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THE UNITED STATES STANDS ALONE: A DIVERGENCE IN THE TREATMENT OF GENUS CLAIMS IN PHARMACEUTICAL PATENTS

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ABSTRACT

The standards governing genus claims within American patent law have changed over the previous three decades. New standards created by the Federal Circuit Court of Appeals invalidate genus claims that would have likely been upheld under previous benches. And the United States stands alone in constricting the genus claim. What does this mean for pharmaceutical industries in the United States? Furthermore, how does this effect the United States' ability to shape international patent doctrine?

Amgen's recently invalidated PCSK9 patents indicate how various patent systems are treating the enablement of genus claims. This Paper discusses the changes in law that have occurred in American patent law and illuminates how these changes have distinguished the American patent system from the rest of the world. This Paper then argues that the pharmaceutical industry should not rely on other mechanisms for achieving exclusivity in the market. Not only is the genus claim indispensable to the effective patenting of pharmaceutical claims, but a hole in patent protection will bring the unwanted attention of countries with more robust protection.

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I. INTRODUCTION

There is arguably no industry more dependent on the patent system than the pharmaceutical industry. Pharmaceutical companies commonly use genus claims – claims that cover a whole genus to prevent generic companies from side-stepping patents with simple substitutions. The loss of such a valuable and commonly used tool would be not only presumably devastating for the pharmaceutical industry but would precipitate the "death" of the genus claim in American law. Pharmaceutical profits have demonstrated that pharmaceutical companies may be less reliant on the patent system in the United States than traditionally believed—that is, for now.[1] While barriers like rigorous Food and Drug Administration ("FDA") regulations may have prevented pharmaceutical companies in the United States from feeling the pain of losing the genus claim thus far, this Paper argues that the method through which pharmaceuticals gain exclusivity matters. Taking a step back and looking at European and Asian patent offices' treatment of genus claims through the lens of Amgen and Sanofi's PCSK9 saga reveals that the United States' treatment of genus claims is diverging from the rest of the World.[2]

Part I of this Article examines the history and importance of the genus claim for life science patents. Genus claims were once a respected way to claim innovation. The experimentation needed to use and make the inventions that genus claims described was understood to be a reasonable consequence of science.[3] Today, the Federal Circuit has transitioned into using a numbers test that requires the patentee to enable the manufacture and use of the *entire* genus with an ease that science rarely accommodates.[4] Part II looks at how this change in the enablement requirements of genus claims was used to invalidate Amgen's Repatha patents in the United States, but has not been utilized by other patenting systems.[5] This creates a discrepancy in intellectual property ("IP") protection addressed in Part III. Part III argues that how an industry acquires exclusivity matters. The Federal Circuit's propensity to invalidate pharmaceutical patents means that the United States may not be offering the strongest IP protection in the world. How does this affect the United States' ability to guide international IP agreements? And, while the United States has other

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[1] *See generally* Dmitry Karshtedt, Mark A. Lemley, & Sean B. Seymore, *The Death of the Genus Claim* 35 HARV. J.L. & TECH. 1 (2021). Karshtedt, Lemley, and Seymore coined the "death" of the genus claim in this article.

[2] *See* discussion *infra*, at Part III.

[3] *See* discussion *infra*, at Part I.

[4] *See id.*

[5] *See* discussion *infra*, at Part II.

mechanisms that soften the impact of heightened enablement standards on pharmaceuticals, industries should not rely on these mechanisms because they were not created to grant exclusivity--it is merely a side effect.[6]

II. THE HISTORY OF GENUS CLAIMS – A CHANGE IN LAW

Genus claims are a central pillar for patenting in the chemical, biotechnology, and pharmaceutical industries. Genus claims allow patentees to claim the genus around an active ingredient or antibody[7] to prevent competitors from making minor changes to avoid patent infringement.[8] A classic example is Amgen's drug Repatha.[9] Amgen's cholesterol drug Repatha is protected by claims 19 and 29 of U.S. Patent 8,829,165 (the "'165 patent") and claim 7 of U.S. Patent 8,859,741 (the "'741 patent").[10] These claims refer to a genus of antibodies that bind to the PCSK9 protein and lower low-density lipoprotein cholesterol ("LPL cholesterol")—the "bad" cholesterol linked to heart disease.[11].

A patent is a gift from the government that is not given freely. In exchange for the limited period of exclusivity that a patent provides an inventor, the inventor must disclose to the public how to make and use the invention.[12] This exchange progresses the art and allows future innovators to build on the innovation of their peers. Once the patent expires, anyone can make or use the invention and the world is presumably a better, more understood place.[13] Section 112(a) of the Patent Act seeks to uphold this bargain by limiting the scope of a patent to what it fully enables a person having ordinary skill in the art ("PHOSITA") to create—the enablement requirement.[14] But, if the creation of an invention covered by a patent requires a PHOSITA to perform "undue experimentation," then the court will find that the patent does not fully enable the claim and satisfy the bargain struck by § 112(a).[15]

To determine whether an invention requires undue experimentation, the court looks back to the time the application was filled and retrospectively determines whether undue experimentation would have been required.[16] The Federal Circuit's holding in *In re Wands* sets forth eight relevant factors to guide this determination: (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of prior art, (7) the breadth of the claims, and (8) the amount of experimentation necessary to

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[6] *See* discussion *infra*, at Part III.

