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WOBBLING 35 U.S.C. § 112(A) STANDARDS AND THEIR IMPACT ON ANTIBODY PATENTS

*Naoko N. Koyano**

* © 2024 Naoko N. Koyano, J.D., 2024, Mitchell Hamline School of Law; Ph.D., 1993, The University of Tokyo; B.A., 1988, The University of Tokyo. Registered Patent Agent at HSML, P.C. For biographical information, see: https://www.linkedin.com/in/naoko-koyano-phd-682a159/. The author thanks Professor Jay Erstling for guidance and discussion for this work and Dr. Iain A. McIntyre (Carlson Caspers) and Douglas P. Mueller (HSML, P.C.) for insightful comments.

LIST OF FIGURES

I. INTRODUCTION

The provision of 35 U.S.C. § 112(a), in its short paragraph, sets forth three requirements for a patent disclosure—written description, enablement, and best mode—to satisfy the "notice function" of a patent specification:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.[1]

The principle of the patent system is based on the concept of "*quid pro quo*": an inventor gets protection for the invention they disclosed to the public.[2] An inventor cannot claim protection for what they did not disclose. Thus, what is disclosed and whether such disclosure satisfies the requirements of the notice function is critical in determining the scope of patent claims. Although Section 112(a) provides the core requirements for a patent disclosure, it has historically been a relatively quiet area in terms of litigation.[3] However, Section 112(a) is quickly turning into an area of hot debate because of rapid development in technological areas such as biotechnology, pharmaceutical, chemical, and computer-related industries, which has started to generate new questions that were not foreseen at the inception of the patent system.[4] Furthermore, the

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1 35 U.S.C. § 112(a) (2018).

2 *See* 3 DONALD S. CHISUM, CHISUM ON PATENTS pt. 1, § 7.03 (2024), Lexis+ (noting that an inventor gets protection in exchange for bringing in new technology into the public domain and notes that the quid pro quo premise of patent law provides a monopoly for inventors of new technology for a limited period of time).

3 *See* Paul Michel & Matthew Dowd, Juno v. Kite*: A Rare Opportunity for the Supreme Court to Grant Rehearing*, IPWATCHDOG (Jan. 4, 2023, 4:15 PM), https://ipwatchdog.com/2023/01/04/juno-v-kite-rare-opportunity-supreme-court-grant-rehearing/id=154794/ [https://perma.cc/5EJ7-SDNW] (stating that Section 112 very rarely has successful rehearing petitions).

4 *See id*. (stating that a case is coming to the Supreme Court for the first time in 75 years to reevaluate the meaning of Section 112 and it will provide the court an opportunity to correct a negative trend in enablement law which has made it harder "to protect groundbreaking, pioneering inventions").

different disclosure requirements applied in different jurisdictions make patent prosecution even more complex for multinational industries.[5]

This Article focuses on patents in the biotechnological area. In particular, it discusses patents related to antibodies and antibody-related molecules that have unique diversity due to their biological nature, and emerging issues related to disclosure requirements. It also compares different approaches taken in the United States., Europe, and Japan with respect to the disclosure requirements, and discusses their impact on pharmaceutical industries, with a focus on the *Amgen v. Sanofi* case that was recently decided by the Supreme Court of the United States.[6] First, Part II discusses the principle of the provisions of 35 U.S.C. § 112(a) and their development.[7] Part III compares the written description and enablement standards in foreign jurisdictions.[8] Part IV then discusses the unique nature and difficulty of antibody patents.[9] Part V discusses recent shifts in the enablement and written description requirements, particularly in connection with the *Amgen* case.[10] Part VI discusses cases related to *Amgen* that were recently decided in foreign jurisdictions.[11] Finally, Part VII concludes by discussing the aftermath of *Amgen* and future perspectives.[12]

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5 *See* Sheena Linehan, *Divided Opinion:* Amgen v Sanofi*: Narrowing the Scope of Protection for Antibody Inventions?* PHARMATIMES MAG. (Apr. 13, 2021) http://magazine.pharmatimes.com/#/reader/38398/111789 [https://perma.cc/M44V-X36X] (noting that in the Amgen and Sanofi global patent cases the differences in approaches present in the validity of functionally defined antibody patents between major jurisdictions was highlighted).

6 Amgen Inc. v. Sanofi, 598 U.S. 594, 594 (2023).

7 *See infra* Part II.

8 *See infra* Part III.

9 *See infra* Part IV.

10 *See infra* Part V.

11 *See infra* Part VI.

12 *See infra* Part VII.

II. THE DEVELOPMENT OF 35 U.S.C. § 112 (A)

This Part provides an overview of the development of written description, enablement, and best mode requirements in the United States. As discussed in this Part, recognition of the distinction between written description and enablement requirements was a relatively recent event in the history of the United States patent system.

A. QUID PRO QUO – THE BEDROCK PRINCIPLE OF THE PATENT SYSTEM

The bedrock principle of the patent system is that a patentee receives protection of an invention for what is disclosed, or a "*quid pro quo*" of the patent bargain.[13] Under this principle, a patentee must disclose a complete description of the invention as well as how to make and use the claimed invention.[14] As such, 35 U.S.C. § 111(a)(2)(A) requires that an application for a patent has a specification.[15] Under 35 U.S.C. § 112(a), a specification of a patent must contain a written description of the invention (the "written description" requirement), and that the specification enables any "person having ordinary skill in the art" ("PHOSITA") to make and use the claimed invention (the "enablement" requirement).[16] Furthermore, the statute requires the disclosure of the best mode of the embodiment (the "best mode" requirement).[17] The best mode requirement, however, is no longer used as the basis for litigation under the America Invents

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[13] *See* CHISUM, *supra* note 2 (stating that the patent bargain is that an inventor gets protection in exchange for bringing in a new technology into the public domain and that the quid pro quo premise of patent law allows for this to be a 14 year monopoly for inventors of these new technologies).

