A Patent a Day Keeps the Patient Away: What's Next in the Wake of *Amgen Inc. v. Sanofi*

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Abstract

Pharmaceutical drug prices have skyrocketed in the United States, leaving many individuals unable to purchase life-saving medications. While the political branches of government have tried to solve this issue through various legislative means, with differing levels of success, the judicial branch remains aptly suited to leverage current law and drive down the cost of drugs. A major motivation for the rising drug costs is companies' careful patenting schemes, aimed at foreclosing the introduction of name-brand and generic competitors into the market. While the Court resoundingly rejected broad patent claims that fail to provide enablement in *Amgen Inc. v. Sanofi*, there are still many schemes for companies to take advantage of to maintain their market exclusivity. One such scheme is product hopping, a process in which companies extend market exclusivity by making small changes to a drug, patenting the new one, and disadvantaging the old one. Existing antitrust and legislative approaches to solve this problem have come up short, but this Essay discusses a possible long-term solution to lower the prevalence of product hopping—and drug prices—as the state of the art develops.

Introduction

On May 18, 2023, Justice Gorsuch delivered the Supreme Court's unanimous opinion in *Amgen Inc. v. Sanofi*.[1] Upon opening the decision some readers may have found themselves running straight to Google. It is not every day that the Court must decide the legality of patents concerning antibodies, amino acids, and low-density lipoproteins (LDL or "bad cholesterol" as Justice Gorsuch helpfully reminds readers).[2] Deciding in favor of Sanofi, the Court simply

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[1] 598 U.S. 594 (2023).

[2] *See id.* at 598.

reaffirmed what both lower courts had already concluded,[3] but in doing so nine Justices found complete consensus in an area that Congress has been struggling to address clearly.[4] In a term that will surely be ripe with controversy and intrigue following numerous cases of grand public and journalistic scrutiny, it is understandable that readers would ignore this case due to its unanimous and technical nature.[5] Nevertheless, I contend that *Amgen* is a highly salient decision as it takes a small step to reduce rising prescription drug costs, a malice that Americans are united against.[6] At the same time, *Amgen* toes the line and risks reducing the incentive for companies to engage in breakthrough research, perhaps leaving the scientific community poorer.

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[3] *See id.* at 595, 616 (affirming judgment for Sanofi).

[4] *See* Arti K. Rai, Rachel E. Sachs & William Nicholson Price II, *Cryptic Patent Reform Through the Inflation Reduction Act,* HARV. J.L. & TECH (forthcoming 2024) (analyzing Inflation Reduction Act's implicit and unclear effect on pharmaceutical patent system).

[5] *See* Mark Berman, Robert Barnes, Ann E. Marimow & Nick Mourtoupalas, *How the Supreme Court Decided Major 2023 Cases*, WASH. POST (May 11, 2023), https://www.washingtonpost.com/politics/2023/05/11/supreme-court-decisions/ [https://perma.cc/34L2-ECNP] (calling most recent Supreme Court term "remarkably consequential").

[6] *See* Ashley Kirzinger, Audrey Kearney, Mellisha Stokes & Mollyann Brodie, *KFF Health Tracking Poll - May 2021: Prescription Drug Prices Top Public's Health Care Priorities*, KAISER FAM. FOUND., (June 3, 2021), https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2021/ [https://perma.cc/3V28-9BED] (noting lowering prescription drug prices a top priority for Democrats, independents, and Republicans).

As the Court eliminates one avenue for raising prescription drug prices, this Essay considers another anticompetitive practice and hypothesizes a future solution to resolve it.

In 2011, Amgen Inc. obtained a patent for a specific antibody that sought out and targeted PCSK9 activity.[7] PCSK9 is a protein that binds to LDL extracellular receptors and prevents said receptors from binding to LDL and taking it out of the bloodstream.[8] In doing so, PCSK9 leads to an increase in LDL levels in circulating blood and can lead to a whole host of health issues.[9] In 2014, Amgen followed up with additional patents that sought to claim "the entire genus of antibodies" that either bind to PCSK9 or prevent it from binding to LDL receptors.[10] Amgen explicitly identified twenty-six antibodies and offered two means for scientists to construct the other antibodies it claimed as part of its patent: a "roadmap" and "conservative substitution."[11]

The "roadmap" technique instructs skilled artisans to generate a large number of antibodies and test them all against the two explicitly-named antibodies to determine which additional ones bind to the same "sweet spot."[12] After doing so, skilled artisans must then do

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[7] *See* Brief for Petitioner at 11-12, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (discussing Amgen Inc. patent).