[7] *See generally* Karshtedt et al., *supra* note 1.

[8] *Id.*

[9] U.S. Patent No. 8,829,165 (issued Sep. 9, 2014); U.S. Patent No. 8,859,741 (issued Oct. 14, 2014).

[10] *Id.*

[11] *Id.*

[12] *See* 35 U.S.C. § 112(a) (1979).

[13] *See* 35 U.S.C. § 154 (2022). The term of a utility patent is generally twenty years from issuance.

[14] *Id.*

[15] United States v. Telectronics, Inc., 857 F.2d 778, 785 (Fed. Cir. 1988). "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."

[16] Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371–72 (Fed. Cir. 1999) (citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986)).

practice the claimed invention.[17] The *Wands* factors indicate that the nature of the art, and the practices of those working within it, affect how much a patent must disclose to satisfy the enablement requirement.[18] For example, in an unpredictable art, like biochemistry, as represented in *Amgen,* a patent must disclose a significant amount of information about determining which antibodies will bind to PCSK9 because a PHOSITA cannot fully anticipate which antibodies will be successful without tests.[19] However, even in unpredictable fields, genus claims have historically been upheld before the 1990s if the disclosure conforms to the nature and specificity of directions that a scientist would reasonably expect to see from colleagues in the field.[20]

Naturally, some experimentation is almost always necessary in unpredictable fields like chemistry and biotechnology. Courts have reasoned that an invention can be enabled, even if an invention requires a significant amount of experimentation that takes both resources and time, as long as the experimentation is not "undue."[21] However, since the 1990s, the federal courts have gradually lowered the threshold of what constitutes "undue" experimentation to invalidate a patent. Today, § 112(a) smothers genus claims.[22] The Federal Circuit has stopped distinguishing between experimentation that is reasonable and what is undue to require a PHOSITA to do in making or using an invention.[23] Instead, the Federal Circuit has made the test an unbeatable numbers game that favors invalidation of the patent.[24]

> This standard gauges enablement not by whether the experimentation needed to make and test particular species is undue, but by how long it would take the PHOSITA to make and screen every species within the claimed genus—even if that work would be routine.[25]

The United States appears to be alone in this approach.[26] The enablement requirement, however, is not a unique aspect of American patent law and is shared by every modern patent act.[27] While the enablement standards of other countries vary from the United States, the core of a standard enablement requirement in any country focuses on whether a PHOSITA, however described, can make and use a claimed invention using the disclosure contained in the patent and commonly known prior

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[17] *See* Karshtdet et al., *supra* note 1, at 8-9 (citing In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)).

[18] Karshtdet et al., *supra* note 1, at 9.

[19] *See* discussion *supra*, at Part II.

[20] *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Wands*, 858 F.2d.

[21] *Wands,* 858 F.2d at 740 (quoting In re Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976)). "The key word is 'undue,' not 'experimentation.'"

[22] *See* discussion *infra*, at Part III(A).

[23] *See* Brief of Intellectual Property Professors as *Amici Curiae* In Support of Petitioners, Idenix Pharm. LLC v. Gilead Sci., Inc., No. 20-38 (U.S. 2020) 12, https://www.supremecourt.gov/DocketPDF/20/20-380/160854/20201116152459763_40206%20pdf%20Karshtedt%20br.pdf.

[24] *Id.*

[25] *Id.*

[26] *See* discussion *infra*, at Part II(B-C).

[27] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights arts. 27-34, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement] at Art. 29(1). Enablement is one of the standardized requirements provided for in the TRIPS Agreement.

art.[28] Amgen's war against Sanofi demonstrates how different systems have treated genus claims from the same patent family. Under the various enablement standards of other countries, Amgen's genus claim has fared well.[29] Even two separate American juries believed that Amgen's patents were enabled.[30] The next Part will look at how three different patent systems have treated Amgen's patent claim—the United States, Europe (Germany), and Japan. Then, Part III will discuss the repercussions of the United States invalidating these valuable patents and why other avenues of exclusivity are not the same.

III. INTERNATIONAL DIVISION AMONGST COURTS IN AMGEN SAGA

Amgen has waged its war against Sanofi and its partners' drug – Praluent -- in three large patent markets. While Amgen is currently losing on both the American and European fronts, enablement was only determinative in the American courts.

A. Litigation in the United States

Amgen v. Sanofi is the most recent in a long line of newsworthy chemical, biotechnological, or pharmaceutical disputes centered on a patent's genus claim.[31] Currently, Amgen is losing on the American front in their battle with Sanofi following a Federal Circuit Court of Appeals' holding that Amgen's genus claims are invalid for a lack of enablement.[32] However, Amgen's petition was granted certiorari on November 4.[33] The Supreme Court will consider Question 2 of Amgen's petition which centers on the "full Scope" and "undue experimentation" aspects of 112(a) jurisprudence.[34] This Section will examine the setbacks that Amgen has had thus far despite favorable jury verdicts in the United States.

