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THE LONG CON: AN EMPIRICAL ANALYSIS OF PHARMACEUTICAL PATENT THICKETS

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THE LONG CON: AN EMPIRICAL ANALYSIS OF PHARMACEUTICAL PATENT THICKETS

S. Sean Tu*

ABSTRACT

Over the past two decades, drug manufacturers have tripled the intensity of patenting around their drugs with 1.86 patents per active ingredient in 2001 to almost six patents per active ingredient in 2019. This three-fold increase in patenting has led to a dense web of overlapping intellectual property rights called "patent thickets." These thickets can include dozens and sometimes hundreds of less innovative "secondary" patents. Many of these secondary patents use a special "continuation" application ("CON"), which allows brand manufacturers to spawn additional patents from a previous patent family member without disclosing anything new. CONs allow brand manufacturers to quickly create less innovative nuisance patents that are designed to delay or deter generic market entry. This Article focuses on the use of CONs in the creation and enforcement of pharmaceutical patent thickets.

This study analyzes data on all continuation applications from 2000 to 2022 (over 7.5 million patent applications) and links these applications to subsequent patent litigation from 2000 to 2022. This study also focuses on continuation applications filed more than five years after the original application's priority date ("Long CONs"). When we compare pharmaceutical patents against all other technology groups, we show that Long CONs are usually part of large patent thickets and are strategically important components of brand firm litigation. We find that the

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use of Long CONs has steadily increased over the last three decades for some technology types, but this increase is more pronounced for pharmaceutical patents.

Long CON patents represent only 8.3% (639,308/7,692,046) of all patent applications; however, Long CONs represent 23% (9,836/43,220) of all litigated patents. Additionally, 51% (323,908/639,308) of all Long CONs come from just a few industries. The pharmaceutical industry disproportionately files and litigates Long CONs patents. We find that Long CONs represent 33% (2,126/6,432) of all small molecule pharmaceutical patents and 36% (900/2,534) of all litigated small molecule pharmaceutical patents. This data shows that patent thickets built upon continuation applications have a disproportionate effect on litigation, which may result in higher drug prices for longer periods of time.

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I. BACKGROUND

Patent thickets are defined by multiple patents with overlapping rights that can hamper innovation.[1] In the pharmaceutical field, patent thickets play an important role in deterring or delaying generic drug market entry by creating transaction barriers or increasing entry costs.[2] Patent thickets are generally composed of less innovative, "secondary patents."[3] In the pharmaceutical field, secondary patents take the form of minor alterations to an existing drug rather than a patent on a new chemical entity.[4] These alterations could include things such as changing the formulation (extended-release); dosage; route of administration (e.g., capsules, tablets, or topicals); new therapeutic uses; polymorphs or enantiomers; or metabolites/prodrugs.[5]

In contrast to secondary patents, "primary patents" are usually composition of matter patents directed to the drug's active ingredient and are typically "stronger" because they are broader in scope and more difficult to invalidate.[6] Primary patents are typically the key patent linked with breakthrough drugs and are typically associated with the drug's active ingredient.[7] Primary patents usually provide the strongest protection because any competitor who uses the same active ingredient will infringe the patent regardless of dosage, route of administration, formulation, method of use, or method of manufacture.

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[1] Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELL. PROP. L.J. 79, 81 (2024); *see generally* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE (Dec. 5, 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3515607/pdf/pone.0049470.pdf [https://perma.cc/ZSU9-TV43].

[2] *See* 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); S. Sean Tu, Rachel Goode & William B. Feldman, *Biologic Patent Thickets and Terminal Disclaimers*, 331 JAMA 355, 355 (2024); *id.*

[3] *See* S. Sean Tu & Ameet Sarpatwari, *A "Method of Use" to Prevent Generic and Biosimilar Entry*, 388 NEW ENG. J. MED. 483 (2023).

[4] *See id.*

[5] *See id.*

[6] S. Sean Tu & Mark A. Lemley, *What Litigators Can Teach the Patent Office About Pharmaceutical Patents*, 99 WASH. L. REV. 1673, 1686, 1692 (2022).

[7] *See* Reed F. Beall, Jonathan J. Darrow & Aaron S. Kesselheim, *A Method for Approximating Future Entry of Generic Drugs*, 21 VALUE HEALTH 1382, 1387 (2018) (showing that generic entry occurs close to the expiration date of the primary patent in Figure 4).

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Previous commentators have argued that the patent system was designed to incentivize the development of primary patents.[8] However, by creating patent thickets, brand firms are manipulating the patent system to do something that it was never intended to do; namely, to deter or delay generic entry without disclosing anything new or useful. Pharmaceutical patent thickets have negative downstream consequences, such as restricting the range of therapies available to patients, increasing costs of health care delivery, and impediments to cooperative research. These adverse outcomes ultimately contribute to elevated pharmaceutical costs and poor patient outcomes.

The problem with pharmaceutical patent thickets has recently drawn the attention of Congress, with six senators drafting a letter on June 8, 2022, to the U.S. Patent and Trademark Office ("PTO"), outlining their concerns with patent thickets created by continuing applications.[9] Additionally, there are several bills working their way through Congress that address pharmaceutical patent thickets.[10] In response, PTO Director Kathi Vidal and Food and Drug Administration ("FDA") Commissioner Robert Califf are collaborating in an attempt to curb patent gamesmanship.[11]

A. Creating Patent Thickets

Patent thickets vary in size and can comprise just a few patents to over a hundred patents.[12] In the pharmaceutical sector, patent thickets act as barriers to

[8] *See* Kapczynski, Park & Sampat, *supra* note 1; *see also* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIS. 590, 617 (2018); *see also* Letter from Patrick Leahy, Sen., U.S., John Cornyn, Sen., U.S., Richard Blumenthal, Sen., U.S., Susan M. Collins, Sen., U.S., Amy Klobuchar, Sen., U.S. & Mike Braun, Sen., U.S. to The Honorable Kathi Vidal, Dir., U.S. Pat. & Trademark Off. (June 8, 2022) (on file with the United States Senate).

[9] Letter from Patrick Leahy, Sen., U.S., John Cornyn, Sen., U.S., Richard Blumenthal, Sen., U.S., Susan M. Collins, Sen., U.S., Amy Klobuchar, Sen., U.S. & Mike Braun, Sen., U.S. to The Honorable Kathi Vidal, Dir., U.S. Pat. & Trademark Off., *supra* note 8.

[10] *See, e.g.*, Press Release, Peter Welch, Sen., U.S., Mike Braun, Sen., U.S., Amy Klobuchar, Sen., U.S., Welch, Braun, and Klobuchar Introduce Bipartisan Legislation to Streamline Drug Patent Litigation, Lower Cost of Prescription Drugs (Jan. 12, 2024) (on file with author).

[11] Kathi Vidal, *Duty of Disclosure and Duty of Reasonable Inquiry Promote Robust and Reliable Patents, Drive Competition and Economic Growth, and Bring Life-Saving Drugs to the American People*, USPTO: DIRECTOR'S BLOG (July 28, 2022), https://www.uspto.gov/blog/director/entry/duty-of-disclosure-and-duty [https://perma.cc/JX86-P4CT]; Joint USPTO-FDA Collaboration Initiatives, Notice of Public Listening Session and Request for Comments, 87 Fed. Reg. 67019 (Nov. 7, 2022).