[14] 2 R. CARL MOY, MOY'S WALKER ON PATENTS § 7.2 (4th ed. 2023).

[15] 35 U.S.C. § 111(a)(2)(A) (2018); MOY, *supra* note 14, at 49.

[16] 35 U.S.C. § 112(a); *see* MOY, *supra* note 14, at 49 (stating that the first paragraph of section 112 requires that the specification for a patent contain a "written description" of the invention that gives exclusive rights along with the manner and process in which the invention is made and used and also that it is the "patent applicant's duty to supply the public with adequate disclosure of the invention").

[17] *See* 35 U.S.C. § 112(a) (stating that a specification for a patent should set forth the best mode contemplated by the inventor); MOY, *supra* note 14, at 49.

Act ("AIA"),[18] and thus, the best mode requirement will only briefly be discussed in this paper.

B. REQUIREMENTS OF 35 U.S.C. § 112(A)

The U.S. Supreme Court has ascribed two purposes under 35 U.S.C. § 112(a):

> [1] to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and [2] to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.[19]

Following this definition, the Federal Circuit has held that Section 112, the first paragraph[20] of 35 U.S.C., contains two separate description requirements: a written description of (1) the invention, *and* (2) the manner and process of making and using the invention.[21] Thus, under United States practice, written description and enablement are considered to be closely related but distinct requirements that ensure the specification provides sufficient notice to the public.[22]

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[18] *See* O'CONNOR'S FEDERAL INTELLECTUAL PROPERTY CODES PLUS 703 (Paul W. Fulbright et al. eds., 2022) (stating "[i]n actions commenced on or after Sept. 16, 2011, failure to meet the best-mode requirement of § 112 may not form the basis on which any claim of a patent may be canceled or held invalid or otherwise unenforceable").

[19] Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1346 (Fed. Cir. 2010) (quoting Schriber-Schroth Co. v. Cleveland Tr. Co., 305 U.S. 47, 57 (1938)).

[20] The language of pre-AIA § 112, first paragraph, is continued in current 35 U.S.C. § 112(a) (2018).

[21] *See Ariad Pharms.*, 598 F.3d at 1344.

[22] *See id.* at 1344–47.

1. Enablement

The "enablement requirement" ensures that the specification of a patent discloses what the claimed invention is for the purposes of both patentability and infringement.[23] The statutory language of § 112(a) has been interpreted to mean that, for a claim to be properly enabled, a PHOSITA must be able to make and use the claimed invention without undue experimentation.[24] It is not necessary that all embodiments of the claimed invention are tested, but it is necessary that the disclosure provide sufficient guidance to enable one skilled in the art to carry out the invention commensurate with the scope of the claims.[25] Accordingly, whether the experimentation required to make and use the claimed invention is undue becomes the touchstone to determine if a claimed invention is enabled.[26] Although enablement under 35 U.S.C. § 112 is a question of law, whether the experimentation required to make and use the claimed invention is undue is determined by applying factors set forth in *In re Wands*.[27]

2. Written Description

The purpose of the "written description requirement" is to assure that an applicant of a patent was in full possession of the claimed invention at the time of filing, and to allow other inventors to develop and obtain patent protection for later improvements and subservient inventions that build on the applicant's teachings.[28] Synonymously called "subjective appreciation," this requirement prevents an applicant from introducing "new matter": subject matter which is invented after the filing of the application or different from what was originally

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[23] *See* CHISUM, *supra* note 2.

[24] *See* Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

[25] *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991).

[26] *See In re Wands*, 858 F.2d at 737.

[27] *See id.* at 735–37 (indicating that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims).

[28] *See* CHISUM, *supra* note 2, § 7.04.

disclosed.[29] It also has an effect of preventing "gun jumping," where an inventor files an application before actually figuring out the invention, and "late claiming," where an inventor figures out the invention after filing the application and amends the claims to achieve an earlier priority date.[30]

3. Best Mode

The "best mode requirement" sets forth that a specification must disclose the embodiment that an inventor most prefers.[31] This requirement originated from the "whole truth requirement" which was recognized as early as the Patent Act of 1790.[32] The purpose of this requirement was to prevent the applicant from keeping the best embodiment secret.[33] Although the legal requirement remains in the statutory language, the AIA eliminated the best mode requirement as a defense available to the defendant in an patent infringement suit, as discussed above.[34]

III. DISCLOSURE REQUIREMENTS IN OTHER JURISDICTIONS

Recent advancements in the biotechnology, pharmaceutical, and chemical arts have created an unforeseen difficulty in applying the traditional enablement and written description standards to inventions in such areas, and finding a set of universally applicable rules to decide the patentability of these patent claims has become a topic of hot debate in the U.S.[35] Furthermore, different jurisdictions have been deciding similar cases in very different ways due to the different interpretations of the disclosure requirements.[36] Before comparing the disclosure requirements as applied to the biotechnology patents, the following Section compares the legal provisions in different jurisdictions and differences in the disclosure requirements in the EU, Japan and the United States.