Amgen's primary battleground against Sanofi and its drug Praluent is the United States. The United States has the largest drug market in the world and its patent system often drives international IP discussions – causing the federal court venue for this battle to be closely monitored around the world.[35] The drawn out battle began on October 17, 2014, when Amgen filed suit against Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S. LLC (collectively, "Sanofi") alleging

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[28] *Id.*

[29] *See* discussion *infra*, at Part III(B)-(C).

[30] *See* discussion *infra*, at Part III(A).

[31] *See generally* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991); Wyeth v. Abbott Lab., 720 F.3d 1380 (Fed. Cir. 2013); Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340 (Fed. Cir. 2019).

[32] *See generally* Amgen Inc. v. Sanofi, 987 F.3d 1080 (Fed. Cir. 2020).

[33] *See generally* Amgen Inc. v. Sanofi, 2022 U.S. LEXIS 1921.

[34] Jason Rantanen, *Rethinking enablement, Court grants cert in Amgen v. Sanofi*, PATENTLYO (Nov. 6, 2022), https://patentlyo.com/patent/2022/11/rethinking-enablement-grants.html.

[35] *See* Eric Sagonowsky, *GlaxoSmithKline backs Amgen in PCSK9 patent fight, arguing court decision could 'devastate' R&D incentives*, FIERCE PHARMA (Apr. 30, 2021), https://www.fiercepharma.com/pharma/glaxosmithkline-wades-into-long-running-pcsk9-patent-fight-between-amgen-and-sanofi.

infringement of their '165 and '741 patents.[36] Sonafi stipulated to a portion of the infringement claims and rested their case on two arguments: lack of enablement and inadequate written description.[37]

In the first bout in federal court, a Delaware jury sided with Amgen and determined both patents were properly enabled and satisfied written description requirements. Amgen proclaimed victory and the district judge entered an injunction on the manufacture and sale of Praluent in the United States.[38]

However, Sanofi successfully appealed this holding on a number of grounds.[39] First, it argued that post-priority-date evidence of Praluent and other antibodies, relevant to both the enablement and disclosure discussions, was improperly excluded from the jury trial.[40] The Court of Appeals agreed, holding that it was legal error for the district court to "categorically preclude all of [Sanofi's] post-priority-date evidence of Praluent and other antibodies" because it could properly be used to prove that the patents did not disclose a representative number of species of the claimed genus.[41] Therefore, such evidence could have been presented in an attempt to persuade the jury that the patents do not encompass Praluent and the written description requirement had not been satisfied.[42] Additionally, the court stated that the same evidence could have been persuasive to a jury on the element of undue experimentation, a determination that would limit the patents for a lack of enablement.[43]

On remand, Sanofi failed to persuade a second jury despite having more evidence.[44] However, to Amgen's dismay, the District Court granted Sanofi's motion for judgement as a matter of law for lack of enablement.[45] Enablement is a legal question based on underlying factual determinations, and therefore, the Court was required to defer to the jury's factual determinations. Using the jury's factual determinations, the District Court reviewed the legal question of enablement *de novo*.[46] Focusing on all eight *Wand* factors, the Court of Appeals agreed that *Amgen* is one of the "spare" cases where the jury should be disregarded as a matter of law.[47] The Federal Court of Appeals affirmed the District Court's position and reasoning for a lack of enablement—leaving Amgen to seek *certiorari* as a final effort.[48]

1. Use of Wand Factors

The District Court used the *Wand* factors to direct their verdict of invalidity. The Federal Circuit's holding in *In re Wands* sets forth eight relevant factors to guide this

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[36] *See generally* Amgen Inc. v. Sanofi, 227 F. Supp. 3d 333 (D. Del. 2017).
[37] *Id.* at 336.
[38] *See generally id.*
[39] *See generally* Amgen Inc. v. Sanofi, 872 F.3d 1367 (Fed. Cir. 2017).
[40] *Id.* at 1373-75.
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *See generally* Amgen, Inc. v. Sanofi, Inc., 2019 U.S. Dist. LEXIS 146305 (D. Del. 2019).
[45] *Id.* at *14-15.
[46] *Id.* (quoting Pannuv. Lolab Corp., 155 F.3d 1344, 1348 (Fed. Cir. 1998)).
[47] *See* Amgen Inc. 987 F.3d at 1080.
[48] *Id.*; *see also* SCOTUSblog, *Amgen Inc. v. Sanofi*, SCOTUSBLOG, https://www.scotusblog.com/case-files/cases/amgen-inc-v-sanofi-2/ (last visited Nov. 14, 2022).

determination: (1) the amount of direction or guidance presented in the disclosure, (2) the existence of working examples, (3) the nature of the invention, (4) the predictability or unpredictability of the art, (5) the PHOSITA's level of skill, (6) the state of prior art, (7) the breadth of the claims, and (8) the amount of experimentation necessary to practice the claimed invention.[49] While the wand factors have upheld genus claims in the past, the way that the district courts currently interpret the factors is unlikely to leave a patent enforceable. Amgen's outcome of unenforceability is standard among recent genus claim cases, but the Supreme Court has taken the opportunity clarify how the *Wand* factors should weighed.

