresses the utility requirement, which does not demand that the applicant show that the invention is in any way better or more useful

[143] *See* 35 U.S.C. § 103; Gregory N. Mandel, *A Nonobvious Comparison: Nonobviousness Decisions at the PTAB and in the Federal Courts*, 24 TEX. INTELL. PROP. L.J. 403, 404-07 (2016).

[144] *See* 35 U.S.C. § 101.

[145] *See id.* § 103.

[146] *See generally* Melody Petersen, *A Question of Timing: A Lawsuit Claims Gilead Sciences Could Have Developed a Less-Harmful Version of Its HIV Treatment Sooner*, L.A. TIMES (May 29, 2016, 8:33 AM PST), https://www.latimes.com/ business/la-f-gilead-20160529-snap-story.html [https://perma.cc/R297-HX8R] ("By modifying a drug's formula, combining it with other medicines or even changing its dispenser, a company can file for additional patents and extend the period when it can charge premium prices.").

[147] *See* 35 U.S.C. § 103.

[148] *See id.*

[149] *See id.* § 102(a).

[150] *See id.* § 103.

[151] *See id.* § 112.

[152] *See id.* §§ 101, 103.

[153] See *supra* Part I.B for a discussion of the patent application process and the full requirements an applicant needs to satisfy in order to be granted a patent from the USPTO.

than what is already readily available.[154] Section 103 requires the patent claim to be non-obvious.[155]

The USPTO is tasked with the difficult role of assessing questions of pharmaceutical drug novelty early on in the drug research process before comprehensive data has been accumulated to verify whether the Sections 101 and 103 elements have been satisfied in a way that is clinically meaningful.[156] At the time of patenting, there is not enough evidence to ascertain a drug's true efficacy in humans.[157] Meeting the elements to obtain a patent does not clearly factor in the clinical significance of the new innovation.[158] The USPTO is a "primarily technical agency with expertise in invention but not in the clinical trials that produce evidence of efficacy."[159] Therefore, the USPTO does not have enough information to see the clinical portion and understand if there are any material differences between the existing patent and any follow-up patent requests.[160] Typically questions of clinical materiality and similarity are in better focus and resolved years after the patent is issued through patent litigation.[161]

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[154] *See* 35 U.S.C. § 101; Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 181 (2016) ("The granting of a patent by the U.S. Patent and Trademark Office . . . certainly does not guarantee, or even suggest, that the reformulated product is superior in any way to existing products.").

[155] *See* 35 U.S.C. § 103.

[156] *See* Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363, 403 (2014) ("The evidence needed to ascertain a drug's true efficacy in humans is not usually available at the time of patenting, which occurs relatively early in the research and development process.").

[157] *See id.*

[158] *See id.*

[159] *Id.* at 401.

[160] *See* Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 396-400 (2008).

[161] *See* CHARLES SHIFLEY & JOSEPH BERGHAMMER, THE BASICS OF U.S. PATENT LITIGATION (2014), https://bannerwitcoff.com/_docs/library/articles/basiclit.pdf [https://perma.cc/SR2E-WVLK]. Though pendency at the trial court level can vary, on the whole, U.S. patent litigation takes years. *Id.* The time it takes from filing a complaint to final judgement typically takes three to five years. *Id.* Factoring in the appeals process, some cases can take between seven to ten years. *Id.* This estimate of time it takes from complaint to judgement at the trial level does not include "rocket dockets" which can take a year. *Id.*

Despite how important it is to limit the development of patent thickets, not all incremental pharmaceutical innovations are bad. In fact, some incremental innovations can provide significant enough changes to drug efficacy.[162] For example, extended-release formulations can offer the same therapeutic benefit from a smaller number of tablets than immediate-release, which can in turn help with patient compliance.[163] Other small modifications can offer large comparative health benefits over their "regular" counterparts, like reduced side effects.[164] However, the fact that some small, incremental changes to bioactive molecules in drugs *can* render a change, further strengthens the position that there needs to be some sort of comparative analysis baked into the patent process.[165] It is necessary to develop a framework within the existing patent process to sift through and identify which of the seemingly incremental changes render large clinical impacts versus those that have no clinical impacts. Only the changes with clinical impacts are meaningfully within the scope of patent protections while those changes lacking clinical significance contribute to patent thickets in the field.[166] Comparative evidence evaluating the clinical impact of follow-up patents has a critical role to play in the patenting process, especially in the pharmaceutical field where companies are filing multiple patents on the same drug.[167] Incremental modifications that

[162] Some drug manufactures argue that the additional, incremental patents are legitimate innovations. *See* Seymore, *supra* note 66, at 83 ("Drug firms contend that these follow-on patents are legitimate innovations.").