[8] *See id.* at 9 (defining PCSK9).

[9] *See id.* (explaining effects of PCSK9); Amgen Inc. v. Sanofi, 598 U.S. 594, 594 (2023) (listing cardiovascular disease, heart attacks, and strokes possible effects of high LDL levels).

[10] *See* Amgen Inc. v. Sanofi, 872 F.3d 1367, 1372 (Fed. Cir. 2017) (noting relevant antibodies' binding and anti-binding capabilities).

[11] *Id.* at 5-6.

[12] Brief for Petitioner at 13-14, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757).

additional testing to confirm that the generated antibodies inhibit "PCSK9's interaction with LDL receptors."[13] Amgen also offered the "conservative substitution" methodology: switching specific amino acids on a working antibody with others of similar chemical properties and then testing each new antibody to determine functionality.[14]

The Court disagreed that Amgen had successfully described methodologies that comported with the enablement requirement of the Patent Act.[15] Instead, Justice Gorsuch described the methodologies as "little more than two research assignments" and a "trial-and-error" means of experimentation that bestowed only "an uncertain prospect" of success.[16] The Court quickly dismissed Amgen's other arguments and repudiated Amgen's assertion that the Court should weigh the purported "[destruction of] incentives for breakthrough inventions" as that is a "policy judgment that belongs to Congress."[17] In quashing Amgen's claims, the Court shut down overbroad patent claims that lack proper enablement and permitted competition to resume, thus lowering drug prices.

The Problems with Antibody Patent Law

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[13] *Id.* at 14.

[14] *Id.* at 15. *See* Brief for Petitioner at 15, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) (explaining "conservative substitution" methodology).

[15] *See* 35 U.S.C. § 112(a) (outlining enablement requirement).

[16] Amgen Inc. v. Sanofi, 598 U.S. 594, 614 (2023).

[17] Brief for Petitioner at 38, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757); *Amgen*, 598 U.S. at 615-16 (dismissing Amgen's three alternative arguments).

The Court's decision in *Amgen* is correct as a matter of law and in practice, though its consequences are worthy of discussion. Firstly, Amgen's efforts to comply with the enablement requirement were minimal at best and absent at worst. The petitioner attempted to side-step an integral part of the Patent Act that has remained, in some fashion, since 1790.[18] Just as it did then, Congress's requirement embodies the "*quid-pro-quo* premise of patent law"[19] that seeks to honor the Constitution's goal of promoting science and useful arts through protecting authors and inventors while ensuring that "'the public may have the full benefit' of the invention or discovery."[20]

Antibody patent law is a peculiar field and these broad genus claims have been routinely made in the past.[21] Due to the novelty and imprecision of this field of science, functional claims that encompass *all objects* that perform a specified function, rather than invention-specific structural claims, were the norm.[22] These functional claims were also necessary in part because antibody science is unpredictable; for example, changing a few amino acids may result in an

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[18] *See Amgen*, 598 U.S. at 605 (noting Congress has left integral enablement requirement largely intact since 1790).

[19] *See id.* at 604.

[20] U.S. CONST. art. I, § 8, cl. 8; *Amgen,* 598 U.S. at 605 (quoting Act of Apr. 10, 1790, § 2, 1 Stat. 110).

[21] *See generally* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994 (2023) (discussing antibody patent law's eventful history); *id.* at 997 (noting historically broad patent protection for inventors).