a. Breadth of the Claims

The District Court held that a "reasonable factfinder could only have found that the scope covered by the claims is [overly] broad."[50] Amgen argued that the genus is justifiably narrow because it only refers to antibodies resulting from making intelligent substitutions.[51] Amgen reasoned that because an antibody scientist would not engage in random mutations to the disclosed antibodies, the claimed genus must be narrow despite it containing millions of antibodies.[52] Following precedent from *Abbott Labs v. Sandoz*, the Court asserted that "except for product-by-process claims or product claims with a process limitation, the method by which the patented product is made has no effect on the scope of the product claim."[53] Therefore in the eyes of the Court, surprisingly, it does not matter how a scientist finds viable antibodies; it only matters how many there are.[54] The breadth of the claims are determined simply by the sheer number of possible candidates falling within the claimed genus, even if in reality, the defendant used a much smaller subset of possible substitutions reasonably known to those in the art.[55]

b. Predictability of the Art

Amgen contended that the antigen has a "sweet spot" where antibodies with a specific three-dimensional shape and chemical structure features bond—making the art predictable.[56] In Amgen's opinion, this distinguishes their patents from those in *Enzo* and *Idenix Pharms. LLC v. Gilead Scis., Inc.*.[57] *Enzo* involved a modification to nucleosides as antiviral agents to treat RNA viruses, in particular a serious chronic liver disease—HCV.[58] The *Enzo* court reasoned that because minor changes to the

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[49] *See* Karshtdet et al., *supra* note 1, at 8-9 (citing *Wands*, 858 F.2d at 737).
[50] *Amgen, Inc.*, 2019 U.S. Dist. LEXIS 146305, at *19-20.
[51] *Id.* at *19-23.
[52] *Id.*
[53] *Id.* (citing Abbott Labs. V. Sandoz, 566 F.3d 1282, 1293 (Fed. Cir. 2009)).
[54] *See Amgen, Inc.*, 2019 U.S. Dist. LEXIS at *19-23.
[55] *See id.*
[56] *Id.* at *23-27.
[57] *Id.*
[58] *See generally* Enzo Idenix Pharms. LLC v. Gilead Scis., Inc., 2018 U.S. Dist. LEXIS 25663 (D. Del. 2018).

active compounds rendered the modified compounds inactive or toxic in unpredictable ways, the field is unpredictable.[59] However, Amgen believes that the structure-function relationship in the contested antigen, and the antibodies that bind to them, rendered the field predictable.[60] Despite contradictory expert evidence between the parties as to whether the structure-function relationship exists, the Court held that the relationship still does not eliminate the need for testing antibodies to determine if they serve the intended function of blocking and binding.[61] The Court held that if an antibody is analogized as a "key" that fits the antigen as its "lock," then this relationship only helps narrow which "key" will fit the "lock."[62] This rationale was hard for Amgen to swallow because, in reality, how to make the exact "key" to fit a particular "lock" in the antibody-antigen context is not fully understood and must always be tested.[63]

c. Nature of the Invention; State of the Prior Art; Relative Skill of Those in the Art

The *Amgen* Court held that the methods used by Amgen, and disclosed in their patent, for identifying and creating the antibodies were "routine and well-known" in the prior art.[64] It was undisputed by the parties that the techniques disclosed (including binning, alanine scanning, x-ray crystallography, immunizing mice, and making amino acid substitutions) adequately presented a person of ordinary skill in the art to make at least a portion of the antibodies claimed in the patent.[65]

d. Amount of Direction or Guidance Presented; Presence and Number of Working Examples

Here, again, the Court focused on the idea that even after following the guidance presented in Amgen's patent, a PHOSITA would still need to test the antibody to determine if it meets the functional limitations of the claim, and therefore falls under the patent assignee's exclusive rights.[66] Citing *MorphoSys AG v. Janssen Biotech, Inc*, a Federal Circuit case that raised the enablement standard, the Court determined that a PHOSITA will have to do a comparable amount of work to the original inventors because anyone trying to make an antibody claimed in the patent is required to test the antibody.[67] Therefore, in light of the unpredictability of the art, a reasonable factfinder must find that the patent does not provide significant guidance or direction to a PHOSITA.[68]

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[59] *Id.*
[60] *See Amgen, Inc.*, 2019 U.S. Dist. LEXIS 146305, at *23-27.
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Id.* at 27-28.
[65] *Amgen, Inc.*, 2019 U.S. Dist. LEXIS 146305, at *23-27.
[66] *Id.* at 28-32
[67] *Id.* at 28-32 (citing MorphoSys AG v. Janssen Biotech, Inc., 358 F. Supp. 3d 354, 368-69 (D. Del. 2019)).
[68] *See id.* at 28-32.