[12] Rachel Goode & Bernard Chao, *Biological Patent Thickets and Delayed Access to Biosimilars, an American Problem*, 9 J.L. & BIOSCIS. 1, 20 (2022); Jonathan J. Darrow & Daniel T.C. Mai, *An Orange*

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delay or deter generic drug manufacturers from entering the market.[13] Patent thickets are especially important for drug firms who wish to prevent competition rather than license their technology.[14] If generic or biosimilar companies do not know which claims they may infringe due to large patent thickets, there will be an underutilization of resources, creating a "tragedy of the anticommons."[15] By refusing to license, brand firms effectively hold up the development of innovation since innovating around a drug may require patent rights to many patents in the thicket. Thus, patent thickets create uncertainty, raise transaction costs, and inhibit pharmaceutical innovation, ultimately resulting in increased drug prices.

Large pharmaceutical patent thickets can be created quickly and relatively easily through "continuing applications."[16] Continuing applications are "child" applications that follow and claim priority to an earlier filed "parent" application.[17] Continuing applications (hereinafter CCD applications) come in three varieties: a continuation ("CON"), a continuation-in-part ("CIP"), or a divisional ("DIV") application.[18]

B. Continuation Patents ("CONS") and Long Continuation Patents ("Long CONS")

CONs are the heart of pharmaceutical patent thickets, and for this study we focus on CONs.[19] CONs, by definition, are patents that are based on the same invention description and drawings as another application that was previously filed. The disclosure in a CON is identical or almost identical to a previously filed patent application. In fact, the defining characteristic of a CON is that it *cannot* include new

Book Landscape: Drugs, Patents and Generic Competition, 77 FOOD & DRUG L.J. 51, 62 (2022); Tu, Kesselheim, Wetherbee & Feldman, *supra* note 2, at 470.

[13] Tu, Kesselheim, Wetherbee & Feldman, *supra* note 2, at 470; Tu & Lemley, *supra* note 6, at 1674.

[14] Carrier & Tu, *supra* note 1, at 79.

[15] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

[16] Tu, Kesselheim, Wetherbee & Feldman, *supra* note 2.

[17] USPTO, MANUAL OF PATENT EXAMINING PROCEDURE § 201.07, https://www.uspto.gov/web/offices/pac/mpep/s201.html [https://perma.cc/YUR4-W3ES] (last updated July 2022).

[18] *Id.* § 201.02.

[19] Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U.L. REV. 63, 69 (2004); *see also* Arti K. Rai & Nicholson W. Price, *An Administrative Fix for Manufacturing Process Patent Thickets*, 39 NATURE BIOTECH. 23 (2021).

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material, new illustrations, or add new matter to the parent application.[20] Accordingly, CONs do not disclose new inventions to the public, but simply allow inventors a procedural mechanism to capture new exclusive rights over a previously disclosed invention.

The purpose of a CON is to rely on a previous disclosure so that inventors can capture subject matter that was not captured in the original patent. The typical story associated with CONs is that an inventor needs to go into the market with some patent protection. To quickly obtain patent rights, they narrow their claims to obtain a patent covering only the commercial embodiment of their invention.[21] However, firms can subsequently obtain broader rights by filing a CON.[22] Accordingly, the CON is filed to obtain broader rights that were not initially obtained due to the time pressure of needing to get to market with enough patent protection to cover the commercial embodiment of the invention.

The main difference between a CON and its parent is that the CON will have different claims than the parent application. Typically, the new claims in the CON are narrower, cover a different aspect of the invention, or might be narrowed to cover a competitor's product that was described but not claimed in the parent application.[23] Because CONs are filed later in time, CONs allow firms to see the different types of products competitors create, and then issue new patents that cover the competitor's technology. These later filed CONs are usually more difficult to invalidate because they are much narrower in scope, covering the competitor's exact product while avoiding prior art due to their narrow scope.

This study also reviews "Long CONs" as a subset of the general CON population. This study defines "Long CONs" as those CONs that are filed at least five years after the priority date of the original parent patent. Long CONs are similar to CONs, but usually claim priority to at least two or three parent applications. Accordingly, Long CONs are typically grandchildren, great-grandchildren, or great-great-grandchildren of the original patent. This study scrutinizes Long CONs because these applications do not disclose anything new over their previous parent

[20] USPTO, *supra* note 17, § 201.07.

[21] *Quality Patents: Claiming What Counts*, WIPO MAG., Feb. 2006, at 17, 18, https://www.wipo.int/wipo_magazine/en/2006/01/article_0007.html [https://perma.cc/CT6U-VSL3].

[22] Vic Lin, *Why File a Continuation Application Before Your Patent is Granted?*, PATENTTRADEMARKBLOG, https://www.patenttrademarkblog.com/why-file-continuation-before-patent-granted/ [https://perma.cc/5SDH-UQ5M] (last visited May 1, 2024).

[23] *Id.*

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applications and almost certainly represent patents that are designed to delay or deter generic drug market entry. Long CONs are defined as patents filed five years after the filing of the original patent, because at this point, Long CONs have already utilized 25% of their 20-year patent term.[24]

In the pharmaceutical context, CONs usually consist of "secondary" patents. Previous commentators have shown that "secondary" patents are based on smaller tweaks to an existing drug rather than a new chemical entity ("primary" patents).[25] Pharmaceutical CONs are usually part of large patent families, suggesting that patentees are trying to strengthen the wall around an already disclosed product, making it more difficult for generics or biosimilars to enter the market. Thus, the original "primary" patent that protects the new chemical entity is usually filed early in the drug's life cycle,[26] while later filed CONs are secondary patents directed to minor alterations filed later in the drug's life cycle.[27]

CONs allow brand firms to quickly create large patent thickets. CONs can move through the patent examination process quickly because they do not disclose any new material. Additionally, CONs from the same family are usually assigned to the same patent examiner who previously examined other related family members.[28] Because the examiner has previously reviewed the parent patent, they should already be familiar with the technology and prior art.

Additionally, many CONs are granted "Track One" status, which is a form of prioritized examination where the applicant pays a fee and the PTO attempts to complete patent prosecution within one year.[29] Thus, many pharmaceutical CONs usually move through prosecution faster than an original application, and typically

[24] USPTO, *supra* note 17, § 2701(c)(1).

[25] *See* Tu & Lemley, *supra* note 6, at 1676; Tu & Sarpatwari, *supra* note 3, at 483.

[26] The broadest claims are usually composition of matter claims that are found in the patents that have been self-identified by those patents that are granted "patent term extension" (PTE). Victor L. Van de Wiele, Aaron S. Kesselheim, Sarosh Nagar & S. Sean Tu, *The Prevalence of Drug Patent Term Extensions in the United States, 2000–2018*, 41 NATURE BIOTECH. 903, 904 (2023); *see generally* 35 U.S.C. § 156 (2018); Carrier & Tu, *supra* note 1, at 82.

