Why Pharmaceutical Patent Thickets Are Unique

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Abstract

Companies have protected their products with large portfolios of patents. The drug company AbbVie, for example, has collected more than 100 patents on its blockbuster drug Humira. Many have raised concerns about such "patent thickets" in the pharmaceutical industry, which have become a pressing concern given the increasing frequency of thickets and effects on patients' lives. In response, some have downplayed concern by pointing to large patent portfolios in other industries, in particular, high technology. This Essay offers the first refutation of this argument, explaining why it fails on two basic levels.

First, pharmaceutical companies have all of the patents they need to enter the market. As a result, they do not need to license, instead accumulating patents to block rivals. In contrast, because of the presence of patents from multiple owners in products, high-technology firms need to engage in "cross licensing," which leads them to amass patents. Exclusion is exacerbated by the pharmaceutical industry's higher regulatory barriers and firm concentration.

Second, we offer original empirical evidence supporting our hypothesis that pharmaceutical firms use duplicative patents to block market entry. We learn useful information from an analysis of "continuation patents," which cannot disclose any new matter. We find that continuations have recently increased in the pharmaceutical industry, especially as compared to the high-technology industry. We also find that the pharmaceutical industry litigates continuation patents at a much higher rate than the high-technology industries, which is consistent with keeping rivals off the market. We show similar results for "method-of-use patents," which drug firms have used to delay generic entry, and for the Humira patent thicket.

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Companies have protected their products with large portfolios of patents. The drug company AbbVie, for example, has collected more than 100 patents on its blockbuster drug Humira.[1] Many have raised concerns about such "patent thickets" in the pharmaceutical industry, which have become a pressing concern given the increasing frequency of thickets and effects on patients' lives. In response, some—such as the industry and U.S. Court of Appeals for the Seventh Circuit[2]—have downplayed concern by pointing to large patent portfolios in other industries, in particular, high technology. This Essay offers the first refutation of this argument, explaining why it fails on two basic levels.

First, pharmaceutical companies have all of the patents they need to enter the market. As a result, they do not need to license, instead accumulating patents to block rivals. In contrast, because of the presence of patents from multiple owners in products, high-technology firms need to engage in "cross licensing," which leads them to amass patents. Exclusion is exacerbated by the pharmaceutical industry's higher regulatory barriers and firm concentration.

Second, we offer original empirical evidence supporting our hypothesis that pharmaceutical firms—in particular, biologic manufacturers—use duplicative patents to block market entry. We learn useful information from an analysis of "continuation

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1 Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 711 (7th Cir. 2022).
2 *See infra* Parts II.B and II.C.

patents," which are patents that cannot disclose any new matter. Continuation patents are particularly important since they are the foundation of most pharmaceutical patent thickets.[3] We find that continuations have recently increased in the pharmaceutical industry, especially as compared to the high-technology industry. We also find that the pharmaceutical industry litigates continuation patents at a much higher rate than the high-technology industries, which is consistent with keeping rivals off the market. We show how the findings on continuations and litigated continuations are mirrored for "method-of-use patents," which drug firms have used to delay generic entry. And in examining the Humira patent thicket, we find that most of the patents are continuations, most of even the original filings are secondary patents, and in the period shortly before exclusivity expired, the percentage of litigated continuation patents significantly increased.

We begin by first describing patent thickets in the pharmaceutical and high-technology industries and introducing continuation patents. We then discuss the most well-known pharmaceutical thicket: AbbVie's Humira. Next, we offer distinctions between pharmaceutical and high-technology portfolios based on licensing, regulatory barriers, and industry concentration. We conclude by discussing our findings, which show how continuation patents are used differently in the industries and are most likely employed to block rivals in the pharmaceutical setting.

I. Patent Thickets

A patent thicket is "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees."[4] Patent thickets can describe two different situations.[5] One involves multiple parties having overlapping patent rights on a single product, which requires competitors to negotiate licenses with each other to bring the product to the market. In this setting, patent thickets raise concerns about the inefficient exploitation of a technology because multiple patent owners must coordinate to cross license the technology.[6]

A second setting involves a single party creating a large web of patents to deter or delay competitor market entry. In this context, the firm need not coordinate or negotiate with others. Each of the two settings can present anticompetitive harms: the first by increasing the costs of reaching the market and the second by excluding competitors from the market.

This Part discusses thickets in the pharmaceutical and high-technology industries. It then introduces continuation patents, explaining the role they play in thickets.

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[3] S. Sean Tu, Aaron S. Kesselheim, Kathrine Wetherbee & William B. Feldman, *Changes in the Number of Continuation Patents on Drugs Approved by the FDA*, 330 JAMA 469, 469 (2023), https://pubmed.ncbi.nlm.nih.gov/37526728/.

[4] Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* INNOVATION POLICY AND THE ECONOMY 119, 119 (2001), https://www.nber.org/system/files/chapters/c10778/c10778.pdf.

[5] Stu Woolman, Elliot Fishman & Michael Fisher, *Evidence of Patent Thickets in Complex Biopharmaceutical Technologies*, 53 IDEA 1, 7 (2013).

[6] The thickets described in the text are often referred to as patent portfolios.

A. Pharmaceutical Thickets

Pharmaceutical patent thickets are generally built from "secondary patents"[7] that take the form of minor alterations to an existing drug rather than new chemical entities.[8] These alterations include, for example, changing the formulation (extended release), dosage, or route of administration (such as capsules, tablets, and topicals).[9]

In contrast, "primary" patents cover the new chemical entity (in other words, the active pharmaceutical ingredient) and tend to be "stronger" because they are broader and more difficult to invalidate.[10] Primary patents typically provide the most robust protection because any competitor who uses the same chemical compound will infringe the patent regardless of dosage, route of administration, formulation, or method of use. Primary patents also are more difficult to invalidate because "prior art"[11] directed to chemical compounds is well indexed in commercial databases.[12] As Scott Hemphill and Bhaven Sampat have demonstrated, drug companies are more likely to win on primary active-ingredient patents (92%) than on secondary patents (32%).[13]

One of us has shown that "[t]he overwhelming majority of litigated [pharmaceutical] patents are not 'primary' patents directed to new chemical entities, but follow-on patents that claim changes in formulation, dissolution profile, new uses, and the like."[14] These "secondary, follow-on patents" are "aimed at complicating generic entry and extending patent life" and in many cases are "from the same family,

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7 *See, e.g.*, S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. U. L. REV. 1673, 1700 tbl.1 (2022); Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE, Dec. 2012, at 4 tbl.1.

8 Michael Burdon & Kristie Sloper, *The Art of Using Secondary Patents to Improve Protection*, 3 INT'L J. MED. MKTG. 226 (2003).

9 Kapczynski, Park & Sampat, *supra* note 7, at 4; *see also* Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, J. L. & BIOSCIENCES, July–Dec. 2022, at 18 tbl.4, https://doi.org/10.1093/jlb/lsac022 (showing different types of patents associated with Humira patent thicket).

10 Tu & Lemley, *supra* note 7, at 1692 fig.4 (showing that 134 of the 142 patents that courts held invalid were secondary while only 8 were primary).

11 Prior art consists of references or documents that can be used to determine the novelty or non-obviousness of claimed subject matter in a patent. It typically takes the form of printed documents such as patents and published patent applications as well as "non-patent literature" such as magazine articles, newspaper articles, electronic publications, online databases, websites, and Internet publications. MANUAL OF PATENT EXAMINING PROCEDURE chs. 2126–28 (9th ed. Rev. 7, Feb. 2023) [hereinafter MPEP], https://www.uspto.gov/web/offices/pac/mpep/index.html; *see, e.g.*, S. Sean Tu. *Patenting Fast and Slow: Examiner and Applicant Use of Prior Art*, 38 CARDOZO ARTS & ENT. L.J. 391, 396 (2020).

12 *See, e.g.*, CAS DATABASES, https://www.cas.org/support/documentation/cas-databases (last visited Apr. 9, 2023) (listing databases including CAS SciFinder and CAS STNext).

13 C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCI. 1386, 1387 (2013) (examining completed patent litigation on drugs first eligible for challenges between 2000 and 2008).

14 Tu & Lemley, *supra* note 7, at 1691 (findings refer to "Orange Book" patents, discussed *infra* note 119).

often obvious variants of each other."[15] The creation of patent thickets through "very large patent families" is designed "to increase costs for generic manufacturers," for example "by rendering inefficient" the use of patent challenge procedures at the U.S. Patent and Trademark Office (PTO).[16] As we show below,[17] patent thickets consist in large part of continuation patents.

The problem of patent thickets and continuation patents has drawn the attention of Congress. In June 2022, six Senators wrote a letter to the PTO outlining concerns with patent thickets created by continuations. In response, PTO Director Kathi Vidal and Food and Drug Administration (FDA) Commissioner Robert Califf have begun to collaborate to implement President Biden's Executive Order to "ensure that the patent system . . . does not . . . unjustifiably delay generic drug and biosimilar competition."[18] In March 2023, a bipartisan group of representatives led by Jodey Arrington (R-TX) asked Director Vidal to consider implementing policies to help prevent pharmaceutical patent thickets.[19] And in April 2023, Senator Elizabeth Warren (D-MA) and Representative Pramila Jayapal (D-WA) asked Director Vidal to address the patent thickets created by large families of continuation patents.[20]

In short, pharmaceutical patent thickets are chiefly made up of secondary patents, which are less innovative than primary patents and more likely to be overturned. This supports our hypothesis that thickets are used in the industry to deter or delay the entry of generic drugs. Drug manufacturers are able to do this by increasing the risk of litigation—and its accompanying large damage awards—based on the sheer size of their portfolios. Pharmaceutical thickets, in other words, are made up of patents that are not licensed to competitors but are used to build a moat around the drug's ability to generate revenue.[21]

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15 *Id.* at 1707–08.

16 *Id.* at 1713–14 ("[J]uries as well as judges may be overwhelmed by the information needed to invalidate each patent . . . .").

17 *See infra* Part IV.

18 Letter from Katherine K. Vidal, Dir., U.S. Pat. & Trademark Off., to Robert M. Califf, Comm'r, U.S. Food & Drug Admin. (July 6, 2022) [hereinafter Vidal Letter], https://www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf; *see also id.* at 6 (suggesting "greater scrutiny" of "continuation applications in large families").

19 Press Release, Jodey Arrington, House of Representatives, Arrington Leads Bipartisan Letter Urging U.S. Patent Office to Address Drug Pricing Through Competition (Mar. 27, 2023), https://arrington.house.gov/news/documentsingle.aspx?DocumentID=956.

20 Press Release, Elizabeth Warren, Senate, Warren, Jayapal Call on Patent Office to Take Critical Steps to Lower Drug Prices and Fight Big Pharma's Patent Abuse (Apr. 27, 2023), https://www.warren.senate.gov/oversight/letters/warren-jayapal-call-on-patent-office-to-take-critical-steps-to-lower-drug-prices-and-fight-big-pharmas-patent-abuse. The Inflation Reduction Act allows Medicare to negotiate prices for drugs, but only those that "lack a generic or biosimilar competitor," which could encourage firms with patent thickets to allow limited biosimilar competition. Arti K. Rai, Rachel E. Sachs & W. Nicholson Price II, *Cryptic Patent Reform Through the Inflation Reduction Act*, HARV. J. L. & TECH. (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4402378. But even if this is the case, there still "remains value in patents in forestalling the bulk of competition, even if all competitors cannot or will not be excluded." *Id.* at 36.