Amgen is hopeful that the Supreme Court will disagree with the District Court's analysis and return to the memorable statements of the *Angstadt* court -- "The key word is 'undue,' not 'experimentation.'"[69] In the 1076 *In re Angstadt,* the genus claim at issue was direct to a method for catalytically transforming a class of organic compounds with metal catalysts. Despite the genus encompassing thousands of species, the court found that the claim was fully enabled as long as the inventor properly demonstrated that at least some of the species functioned as intended and provided adequate directions for how to test the rest. Presumably, a court like the court in *Angstadt* would have found this routine testing to make sure the antibody binds to be exactly the type of experimentation required by the nature of the art and not be considered "undue."[70]

e. Quantity of Experimentation Necessary

Amgen alleged that the quantity of experimentation necessary to make use of the full scope of their patent claims is low.[71] They asserted that "automated high-throughput techniques exist[] for testing a large number of antibodies'" to demine whether they fall within the scope of the claims "quickly, efficiently, and cheaply."[72] But the court found Amgen's evidence "conclusory" and determined that the steps its takes to create and test any given antibody is essentially the same as the time it took the inventors of the patents-in-suit.[73] Therefore, a reasonable factfinder could "only have determined that the experimentation necessary to enable the full scope of the claims would take a substantial amount of time and effort."[74]

2. Invalidation

The Federal Court of Appeals rejected two jury verdicts to uphold the District Court's determination that Amgen's patents lacked enablement.[75] The court weighed the factors in a way that stacked the odds against Amgen, continually coming back to the idea that the patents covered millions of antibodies, but required testing to confirm which ones.[76] To the juries, this seemed like the kind of experimentation that was expected in the field.[77] However, recent Federal Court of Appeals precedent has shifted the *Wand* factors to leave little hope of success for a functionally limited genus claim.[78]

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[69] *Wands,* 858 F.2d at 741 (quoting In re Angstadt, 537 F.2d 498, 504 (C.C.P.A. 1976)).
[70] *See generally In re Angstadt*, 537 F.2d at 503.
[71] *Id.* at 32-34.
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *See* discussion *supra*, at Part III(A).
[76] *See* discussion *supra*, at Part II(A).
[77] *Id.*
[78] *Id.*

B. Litigation in Europe

Amgen holds numerous European patents from the European Patent Office ("EPO") giving claim to their PCSK9 antibodies.[79] These patents give protection in the forty-four countries using the European Patent System.[80] However, to enforce their patents, a European patent holder must seek remedies in each country where they allege infringement.[81] While a ruling of infringement in one country—or similarly, a holding that the patent is invalid—is persuasive in other venues, it is not determinative.[82]

Amgen's European front against Sanofi was initiated in test venues. Presumably because of its large pharmaceutical market and history of strong patent protection, one of Amgen's first suits was filled in Germany. In July 2019, the Dusseldorf Regional Court gave Amgen a huge, but short lived, victory.[83] The Dusseldorf Court held that Sanofi's drug Praluent infringed on Amgen's EP 22 15 124 patent and granted Amgen's injunction preventing Sanofi from producing, marketing, distributing, or selling Praluent in Germany.[84] On the day the holding was released, Amgen remarked on their website that they planned to enforce the court's decision in Germany and were "committed to facilitating a smooth transition to Repatha . . . for patients currently taking Praluent who wish to continue taking a PCSK9 inhibitor."[85]

However, while Amgen initiated suit in Germany, Sonafi initiated a challenge within the EPO itself.[86] While a patent holder is forced to file suit in each venue where they allege infringement, an opposition to a patent can go straight to the source and file a challenge of invalidity at the EPO.[87] The danger of a European patent is that if it is invalidated by the EPO, or limited in a meaningful way, then it will be invalidated or limited in all forty-four member countries.[88] The Dusseldorf holding was preceded by a decision of the Technical Board of Appeal at the EPO—initiated by Sanofi among others.[89] The EPO judges confirmed the patent's validity, but substantially limited the claims to cover only the active ingredient in Repatha—Evolocumab.[90] The EPO

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[79] *See* e.g., EPO, *Global Patent Index EP 22 15 124*, EPO (Nov. 8, 2010).

[80] EPO, *Member states of the European Patent Organization*, EPO, https://www.epo.org/about-us/foundation/member-states.html (last visited May 1, 2022).

[81] *See generally* EPO, *Patent litigation in Europe: An overview of national law and practice in the EPC contracting states*, EPO (July 31, 2019), https://documents.epo.org/projects/babylon/eponot.nsf/0/05B84848CBCF7338C1257833003C2531/$FILE/patent_litigation_in_europe_2019_en.pdf.

[82] *Id.*

[83] Amgen, *Amgen Comments on PCSK9 Patent Litigation in Germany,* AMGEN, https://www.amgen.com/newsroom/company-statements/amgen-comments-on-pcsk9-patent-litigation-in-germany (last visited May 2, 2022); *see also* Mathieu Klos, *EPO decision clears way for Sanofi blockbuster drug Praluent,* JUVE PATENT (Nov. 6, 2020), https://www.juve-patent.com/news-and-stories/cases/epo-decision-clears-way-for-sanofi-blockbuster-drug-praluent/.

[84] Amgen, *supra* note 83.

[85] *Id.*

[86] Klos, *supra* note 83.