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29 *See* MOY, *supra* note 14, § 7.34.

30 *See id.*

31 *See id*. § 7.1.

32 *See id.* § 7.45.

33 *See id.*

34 *See id.* § 7.1.

35 *See generally, e.g.*, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023); Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022) *and reh'g denied*, 143 S. Ct. 631 (2023).

36 *See infra* Part VI.

A. PROVISIONS

In this Section, the provisions for disclosure requirements in different international jurisdictions are compared. Languages used for disclosure requirements are generally broad and similar, meaning that the different manners laws are applied depends on the interpretation of each provision.

1. Patent Cooperation Treaty ("PCT")

The PCT is an international treaty to facilitate global application of patents.[37] It provides a mechanism for submitting a single "international" patent application and seek patent protection for an invention in multiple countries.[38]

The relevant text of the PCT reads as follows:

> Article 5 - The Description
>
> The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.[39]

Under the PCT, the description requirement is painted with a broad brushstroke, and does not clearly define the meaning of "sufficiently clear and complete," the scope of "the invention," or the "person skilled in the art."[40] The distinction of written description and enablement requirements are not clear in this provision.

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[37] *See PCT FAQs: Protecting your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT)*, WIPO, https://www.wipo.int/pct/en/faqs/faqs.html [https://perma.cc/DJQ2-Y6XJ].

[38] *See id.*

[39] Patent Cooperation Treaty, art. 5, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231, 236 (as modified on Oct. 3, 2001), https://www.wipo.int/pct/en/texts/articles/a5.html [https://perma.cc/ZTP2-SDRK].

[40] *See id.*

2. *The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS" or "TRIPS Agreement")*

TRIPS is an international legal agreement between the member nations of the World Trade Organization (WTO).[41] With respect to intellectual property rights, it establishes minimum standards for the regulation by national governments of different forms of intellectual property as applied to nationals of other WTO member nations.[42] The relevant provision of TRIPS is below:

> Article 29 – Conditions on Patent Applicants
>
> 1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
>
> 2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.[43]

As seen above, the TRIPS Agreement requires disclosure "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art," and further recites the "best mode for carrying out the invention."[44] Similar to the PCT provision, the provision of the TRIPS agreement does not distinguish the written description and enablement requirements.

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41 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, 1869 U.N.T.S. 299, 401 (as amended on Jan. 23, 2017), https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm [https://perma.cc/WM7Y-7RHC].

42 *Id.* at 302.

43 *Id.* at 312.

44 *Id.*

3. The European Patent Convention ("EPC")

The EPC is a multilateral treaty instituting the European Patent Organisation and providing an autonomous legal system according to which European patents are granted.[45] It provides a unified patent framework for patents and applications before European Patent Office.[46]

> EPC Article 83 – Sufficiency
>
> The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.[47]
>
> EPC Article 84 – Support
>
> The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.[48]

The EPC uses the same language as the TRIPS Agreement requiring that disclosure be "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art in Article 83, however imposes additional requirement of "support" in Article 84."[49] The EPO Guidelines for Examination explains that the Article 83 sufficiency of disclosure requirement focuses on whether the example is sufficient to allow "a person skilled in the art, using common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill," a definition which is similar to the enablement requirement in the U.S.[50] The support

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[45] Convention on the Grant of European Patents (European Patent Convention), Preamble *et seq.*, Oct 5. 1973, OJ EPO 2020 42, https://link.epo.org/web/EPC_17th_edition_2020_en.pdf [https://perma.cc/Q8V7-CVX6] [hereinafter Convention on the Grant of European Patents].

[46] *Id.* at 42, 62.

[47] *Id.* at 144.

[48] *Id.*

[49] *Id.*; TRIPS Agreement, *supra* note 41, at 312.

[50] *Guidelines for Examination in the European Patent Office*, EUR. PAT. OFF., Part F, Ch. III-1 (Mar. 2023); *Guidelines for Examination in the European Patent Office*,

requirement in Article 84 is likened to the written description requirement in the United States.[51] However, the EPO caselaw does not appear to clearly distinguish, the "sufficiency" and "support" requirements like the United States system distinguishes "enablement" and "written description".[52]

4. Japan

According to Japanese patent law, the description of the patent application must satisfy the following three requirements:

> Patent Act Article 36(4)(i) – enablement requirement
>
> The detailed description of the invention shall be stated in a manner to be clear and sufficient as to enable any person skilled in the art to which the invention pertains to work the invention on the basis of the description, drawings and the common general knowledge at the time of filing in accordance with Ordinance of the Ministry of Economy, Trade and Industry.[53]
>
> Patent Act Article 36(6)(i) – support requirement
>
> The invention for which a patent is sought is stated in the detailed description of the invention.[54]

EUR. PAT. OFF., Part F, Ch. III-1 (Mar. 2023); *see In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

51 *See generally* MARGO A. BAGLEY ET AL., INTERNATIONAL PATENT LAW AND POLICY 532, 531–33 (2013).

52 *See id.* at 533, 537 (comparing European and American disclosure requirements in legislative form and jurisprudential effect).

53 特許法　昭和三十四年法律第百二十一号 [Patent Law Act No. 121 of 1959], art. 36 (2020); *see generally*, *Patent Act Act No. 121 of 1959*, JAPANESE LAW TRANSLATION, https://www.japaneselawtranslation.go.jp/en/laws/view/3118/en [https://perma.cc/6HWB-R84Q]; *Examination Guidelines for Patent and Utility Model in Japan* Part II.1.1–2, JAPAN PATENT OFF., https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html [https://perma.cc/D6NT-4DGE].