[27] Carrier & Tu, *supra* note 1, at 82.

[28] Tu & Lemley, *supra* note 6, at 1678.

[29] USPTO, *USPTO's Prioritized Patent Examination Program*, https://www.uspto.gov/patents/initiatives/usptos-prioritized-patent-examination-program [https://perma.cc/ZFV4-ZCKF] (last visited May 1, 2024).

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are granted "Track One" status.[30] By using the "Track One" prioritized examination program, brand pharmaceutical firms can time the patent issue date to maximize risk to generic/biosimilar firms because many Track One patents issue precisely when FDA market exclusivities end.[31]

For most technologies outside the pharmaceutical industry, this type of CON-based patent thicket strategy does not work because products change so dramatically making older patents obsolete. This, however, is not true for drug patents, where patent families based upon one active chemical ingredient can deter or delay generic market entry for years.[32] Patent thickets for the high-tech field also have many differences compared to pharmaceutical patent thickets.[33] For example, pharmaceutical firms have 100% of the patents covering their products, while high-tech firms have multiple owners and use thickets to cross-license their patents (while pharmaceutical firms have no incentive to license their patents to competitors).[34] Additionally, the pharmaceutical industry has higher regulatory barriers and firm concentration compared to the high-tech industry.[35] Finally, generic pharmaceutical firms can only compete on price, since the generic drug must be almost identical to the brand drug.[36] In contrast, high-tech firms can compete on dimensions other than just price.

C. The Problem with Pharmaceutical CONS

Currently, the PTO allows an applicant to generate an *unlimited* string of child filings from an original patent application.[37] Thus, currently, firms can file as many CONs as they want. As the number of CONs grows from child to grandchild to great-grandchild application, the exchange between the examiner and applicant suffers

[30] Tu & Lemley, *supra* note 6, at 1679; S. Sean Tu & William B. Feldman, *Use of Track One Prioritized Examination for Pharmaceutical Patents*, JAMA HEALTH NETWORK, July 19, 2024.

[31] S. Sean Tu & William B. Feldman, *Use of Track One Prioritized Examination for Pharmaceutical Patents*, JAMA HEALTH FORUM, July 19, 2024, at 1, 1.

[32] Tu & Lemley, *supra* note 6, at 1673.

[33] Carrier & Tu, *supra* note 1, at 84–85.

[34] *Id.* at 84.

[35] *Id.* at 84, 102.

[36] *Id.* at 102.

[37] Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

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from diminishing returns. The disclosure for each CON is identical to the parent disclosure, and typically the applicant is trying to obtain a patent on minor variations on the original patented invention. Furthermore, multiple patents that arise from CONs defeat the public notice function of patent claims because competitors may not know which patents cover their products.[38]

Patents are based on a *quid quo pro*. The inventor discloses a new and useful invention, and in return, society gives a limited exclusionary right to that inventor. Patent thickets weaken this social contract by allowing inventors to gain exclusionary rights over inventions that may not be new or useful. By definition CONs cannot disclose new information.[39] Accordingly, the more we allow CON-based patent thickets, the less society gains while giving more to the inventor. This is not to say that CONs do not play an important role, as many inventors may elect to obtain a narrow patent today while fighting for broader claims in a CON tomorrow. However, when society allows the fifth or sixth patent based on the same disclosure, the public does not gain a beneficial disclosure but surrenders valuable exclusionary rights for the fifth or sixth time on the same disclosure. This is especially important in the pharmaceutical industry where each day of generic drug delay can cost consumers tens of millions of dollars.[40]

One counterargument is that CONs are used by brand manufacturers to protect valuable intellectual property rights lost due to the lengthy FDA approval process. Congress has previously considered this with "patent term extension," where Congress added up to five additional years of patent term to compensate brand manufacturers for the time spent in FDA approval.[41] However, this rationale cannot be used to support the use of CONs. First, CONs are typically filed and issued after FDA approval.[42] Second, CONs typically do not extend the life of the patent because

[38] Robin Feldman, *Paucity of Intellectual Property Rights Information in the US Biologics System a Decade After Passage of the Biosimilars Act.*, PLOS MED., Apr. 25, 2024, at 1, 3.

[39] USPTO, *supra* note 17, § 201.07.

[40] *See* FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf [https://perma.cc/L7JT-S4CT]; S. Sean Tu et al., *The Cost of Drug Patent Expiration Date Errors*, 42 NATURE BIOTECH. 1024 (2024).

[41] Determination of Regulatory Review Period for Purposes of Patent Extension; ISTURISA, 89 Fed. Reg. 14853 (Feb. 29, 2024).

[42] Tu, Goode & Feldman, *supra* note 2, at 356–57 (showing that most biologic patents were filed after FDA approval and most were CONs).

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they typically are associated with terminal disclaimers that tie the expiration dates of the original patent to the CON.[43]

CON-based patent thickets are especially problematic since it is extremely difficult to assess the existence and scope of the patent rights over time.[44] This is especially true if there is at least one child application still in prosecution because more children with claims of undefined scope can spawn from the pending child application. This uncertainty creates additional transaction and innovation costs and increases the risk for the generic manufacturer, which leads to suboptimal levels of investments in Research and Development ("R&D")[45] as well as increased drug prices.

Previous attempts to reign in CON abuse have failed. For example, in 2007, the PTO attempted to address this problem by limiting the applicant to just two CONs but allowing for more CONs with a showing that the later-filed applications were necessary to claim the invention.[46] Industry backlash to this proposal, however, came strong and swift.[47] Additionally, two lawsuits, one by a sole inventor, Dr. Triantafyllos Tafas, and another by GlaxoSmithKline were filed against then PTO Director Dudas, arguing that the Final Rules exceeded the rulemaking authority of the PTO and thus constituted an unlawful agency action under Section 706(2) of the Administrative Procedure Act.[48] After a change in administrative leadership at the

[43] Tu & Lemley, *supra* note 6, at 1700 (showing in Table 1 most invalidated small molecule drug patents are CONs).

[44] Simone Keunen, *Empirically Detecting Patent Thickets*, TILEC DISCUSSION PAPER NO. 2009-047 (2009).

[45] *See* Heller & Eisenberg, *supra* note 15, at 698–701.

[46] Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46716 (proposed Aug. 21, 2007) (to be codified at 37 C.F.R. pt. 1).

[47] Simon J. Elliott & Courtenay C. Brinckerhoff, *New PTO Continuation Rules: Unfair to Biotech?*, PATENT DOCS (Aug. 29, 2007), https://www.patentdocs.org/2007/08/new-pto-continu.html [https://perma.cc/SZ6L-9E9J].

[48] Tafas v. Dudas, 541 F. Supp. 2d 805, 808 (E.D. Va. 2007) (Tafas and GSK claimed that the final rules were unlawful agency action under section 706(2) of the APA and should have been declared null and void).