[87] *Id.*

[88] *Id.*

[89] *Id.*

[90] *Id.*

determined that the patent lacked an inventive step and could not hold claim to the genus in suit.[91]

The inventive step requires that an invention not be obvious to a PHOSITA considering the state of the art and exists as the European equivalent to the USPTO's non-obvious requirement.[92] Being caught between rulings of obviousness (Europe) and lack of enablement (United States) is a difficult position for Amgen. In *Eli Lilly & Co. v. Actavis Elizabeth LLC, et al.,* an inventor declared that their methods for treating ADHD with atomexetine was hypothetical and that a PHOSITA would "not predict atomoxetine would be effective."[93] However, this non-obviousness argument then hurt their enablement claims. A footnote summarized:

> "Plaintiff emphasizes the differences between atomoxetine and the prior art for the purposes of refuting Defendant's obviousness argument, while at the same time asserting that the prior art and atomoxetine are in some ways similar in order to demonstrate enablement/utility. Defendants argue, then, that the Court must find the patent invalid as either obvious or not enabled. For example, if the Court determines that a person of ordinary skill in the art would be able to infer utility based upon the patent's specification, Defendants' enablement argument might fail, but its obviousness argument would presumably be bolstered. In essence, Defendants argue that whichever set of experts is credited, Plaintiff's patent will be invalidated."

Therefore, the EPO did not limit Amgen's patent on the grounds that it did not enable a drug like Praluent to be made,[94] but instead went in the opposite direction and found that it was obvious how to make the drug from the prior art alone. It would be wrong to say that the EPO determined that Amgen's patents were fully enabled. EPO proceedings are limited in nature and the legal burden for a lack of enablement claim rests on the opponent. However, no European court has ruled that Amgen's PCSK9 genus claims are not fully enabled to date.

The EPO's limitations on the patent brought Praluent outside of Amgen's reach. In November 2020, Sanofi was granted a waiver in the Higher Regional Court Düsseldorf, allowing them to resume selling Praluent in Germany.[95] But in the larger discussion of genus claims, the ruling shows that the EPO was at least reluctant, if not unwilling, to invalidate the genus claim on the grounds that the patent's claims did not fully enable a PHOSITA to produce a drug like Praluent.

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[91] Klos, *supra* note 83.

[92] EPO, *European Patent Guide: Chapter 3 – Patentability*, EPO https://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_c3_4.html (last visited Nov. 14, 2022).

[93] *See generally* Eli Lilly & Co. v. Actavis Elizabeth LLC, et al., 2010 U.S. Dist. LEXIS 44913 (D.N.J. 2010).

[94] *See* Klos, *supra* note 83.

[95] *Id.*

C. Litigation in Japan

In Japan—another large pharmaceutical market and common patent battleground—the IP High Court found that Amgen's Japanese patents are valid and that Praluent falls within their scope.[96] Sanofi appealed the decision, and in April 2020, the Japanese Supreme Court upheld the IP High Court's decision.[97]

The Japanese patent defined the antibody functionally in terms of neutralizing activity and the ability to bind with PCSK9, thus giving claim to the larger genus.[98] Unlike the Federal Court of Appeals, the Japanese Supreme Court found that the enablement requirement was met by Amgen's patents because they taught how to make the antibodies that fall within the functional limitations—it was not necessary for the specification to disclose how *every* suitable antibody could be made.[99] Accordingly, Sanofi is restricted from manufacturing, distributing, importing, or offering to sell Praluent in Japan.[100]

IV. REPERCUSSIONS OF AN INTERNATIONAL DIVERGENCE IN LAW AND POLICY

The Supreme Court has granted Amgen's petition for *certiorari*.[101] Amgen is hopeful the Supreme Court will reverse the Federal Circuit Court of Appeals and return the law to something analogous to the precedent created in *In re Angstadt* by the Court of Customs and Patent Appeals ("CCPA"), the predecessor to the Patent Trial and Appeals Board ("PTAB").[102] In *Angstadt*, the CCPA stressed that "[t]he key word is 'undue,' not 'experimentation.'"[103] The *Angstadt* court recognized and allowed the "types and amount of experimentation which the uncertainty of [the] art makes inevitable," regardless of the number of variations the claim may cover.[104]

If the Supreme Court upholds the Court of Appeals' heightened enablement standards for these unpredictable arts, then there are two factors that may force lawmakers to readdress enablement. First is the myth of harmonization that runs throughout international patent law.[105] How can countries like the United States push developing nations like India to give patent protection to pharmaceuticals in the name of "harmonization" if we refuse to do so ourselves? Second, the United States may use other mechanisms to provide exclusivity to pharmaceuticals, including FDA restrictions. But the congressional mandate governing agencies like the FDA is not concerned with gifting exclusivity in exchange for innovation. Exclusivity from FDA regulations is a side-effect—a side-effect often distained. Therefore, how secure is the

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[96] *See* Potter Clarkson, *Amgen v. Sanofi: Narrowing the scope of protection for antibody inventions?*, LEXOLOGY (May 14, 2021), https://www.lexology.com/library/detail.aspx?g=0007ca23-07b2-471d-9c1f-917dade86715.

[97] *Id.*

[98] *Id.*

[99] *Id.*

[100] *Id.*

[101] *See* SCOTUSblog, *Amgen Inc. v. Sanofi*, SCOTUSBLOG, https://www.scotusblog.com/case-files/cases/amgen-inc-v-sanofi-2/ (last visited Nov. 14, 2022).

[102] *In re Angstadt*, 537 F.2d at 504.

[103] *Id.* at 503.

[104] *See id.*

[105] *See* discussion *infra*, at Part IV(A).

pharmaceutical industry's exclusivity in the United States without patent protection? The pharmaceutical industry will surely push back hard if it begins to feel their drugs' exclusivity noticeably shrinking.