[22] *See id.* (contending functional claiming an antibody patent norm).

antibody that works the exact same or is totally useless.[23] Consequently, companies saw a necessity to present broad claims in order to safeguard their discoveries from competitors making small alterations. Nevertheless, courts have seen recent advancements in the science which permit more accurate and specific descriptions of inventions. Thus, at the Court of Appeals for the Federal Circuit, "overbreadth and inadequate disclosure" arguments have led to the demise of all challenged functional patents for many years.[24]

The future of antibody patents remains unclear. The Court indeed left open the question of whether the aforementioned methodologies could suffice to meet the enablement requirement when patentees identify a "quality common to every functional embodiment."[25] Patentees now have some choices. They may try and identify similar antibodies by using the conservative substitution methodology and then patent all compounds with a high level of structural specificity. This is (understandably) the worst option for companies because they must spend more money and resources trying to construct an exhaustive list that is immune from competitors' efforts to change "a few bases here and there and escape infringement."[26] Patentees may also try to identify other antibodies with shared qualities, take a gamble, and apply for a

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[23] *See* Lemley & Sherkow, *supra* note 21, at 1004 (explaining antigens' ability to bind to multiple different antibodies); *id.* at 1016 (describing proclivity of slight changes in antibody sequences to yield nonfunctional embodiments).

[24] *See id.* at 998 (noting antibody patents' repeated failure to survive challenges based on overbreadth and inadequate disclosure arguments).

[25] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 614 (2023).

[26] *See* Lemley & Sherkow, *supra* note 21, at 1015.

structurally-specific smaller genus claim restricted to conservative substitution on a limited number of amino acids with articulable, particular qualities. Or as skilled artisans might put it: replace some amino acids with others that share the same charge (or any one of the other numerous shared qualities between the twenty amino acids).[27] There are two issues with this plan: first, the Court passed on the question of whether it would deem these pronouncements valid, so it remains unknown if such work will end up being thrown out by the Court. Second, and more concerningly, patentees must be sure that all structural inventions satisfy the overall claim; the Federal Circuit has rejected patents that have included nonfunctional inventions within the same claim.[28]

The most drastic course of action is for companies to abandon making patents for their lackluster benefits and instead operate under the cloud of secrecy until a fully-conceived product is ready to hit the shelves. In this field, it is undeniable that making claims on a discrete number of antibodies is economically futile and larger-scale patents may not survive judicial review.[29] Consumers fall on the shorter end of the stick because scientific development will suffer as public knowledge of discoveries is limited. But the other extreme of wide genus claims is also

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[27] *See generally* Chandani Kamble, Rohankumar Chavan & Vikas Kamble, *A Review on Amino Acids*, 8 STM J. 19 (discussing various shared attributes amongst amino acids).

[28] *See, e.g.*, Novozymes A/S v. DuPont Nutrition Bioscis. APS, 723 F.3d 1336, 1338 (Fed. Cir. 2013) (rejecting patent claim for failure to satisfy written description requirement).

[29] *See* Lemley & Sherkow, *supra* note 21, at 1015 (arguing for economic impracticality of narrow claims to specific antibodies).

ripe with issues. Drug prices will go sky high and the public knowledge of these inventions does little to diminish the unfeasibility of obtaining them.[30]

Recent and ongoing litigation does not lend support to any drastic changes in companies' practices. The patents at issue are old and were first constructed around the time the Federal Circuit began resoundingly rejecting broad patent claims.[31] The future of antibody patent law remains unknown as companies must experiment with how much they must include in their patent applications for them to be upheld.[32]

Product Hopping

Only time will tell how companies will react to these changing circumstances: some have argued that theoretical modeling or artificial intelligence may permit wide genus claims that survive judicial review.[33] Thankfully for companies, other patenting schemes exist that maintain significant economic advantages while keeping drugs on the market, though these come at hefty prices. However, Congress has been drumming up scary—at least to the companies—legislation

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[30] *See* IMAK, OVERPATENTED, OVERPRICED 12 (2022), https://www.i-mak.org/wp-content/uploads/2023/01/Overpatented-Overpriced-2023-01-24.pdf [https://perma.cc/VR9B-NS5F] (detailing drug pricing crisis).

[31] *See Is There Any Hope for Antibody Patents in the United States?* OBLON (Jan. 25, 2022), https://www.oblon.com/is-there-any-hope-for-antibody-patents-in-the-united-states [https://perma.cc/WW92-KE9G] (summarizing current antibody patent litigation).

[32] *See id.* (listing varied approaches to written descriptions in current antibody patent litigation).