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PTO, then newly appointed Director Kappos decided to rescind the rules, thus ending both lawsuits.[49]

This study shows that the CON problem has gotten worse over time. This study confirms many other studies finding that the pharmaceutical industry relies heavily on CONs to protect their drug products.[50] However, we also find that, unlike any other industry, the pharmaceutical industry relies heavily on CONs and Long CONs to protect their drug products.[51] This data highlights the importance of these Long CON secondary patents in creating patent thickets and the use of Long CON patents for litigation purposes. First, we find that patents that claim priority to multiple parent patents receive much fewer substantive rejections but have increased numbers of obviousness-type double patenting ("ODP") rejections. Second, we find that Long CON patents are playing an outsized role in litigation, likely because pharmaceutical firms may be able to tailor their claims to cover competitor products while also narrowing those claims to withstand invalidation. Additionally, these Long CON patent thickets are likely designed to increase risk to competitors by confounding the scope of the patented invention.

II. METHODS

A. Identification of CCD Patents

Using publicly available patent data, we identified the number of granted U.S. patent continuations, continuations-in-part, and divisionals filed from 2000 to 2022. This was performed using the Google Patents Public Datasets on Google BigQuery and the *Patent Publication* table from IFI CLAIMS updated through April 6, 2022. We determined the number of child applications that were filed that claimed priority to their earliest original patent application. 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 then segmented the data by CONs. Design and reissue patents were excluded.

B. Identification of Long CON Patent Technology

To determine the patent industry, we use the Cooperative Patent Classification (CPC) codes. We used first CPC group only and counted the number of CONs and

[49] Sheri Qualters, *PTO Rescinds Controversial Patent Rules*, LAW.COM, https://www.law.com/almID/1202434444866/ [https://perma.cc/92J2-V2KH] (last visited June 14, 2024).

[50] *See* Tu, Kesselheim, Wetherbee & Feldman, *supra* note 2; Tu, Goode & Feldman, *supra* note 2; Tu & Sarpatwari, *supra* note 3, at 483.

[51] Carrier & Tu, *supra* note 1, at 84–85.

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original patent applications filed by the first CPC group. We further aggregated CPC groups into "Chemistry" (C07K, C12N, A61K, A61M, A61B, C07D, G01N) and "Electrical/Computer" (H04W, H04L, H04N, G06F, H01L) as seen in Table 1.

C. Identification of Long CON Orange Book Patents

To further analyze continuation applications, we matched CONs to the FDA *Orange Book*. We segmented the data by Long CONs, as defined as CONs which are filed at least five years after the earliest priority date to a non-provisional patent. We then linked these patents to those patents listed in the 1984–2022 *Orange Book*.[52] The *Orange Book* lists all relevant patents associated with small-molecule drugs.[53]

D. Identification of Long CON Patent Litigations

Using U.S. litigation data from Unified Patents, we identified the number of continuation patent applications that went to litigation. This analysis was performed by joining the *Unified Patents Litigation Cases* table to the *Patent Publications* table.

E. Patent Prosecution Analysis

All *Orange Book* patents from the 2001–2022 *Orange Books* were run through PatentAdvisor.com to gather patent prosecution information. Only patents with issue dates after 2001 were analyzed because the PTO's digital records only go back to 2001. This resulted in capturing 4,081 patents (63%) of the 6,432 patents listed in the 2000–2020 *Orange Books*. We recorded data relating to number of office actions, types of rejections (including obviousness-type double patenting; double patenting; anticipation; obviousness; written description/enablement; and indefiniteness), number of words at publication and grant, and number of independent claims at grant.

III. RESULTS

CONs and Long CONs play a particularly important role in the pharmaceutical field. Pharmaceutical firms, more than any other technology type, rely heavily on CONs and Long CONs. Table 1 shows that the pharmaceutical industry files the highest percentage of Long CONs, and also litigates the highest number of Long

[52] *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 [https://perma.cc/ZA6H-2C8M] (last visited May 1, 2024) [hereinafter Orange Book].

[53] 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(b) (2023) (stating that the new drug application shall include a listing of drug substance (active ingredient) patents, drug product (formulation and composition patents), and method of use patents, specifically excluding the listing of "process patents, patents claiming packaging, patents claiming metabolites, and patents claiming intermediates").

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CONs. Figure 1A and 1B show the number of patents, litigated patents, and Long CON patents in all technologies (Figure 1A) and *Orange Book* Patents (Figure 1B) reviewed for this study.

Compared against all technology types, drug and medical device patents represent some of the highest number of Long CON patents of all technology types (Table 1). Table 1 shows that pharmaceutical patent applications represent the top number of continuation applications. Shaded rows are those CPC codes that have *Orange Book* listed patents. There was a total of 1,399 and 901 litigated CON and Long CON *Orange Book* patents, respectively. A high percentage of litigated pharmaceutical patents were CONs and Long CONs, 55% and 36%, respectively. In contrast, over all litigated patents, only 35% were CONs and 23% were Long CON patents. These data show that pharmaceutical firms, more than any other technology type, are building patent thickets from much older original patents. These patents are not innovative but are usually obvious variations of the original patent.

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Figure 1A

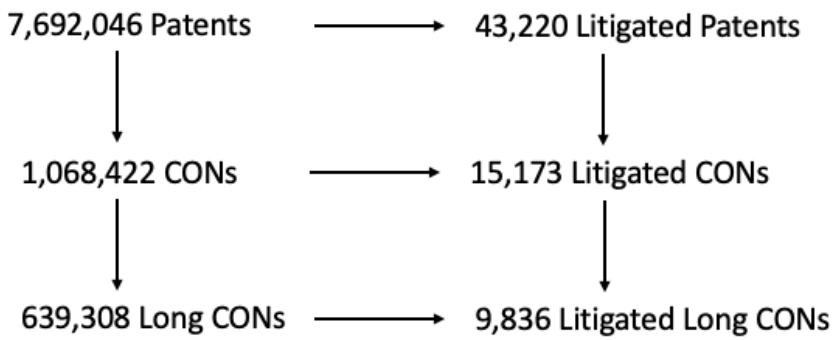
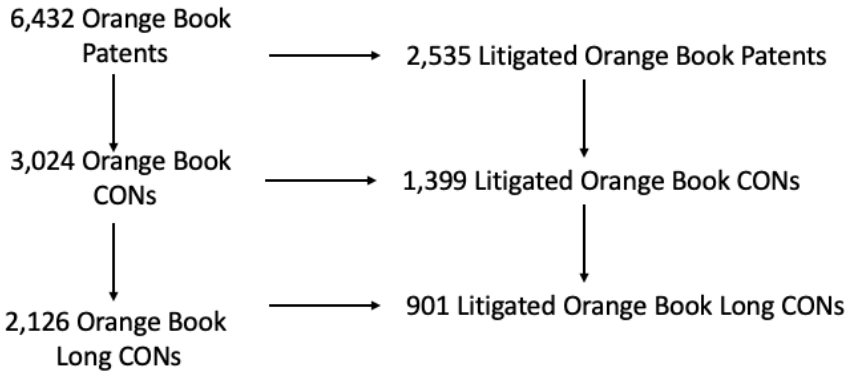


Figure 1B



As an initial matter, very few industries rely on Long CONs. Most industries evolve rapidly and do not require patents built on much older patent applications. Long CON applications represent only 8.3% (639,308/7,692,046) of all patents granted from 2000 to 2022. Many industries rely on CONs, but do not file Long CONs. This is especially true for electrical engineering inventions.[54] For example,

[54] *Cooperative Patent Classification: Electricity*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/patents/classification/cpc/html/cpc-H.html [https://perma.cc/KTG4-HYZJ] (explaining that H01-Basic Electric Elements CPC patents group have high numbers of continuation applications, but very few Long CONs).