21 The one exception are platform-type method-of-manufacture patents, which are cross-licensed

B. High-Technology Thickets

The high-technology industry is different. For starters, thickets are typical. As the U.S. Department of Justice Antitrust Division and the Federal Trade Commission (FTC) have explained: "In many industries, the patent rights necessary to commercialize a product are frequently controlled by multiple rights holders."[22] In the high-technology industry, there can be hundreds, if not thousands, of patents in a single product. One famous estimate, for example, concluded that there are 250,000 patents in a smartphone.[23]

For that reason, companies in these industries frequently must enter into licensing arrangements. Unlike the pharmaceutical industry, where a single firm amasses a thicket, participants across the high-technology industry accumulate patents to increase bargaining power.[24] For example, in the context of standards, which are common platforms allowing products to work together, organizations have adopted rules that encourage licensing.[25] One of the most common such rules requires owners of patents necessary to use the standard (known as standard essential patents, or SEPs) to license those patents on fair, reasonable, and nondiscriminatory (FRAND) terms.[26] At their best, such rules, together with more general licensing norms in the industry, encourage a "litigation-free zone"[27] that enables "patent peace" allowing firms "to improve current products or design new products without fear of infringement."[28]

At the same time, however, licensing can allow "powerful firms to favor themselves and make it more difficult for upstarts to challenge the dominance of current market leaders."[29] One example is offered by IBM, which in the 1980s claimed that "Sun infringed seven of its patents," to which Sun "provided evidence" that it "did not infringe all seven patents, but perhaps only one."[30] IBM then

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between firms. *See* Arti Rai, W. Nicholson Price II & Saurabh Vishnubhakat, *The Accumulation and Assertion of Biologics Manufacturing Process Patents* (unpublished manuscript) (on file with authors).

22 U.S. DEP'T. OF JUSTICE & FED. TRADE COMM'N, ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS: PROMOTING INNOVATION AND COMPETITION (2007) [hereinafter ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS REPORT], https://www.justice.gov/atr/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition.

23 RPX Corporation, *Registration Statement (Form S-1)*, SEC & EXCH. COMM'N 59 (Sept. 2, 2011), https://www.sec.gov/Archives/edgar/data/1509432/000119312511240287/ds1.htm.

24 Olga Gurgula, *Strategic Accumulation of Patents in the Pharmaceutical Industry and Patent Thickets in Complex Technologies—Two Different Concepts Sharing Similar Features*, 48 INT'L REV. INTELL. PROP. & COMPETITION L. 385 (2017).

25 Michael A. Carrier, *Why Property Law Does Not Support the Antitrust Abandonment of Standards*, 57 HOUS. L. REV. 265, 267 (2019).

26 Jorge Contreras, *Global Rate-Setting: A Solution for Standards-Essential Patents?*, 94 WASH. L. REV. 701, 704 (2019).

27 Shapiro, *supra* note 4, at 133.

28 ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS REPORT, *supra* note 22, at 60; *see also infra* note 109 (discussing "patent pools").

29 Shapiro, *supra* note 4, at 133.

30 Darryl K. Taft, *Why IBM Is the Most Innovative Company in IT*, EWEEK (Aug. 4, 2011), https://www.eweek.com/networking/why-ibm-is-the-most-innovative-company-in-it/.

purportedly responded: "[M]aybe you don't infringe these seven patents," but "we have 10,000 U.S. patents" and "[d]o you really want us to go back to Armonk [the IBM headquarters in New York] and find seven patents you do infringe? Or do you want to make this easy and just pay us $20 million?"[31] More recently, Cesare Righi and Timothy Simcoe found that more than half of the SEPs they analyzed "are based on continuation applications filed after standard publication" and that "there is a large increase in continuation filings immediately after a standard is published."[32]

In short, although licensing in the high-technology industry can have anticompetitive effects, it also can be a means to address potential bottlenecks from patent thickets. In fact, given the prevalence of products covered by numerous patents, licensing is crucial in the industry.

C. Continuation Patents

A central technique to creating patent thickets involves continuation patents (continuations).[33] Continuation patents are based on the same invention description and drawings as a previously filed application, and their disclosure is identical or nearly identical to a previous application.[34] In fact, the defining characteristic of a continuation patent is that it *cannot* add new material, new illustrations, or new matter to the parent application.[35]

Because continuation patents cannot disclose new material, they move through patent examination faster than a typical application. Continuations from the same family tend to be assigned to the patent examiner who examined the other related family members.[36] Examiners who previously reviewed the parent patent are likely to be familiar with the technology disclosed in the application as well as the prior art. Speed also is increased as pharmaceutical applicants filing continuations tend to request "Track One" status, a fee-based service that allows for prioritized examination,[37] with the goal of concluding patent prosecution within one year.[38]

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[31] *Id.* For a discussion of how patent thickets "significantly reduce entry into those technology areas in which growing complexity and growing opportunity increase the underlying demand for patent protection," see Bronwyn H. Hall, Georg von Graevenitz & Christian Helmers, *Technology Entry in the Presence of Patent Thickets*, 73 OXFORD ECON. PAPERS 903, 923 (2021).

[32] Cesare Righi & Timothy Simcoe, *Patenting Inventions or Inventing Patents? Continuation Practice at the USPTO* 38–39 (NBER Working Paper No. 27686, 2020), https://www.nber.org/papers/w27686.

[33] *See* MPEP, *supra* note 11, ch. 201.02.

[34] To obtain a valid patent, an application must contain a full and clear disclosure of the invention in the manner prescribed by 35 U.S.C. § 112(a). Requiring an adequate disclosure ensures that the public receives something in return for a patent's exclusionary rights. MPEP, *supra* note 11, ch. 608.

[35] MPEP, *supra* note 11, ch. 211.05(B) (stating that the "disclosure of a continuation application must be the same as the disclosure of the prior-filed application; i.e., the continuation must not include anything which would constitute new matter if inserted in the original application").

[36] Tu & Lemley, *supra* note 7, at 1694.

[37] *Id*. at 1695–96; *see also* Colleen V. Chien, Nicholas Halkowski & Jeffrey Kuhn, *Distinguishing and Predicting Drug Patents*, 41 NATURE BIOTECHNOLOGY 317, 317 (2023).

[38] *See* USPTO's Prioritized Patent Examination Program, https://www.uspto.gov/patents/initiatives/usptos-prioritized-patent-examination-program (last visited Apr. 10, 2023).

Continuation patents that are linked to the same family[39] all have the same expiration date. As a result, these large families do not create an "evergreening" problem that extends the period of exclusion.[40] But continuation patents still can serve as a building block of thickets that can include dozens (if not more) of overlapping patents of questionable validity that may expand the scope of protection. Inventors are allowed only one patent per invention,[41] and many continuations are obvious variations of the claims in the parent patent. That is why the most common rejection faced by continuations is the "obviousness-type double patenting rejection," which provides that the continuation is an obvious variation of a previously granted patent.[42] However questionable the continuations are, the fact that the claims must be different from the original patent can harm competitors for reasons having little to do with innovation. In particular, after seeing a rival's product, a patentee can file a continuation that covers the product, which can expand a thicket's scope because the previous (parent) patent may have described the product but not claimed it.[43] As PTO Director Vidal has explained, "multiple patents directed to obvious variants of an invention could potentially deter competition."[44]

Because patents in the same family have the same priority date, patent applicants have an incentive to keep the family "alive" by filing multiple generations of continuations that all refer back to the original "parent" patent.[45] That way, they keep the priority that allows them to sue rivals that file patents afterwards. And as competitors' products reach the market, they can adjust the patent claims to narrowly cover these products.

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[39] A patent family is a collection of patent applications covering the same or similar technical content. The applications in a family are related to each other through priority claims. A priority claim allows the later filed application to claim the benefit of the filing date of an earlier-filed application. *See* 35 U.S.C. §§ 119(e), 120, 121, 365(c), 386(c); *see also* MPEP, *supra* note 11, ch. 211. Accordingly, most patent families share the same specification and disclose the same invention. *Patent Families*, EUR. PAT. OFF., https://www.epo.org/searching-for-patents/helpful-resources/first-time-here/patent-families.html (last visited May 10, 2023). A patent family ID number includes documents such as "published patent applications, U.S. patents, and foreign references." Jan Comfort, *Documenting Your Institution's Patents: A Case Study from Clemson University*, PTRCA, https://ptrca.org/journal_article/comfort/ (last visited May 10, 2023).

[40] *See* Robin Feldman, *May Your Drug Price be Evergreen*, 5 J. L. & BIOSCIENCES 590, 596 (2018).

[41] 35 U.S.C. § 101 (stating that "[w]hoever invents . . . may obtain *a* patent therefor") (emphasis added); MPEP, *supra* note 11, ch. 2104 (stating that 35 U.S.C. § 101 "requires that whoever invents or discovers an eligible invention may obtain only ONE patent therefor," which "prevents two patents issuing on the same invention to the same inventor").

[42] Tu & Lemley, *supra* note 7, at 1702 (showing that obviousness-type double patenting rejections are the most common type of rejection faced by Orange-Book-listed patents). To overcome this rejection, applicants typically file a "terminal disclaimer," which states that the continuation patent will expire at the same time as the patent on which the rejection is based. *Id.* at 1705 (showing that terminal disclaimers are the typical way applicants obviate an obviousness-type double patenting rejection).

[43] S. Sean Tu, *The Long CON: An Empirical Analysis of Pharmaceutical Patent Thickets* (on file with authors).

[44] Vidal Letter, *supra* note 18, at 6.

[45] 35 U.S.C. § 120.

Applicants can do this multiple times, which leads to a parent application being followed by a "child," "grandchild," and so on. A child application, for example, would have a generation number of "1," a grandchild would be generation "2," and a generation of "9" would be the ninth continuation of the parent patent, again with an identical disclosure.[46] As the generation number increases, the patent claims typically get narrower. The narrower claims indicate that continuation patents with higher generation numbers are more likely to be designed to delay or deter competitors from market entry.[47] These higher generations add protection to the same product. In doing so, they can delay rivals by increasing transaction costs because each patent must be cleared before market entry or—if the thicket is large enough—by leading rivals to forego entry due to the increased risk of litigation.

In theory, continuing applications can "help applicants deal with technological, commercial, legal, or examination uncertainty"[48] by delaying prosecution and allowing for delayed claim drafting. For example, continuation applications have long allowed inventors to quickly obtain narrow claims in an original patent (so they could enter the market with some protection) and then acquire broader claims in a later-filed continuation patent.[49] Additionally, continuations allow applicants to pursue claims that were not initially allowed by a "difficult" patent examiner. Finally, if a company is still deciding if the invention is commercially viable, continuation applications allow the applicant to take a "wait and see" approach to see if a technology is valuable before pursuing patents.

Continuation patents, however, were not intended to be a nuisance tool to make it more difficult for competitors to get to market.[50] Continuation practice has been "linked to opportunistic behavior, litigation, the large USPTO backlog,"[51] and the creation of barriers to unjustly delay or deter competitors. One example of the questionable use of continuations is provided by the pharmaceutical industry.

II. Humira

AbbVie has received significant attention for its patent thicket covering Humira. This Part describes the thicket and provides an overview of a court ruling that dismissed concern based on thickets in the high-technology industry.

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46 MPEP, *supra* note 11, ch. 1895.01.