54 特許法　昭和三十四年法律第百二十一号 [Patent Law Act No. 121 of 1959], art. 36 (2020).

Patent Act Article 36(6)(ii) – clarity requirement

The invention for which a patent is sought is clear.[55]

The Japanese law therefore requires that description be "clear and sufficient as to enable any person skilled in the art."[56] Although the provision distinguishes between enablement and support, which appears like the provision set forth in the EPC,[57] the support requirement has been interpreted to be synonymous with written description, at least in certain cases.[58]

As seen above, the patent disclosure requirements of different international jurisdictions are generally similar and written with broad brushstrokes. It is also apparent that the definitions of the scope of the "invention," what is "clear and sufficient" or "clear and complete," and the definition of "person skilled in the art," are the keys to understanding the different results in the decisions of the validity of biotechnology patents.

B. ENABLEMENT STANDARDS AS APPLIED IN DIFFERENT JURISDICTIONS

Despite having such similar language in the statutes, the disclosure requirements as applied do significantly differ depending on the jurisdiction.[59] In this Section, a representative case for each jurisdiction is discussed to illustrate how the application of these enablement standards can differ.

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55 *Id.*

56 *Id.*

57 Convention on the Grant of European Patents, *supra* note 45, art. 83.

58 *See infra* Section III.3.

59 *See Global Patents Comparative Law Guide: Sufficiency of Disclosure*, NORTON ROSE FULBRIGHT, https://www.nortonrosefulbright.com/en/knowledge/publications/d4098ffa/global-patents-comparative-law-guide-sufficiency-of-disclosure [https://perma.cc/67HU-3H4R] (discussing disclosure requirements for various jurisdictions).

1. United States

The traditional standard for enablement, as discussed above,[60] has been used for over a century in the United States.[61] This standard is well-illustrated in the case, *Minerals Separation v. Hyde*.[62] The claimed invention in *Minerals Separation* was a new method of separating metals from mined ore using a very small amount of oil.[63] As the nature of ores differs from ore to ore, preliminary tests were necessary to determine the amount of oil and the extent of agitation necessary to obtain the best results.[64] The Supreme Court ruled that the process was sufficiently definite to guide those skilled in the art to its successful application.[65] Although *Minerals Separation* was decided more than seventy years earlier than *In re Wands*, which set forth the eight factors to determine if the experimentation is undue,[66] it already recognized that a PHOSITA might need to engage in experimentation in applying the invention.[67] This case shows that the conceptual framework of what is required of a specification (to guide a PHOSITA how to make and use the claimed invention), as well as the determinative factor for enablement (whether the necessary experimentation is undue or not) were already established in the early 20th century.[68]

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60 *See supra* Part II.1.

61 *See* Minerals Separation v. Hyde, 242 U.S. 261, 271 (1916) (stating that something can be properly enabled even if it leaves something to the skills of the person applying the invention).

62 *See id.* (discussing traditional enablement standards).

63 *See* U.S. Patent No. 835,120 (filed May 29, 1905) (issued Nov. 6, 1906) (claiming a process of concentrating and separating ores using a small amount of oil).

64 *See Minerals Separation*, 242 U.S. at 270.

65 *See id.* at 271 (stating that the patent "is clearly sufficiently definite to guide those skilled in the art to its successful application, as the evidence abundantly shows. This satisfies the law.").

66 *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (stating the eight factors for determining the presence of undue experimentation).

67 *See Minerals Separation*, 242 U.S. at 271 (stating that something can be properly enabled even if it leaves something to the skills of the person applying the invention).

68 *See id.; see infra* Part V (discussing subsequent changes and current issues in the enablement standard for antibodies).

2. E.U.

An example of the enablement standard in the European Patent Office ("EPO") can be seen in the *Vinylchloride resins/Sumitomo* Decision of the Technical Board of Appeal 3.3.1.[69] In *Vinylchloride resins/Sumitomo*, the claimed invention was a process for the production of vinyl chloride resins.[70] The claims at issue in the case recited ranges of parameters such as the percent weight of fractions and their relative balance.[71] Further, the specification disclosed the process of how to carry out the claimed invention.[72] The Board recognized that there may be "occasional lack of success of the claimed process," and that "some experimentation is still to be done to transform the failure into success."[73] However, they decided that the presence of such situations "does not impair [the claim's] feasibility in the sense of Article 83 EPC."[74] As seen here, the EPO Board of Appeal clearly used a framework similar to the enablement standard in the U.S., as an occasional lack of success was held to not violate EPC Article 83 so long as a PHOSITA does not have to engage in "undue experimentation."[75]

3. Japan

Similar to the United States., the Japanese Patent Office distinguishes between enablement and support (interpreted similarly as written description) requirements, and also considers undue experimentation for enablement.[76] For

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[69] "Vinylchloride Resins," Case No. T 0014/83, European Patent Office Board of Appeals (June 7, 1983), https://www.epo.org/en/boards-of-appeal/decisions/t830014ep1 [https://perma.cc/4WAF-AY32].

[70] *Id.* at 1.

[71] *See id.* at 5–6 (stating the invention involved 10-80% of a gel fraction and a balancing soluble fraction).