[33] *See id.* (suggesting patent applicants may use theoretical modeling and artificial intelligence to generate and disclose candidate sequences).

aimed at curtailing the various efforts to delay drug competition and outlaw practices which lead to practical monopolies and the associated high prices.[34]

In particular, Congress and the Federal Drug Administration (FDA)[35] have taken issue with a scheme commonly known as "product hopping."[36] Companies take advantage of this strategy when they realize that a specific drug's patent is expiring and endeavor to introduce a

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[34] *See* Kevin Dunleavy, *Senate Takes Aim at Pharma's Patent Schemes, Pay-for-Delay Deals in Renewed Drug Pricing Crackdown,* FIERCE PHARMA, (July 30, 2021), https://www.fiercepharma.com/pharma/as-a-way-to-reduce-drug-prices-and-enhance-competition-senate-takes-aim-at-patent [https://perma.cc/QWF5-F9GD] (discussing Senate Judiciary Committee's unanimous vote to advance four pieces of legislation aimed at curtailing prescription drug costs).

[35] *See* Affordable Prescriptions for Patients Act, S. 150, 118th Cong. (2023) (prohibiting drug manufacturers from product hopping); Letter from Janet Woodcock, Acting Commissioner of Food and Drugs, to Andrew Hirschfeld, performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (Sept. 10, 2021), https://www.fda.gov/media/152086/download [https://perma.cc/D247-2QZU] [hereinafter Letter] (listing product hopping as a concerning practice used to keep drug prices high).

[36] Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework,* 92 NOTRE DAME L. REV. 167, 167 (2017).

highly similar alternative that is covered by a patent that extends longer.[37] After introducing an alternative, companies may attempt to "disadvantage their old drug, including destroying the inventory of their old drug, pulling it from the market, aggressively raising the price, badmouthing their old drug, or even diminishing its safety."[38] By switching to a highly similar drug, companies also foreclose the generic drugs from entering the fray and avoid the associated lowering of prices.[39] Despite this anticompetitive technique, the preferable methodology of raising antitrust challenges[40] faces difficulties because of the complex interplay of federal patent

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[37] *See* Kevin T. Richards, Kevin J. Hickey, & Erin H. Ward, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 2 (2020) (defining product hopping).

[38] Press Release, John Cornyn, Cornyn, Blumenthal Introduce Bill to Lower Drug Costs by Preventing Patent System Abuse (Jan. 31, 2023), https://www.cornyn.senate.gov/news/cornyn-blumenthal-introduce-bill-to-lower-drug-costs-by-preventing-patent-system-abuse/ [https://perma.cc/4YJB-MGZY].

[39] *See* Arti K. Rai & Barak D. Richman, *A Preferrable Path for Thwarting Pharmaceutical Product Hopping*, HEALTH AFFS. FOREFRONT (May 22, 2018), https://www.healthaffairs.org/content/forefront/preferable-path-thwarting-pharmaceutical-product-hopping [https://perma.cc/9Y4R-8DFG] (noting product hopping causes patients to pay monopoly prices due to lack of generic alternatives).

[40] *See id.* (suggesting antitrust law best route for addressing product hopping).

and antitrust law coupled with state drug substitution laws bundled within a regulatory framework.[41]

Some senators have proposed altering the Federal Trade Commission Act to declare product hopping to be an "unfair method of competition" and empowering lawsuits to be raised in district courts to reaffirm such a declaration.[42] For numerous reasons, there is hesitancy to be had regarding an antitrust approach. Specifically with respect to antibody patent law, scholars have noted antitrust litigation is an "expensive and time-consuming [process]."[43] Broadly, it puts important decisions in the hands of "dozens of different courts with different nonexpert judges and different nonexpert juries" which may lead to a hodgepodge of different judicial decisions with varying success.[44]

But this is not a newly-discovered problem; some have pushed for the utilization of "suitability petitions," as authorized by the Hatch-Waxman Act, to permit more generic drugs into the market.[45] Unfortunately, historical analysis shows that the FDA takes years and years to

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[41] *See* Carrier & Shadowen, *supra* note 36, at 168 (discussing intersection of antitrust law, patent law, and state drug product selection laws).

[42] Affordable Prescriptions for Patients Act, S. 150, 118th Cong. § 27(b)(1) (2023).

[43] Rai & Richman, *supra* note 39.

[44] Credit Suisse Secs. (USA) LLC v. Billing, 551 U.S. 264, 281 (2007).