47 Tu, *supra* note 43.

48 Cesare Righi, Davide Cannito & Theodor Vladasel, *Continuing Patent Applications at the USPTO*, 52(4) RSCH. POL'Y, May 2023, at 1.

49 Greg Reilly, *Amending Patent Claims*, 32 HARV. J.L. & TECH. 1, 14 (2018).

50 Most biologic continuations are directed to "secondary" patents (such as formulations, methods of treatment, and methods of manufacture) and not the "primary" patents covering the drug's active ingredient. *See, e.g.*, Rachel Goode, William B. Feldman & S. Sean Tu, *Biologic Patent Thickets and Terminal Disclaimers*, 331 JAMA 355, 356 tbl.1 (2023) (showing that 5/129 (4%) of biologic patents with a terminal disclaimer were primary patents, while 124/129 (96%) were secondary patents).

51 Righi, Cannito & Vladasel, *supra* note 48.

A. Humira's Thicket

Humira is the world's best-selling drug. From 2007 to 2021, Humira generated a staggering $122 billion in revenue.[52] Approved by the FDA in 2002, Humira treats a number of diseases including arthritis, Crohn's disease, ulcerative colitis, and plaque psoriasis.[53] The twelve-year exclusivity period under the regulatory regime expired in 2014, and the primary patent, which covered the active ingredient, expired in 2016.[54]

Humira is a biologic product. Biologics are made from living organisms and are more complex than small-molecule drugs.[55] Biologics face potential rivals known as biosimilars.[56] In part because of the difficulty of developing biosimilars, the price decline in this setting is less dramatic than for small-molecule drugs, albeit still in the range of 20% (for a single entrant) to 30% to 50% (for multiple entrants).[57]

Recognizing an impending dramatic decline in profits from Humira, AbbVie began amassing patents in 2014. In fact, even though the drug was first marketed in 2002, more than 90% of its patents were issued in or after 2014.[58] These additional patents covered aspects less central to the drug, such as the first indication (treatment of rheumatoid arthritis),[59] formulations[60] (such as double concentration[61]), secondary indications (treatment of Crohn's disease),[62] purity levels and method of manufacture,[63] and additional indications (like juvenile diseases).[64]

Even though the patent on the active ingredient expired in 2016, these patents potentially extend exclusivity until 2034.[65] And in fact, the thicket, when combined

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52 *See generally* SSR HEALTH, http://www.ssrhealth.com/ (last visited May 10, 2023) (containing data on more than 1,000 brand-name drugs manufactured by public companies).

53 Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 711 (7th Cir. 2022).

54 *Id.*

55 *What Are "Biologics" Questions and Answers*, U.S. FOOD & DRUG ADMIN. (Feb. 6, 2018), https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

56 *Biosimilar and Interchangeable Biologics: More Treatment Choices*, U.S. FOOD & DRUG ADMIN. (Oct. 12, 2021), https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices ("Unlike conventional medications, biologics generally cannot be made by following a chemical 'recipe.' Because biologics generally come from living organisms, their nature varies, and their structures are generally more complex.").

57 *An Inflection Point for Biosimilars*, MCKINSEY & CO. (June 7, 2021), https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars.

58 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 822 (N.D. Ill. 2020).

59 U.S. Patent No. 8,889,135. An indication is the FDA's approved use(s) of a medication.

60 U.S. Patent No. 8,216,583.

61 U.S. Patent No. 8,420,081.

62 U.S. Patent No. 8,889,136.

63 U.S. Patent No. 8,916,153.

64 U.S. Patent Nos. 8,747,854 & 8,999,337. All indications are related to diseases with an inflammatory response. Ryan Knox & Gregory Curfman, *The Humira Patent Thicket, the Noerr-Pennington Doctrine and Antitrust's Patent Problem*, 40 NATURE BIOTECHNOLOGY 1761, 1761–63 (2022).

65 Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709, 711 (7th Cir. 2022); U.S. Patent No. 6,090,382. For a discussion of how the Humira portfolio consists of only eight patent families,

with entry-delaying settlements, blocked U.S. biosimilar entry until 2023.[66] This was quite lucrative for AbbVie. Of the $122 billion in revenues it received,[67] roughly $48 billion came in the 9 years before the primary patent's expiration, a period in which it was covered by both regulatory and primary patent exclusivity.[68] The remaining $74 billion, then, came outside this period of recoupment envisioned by legislation, reflecting more of an unjustified windfall.

The European Patent Office, in contrast, does not allow continuation patents, which has led to substantially fewer European patents covering Humira.[69] It is not a surprise, then, that Humira biosimilars appeared in Europe as early as 2018 and that prices have significantly fallen as a result.[70]

Continuations play a central role in disputes involving biologic products like Humira. These products, together with certain patent information, are collected in a database known as the "Purple Book."[71] We analyzed the Humira patents in the Purple Book. To be listed in the Purple Book, a patent must be asserted in litigation.[72] Table 1 shows that 52 of the 66 Humira patents (79%) listed between 2003 and 2020 are continuation patents. A staggering 33 of these 52 continuations (63%) were filed in just two years—2014 and 2015—most likely in anticipation of the loss of regulatory exclusivity and expiration of the original primary patent.

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with many patents in each family "linked by terminal disclaimers and so . . . not patentably distinct," see Goode & Chao, *supra* note 9, at 18.

66 *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 824 (N.D. Ill. 2020). *See also* Goode & Chao, *supra* note 9, at 20. We use the terms "thicket" and "portfolio" interchangeably in this piece. Each refers to a collection of patents. Although the former term has more recently been used to denote the more anticompetitive conception of blocking access to the market, the more traditional conception is not so limited. *See* Shapiro, *supra* note 4, at 119 (defining patent thicket as "an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees").

67 *See* SSR HEALTH, *supra* note 52 and accompanying text.

68 *Id.*

69 Goode & Chao, *supra* note 9, at 19–20.

70 Per Troein, Max Newton, Kirstie Scott & Chris Mulligan, *The Impact of Biosimilar Competition in Europe*, IQVIA, at 21 (2021), https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2021.

71 *Purple Book Database of Licensed Biological Products*, U.S. FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/about (last visited Apr. 7, 2023).

72 *See infra* note 126 and accompanying text.

Table 1[73]

Patent Filing Year	Number of Purple Book Patents	Number of Purple Book Continuation Patents / Number of Purple Book Patents	Average Generation Number	Average Duration in Patent Prosecution (Years)
2003 (FDA approval 12/31/2002)	1	0/1 (0%)	1.0	1.5
2004	0	N/A	N/A	N/A
2005	1	0/1 (0%)	1.0	9.6
2006	1	0/1 (0%)	1.0	8.0
2007	1	0/1 (0%)	1.0	10.0
2008	2	0/2 (0%)	1.0	5.6
2009	0	N/A	N/A	N/A
2010	1	1/1 (100%)	2.0	1.9
2011	1	1/1 (100%)	2.0	2.3
2012	3	1/3 (33%)	2.0	2.9
2013	9	4/9 (44%)	2.3	2.0
2014	23	22/23 (96%)	3.0	0.96
2015 (FDA regulatory exclusivity expires)	11	11/11 (100%)	4.1	0.78
2016 (Original primary patent expires)	8	8/8 (100%)	3.9	0.99
2017	1	1/1 (100%)	9.0	0.45
2018	1	1/1 (100%)	9.0	2.8
2019	0	N/A	N/A	N/A
2020	2	2/2 (100%)	8.0	0.90
2003-2013	20	7/20 (35%)	1.9	4.9
2014-2020	46	45/46 (98%)	3.9	1.1
2003-2020 Total	66	52/66 (79%)	3.3	3.4

More generally, AbbVie's patenting behavior seemed to change in 2014 with the impending expiration of exclusivity. While, as Table 1 shows, there were 20 patents listed in the Purple Book with a filing date of 2003 to 2013 (an average of 1.8

[73] The chart ends with 2020 because these were the last patents in the Purple Book as of April 7, 2023.

per year), that rose to 46 with filing dates from 2014 to 2020 (an average of 6.6 per year). This 265% increase in Purple Book patents was accompanied by a significant increase in Purple Book continuations (which, again, by definition were litigated given such a requirement for listing). From 2003 to 2013, 7 of the 20 Purple Book patents (35%) were continuations, but from 2014 to 2020, that figure rose more than 180% to 45 of 46 (98%).[74] Not surprisingly, the increase in continuations was accompanied by a decrease in time in patent prosecution, which fell from roughly 5 years (2003–2013) to 1 year (2014–2020). This reduction in time allowed AbbVie to use continuation patents to quickly establish an extensive network of patents, forming a dense patent thicket based on only a few original disclosures.

The continuation patents used in the Humira patent thicket also are questionable given their reliance on fairly old original patents, with an average generation number of 3.3. In other words, most patents are grandchildren or great-grandchildren of an original patent, signifying narrower claims and potentially anticompetitive continuations.[75] This trend accelerated over time. The patents filed after 2017 had an average generation number of 8 or 9, suggesting that these patents are very narrow and were designed to delay or deter biosimilar entry.[76]

A deeper dive reveals more detail on the patents that were the subject of continuations. Figure 1 shows the Humira patent portfolio segmented by type. The majority of the primary patents (4/7, 57%) are original patents.[77] In contrast, most secondary patents (36/58, 62%) are continuations.[78] Overall, more than half of the Humira portfolio (37/65, 57%) consists of continuation patents.[79] We also found, interestingly, that the majority of original filings (10/14, 71%) are secondary patents directed to method of use (4), formulation (1), device (1), or method of manufacture (4). These data suggest that even the most distinct "original" patents are narrower secondary patents.

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74 This trend was confirmed by an increase in generation number from 1.9 (2003–2013) to 3.9 (2014–2020).

75 Tu, *supra* note 43.

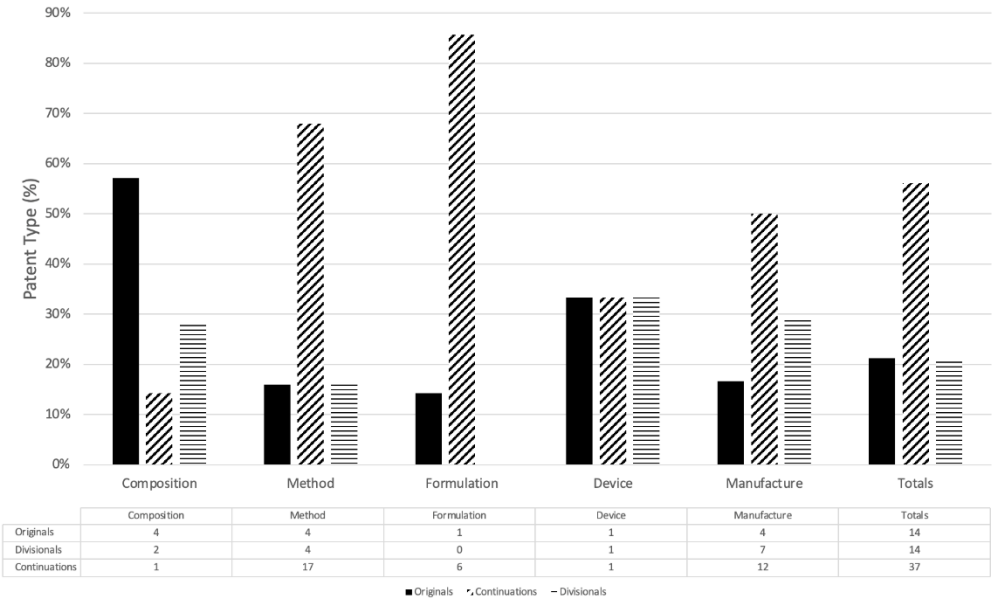
76 For example, the U.S. 9,913,902, U.S. 11,083,792, U.S. 11,167,030, and U.S. 11,191,834 patents each contain narrow formulation claims that are generation 8 or 9. *See also* Goode & Chao, *supra* note 9, at 18–19 (finding that "80% of the U.S. Humira patents are not directed to new, non-obvious inventions").