A. Call it Harmonization, Call it Maximization

Call it harmonization, call it maximization. Regardless, the United States loses valuable credibility in international treaty negotiations by giving companies considerably less patent protection that other countries.[106] This Section introduces the harmonization and maximization theories of international patent laws to demonstrate that the United States' revocation of Amgen's U.S. patent does not go unnoticed abroad.

The myth of harmonization has driven the creation of the world's first comprehensive patent agreements. Following World War II, the General Agreement on Trade and Tariffs ("GATT") made international trade easier than ever before.[107] Industries reliant on IP protection and interested in international trade lobbied for protection in countries that historically gave little consideration to IP.[108] Thus, IP considerations were included in the Uruguay Round Agreement that created the World Trade Organization ("WTO").[109] Then, in the 1990s, the Trade-Related Aspects of Intellectual Property Rights Agreement (the "TRIPS Agreement") was created.[110] The TRIPS Agreement set its aim on standardizing IP protection—an idea that less-developed countries with fewer creative industries (often called the "Global South") were hesitant to accept because it stripped away their autonomy to create domestic policies specific to their priorities.[111] However, through the narrative of harmonization, countries with robust creative and innovative industries (often referred to as the "Global North") promised that the foreign investment that would flow into the Global South from the heightened protection would be well worth their sacrifices.[112]

Pharmaceuticals are a notable industry affected by the TRIPS agreement's minimum protection requirements. Particularly in India there has been a historied struggle to get IP protection for pharmaceuticals.[113] Throughout the 1970s, India built a generic drug empire by refusing IP rights to pharmaceuticals.[114] In the early 2000s, once India's TRIP requirements kicked in, India was pressured to give the required minimum level of protection to the pharmaceuticals. However, India has found gray areas in the TRIPS requirements to effectively deny pharmaceutical protection—like issuing easily attainable compulsory licenses.[115] This has spurred countries to

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[106] *Id.*

[107] Sarah R. Wasserman Rajec, *The Harmonization Myth in International Intellectual Property Law,* 62 ARIZ. L. REV. 735, 738 (2020).

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *Id.* at 737-39.

[112] Rajec, *supra* note 107, at 737-39.

[113] *See generally* Janice Mueller, *The Tiger Awakens: The tumultuous transformation of India's patent system and the rise of Indian pharmaceutical Innovation,* 68 U. PITT. L. REV. 491 (2007).

[114] *Id.* at 495.

[115] *Id.* at 495-96.

undertake formal investigations of India's patenting practices, such as the United States being nudged ahead by the pharmaceutical industry.[116] For India, the direct result has been a refusal of many large international pharmaceutical companies to do business within their borders.[117]

Amgen and the legal scholars who drafted the amicus briefs supporting *certiorari* believe that the genus claim is an indispensable tool for patenting within the life sciences.[118] If the United States continues to invalidate patents with the Federal Courts' heightened enablement standard, then how can the United States argue that India is failing to satisfy their TRIPS obligations for denying protection to patents that the United States has also invalidated? While both countries are arguably acting within the letter of the TRIPS Agreement, they certainly are not acting in accordance with the façade of global IP harmonization. The United States will have trouble arguing for future harmonization if it continues to restrict one of the most important industries filing for patent protection.

Patent Professor Sarah R. Wasserman Rajec argues that the harmonization myth has already been debunked by the Global North's use of bilateral and multilateral treaties to heighten IP protection in the Global South above the minimum requirements provided for in both the TRIPS Agreement.[119] In fact, many countries in the Global South offer more protection today than the Global North.[120] Professor Rajec reasons that this looks more like maximization of IP protection than harmonization of international systems.[121] However, even if the United States completely drops the guise of trying to "harmonize" global IP protection, the invalidation of these pharmaceutical patents will draw the attention of other countries in the Global North—much like how India drew the attention of the United States.

Call it harmonization. Call it maximization. Either way, excluding valuable pharmaceutical patents in the United States may hurt its ability to affect international IP standards. In the most extreme case, it may even bring the unwanted attention of the other Global North countries.

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[116] *See* Medecins Sans Frontieres, *A Timeline of U.S. Attacks on India's Patent Law & Generic Competition*, MEDECINS SANS FRONTIERS (2015), https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf; Lawrence Gostin et al., *How The US Elevates Corportate Interests Over Global public Helath. And How the World Can Respond,* HEALTHAFFAIRS (Sept. 5, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180830.186562/full/.

[117] McKinsey & Co., *India Pharma 2020: Propelling access and acceptance, realizing true potential,* MCKINSEY & CO. (2020) 13, https://www.mckinsey.com/~/media/mckinsey/dotcom/client_service/Pharma%20and%20Medical%20Products/PMP%20NEW/PDFs/778886_India_Pharma_2020_Propelling_Access_and_Acceptance_Realising_True_Potential.ashx.

[118] *See generally* Brief of Intellectual Property Professors as *Amicus Curiae* in Support of Rehearing *En Banc*, Amgen, Inc. v. Sanofi, et al., No. 1:14-cv-01317-RGA (Fed. Cir. 2020), https://law.stanford.edu/wp-content/uploads/2021/04/AmgenInc-Profs.Brief-28Apr2021.pdf.