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CPC Class H01R: Electrically-Conductive Connections has a high number of continuation applications (96,955), but only 1,296 (1.34%) are Long CONs. Similarly, CPC H01J (Electric Discharge Tubes) and H01H (Electric Switches) have 86,431 and 79,058 continuation applications, but only have 2,507 (2.9%) and 621 (0.79%) Long CONs, respectively.

Only three industries produce 51% of all Long CONs (323,908/639,308). These industries include biotechnology, software, and electronics. Over the past fifteen years, these three industries have been increasingly using Long CONs. Figure 2A shows the overall yearly growth in Long CONs. For example, in 2000, only 4,758 Long CON applications were filed, while in 2017, there were almost 30,000 Long CON applications filed. Long CONs play a large role in pharmaceutical patents. Figure 2B shows a larger increase in *Orange Book* Long CON patents from 16 to 339 in 2000 to 2017, respectively.

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Figure 2A

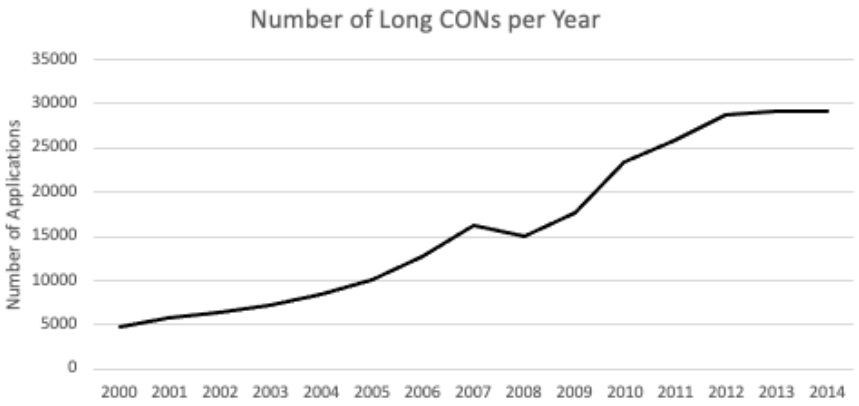
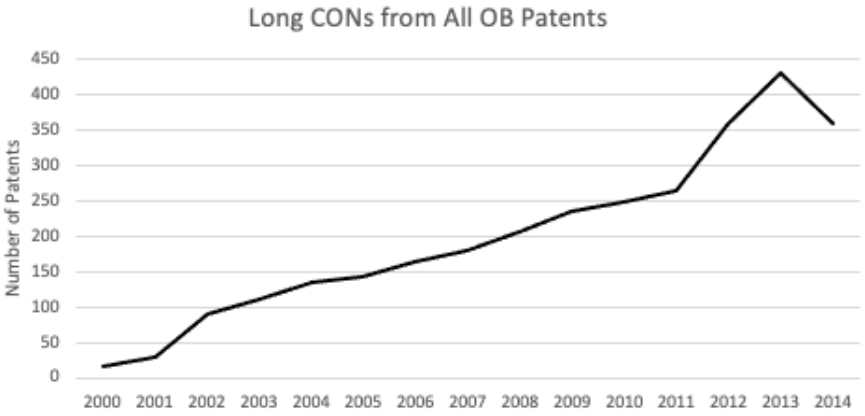


Figure 2B



In contrast to most industries, the biotechnology industry relies heavily on Long CONs. As shown in Table 1, the top five technologies that use Long CONs are all from the biotechnology industry (as a percentage of CONs). Furthermore, the shaded cells in Table 1 represent those CPC classes that are associated with *Orange Book* patents (patents directed to small molecule drugs). Over 33% (3,024/6,432) of all *Orange Book* CONs are Long CONs. Furthermore, the density of these pharmaceutical patent thickets is very high, with 40-60% of the patent families having at least two CONs. These data argue that patent thickets based on CONs play a key role in pharmaceutical life cycle management.

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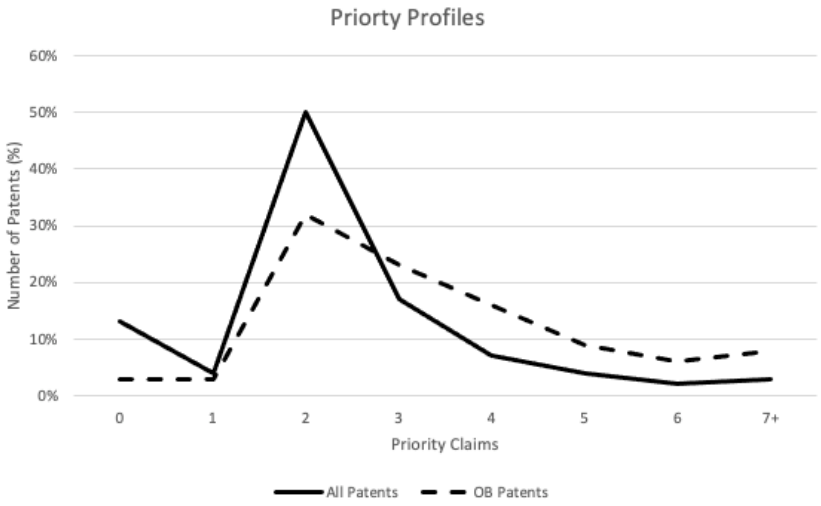
Orange Book CONs also claim priority to many more parent applications. Figure 3 shows the priority profile for *Orange Book* patents versus all other technologies. For example, 50% (535,799) of CONs for most technologies only claim two priority documents (grandchild), in contrast, only 32% (961) of *Orange Book* CONs are grandchildren. 23% (690) and 16% (484) of *Orange Book* CONs are great-grandchildren (3 priority claims) or great-great grandchildren (4 priority claims), respectively. In contrast, only 17% (178,704) and 7% (77,342) of all CONs are great-grandchildren or great-great grandchildren (respectively).

Figure 3



This data is somewhat unsurprising, since it is known that the biotechnology industry relies heavily on "patent thickets," which are based primarily on less innovative continuation applications. What is surprising is the frequency and depth of the problem and the fact that many of these Long CONs are granted long after the original patents are granted.