[72] *See id.* (stating that a process including the features of the claims can be carried out by an expert).

[73] *Id.* at 6–7.

[74] *Id.* at 7.

[75] *See id.* (stating that occasional lack of success does not impair the feasibility of the claimed invention even if some additional experimentation is required).

[76] *See* Tōkyō Chihō Saibansho (東京地方裁判所) [Tokyo Dist. Ct.] Mar. 26, 2020, Hei 29 (ワ) no. 24598 (Japan), https://www.courts.go.jp/app/hanrei_jp/detail7?id=89458 [https://perma.cc/2RNY-EZVS] [hereinafter "Cellulose Powder"] (stating

example, in the case *Cellulose Powder*, claim 1 of the patent at issue was directed to "cellulose powder having an average polymerization degree of 5-300 higher than the level-off polymerization degree obtained by measuring a viscosity by hydrolyzing said cellulose powder by boiling for 15 minutes in 2.5N hydrochloric acid."[77] In this case, the court determined that the specification sufficiently disclosed the method of hydrolysis, and that a PHOSITA would not need to engage in undue experimentation—therefore, the claim is enabled under Patent Act Article 36(4)(i).[78] However, with respect to the support requirement, the court found that a PHOSITA would not recognize that the level-off polymerization degree of raw pulp disclosed in the specification is the same as the level-off polymerization degree of cellulose powder obtained by hydrolyzing a raw pulp, and decided that the support requirement was not satisfied under Patent Act Article 36(6)(i).[79] Hideki Takaishi of the Nakamura patent office commented on this ruling, stating that "Japanese courts tend to not clearly distinguish enablement and support requirements. This is a relatively rare case in which the court clearly distinguished enablement and written description."[80] Thus, the distinction between the enablement and support requirements in the Japanese system appears to be not as clear-cut as the distinction between enablement and written description within the United States patent system.

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that failure to provide support to allow the invention to be carried out by those of skill in the art shows a failure to enable the invention).

77 *Id.* at 3.

78 *See id.* at 77.

79 *See id.* at 94.

80 Hideki Takaishi (高石秀樹), *Tokyo District Court 2017 (Wa) No. 24598 "Cellulose Powder" Case (東京地判平成29年（ワ）第24598号「セルロース粉末」事件)*, Nakamura & Partners (Apr. 14, 2023), https://www.nakapat.gr.jp/ja/legal_updates_jp/%e6%9d%b1%e4%ba%ac%e5%9c%b0%e5%88%a4%e5%b9%b3%e6%88%9029%e5%b9%b4%ef%bc%88%e3%83%af%ef%bc%89%e7%ac%ac24598%e5%8f%b7%e3%80%8c%e3%82%bb%e3%83%ab%e3%83%ad%e3%83%bc%e3%82%b9%e7%b2%89%e6%9c%ab%e3%80%8d/ [https://perma.cc/UPF5-B7EU].

4. Study by the Trilateral Patent Offices

As discussed above, the United States, E.U. and Japanese patent offices each have their own enablement and written description (or support) requirements and recognize that they are separate requirements, although the degree of distinction between these requirements differ. Furthermore, each of the offices considered the experimentation that a PHOSITA would need to engage in to make and use the claimed invention to determine whether a claim is enabled. Such similarity of the standards is corroborated by a study that was conducted by the Trilateral Patent Offices in 2001, with the goal of mutual understanding in search and examination of each office and to harmonize patents.[81] In the study, entitled "Trilateral Project B3b", a comparative study on "reach-through claims" of biotechnology patents was conducted.[82] "Reach-through claims" are defined as "claims to future inventions based on currently disclosed inventions."[83] The determination of patentability standards and examination strategies of the reach-through claims is conceptually similar to determining whether the experimentation required of a PHOSITA is undue to determine whether a claim is enabled. In this study, the three offices (the USPTO, EPO, and JPO) considered the patentability of hypothetical patent claims.[84] Notably, for a claim of a monoclonal antibody specific to a given protein, which I will discuss in the following Parts,[85] the three offices completely agreed in their determinations of whether the written description and enablement requirements were satisfied in four different fact patterns.[86] Therefore, in 2001, the three offices were in agreement with respect to

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81 *See* European Patent Office, Japan Patent Office, & USPTO, TRILATERAL PROJECT B3B: MUTUAL UNDERSTANDING IN SEARCH AND EXAMINATION, REPORT ON COMPARATIVE STUDY ON BIOTECHNOLOGY PATENT PRACTICES, THEME: COMPARATIVE STUDY ON "REACH-THROUGH CLAIMS" 1 (Nov. 5-9, 2001) https://link.epo.org/trilateral/B3b_reachthrough_text.pdf [https://perma.cc/3BQ9-7NY5] [hereinafter TRILATERAL PROJECT B3B]. The Trilateral Patent Offices was established by the EPO, JPO, and USPTO in 1983 to improve efficiency of the global patent system and to exchange information and views on patent administration and examination practice in order to gain mutual benefits. *See* THE TRILATERAL CO-OPERATION, https://www.trilateral.net/home [https://perma.cc/W2HS-L86G].

82 TRILATERAL PROJECT B3B, *supra* note 81, at 1.

83 *Id.*

84 *See id.*

85 *See infra* Parts IV-VI.