[119] *See generally* Rajec, supra note 107.

[120] *Id.*

[121] *Id.*

B. The Reassurance of Purpose

Surprisingly, pharmaceutical companies are continuing to file patents with genus claims.[122] In fact, pharmaceutical companies in the United States are doing better than ever, with "[p]harmaceutical patent owners [now] making record revenues, up more than 800% from 1992 to 2017."[123] Not only are they filling patents, but pharmaceutical patent owners are also filing, and winning, enforcement actions more than most other industries.[124]

How can this be true? The authors of *The Death of the Genus Claim*, believe it is unlikely that the pharmaceutical industry has not "internalized the sea change" made by the federal courts.[125] Patents are incredibly important to the pharmaceutical industry.[126] The industry is active in their lobbying and the pharmaceutical patents are given among the highest dollar evaluations.[127] The industry must know what is going on. Instead, the authors of *The Death of the Genus Claim* argue that the substance of patent doctrine may not actually affect these industries as much as expected because of unintentional regulatory stopgaps external to the patent system.[128]

The USPTO rarely rejects patents on enablement and written description.[129] Therefore, while applicants are still likely to receive genus claims, they are vulnerable in court.[130] But, Mark A. Lemley, a professor at Stanford Law School, explains that a significant portion of the value of a patent comes from the ability to file cases, regardless of whether the assignee can win.[131] In particular, the FDA provides numerous regulatory hurdles that slow generics and benefit patent holders. First, brand-name companies can delay a generic from getting FDA approval automatically for 30-months by just filing a suit.[132] Another barrier comes from FDA approval.[133] Because those looking to exploit the species in a genus must choose a different species than the one being used by the patent owner, they must file a New Drug Application.[134] A New Drug Application is a lengthy process that cannot piggyback on the approved species' studies.[135] And these are just two of many examples of the unintentional exclusivity created by the FDA. Perhaps, although it is unclear, these significant barriers create enough exclusivity that pharmaceutical companies are not bothered by the recent developments described above.

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[122] Karshtedt et al., *supra* note 1, at 63-65.
[123] *Id.*
[124] *Id.*
[125] *Id.* at 65-66.
[126] *Id.*
[127] Karshtedt et al., *supra* note 1, at 65-66.
[128] *Id.* at 66-70.
[129] *Id.* at 66.
[130] *Id.*
[131] Mark A. Lemley, *The Surprising Resilience of the Patent System*, 95 TEX. L. REV. 1, 40-42 (2016).
[132] Karshtedt et al., *supra* note 1, at 67.
[133] *Id.* at 67-68.
[134] *See* FDA, *New Drug Application (NDA)*, FDA, https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last visited Nov. 14, 2022).
[135] *Id.*

But they should be! Unintentional exclusivity from a patchwork of regulatory red tape is not the same as a governmental patent grant which has the *purpose* of giving the inventor exclusivity and encouraging innovation. The FDA is responsible for:

> protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation . . . [and] also provid[ing] accurate, science-based health information to the public.[136]

Nothing in the FDA's congressional charge speaks about "innovation" or "exclusive rights."[137] Therefore, losing the genus claim has greater implications than just the immediate effect on the market would indicate. While the pharmaceutical companies may still have exclusivity, they are losing the purpose behind the exclusivity. And in a country outraged by the price of medicine, the unintentional exclusivity provided by FDA approval side-effects is far from sacred.[138] Indeed, "pay-for-delay" methods are already under attack.[139] The public wants generics, and the FDA is not a likely savior for the pharmaceutical industry – at least not long term.

V. CONCLUSION

The federal courts' new methods for evaluating genus claims make it difficult to patent in the life sciences. Through the lens of the Amgen saga, the United States is alone in this practice and finds itself in the unusual position of offering less IP protection than much of the rest of the world. If the Supreme Court does not rectify this area of law, then the United States may be to provide protection offered elsewhere. Shrinking the umbrella of patent protection hurts the United States' ability to argue for harmonization or maximization. While the pharmaceutical industry may not yet feel the pain of losing the genus claim, it would be foolish for the industry to let it slip away. The patent system has power in its purpose to spur innovation – it is prohibitively harder to take away that power than it is to remedy the FDA's unintended side-effects. The Supreme Court's grant of Amgen's petition was a surprise for many—will Lemley, Karshtedt, and Seymore have to write their next paper on the resurrection of the genus claim?

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[136] USAGov, *Food and Drug Administration,* USAGOV, https://www.usa.gov/federal-agencies/food-and-drug-administration#:~:text=The%20Food%20and%20Drug%20Administration,and%20products%20that%20emit%20radiation (last visited May 1, 2022).

[137] *Id.*

[138] *See* Sydney Lupkin, *A Decade Marked By Outrage Over Drug Prices*, NPR (Dec. 31, 2019), https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices.

[139] *See* Lawrence Gostin, *Supreme Court Decision on "Pay-for-Delay" Case Will Speed Marketing of Generic Drugs and Save Consumes and Taxpayers Billions,* JAMA NETWORK (Jul. 22, 2013), https://jamanetwork.com/channels/health-forum/fullarticle/2760420.