[45] *See* Rai & Richman, *supra* note 39 (advocating for FDA implementation of suitability petitions). Suitability petitions allow generic drugs with altered characteristics to substitute for branded ones. *See id.* (explaining suitability petitions).

review these petitions, at which point their usefulness may be significantly diminished.[46] Moreover, there is the slight normative issue: generic drugs filed under a suitability petition will not be the exact same as the drug they will supposedly be equivalent to. The generic drugs are identical to drug one; but after a product hop, the generics are not identical—but share largely the same function—to drug two. A suitability petition aims to make the original generic drugs substitutes for drug two. In reality the difference between the drugs in a product hop tend to be miniscule, for example, an extended-release version, varying dosage, differing administration route, or a minute change in the chemical structure.[47] Though, this is not the definition of "generic" that consumers are accustomed to: they understand that generic is a substitute for cheaper and perhaps a different form-factor, not a changed mechanism.[48] This issue is nuanced, but there might exist an alternative way that resolves these problems.

In a letter to the United States Patent and Trademark Office, the FDA inquired about a "[p]ossible [m]isuse of the [p]atent [s]ystem" while noting that inventions claimed must be "new

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[46] *See* Kurt R. Karst, *Letting the Devil Ride: Thirty Years of ANDA Suitability Petitions Under the Hatch-Waxman Act*, 40 WM. MITCHELL L. REV. 1260, 1279 (2014) (discussing FDA's slow track record with suitability petitions).

[47] *See* Richards et al., *supra* note 37, at 20 (listing examples of new product versions).

[48] *See* Kevin Hein, *Brand Name vs. Generic Drugs: Understanding the Difference*, NW. FAM. CLINICS (Oct. 4, 2018), https://www.northwestfamilyclinics.com/blog/brand-name-vs-generic-drugs-understanding-difference [https://perma.cc/QF36-FHHL] (detailing differences between generic and brand-name drugs).

and non-obvious."[49] The patents assuredly meet the first part of this requirement, regardless of how miniscule the changes are. Companies engaging in product hopping are certainly changing their original product to one that is "new," at least to the extent that word has any legal weight. The more curious question is whether these post-hop drugs are non-obvious, but such an analysis opens up a pandora's box of its own.

In order for an invention to be patentable material, the distinctions between the "claimed invention and the prior art [must not be]… obvious… to a person having ordinary skill in the art."[50] The Court has determined that this analysis is a matter of law[51] and has routinely preached "caution in granting a patent based on the combination of elements found in the prior art."[52] Despite the Court's admittance that this consolidation of past art merely adds more to a company's monopoly and "diminishes the resources available to skillful men," it seems that product hopping still persists while doing much of the same.[53]

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[49] Letter, *supra* note 35, at 4.

[50] 35 U.S.C. § 113.

[51] *See* Graham v. John Deere Co., 383 U.S. 1, 17 (1966) (concluding patent validity ultimately question of law).

[52] KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415 (2007).

[53] Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152-53 (1950).

Therefore, utilizing obviousness challenges may be an additional means—apart from the traditional antitrust litigation—to limit drug prices from rising unnecessarily.[54] To effectively utilize this framework, however, litigants need to be able to show that altered drugs simply are yielding "predictable results," at least in the eyes of skilled artisans.[55] Or, challengers can argue that the minor changes a company utilized in its product hop were "obvious to try" and thus the applied patent should fail.[56] Unfortunately, to do so there needs to be a twofold improvement: scientists must be more skillful in the art and courts must recognize this development through extensive litigation.

Going past these problems, there are numerous advantages to utilizing this framework for limiting product hopping. This timeline speeds up the process by attacking altered drugs while they are patented and before they have even gone to the FDA for approval. Moreover, along with litigation in district courts, Congress has established the "inter partes review" process[57]

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[54] *See* Rai & Richman, *supra* note 39 (noting antitrust litigation most common means of attacking product hopping).

[55] *See KSR*, 550 U.S. at 416 (detailing predictable results test).

[56] *See id.* at 421.