86 TRILATERAL PROJECT B3B, *supra* note 81, at 14.

the enablement and written description standards of antibody patents.[87] It should further be noted, relevant to the topic of this paper, that all three offices said that the antibodies described by the antigen they bind to are enabled because a PHOSITA could obtain a monoclonal antibody specific to a given protein, using routine and well known methods.[88] However, in the following years, this notion underwent a dramatic change. How the three jurisdictions diverged in the determination of the patentability of antibody patents is discussed in Part VI of this paper.[89]

IV. UNIQUE ISSUES IN ANTIBODY-RELATED PATENTS

The antibody-based drug market is one of the largest bio-medical markets in the world.[90] Antibodies are used for the targeted treatment of specific diseases, in diagnosis, and in research.[91] Due to their target specificity, antibody-based drugs have revolutionized treatment in various areas of medicine where no treatment was previously available.[92] The global monoclonal antibodies market size was valued at 210.06 billion United States dollars in 2022 and is projected to grow continuously.[93] As such, securing the intellectual property rights of antibody-based products has become a major concern for pharmaceutical industries.

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87 *See id.* ("The claim complies with enablement and/or support requirements in Case 2 and 4, since the person skilled in the art could obtain a monoclonal antibody specific to a given protein, using routine and well known methods, and use the antibodies in diagnostic methods.").

88 *Id.*

89 *See infra* Part VI.

90 *See* Mark A. Lemley & Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 YALE L.J. 994, 994 (2023).

91 *Id.* at 1004–07.

92 *See Immunotherapy*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy.html [https://perma.cc/NVU7-RGMJ].

93 *Monoclonal Antibodies Market Size, Share & Trends Analysis Report By Source Type (Chimeric, Murine, Humanized, Human), By Production Type (In Vivo, In Vitro), By Application, By End-use, By Region, And Segment Forecasts, 2023 – 2030*, GRAND VIEW RSCH., https://www.grandviewresearch.com/industry-analysis/monoclonal-antibodies-market [https://perma.cc/X62R-D4RC] [hereinafter *Monoclonal Antibodies*].

The complexity of patents for antibody and antibody-related molecules arises from their unique biological nature.[94] Antibodies and antibody-related molecules, such as T-cell receptors, are the central players of the immune system that prepare an animal to fight any foreign substances that enters the animal's body, such as pathogenic bacteria and viruses.[95] The immune system is flexible so as to be able to fight any new antigens that the animal's body might encounter, and to properly eliminate them.[96] This incredible flexibility comes from a mechanism called somatic recombination, in which the genomic DNA of an immune cell is shuffled, followed by a selection of cells that expresses a suitable antibody from a large pool of cells that have independently gone through somatic recombination.[97] By this mechanism, millions of different antibodies are generated in a body, and virtually no two antibodies are identical in terms of their amino acid sequences.[98] This unique biology of antibodies causes a disclosure problem when it comes to patent specification.[99] As T-cell receptor and other antibody-related molecules have basic structures similar to antibodies,[100] I will discuss the structure of antibodies as an example in this Article.

94 *See* Lemley & Sherkow, *supra* note 90, at 1001.

95 *See id.* at 1001–02.

96 *Id.*

97 *See* Susumu Tonegawa, *Somatic Generation of Antibody Diversity*, 302 NATURE 575, 575 (1983). Tonegawa was awarded The Nobel Prize in Physiology or Medicine 1987 for his discovery of the genetic principle for generation of antibody diversity. *The Nobel Prize in Physiology or Medicine 1987*, THE NOBEL PRIZE, https://www.nobelprize.org/prizes/medicine/1987/summary/ [https://perma.cc/6ZG5-VEBN].

98 *See* Tonegawa, *supra* note 97, at 575 (explaining that the body makes at least one million antibodies).

99 Lemley & Sherkow, *supra* note 90, at 1001.

100 Tonegawa, *supra* note 97, at 575.

A. STRUCTURE OF AN ANTIBODY

An antibody, also called an immunoglobulin, is a Y-shaped molecule that has two identical light (L) chains and two identical heavy (H) chains.[101] See the diagram below:

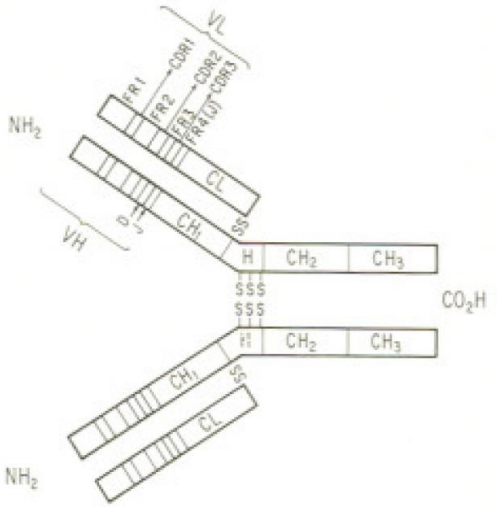

Figure 1. Basic structure of a mouse IgG molecule.[102]

Each of the chains (L and H chains) has constant (*C*) regions and variable (*V*) regions.[103] The *V* regions are primarily responsible for antigen recognition, and have particularly variable regions implicated in actual antigen contact, which are referred to as complementarity determining regions (CDR1, CDR2, and CDR3).[104] CDR regions are surrounded by frame regions (FR1, FR2, FR3, and FR4), which are invariable.[105] Two H chains are covalently bonded to each other through disulfide bonds to form the base of the "Y" shape, and one L chain and one H chain are bonded together through a disulfide bond to form the two "arm" portions of

101 *Id.*

102 *Id.* at 575, fig.1.