77 Primary patents are reflected by the composition category in Figure 1. Primary patents can be continuation patents. For example, a polymorph or enantiomer patent is directed to the drug's active ingredient but is also directed to a narrower version of the active ingredient. In addition, original primary patents can have broad chemical genus claims while continuation primary patents will have chemical species claims.

78 For example, 17 of 25 (68%) method-of-treatment patents and 6 of 7 (86%) formulation patents are continuations. Our figures on secondary patents include the method, formulation, device, and manufacture categories.

79 We found that 14 of 66 (21%) of the patents are original. We also found that 14 of 66 (21%) patents were divisional patents (which claim a different invention based on the same disclosure) and 1 of 66 (2%) was a continuation-in-part patent, which adds new material (and is not included in Figure 1).

Figure 1
Humira Patents



	Composition	Method	Formulation	Device	Manufacture	Totals
Originals	4	4	1	1	4	14
Divisionals	2	4	0	1	7	14
Continuations	1	17	6	1	12	37

In short, our analysis of the Humira patents listed in the Purple Book finds that in the period shortly before exclusivity expired, the number of listed patents, the percentage of litigated continuation patents, and the generation number significantly increased. We also found that the majority of the Humira patents were continuations and that most of even the original filings were secondary patents. Each of these developments is consistent with the use of a patent thicket to delay rivals.

B. Antitrust Litigation

The Humira thicket was the subject of antitrust litigation. In 2019, a group of indirect purchasers, led by the City of Baltimore, sued AbbVie, contending that the company's patent thicket violated antitrust law. The plaintiffs claimed that "in the months and years leading up to the expiration of the [patent on the active ingredient], AbbVie created a thicket of intellectual property protection so dense that it prevented would-be challengers from entering the market with cheaper biosimilar alternatives."[80] The plaintiffs also claimed that the defendants "used that intellectual property as leverage during negotiations" to "forc[e] [competitors] to agree to delay their market entry in return for licensing agreements that cut through AbbVie's patent thicket."[81]

The district court dismissed the lawsuit, and the Seventh Circuit affirmed. The appellate court upheld the dismissal of the plaintiffs' claims based on sham litigation

[80] *In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020).
[81] *Id.*

and anticompetitive settlements.[82] Although the issues are nuanced, one of us has explained why those rulings were not supported by the caselaw as these courts relied on extraneous issues in analyzing sham litigation and applied an overly rigid analysis in evaluating settlements.[83]

Our focus here is different: the justification of a patent thicket in the pharmaceutical industry based on the presence of large patent accumulations in the high-technology industry. Writing for the Seventh Circuit, Judge Frank Easterbrook began with the number of patents:

> [W]hat's wrong with having lots of patents? If AbbVie made 132 inventions, why can't it hold 132 patents? The patent laws do not set a cap on the number of patents any one person can hold—in general, or pertaining to a single subject.[84]

Relatedly, "the fact that the 132 patents" in AbbVie's thicket "can be traced to continuation applications from 20 root patents seems to [the court] neither here nor there."[85] The reason is that although "[i]t may be easier to attack 20 clusters of patents than 132 independent patents, . . . the fact remains that every patent comes with a presumption of validity."[86]

Judge Easterbrook additionally dismissed concern based on the number of patents by considering the high-technology industry. He noted that "[t]ech companies such as Cisco, Qualcomm, Intel, Microsoft, and Apple have much larger portfolios of patents."[87] Going back further, he pointed to Thomas Edison, who "alone held 1,093 U.S. patents."[88] And "[w]hen the FTC challenged Qualcomm's patent practices, it objected to licensing terms rather than the sheer size of the portfolio."[89]

Judge Easterbrook is not the only one to offer an argument like this. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA), the leading industry association representing drug companies, has stated that (1) "between 2016 and 2021, the five companies with the most issued patents were all high-tech companies, not biopharmaceutical companies";[90] (2) "[t]he top 20 patent owners have an average of 0.55 patents per million of R&D spend based on 2021

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82 Mayor & City Council of Baltimore v. AbbVie Inc., 42 F.4th 709 (7th Cir. 2022).

83 Michael A. Carrier, *Back to 2012: The Seventh Circuit's Reliance on Pre-Actavis Law in Dismissing Patent-Thicket Claims*, COMP. POLICY INT'L, Nov. 2022, at 2–9, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4267354.

84 *AbbVie*, 42 F.4th at 712.

85 *Id.* at 713.

86 *Id.* The court did not mention that it is the *patentholder* that bears the burden of persuasion on proving infringement. *See, e.g.*, Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 678 (Fed. Cir. 2008).

87 *AbbVie*, 42 F.4th at 713.

88 *Id.*

89 *Id.* at 712.

90 Pharmaceutical Research and Manufacturers of America, Comments in Response to the USPTO's Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, at 7 (Feb. 1, 2023), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Comments---PTO-P-2022-0025.pdf ("[I]n 2021, the top 20 patent owners with the largest numbers of patents were not biopharmaceutical companies, and fewer than 3% of the top 300 patentees are biopharmaceutical companies.").

figures; in contrast, biopharmaceutical companies in the top 300 patent owners have an average of 0.05 patents per million of R&D spend";[91] and (3) "there tend to be fewer patents per medicine than for many other marketed products, ranging from golf balls and golf clubs to cell phones to certain athletic shoe technology."[92]

In the next Part, we explain three fundamental reasons why the reliance on high-technology portfolios to minimize concern with pharmaceutical patent thickets is not persuasive.

III. Different Product Natures

Pharmaceutical products are different from those in the high-technology industry. This Part analyzes three such differences, based on licensing, regulatory barriers, and concentrated markets. Each of these distinctions reveals heightened anticompetitive concerns with drug thickets compared to high-technology thickets.[93]

A. Licensing

The first difference involves licensing. A drug company tends to have all of the patents it needs to enter the market. Brand firms do not need to deal with generics and biologic manufacturers do not need to deal with biosimilars to obtain licenses to necessary technologies because the generics and biosimilars do not have patents that can prevent brand market entry.[94]

In addition, brand and biologic firms have no interest in helping their rivals through licensing because revenues typically plummet after generic or biosimilar market entry. Generics are nearly identical to the brand and cannot enter without showing that they have the same active ingredient, route of administration, bioequivalence (i.e., rate and extent of drug absorption), and other characteristics.[95]

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91 *Id.*

92 *Id.* Similarly, the Biotechnology Innovation Organization (BIO), the largest organization representing the biotechnology industry, wrote that the "average ranking of drug and biopharmaceutical companies among the top 300 patent holders" is "198th" and these firms only "[c]onstitute 2.6% of the top 300 patent holders." Biotechnology Innovation Org., Comments in Response to the USPTO Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights, at 3 (Feb. 1, 2023), https://www.regulations.gov/comment/PTO-P-2022-0025-0111.

93 This is not to say that antitrust concerns are never present in high-technology markets. *See, e.g.*, Michael A. Carrier, *Patent Assertion Entities: Six Actions the Antitrust Agencies Can Take*, CPI ANTITRUST CHRONICLE (Jan. 2013), https://papers.ssrn.com/sol3/papers.cfm?abstract_ id=2209521 (detailing antitrust concerns related to patent assertion entities); Michael A. Carrier, *Why Is FRAND Hard?*, 2023 UTAH L. REV. 931, 937–38 (2023) (explaining antitrust issues posed by standards). In addition, much of the conduct challenged in the pharmaceutical industry bears additional markers of anticompetitive conduct such as a lack of economic sense other than harm to a rival. *See infra* notes 141–50 and accompanying text.

94 *See, e.g.*, *Generic Drug Facts*, FOOD & DRUG ADMIN., http://www.fda.gov/drugs/generic-drugs/generic-drug-facts (last visited Apr. 17, 2023) (noting similarities between generic and brand medicines).

95 FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 5 (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-

Biosimilars are required to be "highly similar to" the biologic and have "no clinically meaningful differences" in relation to "safety, purity, and potency."[96]

Arrival of these low-priced competitors leads to a significant reduction in brand revenues. When a single generic enters the market, the price falls roughly 40%, and when multiple generics enter, it falls more than 90%.[97] Though the reduction is less dramatic, biologic firms' revenues decline 20% to 50% when biosimilars enter.[98] Combined with the ownership by brand and biologic firms of necessary patents, this dramatic price decline results in a lack of licensing in the pharmaceutical industry.[99]

Drawing on the economic literature, the pharmaceutical industry presents characteristics of a "discrete" industry, as it is "comprised of a relatively discrete number of patentable elements."[100] Although biologics are characterized by a greater number of patents than the small-molecule drugs previously considered, the relationship between firms still resembles the discrete model in which it is not necessary to accumulate patents to trade with rivals.

A very different setting is presented by complex technologies such as "electronic products [that] tend to be comprised of . . . often hundreds [or even thousands] of patentable elements."[101] In these industries, companies do not have "proprietary control over all the essential complementary components of at least some of the technologies they are developing."[102] In particular, "[f]irms hold rights over technologies that others need, and vice-versa, creating a condition of mutual dependence that fosters extensive cross-licensing"[103] by which firms have "the right to practice the other's patents."[104] This is especially needed because patent thickets have historically been denser in complex industries like high technology.[105] In

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expiration-ftc-study/genericdrugstudy_0.pdf; *see also* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355) (allowing generics to piggyback on brand firms' clinical trials and experiment on their products during the patent term); *see generally* Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 41–47 (2009).

96 42 U.S.C. § 262(i)(2).

97 *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices (last updated Oct. 5, 2023).

98 *See supra* note 57 and accompanying text.

99 *See* Uri Y. Hacohen, *Evergreening at Risk*, 33 HARV. J.L. & TECH. 479, 497–98 (2020) (explaining that licensing between rivals in the industry is "rare to nonexistent"); *see also* Woolman et al., *supra* note 5, at 24 (stating that "the most frequent number of [pharmaceutical] licenses was zero").

100 Wesley M. Cohen, Richard R. Nelson & John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)* 19 (Nat'l Bureau of Econ. Rsch., Working Paper No. 7552, 2000), https://www.nber.org/papers/w7552.

101 *Id.*

102 *Id.*

103 *Id.*

104 Shapiro, *supra* note 4, at 127; *see also* Amber L. Hatfield, *Patent Exhaustion, Implied Licenses, and Have-Made Rights: Gold Mines or Mine Fields?*, 2000 COMPUT. L. REV. & TECH. J. 1, 1 (noting that in the semiconductor industry, "cross-licenses have been extremely broad").