[57] *See* Joe Mullin, *Our Right to Challenge Junk Patents Is Under Threat*, ELEC. FRONTIER FOUND. (June 2, 2023), https://www.eff.org/deeplinks/2023/06/our-right-challenge-junk-patents-under-threat [https://perma.cc/4ZAV-VB5C] (discussing inter partes review process).

which is "analogous to shortened litigation" and must ordinarily be completed within a year.[58] Even more, all appeals from this process, along with all patent litigation in district courts, go straight to the Court of Appeals for the Federal Circuit[59] as it has exclusive nationwide jurisdiction of patent matters.[60] This funneling of cases amounts to a greater consistency in jurisprudence than what arises from the antitrust litigation occurring in various circuit courts.[61]

Companies also benefit from this approach. Fact-heavy inquiries from review boards, district courts, and the Federal Circuit provide more incremental and steady changes in the law, hopefully preventing pharmaceutical companies from getting cold feet and quickly changing their practices at the expense of consumers. Companies may also better predict whether their patents will survive review at the onset; their skilled artisans must simply track the development of the art. Certainly, Congress could swoop in and change the law directly and rapidly. But cumulative changes through litigation may be the way of preserving the status quo so that patents remain economically beneficial items for companies to seek. Currently, patents are integral for

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[58] *See* Maier & Maier, PLLC, *Inter Partes Review (IPR)* (2023), https://maierandmaier.com/practice-areas/post-grant-practice/inter-partes-review-ipr/ [https://perma.cc/6SYV-NBBU] (noting statutory restrictions on proceeding's length).

[59] *See id.* (discussing process for appeals of inter partes review).

[60] *See* 28 U.S.C. § 1295(a)(4) (granting U.S. Court of Appeals exclusive jurisdiction over patent matters).

[61] *See, e.g.*, Credit Suisse Securities (USA) LLC v. Billing, 551 U.S. 264, 281 (2007) (detailing difficulty of reaching consistent results in circuit courts).

pharmaceutical companies to defray the enormously expensive process of drug development.[62] Should Congress slash profits, some smaller pharmaceutical companies may not be able to handle the additional financial burden.

While I propose that obviousness challenges are a growingly viable means to attack malicious pharmaceutical patents, this is not an entirely new concept.[63] Some scholars have noted that recent scientific developments may allow courts to sustain obviousness challenges in the highly technical, nuanced field of antibody science.[64] It stands to reason that if courts can make nonobvious inquiries in a subfield of drug manufacturing as the art advances, greater development in the pharmaceutical industry as a whole may render inter partes challenges the most effective means of combatting product hopping. By extension, a reduction in successful product hopping will permit generic drugs to hit the market quicker and will lower prescription drugs prices.

Conclusion

This approach is by no means a panacea for the rising cost of prescription drugs. It also will not have any immediate effect. But over time, as artisans become more skilled in their craft, they will be able to better predict the effects of miniscule changes in drugs which may render

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[62] *See* Lemley & Sherkow, *supra* note 21, at 1012 (discussing high value of antibody patents).

[63] *See* Carla Mouta-Bellum, Stacy Lewis, & Li Feng, *Patenting Antibodies: Obviousness Considerations*, IPWATCHDOG (Feb. 27, 2018), https://ipwatchdog.com/2018/02/27/patenting-antibodies-obviousness/id=94024/ [https://perma.cc/LB8P-44LS] (analyzing various obviousness issues related to antibody patents).

[64] *See id.* (observing trends of obviousness findings in antibody-related claims).

contemporary product hopping schemes untenable. In so doing, advancements in the art will force companies seeking to product hop to make larger scale changes in their products, such that they lead to identifiable and worthy improvements for consumers.

The Supreme Court put the final nail in the coffin for overly-broad genus claims that lack proper enablement,[65] though the problems with drug prices and patenting still remain. This Essay discussed some consequences of the decision and paths drug manufacturers and Congress can respectively take to maintain their strategic advantages and further reduce prices. I posit another strategy involving obviousness challenges which may become more fruitful as the state of the art develops. The swift hand of Congress may resolve issues but will surely bring about others. For the time being, the slow pace of the courts is the most optimal pathway to lower prescription drug prices without disturbing the water too much.

[65] *See* Amgen Inc. v. Sanofi, 598 U.S. 594, 616 (2023) (holding Amgen's broad antibody patents failed to meet enablement requirement).