A. Orange Book *Prosecution History*

As the number of children, grandchildren and great-grandchildren increase, the greater the chances that subsequent patents are nuisance patents. This results in patents that are not innovative but are simply used to capture narrower versions of the first patented iteration of the invention. The average number of words in a

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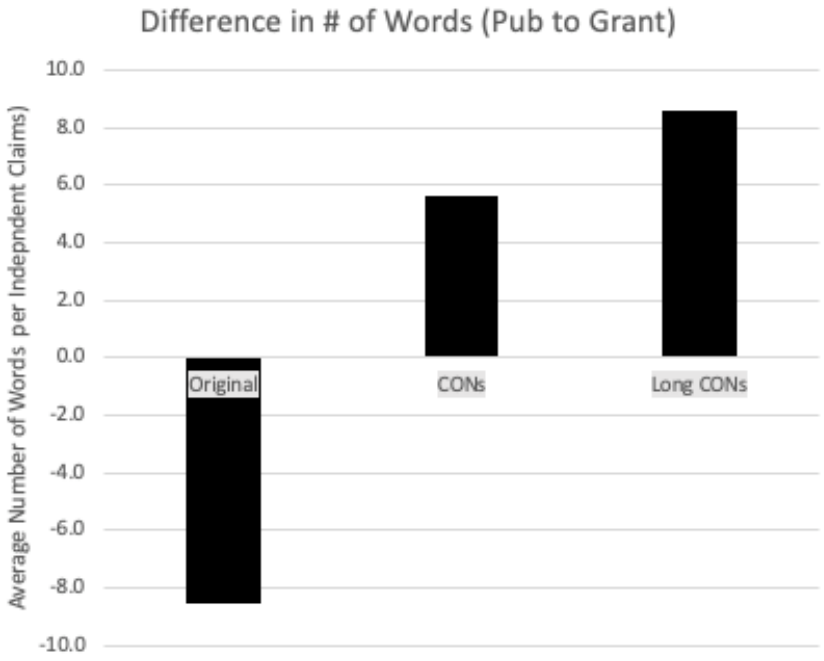
patent's first claim is used as a proxy for claim scope.[55] Typically, more words in a claim represent narrower claims, while fewer words represent broader claims.[56] Figure 4 shows that the average number of words in the independent claims of an originally granted *Orange Book* patent is eight words less than average number of words in the originally filed publication. In contrast, CONs and Long CONs have, on average, 5.6 and 8.6 more words in their granted patents versus their published applications. This infers that the original claims are likely the broadest patents, while CONs and Long CONs further narrow the claims.

Figure 4



[55] Jeffery M. Kuhn & Neil C. Thompson, *How to Measure and Draw Causal Inferences with Patent Scope*, 26 INT'L J. ECONS. BUS. 5, 7 (2019).

[56] *Id.* at 11.

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Similarly, the number and types of rejections change when looking at different generations of the same patent family. Figure 5A shows that as we move deeper down the priority chain, we see fewer substantive rejections of almost all types.[57] This is somewhat unsurprising, since narrower claims found in the great-great-grandchild are likely not to experience the prior art or written description/enablement issues found in their parent applications. Accordingly, most of the substantive patentability issues are worked out during the prosecution of the original patent.

There is a dramatic increase in the number of ODP rejections in higher priority patents from the same families. This is unsurprising, because an ODP rejection is based on the idea that a previously granted patent renders the new application "obvious." Applicants, however, file a terminal disclaimer to overcome this type of rejection.[58] A terminal disclaimer allows the applicant to link the patent family together so that they all expire on the same date.[59] Figure 5B shows that there is a dramatic increase in the use of ODP rejections as the priority claims increase. This is unsurprising as great-great-grandchildren are likely to be obvious over parent applications.

[57] 35 U.S.C. § 101 (patentable subject matter and utility). Rejections as well as Statutory 101 double patenting rejections were not included in this graph because there were less than 150 rejections based on these statutory categories. *Patent Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF. (Feb. 16, 2023, 12:58 PM), https://www.uspto.gov/web/offices/pac/mpep/s2106.html [https://perma.cc/DVU3-JKGM] (detailing the conditions under which a 35 U.S.C. § 101 is made).

[58] USPTO, *supra* note 17, § 1490.

[59] *Id.*

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Figure 5A

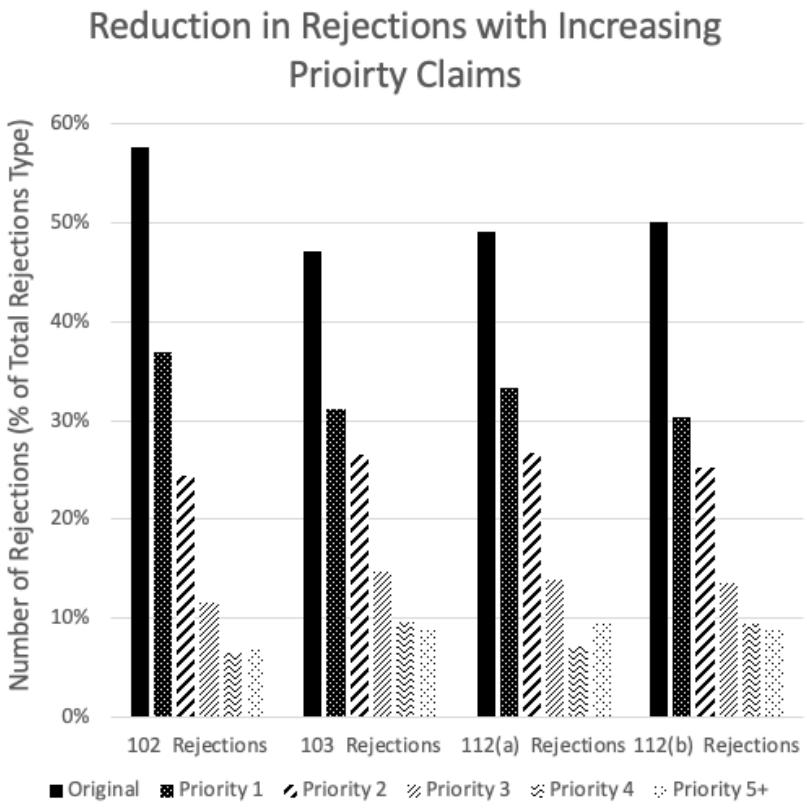

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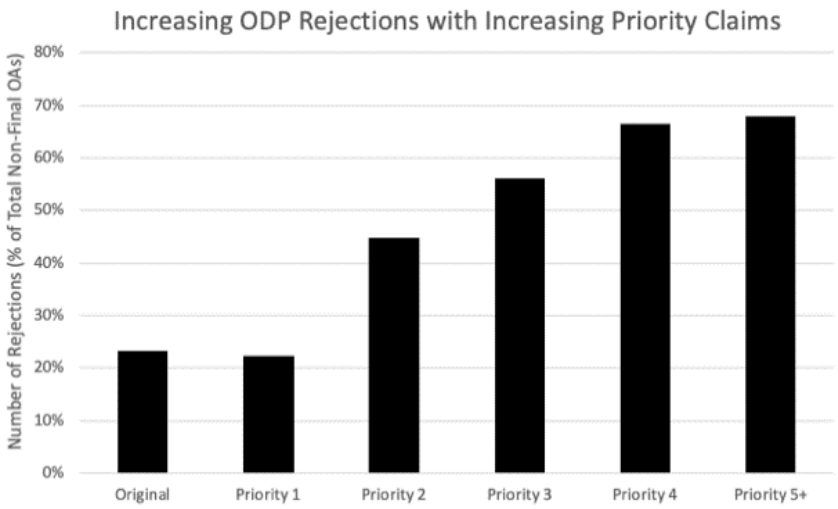
Figure 5B



B. Litigated Patents

Less than 1% (43,220/7,692,046) of continuing applications are litigated (Table 2). Long CONs, however, are playing an outsized role in litigation. Although Long CONs represent only 8% of all continuation applications, they represent 23% (9,836/43,220) of all litigated patents (Table 2). This suggests that Long CONs play an important role in protecting the most valuable intellectual property rights.