105 Georg von Graevenitz, Stefan Wagner & Dietmar Harhoff, *How to Measure Patent Thickets—a Novel Approach*, 111 ECON. LETTERS 6, 8 (2011).

markets for computer microprocessors, for example, Carl Shapiro has found that "broad cross licenses are the norm"[106] and that such licenses "permit the more efficient use of engineers . . . , better products, and faster product design cycles."[107]

Because high-technology industries like computers and semiconductors are not made up of single patentholders contributing all of the patents to a product, patents provide parties with a position at the bargaining table that allows them to trade, thereby obtaining access to patents they need. In this setting, a larger portfolio means a greater likelihood of being able to successfully market the product. Litigation is part of the ecosystem. As Shapiro further noted, lawsuits "are a necessary part of the threat point behind any cross-licensing negotiation[;] if one party is not happy with the terms offered by the other, it always has the option of initiating patent litigation."[108] Similarly, Rosemarie Ham Ziedonis has explained that "aggressive patenting by manufacturing firms" in the semiconductor industry "is driven by a desire to deter such litigation and to negotiate more favorable access to external technologies."[109]

Licensing in high-technology industries also is prevalent because of cumulative innovation, which is the process of "build[ing] on each other's discoveries."[110] The presence of patents across multiple generations necessitates licensing.[111] More generally, the antitrust agencies have recognized cross licenses as procompetitive in "integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation."[112]

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106 Shapiro, *supra* note 4, at 129.

107 *Id.* at 130.

108 *Id.* at 131.

109 Rosemarie Ham Ziedonis, *Patent Litigation in the U.S. Semiconductor Industry*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 180, 208 (2003); *see also* Deepak Hegde, David C. Mowery & Stuart J.H. Graham, *Pioneering Inventors to Thicket Builders: Which U.S. Firms Use Continuations in Patenting?*, 55 MGMT. SCI. 1214, 1217 (2009) (explaining that licensing is employed to "preserve . . . freedom of action"); Jay Pil Choi, *Patent Pools and Cross-Licensing in the Shadow of Patent Litigation*, 51 INT'L ECON. REV. 441, 441 (2010) ("[M]any patent pools and cross-licensing arrangements arise as an attempt to settle disputes on conflicting claims in the litigation process or in expectation of impending litigation."); Suzanne Scotchmer, *Cumulative Innovation in Theory and Practice* 2 (Goldman Sch. of Pub. Pol'y, Working Paper, 1999) (on file with authors) (patents "establish bargaining positions from which licenses are negotiated"). In addition to the cross-licensing discussed in the text, industries have entered into patent pools, which "are created when a group of patent holders each decides to license its respective patents to each other and to third parties collectively." ANTITRUST ENFORCEMENT AND INTELLECTUAL PROPERTY RIGHTS REPORT, *supra* note 22, at 64.

110 Scotchmer, *Cumulative Innovation*, *supra* note 109, at 2; *see generally* Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSPS. 29 (1991); Peter S. Menell, *Tailoring Legal Protection for Computer Software*, 39 STAN. L. REV. 1329, 1338 (1987) ("'[S]econdary inventions'—including essential design improvements, refinements, and adaptations to a variety of uses—are often as crucial to the generation of social benefits as the initial discovery.").

111 Scotchmer, *Standing on the Shoulders of Giants*, *supra* note 110, at 30.

112 U.S. DEP'T OF JUST. & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 5.5 (Apr. 6, 1995); *see* Hall, Graevenitz & Helmers, *supra* note 31, at 923 (showing that "patent thickets significantly reduce entry into those technology areas in which growing complexity and growing opportunity increase the underlying demand for patent protection").

The identity of patent owners in high-technology thickets also encourages patenting. The high-technology industry tends to be one of the highest in terms of "patent assertion entities" (PAEs), which do not manufacture products but use patents to obtain license fees.[113] As a result, PAEs obtain numerous patents to force industry participants to the negotiating table. In contrast, the pharmaceutical industry has not been plagued by PAEs, with patents being filed by practicing entities.[114] As one study showed, "litigation of drugs and medical patents, and separately chemical patents, is the domain of product companies while computer and communications patent litigation is dominated by NPEs and PAEs."[115] These findings provide additional evidence that pharmaceutical companies primarily employ patents as a means to deter competition and not for the purpose of licensing.

Finally, as discussed above,[116] in the setting of standards, organizations have addressed patent holdup by adopting rules requiring patent holders to license their patents on FRAND terms. Such systems, carried out in many organizations affecting countless products across the high-technology ecosystem, show how patents are used for licensing. Relatedly, patent pools can allow companies to obtain access to multiple patents.[117]

The combination in the high-technology industry of numerous parties owning patents in a product, robust cross-licensing, PAEs, and standards provides a setting in which licensing is a common—and in fact necessary—response to thickets.[118] In contrast, the pharmaceutical industry has none of these characteristics, which raises concern with a single company's amassing of a patent thicket.

B. Regulatory Barriers

The regulatory regime presents another significant distinction between the pharmaceutical and high-tech industry. A complex regulatory regime characterizes pharmaceuticals but not high technology. There are two regimes governing the pharmaceutical industry: one covering small molecules and one—most relevant for

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[113] *NPE Litigation Database*, STANFORD L. SCH., https://npe.law.stanford.edu/ (last visited May 22, 2023) (noting that PAEs have also been called "patent trolls"). *See, e.g.*, Robin Feldman & Mark A. Lemley, *Do Patenting Licensing Demands Mean Innovation?*, 101 IOWA L. REV. 137, 142 ("[M]uch of the patent troll activity occurs in fast-moving technologies such as computers and telecommunications.").

[114] Orange Book patents are patents associated with Food and Drug Administration approval. As a result, all Orange-Book listed patents are associated with practicing entities. *See infra* note 119 (discussing these patents).

[115] Shawn P. Miller et al., *Who's Suing Us? Decoding Patent Plaintiffs Since 2000 with the Stanford NPE Litigation Dataset*, 21 STAN. TECH. L. REV. 234, 264 (2018); *see also id.* at 263 tbl.6 (showing that "product companies" filed 111 out of 116 (96%) lawsuits in the pharmaceutical technology and that 390 out of 518 (78%) lawsuits in the Computer & Communications industry were "PAE only").

[116] *See supra* note 26 and accompanying text.

[117] *See* Michael A. Carrier, *Resolving the Patent-Antitrust Paradox Through Tripartite Innovation*, 56 VAND. L. REV. 1047, 1093–98 (2003) (offering examples).

[118] *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 1987 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 793–98 (discussing the importance of patents in the pharmaceutical and biotechnology industries); Cohen, Nelson & Walsh, *supra* note 100, at 10.

patent thickets—covering biologics. In stark contrast, the high-tech industry operates with minimal regulatory oversight.

Patents directed to small molecule drugs are listed in the "Orange Book," which includes the drugs, therapeutically equivalent products, and relevant patents.[119] The identity and strength of each patent covering the small-molecule drug is transparent because the Hatch-Waxman Act requires all relevant patents to the drug to be listed in the Orange Book, with each of the patents analyzed, and often challenged, before the generic can enter.[120] As of December 2021, the Orange Book included 5,323 unique patents associated with 1,103 drugs for an average of roughly five patents per drug.[121]

Biologics are regulated by the less transparent Biologics Price Competition and Innovation Act (BPCIA).[122] In creating a pathway for follow-on biosimilars, the FDA began publishing the "Purple Book."[123] Originally, the Purple Book did not include relevant patents but rather listed only non-patent exclusivities such as the twelve-year regulatory exclusivity.[124] Beginning with the 2021 passage of the Purple Book Continuity Act, biologic firms have been required to list certain patents covering biologic products.[125]

Unlike the Orange Book, however, which requires patent listing upon FDA approval, Purple Book patents need to be listed only if they are implicated in biosimilar litigation, which may occur years after FDA approval.[126] Increasing the challenge, each biosimilar product may be slightly different from each other.[127] As a

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[119] *Approved Drug Products with Therapeutic Equivalence Evaluations*, FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book (last updated Oct. 13, 2023). The publication is known as the Orange Book because of the color of its cover when it was distributed in printed form.

[120] *See supra* note 119; *see also* 21 U.S.C. § 355(j)(2)(A)(vii) (stating that before entering the market on a drug listed in the Orange Book, generic manufacturers are required to make one of four certifications: no patent information appears in the Orange Book, the patent has expired, they will not seek approval until the patent expires, or the patent is invalid or will not be infringed by the generic product).

[121] Maya Durvasula, C. Scott Hemphill, Lisa Larrimore Ouellette, Bhaven N. Sampat & Heidi L. Williams, *The NBER Orange Book Dataset: A User's Guide* (Nat'l Bureau of Econ. Rsch., Working Paper No. 30628, 2022); *see also* Tu, *The Long CON*, *supra* note 43.

[122] 42 U.S.C. § 262.

[123] *See Background Information: List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book)*, FOOD & DRUG ADMIN. (Aug. 3, 2020), https://www.fda.gov/drugs/biosimilars/background-information-list-licensed-biological-products-reference-product-exclusivity-and (noting that the technical name of the Purple Book is the *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*).

[124] Bryan S. Walsh, Jonathan J. Darrow & Aaron S. Kesselheim, *Recent Orange Book and Purple Book Legislation Suggests a Need to Bridge Drug and Biologic Patent Regimes*, 40 NATURE BIOTECHNOLOGY 167, 168 (2022).

[125] *Id.* at 168.

[126] Further Extension of Continuing Appropriations Act, 2021, H.R. 1520, 116th Cong. (2020).

[127] *Level 1: Foundational Concepts Biosimilar and Interchangeable Products*, FOOD & DRUG ADMIN., 11–12, https://www.fda.gov/drugs/biosimilars/curriculum-materials-health-care-degree-programs-

result, the second biosimilar company to enter the market may need to prevail on a different set of patents than what was litigated in the first biosimilar's case. As of April 2023, the Purple Book has 245 patents directed to nine products (Neulasta, Humira, Avastin, Tysabri, Lucentis, Stelara, Actemra, Prolia and Xgeva, and Eylea) for an average of roughly 27 patents per product.[128]

The biologics regulatory regime encourages manufacturers to amass as many patents as possible. The BPCIA envisions two potential waves of litigation. The first wave is triggered when the biosimilar applicant submits a Biologic License Application (BLA).[129] The "patent dance" is a pre-suit exchange between the biosimilar and the biologic firm to identify and potentially narrow the list of litigated patents.[130] This process, however, is not as transparent as the Hatch-Waxman Act, which results in increased risk and more opportunities for gamesmanship for biologics as compared to small molecule drugs.[131]

For example, patent claims covering biologics' manufacturing processes are opaque.[132] For these patents, competitors cannot know whether the examiner erroneously granted the patent or lacked critical information about the process, or whether the patent covers a non-obvious post-approval modification.[133] Because of this, biologic firms have an incentive to file large numbers of such patents to deter biosimilar market entry. Indeed, one study found that manufacturing-process patents make up 52% of litigated biologic patents, with 61% filed more than one year after FDA approval.[134] In addition, of the litigated manufacturing-process patents, 71%

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biosimilars#level1 (last visited June 10, 2023) (discussing inherent variations in biological products on slide 11 and stating that "[m]anufacturers must demonstrate that their proposed biosimilar product has similar variations compared to the reference product and that their product has no clinically meaningful differences in terms of safety and effectiveness" on slide 12).

128 *Purple Book Database of Licensed Biological Products*, FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/patent-list (last visited Nov. 8, 2023).

129 *See* Mitchell Wong & Yom-Ming Wang, *Development of a Biosimilar 351(k) BLA Clinical Pharmacology Study Database*, FOOD & DRUG ADMIN. (Aug. 12, 2021), https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/development-biosimilar-351k-bla-clinical-pharmacology-study-database (stating that biosimilars are licensed through "the 351(k) BLA pathway").