103 *Id.*

104 *Id.*

105 *Id.*

the "Y" shape.[106] Each of the paired portions of VH and VL chains contain CDR1, CDR2, and CDR3, and forms the antigen binding domain.[107]

B. VARIABILITY OF THE ANTIBODY IS GENERATED BY SOMATIC RECOMBINATION

A remarkable feature of antibodies is that their diversity is generated via somatic recombination.[108] This process is illustrated in a simplified diagram below.[109] Genes coding for antibodies comprise multiple copies (up to hundreds) of segments called *V*, *D*, and *J* segments, each copy being slightly different from each other.[110] One copy from each segment is selected and joined to generate a DNA encoding a mature antibody via the process called "*V(D)J* recombination" (*see* diagram below):

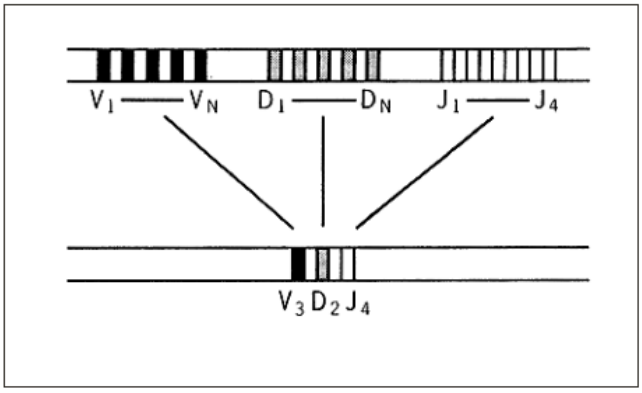

Figure 2. Schematic diagram of *V(D)J* recombination that occurs during the development from an progenitor cell (top) to an antibody-producing B cell (bottom).[111]

V(D)J recombination generates numerous different antibodies by this mix-and-match mechanism.[112] Furthermore, there are variations in the number of

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106 *Id.*

107 *Id.*

108 *Id.* at 576.

109 THE NOBEL PRIZE, *supra* note 97.

110 *Id.*

111 *Id.* fig. 3.

112 *Id.*

nucleotides that are inserted in the joins between the recombined *V* and *D* segments and *D* and *J* segments, respectively, and there are variations in the *C* regions as well.[113] Due to this recombination mechanism, it is estimated that the human immune system comprises hundreds of millions of different antibodies, or an "antibody repertoire."[114]

C. MONOCLONAL & POLYCLONAL ANTIBODIES

B cells are the precursors of plasma cells that produce antibodies in an organism.[115] The *V(D)J* recombination takes place in B cells, and as a result, each B cell carries a gene encoding an antibody that is different from any other antibodies.[116] There are two kinds of antibodies: "monoclonal" and "polyclonal" antibodies.[117] Monoclonal antibodies are obtained by immunizing an animal, immortalizing B cells (by making a "hybridoma" of a B cell with an immortalizing cell), and expanding a hybridoma that expresses an antibody that has the desired specificity to a target.[118] Monoclonal antibodies are unlimited in availability because the B cells are immortalized and can be expanded indefinitely.[119] The nucleotide sequence of a monoclonal antibody can be determined by sequencing.[120] Because of their unlimited availability and uniformity, monoclonal antibodies are generally used for therapeutics.[121] By contrast, polyclonal antibodies are obtained by immunizing an animal and purifying antibodies from the animal's blood when the antibody titer against the antigen has increased.[122] As such, "a polyclonal antibody" is a mixture of many different antibodies, and the supply is limited by the volume of the blood of the immunized animal—accordingly, polyclonal antibodies are not suited for therapeutics.[123]

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113 Tonegawa, *supra* note 97, at 577–79.

114 THE NOBEL PRIZE, *supra* note 97.

115 Lemley & Sherkow, *supra* note 90, at 1002.

116 *Id.* at 1008.

117 *Id.*

118 *Id.*

119 *See id.* at 1007–08.

120 *Id.* at 998.

121 *Id.* at 997.

122 *Id.* at 1008.

123 *Id.*

D. ANTIBODY PATENTS HAVE UNIQUE DISCLOSURE ISSUES DUE TO THE DIVERSITY OF ANTIBODIES ARISING FROM GENOMIC RECOMBINATION

As discussed above, antibodies are naturally diverse, and each monoclonal antibody is different from any other antibody because it derives from one B cell that had gone through a unique *V(D)J* recombination in a single cell.[124] This nature raises several issues in claiming antibodies in a patent that do not appear in other technological areas.

First, while the chance to generate an exact same antibody is virtually zero even by strictly following the disclosure of a specification, the technology of raising antibodies is well-established, and a PHOSITA can obtain a monoclonal antibody that has similar properties with high likelihood by following a standard protocol.[125] Thus, antibodies obtained according to the disclosure of a patent will likely have the same function as originally described, but would never be materially identical.[126] From the predictability standpoint, the disclosed technique can be said to be predictable because a PHOSITA will obtain with high likelihood an antibody having the desired characteristics.[127] However, the technique can also be said to be unpredictable because the number of hybridomas the PHOSITA would have to screen is unknown, the number of antibodies the PHOSITA would obtain is unknown, and the exact sequence of the antibody the PHOSITA would obtain is unknown. Second, a screening step is always necessary to find a hybridoma that produces an antibody with the desired character.[128] For example, if the desired hybridoma can be found in 2% of the hybridoma population, a PHOSITA would have to engage in experimentation to screen out the 98% of hybridomas that are undesired and find the 2% of the target hybridomas.