[163] Dimitry Karshtedt, *The More Things Change: Improvement Patents, Drug Modifications, and the FDA*, 104 IOWA L. REV. 1129, 1141 (2019).

[164] *Id.*; *see also* Ali Nokhodchi, Shaista Raja, Priya Patel & Kofi Asare-Addo, *The Role of Oral Controlled Release Matrix Tablets in Drug Delivery Systems*, 2 BIOIMPACTS 175, 175-78 (2012).

[165] *See* Exec. Order No. 14036, 86 Fed. Reg. 36987, 36997 (July 9, 2021) ("[T]o help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law . . . through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office . . . .").

[166] *See id.*; Petersen, *supra* note 146.

[167] *See* Hacohen, *supra* note 2, at 486-87 ("The market value for the anti-inflammatory biologic drug Humira, for example, is worth close to $40 million a day to AbbVie, its brand-name manufacturer. As of 2017, AbbVie filed 247 patent applications related to

have clinically significant effects for the patient, such as reduction in side effects and improvement in drug efficiency, are a tangible starting point to begin differentiating between modifications that are worthy of a patent versus those that are not.[168]

C. Perverse Incentives Affect Public Health

The intersection of patent law incentives pushing for the monetization of exclusivity rights, combined with the inefficient market outlined in Part I,[169] can lead to the patenting of harmful commodities[170] to get around the obviousness requirement.[171]

An example of this practice is the drug Imbruvica.[172] Imbruvica is an anticancer agent which utilizes its toxic design to kill the cancer cells within the target body.[173] The manufacturer of Imbruvica recommended a dosage much higher than what was needed to realize its therapeutic effect.[174] The recommended dosage of Imbruvica was set at the high level because the USPTO had rejected patents for the lower dosages because they were "obvious" and therefore unpatentable.[175] During trials for FDA approval of Imbruvica, the FDA reiterated its assessment that the

Humira, over 100 of which have already been issued. If unchallenged, the combined legal protection provided by these patents would reach 2034, over three decades since the drug was launched and nearly two decades after the lead patent for the drug has expired.").

[168] Some drug manufacturers argue that the additional, incremental patents are legitimate innovations. *See* Karshtedt, *supra* note 163, at 1141; Seymore, *supra* note 66, at 83 ("Drug firms contend that these follow-on patents are legitimate innovations."); *see also* Nokhodchi et al., *supra* note 164, at 175-78.

[169] See *supra* notes 79 for a discussion of the unique market structure within the pharmaceutical industry and some of the reasons for this.

[170] *See* Feldman et al., *supra* note 140, at 914.

[171] *See* 35 U.S.C. § 103.

[172] *See* Feldman et al., *supra* note 140, at 914.

[173] *See id.*

[174] *See id.* (the FDA asserting that "the proposed dose is 2.4-fold higher than the lowest dose that resulted in . . . maximum clinical response").

[175] *See id.* at 915 ("The patent examiner evaluating Pharmacyclics' method of treatment patents found lower doses obvious on the basis of the 2009 and 2010 conference and press release disclosures, which occurred more than a year before the relevant patent was filed. Only the highest doses — 420 mg and higher — were granted in the issued method of treatment patent.").

labeled dose was higher than necessary and explicitly suggested studying the clinical effect of lower doses.[176] This case exemplifies how patent law created the perverse incentive to pursue a patent for a higher dose of a toxic drug[177] rather than the lower dose the FDA suggested be explored more through clinical trials.[178]

As seen in the Imbruvica example, the motivation to secure a patent within the current structure of the patent system can have harmful effects on the general public.[179] In this case, Imbruvica pursued patenting of higher and higher dosages, even when the clinical prudency was questioned by the FDA.[180] The manufacturer did not follow FDA recommendations to study the lower dosages because they lacked the economic incentives to do the research.[181] Professor Feldman, a leading legal scholar in the field, wrote: "[A]ny information on safer dosing outside the scope of the issued claims would undermine the value of the existing patent, and they would be unable to get a new patent for the safer dose on grounds of obviousness."[182]

Although Imbruvica is one example, it may be an indicator for a broader problem in the pharmaceutical industry, with far reaching policy implications.[183] For instance, Gilead Sciences may have intentionally delayed a less-toxic version of its HIV medication until its release benefited their patent portfolio, when the original patent was close short of expiring.[184] Moreover, a U.S. Senate investigation found that certain antibiotic drugs were either useless or dangerous.[185] All of the drugs were developed with the incentive to bring something "new"

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[176] *See id.* at 914-15.