130 *E.g.*, Michael A. Carrier & Carl J. Minniti III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1, 17 (noting that BPCIA allows a biologic manufacturer to assert any patent against which it "believes a claim of patent infringement could be reasonably asserted").

131 Walsh, Darrow & Kesselheim, *supra* note 124.

132 Arti K. Rai & W. Nicholson Price II, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECHNOLOGY 20, 21 (2021).

133 *Id.* at 21; *see also* Chorong Song, *How Non-Product-Specific Manufacturing Patents Block Biosimilars*, 71 DUKE L.J. 1923, 1943 (2022) (noting that manufacturing patents "are written broadly such that other biosimilar manufacturers cannot practice these patents solely based on their descriptions," that "through the patent dance, brand-name manufacturers can detect instances of infringement that would not have been otherwise detected," and that "because of their non-product-specific natures, biosimilar manufacturers cannot proactively seek invalidation of these patents at the PTO").

134 Song, *supra* note 133, at 1939.

"could not have been used to make products at launch, yet were asserted to block biosimilar competition."[135]

The high-technology industry has no regulatory regime similar to the BPCIA. In fact, the requirements necessary to create an electronics or software firm can be relatively low. Amazon, for example, started in Jeff Bezos's home garage and Facebook began in Mark Zuckerberg's college dorm room.[136] To state the obvious, one cannot create a pharmaceutical firm in a similar manner. In short, there is no regulatory regime for high-technology—let alone one as uncertain and complex as the BPCIA—that is subject to gamesmanship.[137]

C. Market Concentration

A third difference exacerbating the danger of pharmaceutical thickets stems from concentration in the biologics industry. Because of the cost of developing products, which can run into the hundreds of millions of dollars,[138] the universe of potential entrants is finite. Even the less cost-intensive small-molecule setting has witnessed large drug companies staying large over time, with small companies being acquired by larger companies because they lack the resources to reach the market by conducting lengthy and expensive clinical trials.[139] Given the even higher cost of developing biosimilars, many of these manufacturers are traditional brand-name firms like Pfizer, Amgen, and Novartis.[140] This concentration means there are fewer

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[135] *Id.*

[136] Caroline Fox & Erin McDowell, *15 of the Most Successful Companies that Started in Homes, Basements, Sheds, and Bedrooms*, INSIDER (Apr. 20, 2023, 3:08 PM), https://www.businessinsider.com/successful-companies-started-in-basements-garages-bedrooms-2020-4?op=1.

[137] *See infra* notes 141–46 and accompanying text (providing additional discussion on gamesmanship in the pharmaceutical industry).

[138] *See, e.g.*, *Emerging Health Care Issues: Follow-on Biologic Drug Competition*, FED. TRADE COMM'N 14 (2009), https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf (estimating, in 2009, a cost of $100 to $200 million); *see also, e.g.*, Juhi Modi, *Why Are Biologics So Expensive?*, BUZZRX (Sept. 6, 2022), https://www.buzzrx.com/blog/why-are-biologics-so-expensive (discussing higher cost of producing biologics as compared to chemically synthesized drugs because of the complex manufacturing process, use of genetic modification technology, and injection and infusion routes of administration).

[139] *See* Patricia M. Danzon & Michael A. Carrier, *The Neglected Concern of Firm Size in Pharmaceutical Mergers*, 84 ANTITRUST L. J. 487, 492–97, 517–18 (2022) (discussing the acquisition of small companies by larger firms generally); *see also* Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009–2018*, 323(9) JAMA 844, 845 (2020) (finding that "the estimated median capitalized research and development cost per product was $1.1 billion, counting expenditures on failed trials").

[140] Kevin Dunleavy, *The Top 20 Pharma Companies by 2022 Revenue*, FIERCEPHARMA (Apr. 18, 2023, 3:00 AM), https://www.fiercepharma.com/pharma/top-20-pharma-companies-2022-revenue; *see also* Anna Rose Welch, *Biosimilar Industry Experts Highlight 2019 Triumphs, Tribulations*, BIOSIMILAR DEV. (Dec. 11, 2019), https://www.biosimilardevelopment.com/doc/biosimilar-industry-experts-highlight-triumphs-tribulations-0001 (highlighting development costs, trade secrets, FDA substitutability regulations, disparagement, and contracting practices as factors hindering biosimilar development).

rivals that need to be kept off the market. Brand firms' abuse of regulatory regimes and range of anticompetitive behavior has narrowed this list even further.

Some examples of behaviors that delay rivals include (1) "pay-for-delay" settlements by which brand firms pay generics to delay entering the market;[141] (2) "product hopping" from one version of a drug to another to delay generics;[142] (3) denying samples that generic manufacturers need to enter the market;[143] (4) patenting Risk Evaluation and Mitigation Strategies (REMS) to prevent market entry;[144] (5) filing frivolous "citizen petitions" to delay generic approval;[145] and (6) filing "skinny label" lawsuits against generics that avoid brand firms' patent-protected indications.[146] This carries over and picks up new variations (like the disparagement of biosimilars) in the biologics setting.[147]

Patent thickets in particular can be used to delay rivals. In an exhaustive report, the European Commission found that the creation of a thicket could be motivated by "remov[ing] legal certainty" by "fil[ing] as many patents as possible in all areas of the drug and creat[ing] a 'minefield' for the generic to navigate."[148] The result of dramatically increasing risk is that it is "impossible to be certain prior to launch" that the generic's "product will not infringe" and "will not be the subject of an interim injunction."[149] The study also gave the example of a brand firm conceding the purpose of "[e]stablish[ing] an effective barrier to generic competition by extending the term

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[141] *See, e.g.*, FTC v. Actavis, Inc., 570 U.S. 136, 154 (2013) (explaining how brand and generic companies have entered into settlements that delay generic competition).

[142] *See, e.g.*, New York v. Actavis PLC, 787 F.3d 638, 642–43 (2d Cir. 2015) (upholding preliminary injunction against pharmaceutical company for introducing new drug near the end of its original drug's patent term and withdrawing the original from the market so that consumers would switch to the new drug before a generic for the original became available).

[143] *See, e.g.*, Mylan Pharms., Inc. v. Celgene Corp., No. 14-CV-2094, 2018 WL 11299447, at *1 (D.N.J. Oct. 3, 2018) (discussing Mylan's assertion that Celgene refused to provide samples of brand-name drugs to Mylan in order to stifle generic competition).

[144] Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC 60 F.4th 1373, 1380–81 (Fed. Cir. 2023); Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1662 (2017).

[145] *See generally* Michael A. Carrier & Gwendolyn J. Lindsay Cooley, *Prior Bad Acts and Merger Review*, 111 GEO. L.J. ONLINE 106, 109 (2023) (citing FTC v. Shire ViroPharma, Inc., 917 F.3d 147, 152 n.7 (3d Cir. 2019)).

[146] Bryan S. Walsh, Doni Bloomfield & Aaron S. Kesselheim, *A Court Decision on "Skinny Labeling": Another Challenge for Less Expensive Drugs*, 326 JAMA 1371, 1371 (2021); *see generally* Alexander C. Egilman et al., *Frequency of Approval and Marketing of Biosimilars with a Skinny Label and Associated Medicare Savings*, 183 JAMA INTERNAL MED. 82 (2023) (discussing skinny label generic drugs and the way they are approved).

[147] *See* Carrier & Minniti, *supra* note 130, at 60–66; *see also* Victor L. Van de Wiele, Aaron S. Kesselheim & S. Sean Tu, *Biologic Patent Challenges under the America Invents Act from 2012–2021* (on file with authors) (showing that 63% of challenges to biologic patents using the PTO process known as *inter partes* review are filed by brand firms).

[148] EUROPEAN COMM'N DIRECTORATE-GENERAL FOR COMPETITION, PHARMACEUTICAL SECTOR INQUIRY: FINAL REPORT ¶ 525 (July 8, 2009), http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

[149] *Id.*

of the existing compound patent and by filing patents on further inventions that last beyond the expiration of the compound patent."[150]

All of these observations on concentration are exacerbated by unique market forces in the industry. As one of us has explained, the industry is characterized by a "price disconnect" in that "the doctor who prescribes the product does not pay for it, and the consumer (or her insurer) who pays for it does not choose it."[151] The pharmaceutical industry, in other words, is shielded from the typical market forces of supply and demand. Patients with insurance or Medicare coverage, for example, do not see the majority of the costs associated with brand-name drugs and thus are insulated from the large prices paid by insurers.[152] Insurance companies, for their part, have no choice but to cover new drugs that are "first in class."[153]

High-technology industries do not present the same level of concern from concentration because they are easier to enter.[154] The consumer electronics manufacturing industry, for example, is "highly competitive" and "constantly evolving," with "[n]ew technologies and products . . . constantly being introduced, and old ones . . . becoming obsolete."[155] Similarly, semiconductor companies "compet[e] with each other" and "also with customers looking to establish dominance" in "emerging high-growth areas" such as "Internet of Things (IoT), artificial intelligence (AI), automotive, and 5G."[156]

Relatedly, high-technology industries are less worrisome because rivals can compete on grounds other than price. The pharmaceutical industry requires that the follow-on products be, at a minimum, highly similar to the reference product, which means that they cannot diverge too far from the reference product. In contrast, high-technology products could compete on dimensions like quality and innovation.

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[150] *Id.* ¶ 526–27 (providing example of brand firm that admitted that secondary patents "may delay generics for a number of years," which protects revenue "for a period of time").

[151] Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 179 (2016).

[152] *See generally* Louise Norris, *An Overview of Prescription Drug Insurance*, VERYWELLHEALTH (Oct. 18, 2023), https://www.verywellhealth.com/prescription-drug-insurance-4013242 (discussing different types of insurance plans and how they cover pharmaceutical costs).

[153] For example, when Gilead's new ground-breaking hepatitis-C drug Sovaldi debuted in 2013, insurance companies were required to cover it. Although it cost more than $80,000 for a 12-week course of treatment, the drug, which essentially cured a debilitating disease, had no competition. Bill Berkrot & Deena Beasley, *U.S. Lawmakers Want Gilead to Explain Sovaldi's Hefty Price*, REUTERS (Mar. 21, 2014, 10:15 AM), https://www.reuters.com/article/us-gilead-sovaldi-idUSBREA2K18H20140321.

[154] Jon Polenberg, *tfosorciM and croMiftos: Why High-Technology Antitrust Inquiry Is Backwards and Inside-Out*, 57 U. MIAMI L. REV. 1275, 1299 (2003).

[155] James Humphreys, *19 Electronics Manufacturing Process Challenges and the Solution*, KATANA (Aug. 16, 2023), https://katanamrp.com/blog/electronics-manufacturing-process/ (discussing trends in voice-controlled assistants and wearables).

[156] Gregg Albert & Syed Alam, *Outside Competition Increasing for Semi Industry*, ACCENTURE (June 18, 2020), https://www.accenture.com/us-en/blogs/high-tech/semiconductor-competition-increasing.

In short, the pharmaceutical industry offers several characteristics that heighten concern with thickets. There is no need to amass patents for licensing, the regulatory regime imposes barriers on rivals, and these advantages are exacerbated by industry concentration with a limited number of competitors. This apprehension with pharmaceutical thickets is confirmed by the research we discuss in the next Part.