CONs and Long CONs play an outsized role in pharmaceutical patent litigation. Table 3 shows that 7.2% of litigated pharmaceutical patents are CONs, which is the second highest percentage of litigated CONs. Similarly, litigated Long CONs play a disproportionate role in the pharmaceutical industry. Table 3 shows that the top fifteen technologies that use CONs in litigation. Six of the top ten technologies that litigate using Long CONs are from biotechnology. While it is true that some electronic/software technology types have high numbers of CONs, this is likely because the high-technology industry uses CONs as leverage for cross-licensing

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negotiations while pharmaceutical patent thickets are used to prevent competitor market entry.[60]

Orange Book Long CON patents, and particularly pharmaceutical composition Long CON patents, play an outsized role in patent litigation. Long CON *Orange Book* patent CPC groups represent (160,636/702,205) (22.9%) of all Long CON patents, and pharmaceutical compositions patents represent the largest single group (51,238/702,205) (7.3%) of all Long CON patents.[61] Long CON *Orange Book* patent groups represent (2,041/10,520) (19.4%) of all litigated Long CON patents, with pharmaceutical composition Long CON patents representing the single highest group of all litigated Long CON patents (1,162/10,520) (11.0%). Furthermore, these litigated Long CON patents represent 37% (1,162/3,116) of all litigated pharmaceutical compound continuation patents.

IV. DISCUSSION

The pharmaceutical industry relies heavily on CONs and Long CONs to quickly build dense patent thickets likely to deter or delay generic market entry. These CONs and Long CONs are not novel and typically are narrower in scope than their original patents. Additionally, these CON patent thickets move through patent prosecution with fewer and fewer substantive rejections but with an increasing number of ODP rejections, arguing that they do not cover anything new. Ultimately, this study argues that pharmaceutical firms are generating large patent thickets based on obvious variations of inventions claimed in the original patent. These subsequent patents are being enforced and litigated to prevent generic drug entry.

Long CONs and patent thickets create at least three distinct harms: (1) defeating the *quid quo pro* rationale behind the patent system; (2) increasing risk

[60] Carrier & Tu, *supra* note 1, at 110 (showing that pharmaceutical patent thickets are used to prevent competitors from entering the market while high-tech patent thickets are used to cross-license).

[61] *See Cooperative Patent Classification*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/patents/classification/cpc/html/cpc-A61K.html [https://perma.cc/B68G-G3HZ] (explaining that A61K is the CPC code that represents drug or other biological compositions that are capable of preventing, alleviating, treating, or curing abnormal or pathological conditions of the living body). Other Orange Book CPC groups include: C07K (Peptides); G01N (Chemical Analysis); C07D (Heterocyclic Compounds); A61F (Implantable Filters); A61M (Medical Devices); A61N (Electrotherapy/Radiation Therapy); C07C (Acyclic or Carbocyclic Compounds); A01N (Biocides); C08G (Macromolecular Compounds); C07H (Nucleosides; Nucleotides and Nucleic Acids); C07F (Acyclic, Carboxcyclic or Heterocyclic Compounds); and C07J (Steroids). *See generally* Orange Book, *supra* note 52.

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to competitors due to undefined claim scope, and (3) unjustifiably increasing transaction costs for competitors, thereby delaying or deterring market entry.

Limiting the unfettered use of continuation practice will make the exchange between examiners and applicants more efficient, will shorten the time it takes to obtain a patent, and improve the quality of issued patents. Additionally, limiting Long CONs better reflects the goal of the patent system, which is to grant one patent for one invention.[62] Long CONs defy this principle by allowing an almost unlimited number of patents directed toward the same product. Congress and the PTO should prevent patent thickets built on much older technology that not only hinder innovation but can deter or delay access to important prescription drug products.

Previous attempts to limit continuation practice have failed. For example, in 2006, the PTO proposed to limit the unfettered submission of CONs by limiting applicants to two CONs and one Request for Continuation (RCE) application.[63] The problem with allowing an unlimited number of patent applications directed towards the same product is that the patent examiner can never really terminate prosecution. Applicants can "wear down" the patent examiner by crowding their docket with lower count versions of the same application, thus giving examiners even more incentive to allow these cases to remove them from their dockets.[64]

A. Possible Solutions

As an initial matter, most industries would be unaffected by changing rules regarding Long CONs, because 51% of all Long CONs come from one of three industries. Accordingly, these changes would likely not affect most industries. Many of these solutions, however, would likely need to be enacted with legislative action.

First, the PTO could time restrict CONs to only three years after the first office action in the original priority application. Second, in conjunction with the time bar, the PTO could prevent narrowing CONs to two years after the first office action of the original priority application. Third, the PTO could abolish the use of terminal disclaimers to obviate an ODP rejection. Finally, the PTO could take measures to allow examiners to make a "final" rejection where applicants could then only

[62] ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES: THE UNSTOPPABLE GROWTH OF PRESCRIPTION DRUG PRICES 104 (Cambridge Univ. Press 2019).

[63] Changes to Practice for Continuing Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims, 71 Fed. Reg. 48 (proposed Jan. 3, 2006) (to be codified at 37 C.F.R. pt. 1).

[64] Lemley & Moore, *supra* note 19, at 75.

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challenge the examiner's rejection in an appeal to the Patent Trial and Appeal Board ("PTAB") or the Federal Circuit.

The PTO could time bar CONs. Specifically, allowing the applicant to file CONs within three years of receiving the first office action in the original priority application. Applicants would still be able to file CONs after this time period, but would have to justify why a late-filed CON was necessary. This flexible rule would allow applicants to receive some additional protection without barring CONs. This would allow those firms to obtain an original patent with narrow protection over their commercial embodiment while allowing them to fight for additional claims, but only for the next two years.

Similarly, the PTO could limit the timing for narrowing CONs. This would be similar to reissue practice which prevents an applicant from broadening their claims through a reissue application. This would allow competitors to better understand their risks and help generic firms design around patent thickets. Thus, under this proposal, firms would still be allowed to file CONs, but would only be able to file broader claims and not narrower claims. In this way, we protect the "good" story behind CONs, which is to allow firms to go to market with narrow protection while fighting for broader claims later. Additionally, this solution would prevent patent gamesmanship based on filing narrower and narrower obvious variations over the same invention.