[177] *See id.* at 916 (discussing how the excess dosing may result in unnecessary cardiovascular toxicities for patients).

[178] *See id.* at 914.

[179] *See id.*

[180] *Id.*

[181] *Id.*

[182] *Id.* at 915.

[183] *Id.*

[184] *See* Petersen, *supra* note 146 ("The critics believe the new, less harmful form of the drug could have been developed sooner — and wasn't because [Gilead] wanted to extend its patent-protected profits.").

[185] *See* Feldman et al., *supra* note 140, at 915.

to the market.[186] The pressure within the pharmaceutical industry to continue developing and patenting technologies can have serious consequences for the public.[187]

III. SOLUTION: INTEGRATING THE USPTO AND FDA EARLY IN THE PATENT PROCESS

Patents are typically obtained and later used to take legal action against alleged infringers to limit competition in a business sector.[188] Involving the FDA earlier in the patent process for applications seeking approvals for incremental changes can help detect patents that contribute to the patent thicket, while allowing clinically significant patent applications to move forward.[189] More communication between the FDA and the USPTO can help bridge the clinical utility and non-obviousness gap that is described above[190] sooner than patent litigation, which is often years down the line. The USPTO and the FDA ask two legally different but inherently linked questions with the overarching goal to improve the quality of the healthcare system. The USPTO examines an invention to determine if it possesses the qualities necessary to warrant exclusivity protection,[191] while the FDA analyzes clinical data, among other things, to approve drugs for public use.[192]

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[186] *Id.*

[187] *See id.*

[188] *See generally* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEXAS L. REV. 503, 505 (2009) (discussing how patents offer a way to postpone competition from generic drugs which allows pharmaceutical companies to recoup profits to offset high research and development costs).

[189] *See* Exec. Order No. 14,036, 86 Fed. Reg. 36987, 36997 (July 9, 2021) ("[T]o help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law . . . through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office . . . ."); *see also* Petersen, *supra* note 146 ("By modifying a drug's formula, combining it with other medicines or even changing its dispenser, a company can file for additional patents and extend the period it can charge premium prices.").

[190] See *supra* Part II for a discussion of ways pharmaceutical companies push the boundaries of the obviousness requirement within the existing patent framework.

[191] *See* 35 U.S.C. §§ 101, 102, 103, 112.

[192] 21 U.S.C. § 393; *see* Karshtedt, *supra* note 163, at 1139-41.

Typically, the FDA is not involved in weighing in on the comparative importance of new drug iterations compared to the original when the USPTO is examining a patent application for an incremental change to an existing technology. In particular, this allows pharmaceutical companies to seek patents on modifications to their original patent that may provide little to no therapeutic benefit to the patient when compared to the original drug.[193] Including the FDA into the assessment of patents for iterative improvements to already existing drugs can provide the USPTO with the clinical expertise needed to grapple with the fundamental Sections 101 and 103 questions that are at the heart of patentability.[194]

Involving the FDA and USPTO aides in weeding-out applications containing marginal cosmetic changes from meaningful clinical output. Giving two complimentary regulatory agencies, like the FDA and USPTO, the opportunity to provide input at the same time in the patent process can help reduce patent redundancies and improve the clinical significance of incremental patents.[195] Centralizing two of the main agencies involved in the pharmaceutical drug space and allowing them to provide their input on patents before they are issued will increase the clinical quality of the patents issued, and in turn reduce the number of patents that may be contributing to patent thickets.[196]

Though a framework to prevent evergreening has not yet been developed into the patent process here in the United States, other countries, like India, have integrated this safeguard into the text of their

[193] Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies — Should Competition Law Intervene?*, 51 INT'L REV. INTELL. PROP. & COMPETITION L. 1062, 1069 (2020). *See generally* G. Caleb Alexander & Randall S. Stafford, *Does Comparative Effectiveness Have a Comparative Edge?*, 301 JAMA 2488, 2488-89 (2009) (suggesting how to incorporate comparative effectiveness analysis in the FDA approval process).

[194] *See* 35 U.S.C. §§ 101, 102, 103, 112.

[195] *See generally* Karshtedt, *supra* note 163, at 1144 ("At present, drug modifications are driven largely by the carrot of patentability, but the regulatory mix lacks an effective stick against firms that undertake drug changes that are, at best, questionable in terms of their marginal clinical benefits.").