IV. Results

Continuation patents offer a window into how companies use patents and litigation. In this Part, we discuss an empirical analysis we conducted to learn about pharmaceutical and high-technology thickets.

Using publicly available patent data, we identified the number of granted U.S. continuation patents filed between 2000 and 2022.[157] We examined four industry-wide patent landscapes: two in the pharmaceutical industry and two in the high-technology industry. By providing lists of drugs and their accompanying patents, the Orange Book and Purple Book provide the framework for our analysis of the pharmaceutical industry.[158] Our Orange Book data encompassed all patents listed between 2000 and 2022, as supplemented by the FDA's electronic Orange Book.[159] We downloaded Purple Book patents from the FDA website.[160]

To locate a set of patents that matched the high-technology industry, we used Cooperative Patent Classification (CPC) codes. CPC codes are a patent classification system with more than 250,000 categories jointly developed by the European Patent Office (EPO) and the PTO.[161] Where there were multiple CPC codes covering a

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[157] We used the Google Patents Public Datasets on Google BigQuery and the *Patent Publication* table from IFI CLAIMS, as updated through April 6, 2022. *BigQuery*, GOOGLE CLOUD, https://cloud.google.com/bigquery (last visited May 11, 2023) [hereinafter *BigQuery*]; *Leading Platform for Patent Data Analytics*, IFI CLAIMS PATENT SERVICES, https://www.ificlaims.com/start.htm (last visited May 11, 2023) [hereinafter *IFI*].

The publication priority date is the earliest filing date among all priority claims of the application. To determine trends in the data, we reviewed the number of child applications filed per year over the total applications filed per year.

We excluded design patents, which protect only the appearance of an article as opposed to structural or utilitarian features. *See* MPEP, *supra* note 11, ch. 1502 (providing the definition of a design patent). We also excluded reissue patents, which applicants use to correct errors in previously granted patents. *See* 35 U.S.C. § 251 (2023) (explaining reissued patents); MPEP, *supra* note 11, ch. 1401 (2023) (same). And because they may not have identical specifications, we excluded continuation-in-part patents (which by definition add new material) and divisional patents (which claim a different invention based on the same disclosure).

[158] *See supra* notes 119–21, discussing the Orange Book, notes 123–28, discussing the Purple Book, and accompanying text.

[159] *Orange Book Patent and Exclusivity Data - 1985–2016*, NAT'L BUREAU OF ECON. RSCH., www.nber.org/research/data/orange-book-patent-and-exclusivity-data-1985-2016 (last visited Apr. 22, 2023); *Orange Book and Exclusivity Information*, FOOD & DRUG ADMIN., https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book#Patent (last visited Jan. 3, 2024).

[160] *Purple Book Database of Licensed Biological Products*, FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/patent-list (Mar. 30, 2023).

[161] *Cooperative Patent Classification*, EUROPEAN PATENT OFFICE, https://www.epo.org/searching-for-

product, we focused our analysis on the first CPC code, which is typically the most relevant classification code.[162] For the high-technology group, we examined Electrical Digital Processing (G06F, defined as "computer systems based on specific computational models"[163]) and Semiconductor Devices (H01L) because they were the two technologies with the highest number of continuation patents.[164]

A. Continuations

Only a handful of technologies rely significantly on continuations. Between 2000 and 2022, 14% of patents covering all technologies were continuations,[165] while the top 15 CPC classes by total granted patents generated 48% of all continuations.[166]

We first found that the pharmaceutical industry often uses continuations. As Table 2 shows, between 2000 and 2022, there were continuations for 45% of Orange Book patents[167] and 57% of Purple Book patents.[168] The figures are similar for the most relevant CPC code, A61K, which covers most—roughly 66%[169]—of Orange Book patents.[170] In contrast, the sectors of the high-technology industry with the most continuations had fewer continuations (percentage-wise): 20% in Electrical Digital Processing[171] and 14% in Semiconductor Devices.[172]

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patents/helpful-resources/first-time-here/classification/cpc.html (last visited May 7, 2023); *see also* COOPERATIVE PATENT CLASSIFICATION, https://www.cooperativepatentclassification.org/home (last visited May 27, 2023) (discussing the joint development of the CPC by the EPO and PTO).

162 *See generally Cooperative Patent Classification*, EUROPEAN PATENT OFFICE, *supra* note 161.

163 *Classification Resources: Cooperative Patent Classification G06F*, U.S. PAT. & TRADEMARK OFF. (Aug. 2023), https://www.uspto.gov/web/patents/classification/cpc/html/cpc-G06F.html.

164 We did not use H04L, which classifies Transmission of Digital Information, because of the overlap between Electrical Digital Data Processing and Transmission of Digital Information.

165 Of a total of 7,799,906 patents, 1,092,519 were continuations.

166 The top 5 CPC classifications for technology are G06F (Electric Digital Data Processing), H04L (Transmission of Digital Information), H01L (Semiconductor Devices), H04N (Pictorial Communication, e.g., Television), and H04W (Wireless Communication Networks). The top 5 CPC classifications for pharmaceuticals are A61B (Diagnosis and Surgery), A61K (Medical Preparations), C07D (Heterocyclic Compounds), G01N (Analyzing Materials by Determining their Chemical Properties), and C07K (Peptides). Each of the top 15 classes were in the pharmaceutical or high-technology industries. The top 15 classes generated 34% (2,658,080 of 7,799,906) of all patents and 48% (519,811 of 1,092,519) of all continuation patents.

167 4,083 of 9,088 Orange Book patents were continuations.

168 95 of 168 Purple Book patents were continuations.

169 A61K covers 5,992 of 9,051 Orange Book patents.

170 36,694 of 144,950 (25%) were continuations. Continuations were found at a higher rate for Orange Book patents than the general A61K classification because Orange Book patents are some of the most valuable patents within this CPC group. Additionally, A61K generally covers "preparations for medical, dental or toiletry purposes," which includes technology types such as dental and cosmetics that do not tend to rely as heavily on continuation patents.

171 104,148 of 511,180 patents with a primary CPC code of G06F were continuations.

172 56,378 of 391,745 patents with a primary CPC code of H01L were continuations.

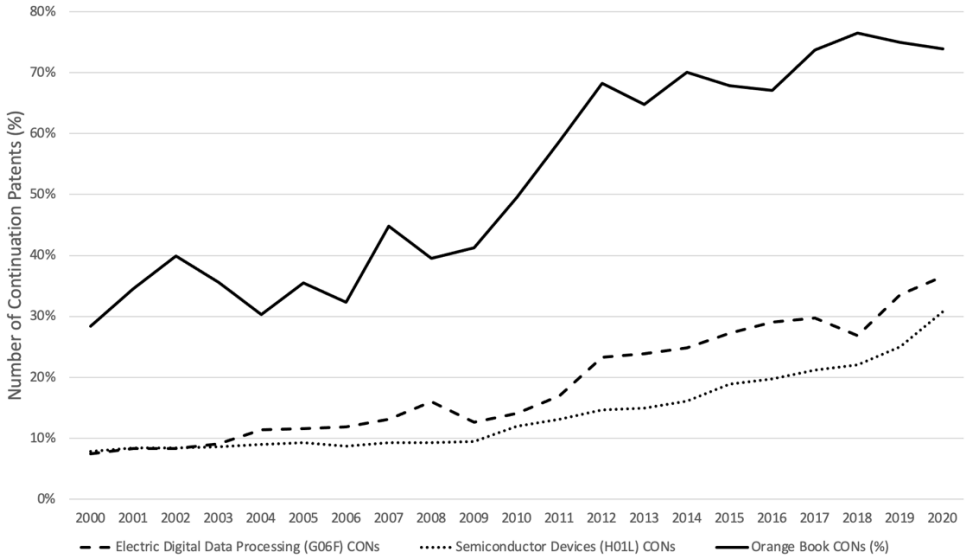
Table 2
Pharmaceutical Continuations (CONs)

Classification	Total Orange Book Patents	Orange Book CONs	Total Purple Book Patents	Purple Book CONs	Total Electric Digital Data Processing (G06F)	G06F CONs	Total Semiconductor Devices (H01L)	H01L CONs
Count (%) / Average Generation Number	9,088 (100%) / 2.6	4,083 (45%) / 3.8	168 (100%) / 2.9	95 (57%) / 4.1	511,180 (100%)	104,148 (20%)	391,745 (100%)	56,378 (14%)
Litigated (%) / Average Generation Number	2,984 (33%) / 2.6	1,520 (51%) / 3.8	132 (79%) / 2.8	76 (58%) / 3.9	3,464 (0.68%) / 2.1	1,252 (36%) / 3.6	1,206 (0.31%) / 1.8	384 (32%) / 3.7

Thickets generated by continuation patents are a recent phenomenon, one that has dramatically escalated in the pharmaceutical industry. Presenting the numbers from Table 2 by year, Figure 2 shows the percentage of continuation patents as a function of total patents per year from the Orange Book, G06F, and H01L groups. In 2000, continuation patents made up only 28%, 8%, and 8% of Orange Book, G06F, and H01L groups, respectively. By 2020, continuation patents made up 74%, 37%, and 31% of the Orange Book, G06F, and H01L groups, respectively.[173] While all three areas witnessed a significant increase, the results in the pharmaceutical industry—in which roughly *3 of 4 patents* are continuations—stand out.

[173] Table 2 shows the number and percentages of continuation patents for all years in each of the categories previously discussed. Figure 2 segments these data by year to show the increasing use of continuation patents by each technology group. We do not know why the number of continuations has increased in recent years though one possibility is a response to the introduction of PTO administrative proceedings like *inter partes* reviews.

Figure 2
Continuation Patents by Year



B. Litigated Continuations

In addition to filing more continuations, especially recently, the pharmaceutical industry—in comparison to the high-technology industry—has more frequently *litigated* continuation patents.

Using U.S. litigation data from Unified Patents, which covers all patent litigation between 2000 and 2022, we identified the number of continuation patents that were litigated.[174] Table 2 above shows how from 2000 to 2022, 51% of litigated Orange Book patents and 58% of Purple Book patents were continuations. In contrast, only 36% of litigated G06F patents[175] and 32% of H01L patents were continuations.[176]

The figures are even more stark when litigated continuations are considered against the universe of all—rather than litigated—patents in the sectors: 17% Orange Book[177] and 45% Purple Book[178] patents as compared to 0.24% of G06F[179] and 0.09% of H01L[180] patents.[181]

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[174] We performed this analysis by considering the *Unified Patents Litigation Cases* table along with the *Patent Publications* table. Both tables are publicly available through *BigQuery*, *supra* note 157.

[175] 1,252 of 3,464 patents with a primary CPC code of G06F were continuations.

[176] 384 of 1,206 patents with a primary CPC code of H01L were continuations.

[177] 1,520 litigated patents of 9,088 total Orange Book patents were continuations.

[178] 76 litigated patents of 168 total Purple Book patents were continuations.

[179] 1,252 litigated patents of 511,180 total G06F patents were continuations.