This solution should not harm innovation. For example, this solution would not prevent a brand firm that wished to patent new uses for an old drug. This is because these new uses would be the basis for a new *original* patent application. A CON would not be necessary for this type of innovation, because it would not be considered "follow-on" innovation. Additionally, it is likely that the parent application would not have either the written description support or the enablement support for the new use. Similarly, this solution would not prevent a brand firm from patenting modifications to an old drug to make it more effective or modify it for new uses. Again, a brand firm could simply use an original patent application to cover these new modifications or new uses.

The most dramatic solution would call for the end to the use of terminal disclaimers to overcome ODP rejections. Most CONs filed face this type of rejection, since the CON is typically an obvious variation of the original patent. To overcome this type of rejection, applicants typically file a terminal disclaimer, which is a procedural way to obviate the ODP rejection.[65] Obviousness-type double patenting

[65] S. Sean Tu, *Patenting Fast and Slow: Examiner Rejections and Applicant Traversals to Non-Prior Art Rejections*, 2021 MICH. ST. L. REV. 411, 443 (2021).

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rejections, however, originate from common law, and are not codified as part of the Patent Act. If Congress abolished the use of ODP rejections, requiring applicants to explain how their new application differs from their previously granted patent, then these types of thickets would likely disappear. This type of solution would put us in conformity with other European countries, which typically do not allow obvious variations of granted patents.[66]

Finally, the PTO could increase fees associated with CONs that claim priority to more than one application. This solution would not require legislative action. Increasing fees proportionally to the number of priority claims might help discourage applicants from filing too many CONs and Long CONs. However, unless the fees are dramatically increased, it is unlikely that a fee increase will prevent pharmaceutical firms from creating patent thickets. This is because even delaying generic market entry by a few weeks may be worth hundreds of millions of dollars.

CONCLUSION

This study finds that patent thickets play an important role in a brand firm's patent portfolio. These thickets are primarily built on CONs and Long CONs that are disproportionately represented in the pharmaceutical industry. Congress and the USPTO should take action to stop the creation of these patent thickets that increase drug costs without contributing to innovation.

[66] *See* Brian Cronin, *The Quest for Patent Quality: European Inventive Step and US Obviousness*, IP WATCHDOG (Dec. 21, 2016, 5:15 AM), https://ipwatchdog.com/2016/12/21/patent-quality-european-inventive-step-us-obviousness/id=75860/ [https://perma.cc/SX4L-DZQH].

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Table 1- Technologies with the Highest Percentage of Long CONs

Type of Patents	CPC Code	Total Number of CONs (OB)	Long CONs 5 Year CONs (OB)	% Long CONs % 5 Year CONs (OB%)	% CONs in Family (Dups/Num Family)	CONs in Family (Children/Num Family)
Peptides	C07K	101,282 (24)	24,871 (8)	24.6% (33.3%)	58% (37179/64103)	1.58 (101282/64103)
Microorganisms or Enzymes	C12N	90,879 (2)	19,058 (N/A)	21.0% (N/A)	47% (29121/61758)	1.47 (90879/61758)
Pharmaceutical Compounds	A61K	274,209 (1156)	51,238 (471)	18.7% (40.7%)	42% (80942/193267)	1.42 (274209/193267)
Medical Devices	A61M	99,494 (35)	13,611 (11)	13.7% (36.5%)	31% (23366/76128)	1.31 (99494/76128)
Analyzing Biological Materials	A61B	253,757	34,157	13.5%	33% (62959/190798)	1.33 (253757/190798)
Wireless Communication Networks	H04W	197,133	19,892	10.1%	29% (44584/152549)	1.29 (197133/152549)
Transmission of Digital Information	H04L	384,062	36,316	9.5%	28% (83887/300175)	1.28 (384062/300175)
Television	H04N	278,372	26,557	9.5%	23% (51443/226929)	1.23 (278372/226929)
Heterocyclic Compounds	C07D	192,313 (13)	16,484 (61)	8.6% (36.5%)	26% (39115/153198)	1.26 (192313/153198)
Chemical Analysis	G01N	200,152 (7)	16,644 (3)	8.3% (42.9%)	19% (31687/168465)	1.19 (200152/168465)
Electrical Digital Data Processing	G06F	689,768	49,050	7.1%	24% (134707/555061)	1.24 (689768/555061)
Semiconductor Devices	H01L	508,022	29,641	5.8%	30% (117118/390904)	1.30 (508022/390904)

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Table 2- Number of Continuation Applications and Litigated Continuation Patents

	Count	**Percentage of Total**
Total Patents	7,692,046	100%
Total CONs (patents)	1,068,422	14%
5 Year CONs (Long CONs) (patents)	639,308	8%
Total Orange Book (patents)	6,432	100%
Orange Book CONs	3,024	47%
Orange Book 5 Year CONs	2,126	33%
Total Litigated (patents)	43,220 (0.31% litigated)	100%
Litigated CONs	15,173	35%
Litigated 5 Year CONs (Long CONs)	9,836	23%
Total Orange Book Litigated (patents)	2,535 (39% litigated)	100%
Litigated Orange Book CONs	1,399	55%
Litigated Orange Book 5 Year CONs (Long CONs)	901	36%

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Table 3- Litigated Patents by Narrow Classification

Type of Litigated Patents	CPC Code	Total Number of Litigated CONs (%)	Litigated Long CONs Litigated 5 Year CONs (% of Litigated CONs in Technology)
Measuring or Testing Processes Involving Enzymes, Nucleic Acids or Microorganisms	C12Q	0.83% (358)	43.9% (157)
Pharmaceutical Compounds	A61K	7.2% (3116)	37.3% (1162)
Wireless Communication Networks	H04W	2.8% (1213)	36.9% (447)
Pictorial Communication (Television)	H04N	3.5% (1499)	35.6% (534)
Diagnosis; Surgery	A61B	2.4% (1050)	34.8% (365)
Peptides	C07K	0.92% (396)	33.6% (133)
Devices for Introducing Media into the Body	A61M	1.1% (479)	33.2% (159)
Transmission of Digital Information	H04L	6.5% (2796)	31.3% (876)
Investigating or Analyzing Materials by Determining their Chemical or Physical Properties	G01N	1.1% (474)	30.2% (143)
Telephonic Communication	H04M	1.6% (708)	27.5% (195)
Electric Digital Data Processing	G06F	7.8% (3384)	26.5% (896)
Transmission	H04B	1.0% (433)	24.5% (106)
Heterocyclic Compounds	C07D	1.5% (627)	22.7% (142)
Apparatus for Physical Training	A63B	1.3% (542)	21.2% (115)
Semiconductor Devices	H01L	2.7% (1172)	17.1% (200)
Total		18247 (42.2%)	30.9% (5630)

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Table 4- Litigated Patents by Broad Classification

Type of Litigated Patents	CPC Code	Total Number of Litigated CONs (%)	Litigated Long CONs Litigated 5 Year CONs (% of Litigated CONs in Technology)
Pharmaceuticals	A61	13% (5409)	35% (1878)
Transmission of Data	H04	16% (7110)	32% (2272)
Transmission Electrical Digital Communication	G06	10% (4178)	26% (1094)
Peptides	C07	3% (1351)	26% (349)
Semiconductors	H01	5% (1992)	26% (367)
Total		46% (20,040)	30% (5960)

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