[196] *See* Feldman et al., *supra* note 140, at 916 (discussing how there needs to be more coordination between the FDA and the USPTO to help prevent patent repetition and instances of patent gaming).

patent law.[197] The Indian system proved efficient in distinguishing between novel incremental changes and cosmetic changes that furthered pharmaceutical evergreening in the case of the drug Glivec.[198] Glivec is a drug manufactured by the pharmaceutical company Novartis to treat Chronic Myeloid Leukemia, a common blood cancer in Eastern countries.[199] In 2006, the Indian Patent Office refused to issue Novartis a patent for Glivec, citing Section 3(d) of the Indian Patent Act.[200] Under Section 3(d), the Patent Office held that what Novartis was applying for was only a modified version of an already existing drug, Imatinib.[201] Therefore, it was not innovative and unpatentable. After many rounds of appeals, the Supreme Court of India held that Novartis' patent application for Glivec did show an improvement of bioavailability, but lacked enhanced efficiency, and was therefore not patentable.[202] The standard set forth by Indian Patent law that the pharmaceutical manufacturer must meet is "enhanced or superior efficacy."[203] The court emphasized that not all incremental patents are barred by the Patent Act, only those failing to show improvement to efficacy when compared to the existing drug.[204] The U.S. patent law framework has not addressed evergreening, but looking at other countries, like India, which have taken steps to tackle the evergreening problem can provide an important foundation for the U.S. moving forward.[205]

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[197] *See* Ravinder Gabble & Jillian Clare Kohler, *To Patent or Not to Patent? The Case of Novartis' Cancer Drug Gilvec in India*, 3 GLOBALIZATION & HEALTH, 2014, at 1, 1-2 ("India's pharmaceutical industry is considered as the [third] largest in the world in terms of volume and the [fourteenth] in terms of its value.").

[198] *See id.*

[199] *Id.* at 1.

[200] The Patents Act, 1970, § 3(d) (India); *see* Gabble & Kohler, *supra* note 197, at 1.

[201] The Patents Act, 1970, § 3(d) (India); *see* Gabble & Kohler, *supra* note 197, at 1.

[202] *See* Gabble & Kohler, *supra* note 197, at 1.

[203] Editorial, *India's Novartis Decision*, N.Y. TIMES (Apr. 4, 2013), https://www.nytimes.com/2013/04/05/opinion/the-supreme-court-in-india-clarifies-law-in-novartis-decision.html [https://perma.cc/4W38-ESYY] ("[T]he court found that Novartis did not convincingly show that the drug offered 'enhanced or superior efficacy' as Indian law requires.").

[204] *Id.* ("The court noted that the decision should not be read as prohibiting patents on all incremental innovation.").

[205] *Id.*

CONCLUSION

The pharmaceutical industry continues to grow its profit margins year after year,[206] and does so in part by weaponizing the patent system beyond its intended purpose.[207] Companies have been able to continuously monetize their innovations past the intended twenty-year exclusivity period, partly because courts are relying on the surface level of patent issuance rather than scrutinizing how that patent plays into a defensive portfolio to build a wall around profitable drugs.[208] Further, the language of patent legislation itself is lending to the gaming of the patent system. Specifically, Sections 101[209] and 103[210] of the Patent Act contribute vagueness in the patenting process that allows incremental patents to get approved "under the radar," which then contributes to patent thickets. Therefore, there needs to be a modification of the patent law framework to help re-align the incentives of the pharmaceutical industry with patents that are clinically insignificant, rather than monopolizing their innovations past the twenty-year period.[211] For this reason, the proposed solution of having the FDA play a role in the patent application and approval process can help vet patent applications for incremental, insignificant clinical purposes before they ever get approved.[212] Coordination between the FDA and USPTO can ultimately help prevent patent thickets at the source.

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[206] *See* Chris Kolmar, *26 Incredible U.S. Pharmaceutical Statistics* [*2022*]*: Facts, Data, Trends and More*, ZIPPIA (Sept. 25, 2022), https://www.zippia.com/advice/us-pharmaceutical-statistics/ [https://perma.cc/2F6L-X865].

[207] *See* U.S. CONST. art. I, § 8, cl. 8. This notion has been reinforced by the Supreme Court. *See* Motion Picture Pats. Co. v. Universal Film Mfg. Co., 243 U.S. 502, 511 (1917).

[208] *See* Immunex Corp. v. Sandoz Inc., 964 F.3d 1049, 1065-67 (Fed. Cir. 2020); Mayor of Baltimore v. AbbVie Inc., 42 F.4th 709, 713 (7th Cir. 2022).

[209] 35 U.S.C. § 101.

[210] *Id.* § 103.

[211] *See supra* Part II.

[212] *See* Karshtedt, *supra* note 163, at 1141; *supra* Part III.