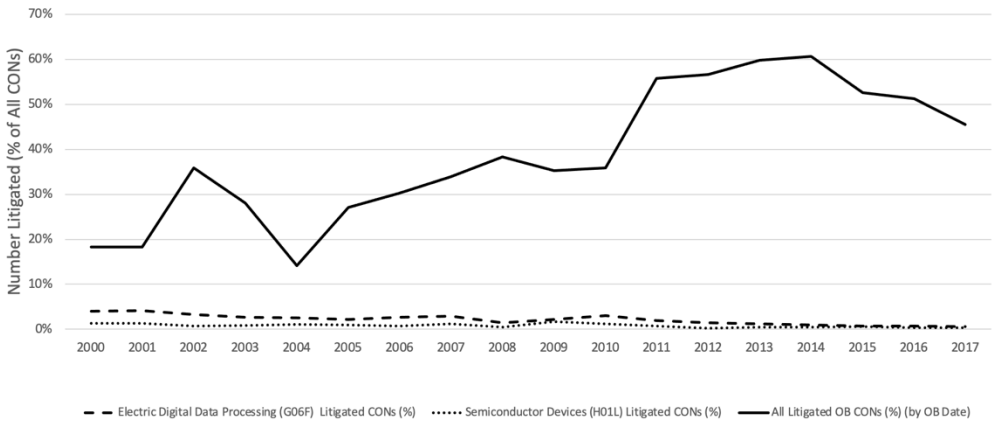
[180] 384 litigated patents of 391,745 total H01L patents were continuations.

[181] The figures are more extreme with this calculation because of the significantly higher incidence of litigation in the pharmaceutical setting. *See supra* Table 2 (noting 33% Orange Book and 79% Purple Book patents litigated versus 0.68% G06F and 0.31% H01L patents).

Similar to the recent increase in continuations we discussed in the last Part, the pharmaceutical industry has also recently increased its use of litigated continuations. Figure 3 shows a marked rise in litigated continuations in the pharmaceutical industry, which has not been matched by a similar increase for high-technology continuations.

As discussed above, the pharmaceutical industry presents characteristics of a discrete industry in which patents are not needed to cross-license patents to competitors[182] and patent thickets are "aimed at complicating generic entry."[183] Given that, an increase in litigated continuations cannot be explained by an increase in needed licensing. It would more naturally reflect a more sustained use of a litigation strategy to keep rivals off the market.

Figure 3
Litigated Continuation Patents



In contrast, use of litigation in high-technology industries has not increased. That is consistent with the lack of a rise in litigation in the industry to compel licensing. One example is provided by standards.[184] Because of the prevalence of patents in these settings, standards development organizations typically have adopted rules facilitating licensing. In particular, and as discussed above,[185] the organizations require the owners of patents necessary for use of the standard to license those patents on FRAND terms.[186] Although this system has received attention when it has not worked, most of the time it does.[187]

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182 *See supra* note 100 and accompanying text.
183 Tu & Lemley, *supra* note 7, at 1707–08. *See supra* notes 11–16 and accompanying text.
184 *See supra* note 25.
185 *See supra* note 26 and accompanying text.
186 Jorge Contreras & Meredith Jacob, *Standards-Essential Patents and FRAND Licensing*, PROGRAM ON INFO. JUST. & INTELL. PROP., http://www.pijip.org/standards-essential-patents-and-frand-licensing/ (last visited May 17, 2023).
187 *See* Carrier, *supra* note 25, at 274–75 (discussing problems arising from patent owners engaging in

C. Method-of-use Patents

One example of recent increases in continuations is provided by "method of use" patents that drug companies have used to delay entry.

As Figure 4 shows, there has been a noticeable increase in the use of continuations for method-of-use claims. These continuations rose from 27% in 2001 to 45% in 2014, accompanied by original patents decreasing from 65% in 2001 to 36% in 2014.[188] Method-of-use patents are particularly troubling because even if the older active ingredient or prior method patents expire, newer method-of-use patents can prevent generic entry. These method-of-use patents are "secondary" patents that are invalidated at a much higher rate than "primary" active ingredient patents.[189]

One setting in which method-of-use patents has gained attention is the "skinny labeling" pathway that allows generic firms to "carve out" patent-protected indications. By doing this, generics can avoid thickets made up of method-of-use patents and enter the market on the older indication.[190] In 2022, however, the Federal Circuit jeopardized this pathway, entrenching the power of method-of-use patents.[191]

"holdup" by seeking an injunction or excessive royalties after an industry has adopted a patented technology).

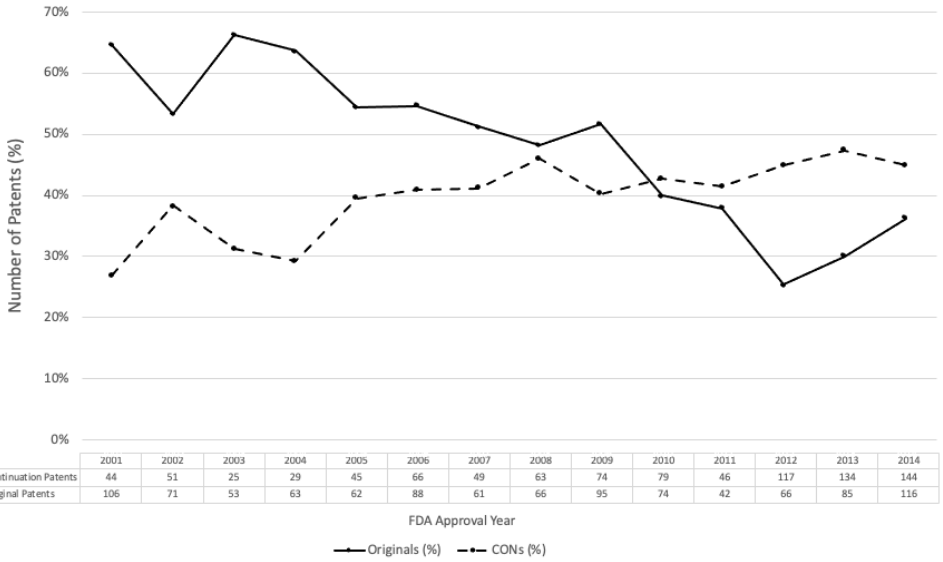
[188] The sum of continuations and original patents does not always equal 100% because we exclude divisional and continuation-in-part patents. In addition, as one of us has shown, there was a six-fold increase in the number of use codes from 2001 (1,275) to 2019 (7,919). Each use code is associated with at least one method of use patent. *See* S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Market Entry*, 388(6) N. ENGL. J. MED. 483, 483–85 (2023).

[189] Tu & Lemley, *supra* note 7, at 1692 fig.4 (showing that only 8 (6%) of the 142 invalidated patents were primary patents while 134 (94%) of the 142 invalidated patents were secondary patents).

[190] S. Sean Tu & Charles Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 N.Y.U. J. INTELL. PROP. & ENT. L. 1, 4 (2022).

[191] *See generally* GlaxoSmithKline LLC v. Teva Pharms. USA, 25 F.4th 949 (Fed. Cir. 2022), *cert. denied*, 2023 WL 3440748 (2023).

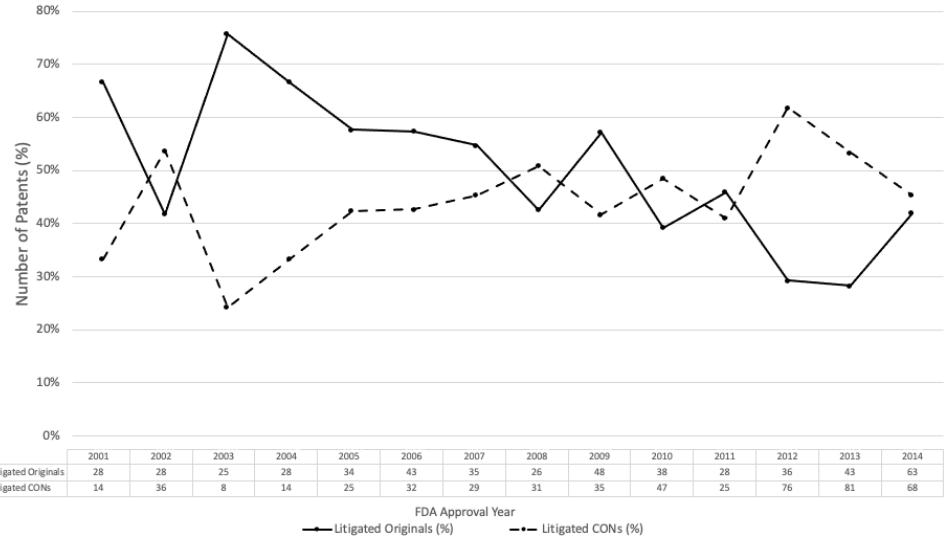
Figure 4
Method of Use Patents



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Continuation Patents	44	51	25	29	45	66	49	63	74	79	46	117	134	144
Original Patents	106	71	53	63	62	88	61	66	95	74	42	66	85	116

The same trend appears with *litigated* method-of-use patents. As Figure 5 shows, litigated original method-of-use patents fell from 67% in 2001 to 42% in 2014 while litigated continuation method-of-use patents increased from 33% in 2001 to 45% in 2014.[192] Again, given the lack of a need for licensing, this is consistent with an increased use of pharmaceutical patent thickets to delay rivals.

Figure 5
Litigated Method of Use Patents



	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Litigated Originals	28	28	25	28	34	43	35	26	48	38	28	36	43	63
Litigated CONs	14	36	8	14	25	32	29	31	35	47	25	76	81	68

[192] These data do not add up to 100% because we excluded litigated continuation-in-part and divisional patents. *See supra* note 188 and accompanying text.

In short, the increase in continuations and litigated method-of-use patents mirrors that of pharmaceutical patents. The concern presented by method-of-use patents offers a specific example of the general findings in the industry on patent thickets. That example aligns with previous findings of continuation patents consisting of less innovative secondary patents that are invalidated at a higher rate.[193] Unlike original primary patents, continuation patents can be used to increase transaction costs resulting in the delay or deterrence of generic and biosimilar entry.

V. Conclusion

A patent thicket is not a patent thicket—not when it is in such different industries as pharmaceuticals and high technology. As we have shown, the nature of the product is different in the two settings, as are the different uses of continuation practice. It thus is inappropriate to seek false reassurance by relying on examples from other industries when assessing the anticompetitive effects of pharmaceutical patent thickets.

Similar to the pharmaceutical industry, the high-technology industry relies on continuation patents to create large patent portfolios. But these two industries use portfolios differently.

High-technology firms tend to build patent portfolios as negotiation tools in cross-licensing their technology. Firms in these industries need to enter into licenses because a single product tends to be covered by many patents. These patents, however, typically do not prevent competitor market entry. For example, standards organizations often require patents to be licensed on reasonable terms.

Pharmaceutical thickets have been created and used differently. Firms in the industry have employed these thickets to delay and deter competitor market entry. Drug companies do not need to amass patents to engage in licensing, and their power increases from a regulatory framework and industry concentration making it difficult for rivals to enter.

Our data show that the pharmaceutical industry frequently (and especially recently) uses continuation patents and frequently (and increasingly recently) litigates these patents. We found similar results for a type of patent that drug firms have exploited in the "skinny label" context: method-of-use patents. And we found that in the Humira thicket, most of the patents are continuations, most of even the original filings were secondary patents, and in the period shortly before exclusivity expired, the number of listed patents, percentage of litigated continuation patents, and generation number significantly increased.

In short, unlike the high-technology industry, patent thickets in the pharmaceutical industry are designed to be anticompetitive. It is not persuasive to justify such thickets based on those in the high-technology industry. Given the increase in pharmaceutical thickets and effects on patients' lives, a recognition of this difference would be helpful.

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[193] Tu & Lemley, *supra* note 7, at 1692 fig.4.