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124 Tonegawa, *supra* note 97, 577–79; *also see* BRUCE ALBERT ET AL., MOLECULAR BIOLOGY OF THE CELL 1319–1322 (6th ed. 2015).

125 Hyung-Yong Kim et al., *Immunization, Hybridoma Generation, and Selection for Monoclonal Antibody Production*, in MONOCLONAL ANTIBODIES: METHODS AND PROTOCOLS 33, 33–46 (Vincent Ossipow & Nicolas Fischer eds. 2014); *see also* ALBERT ET AL., *supra* note 124, at 1320–21. The theoretical estimate of antibodies *V(D)J* recombination alone can generate is 1.5×10^6. Further considering the junctional diversification, it is estimated that the diversity of antibodies is up to 1×10^8. It is very unlikely that two independently isolated antibodies are molecularly identical.

126 ALBERT ET AL., *supra* note 124.

127 Kim et al., *supra* note 125, at 33–46.

128 *Id.*

The nature of the antibodies and their production process discussed above raises important questions with respect to disclosure requirements. For example, if a patent claims a monoclonal antibody, and a PHOSITA follows the method to make the monoclonal antibody exactly as disclosed and obtains a new antibody that has the same function, does this antibody infringe the original patent? Due to the nature of the monoclonal antibody, the antibody the follower makes is materially distinct from the patented antibody. If the scope of the patent protection is limited exactly to what the inventor has materially disclosed, for example, by the sequence of the antibodies, the new antibody a PHOSITA makes would never infringe the patent, and the patent would provide very limited protection to the first inventor. This would disincentivize pharmaceutical companies from investing huge amounts of resources in research and development for the production of antibody-based drugs and thus reduce the number of therapies available for many different diseases.[129] In the other extreme, if the patent system allows protection of any antibodies obtained by the method disclosed in the patent specification, it would dominate the field of antibodies against the disclosed antigen, and the protection given to the patentee would be too broad, and effectively lock up a scientific discovery.[130]

It is clear that the patent system needs to find an adequate middle-ground to provide rightful protection to the deserving inventors. So, what would be the adequate way to provide protection to antibody patents? In the following Parts, I discuss the challenges the U.S. courts have faced, and the changing standards of these disclosure requirements.[131]

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[129] This is one of the contentions of Amgen in *Amgen v. Sanofi*. *See infra* Section V.C.1.c.

[130] O'Reilly v. Morse, 56 U.S. (15 How.) 62, 113 (1853) (noting that claim 8 of Morse's 1840 patent, which attempted to cover any application of electro-magnetism, was too broad).

[131] *See infra* Parts V and VI; for a comprehensive review of the history of antibody claiming, *see also* Lemley & Sherkow, *supra* note 90.

V. SHIFT IN THE ENABLEMENT & WRITTEN DESCRIPTION REQUIREMENTS RELATED TO ANTIBODY PATENTS IN THE U.S.

As discussed in the preceding Parts, antibody patents have a unique difficulty in defining the scope of their patent protection.[132] Historically, due to the unavailability of techniques for sequencing antibody molecules and defining them by structure, such as amino acid sequences, the United States Patent Office has allowed antibodies to be claimed by the antigen it binds to by a claiming method called "functional claiming."[133] Functional claiming allows an applicant of a patent to claim a product by its function, but not by what it is, which often results in a broad "genus" claim, which encompasses all of the species of the biological compounds capable of carrying out the claimed functional properties.[134] In the case of antibodies, an applicant for a patent would be able to define an antibody by the antigen it binds to, not by the structure of the antibody itself.[135] This is often analogized to the relationship of a lock and a key; as only one key can open a specific lock, one should effectively be able to define the key by defining the lock.[136] However, with the advancement in the knowledge of antibody structure—the development of sequencing technologies and technologies to define the three-dimensional structure of molecules such as NMR spectroscopy and X-ray crystallography[137]—describing antibodies as a material has technically become possible. This possibility has given rise to the thought that for the genuine *quid pro quo* bargain of the patent system, the structure of the claimed antibody should be disclosed, rather than the antigen that it binds to.[138]

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132 *See supra* Part IV.

133 Dmitry Karshtedt et al., *The Death of the Genus Claim*, 35 HARV. J.L. & TECH. 1, 41 (2021); Jonathan B. Fitzgerald, *Navigating Claim Scope for Functionally Claimed Biological Compounds After* Amgen v. Sanofi, OUTSOURCED PHARMA (Mar. 14, 2023), https://www.outsourcedpharma.com/doc/navigating-claim-scope-for-functionally-claimed-biological-compounds-after-amgen-v-sanofi-0001 [https://perma.cc/94EC-HGU4].

134 CHISUM, *supra* note 2.

135 Lemley & Sherkow, *supra* note 90, at 1009.

136 *Id.* at 1004.

137 Anna Pomés, et al., *Structural Aspects of the Allergen-Antibody Interaction*, 11 FRONTIERS IN IMMUNONLOGY, Sept. 2, 2020, at 1–3, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7492603/pdf/fimmu-11-02067.pdf [https://perma.cc/94LX-WEKP].

138 Lemley & Sherkow, *supra* note 90, at 1056–57.

A related issue that has arisen in determining the patentability of antibody claims is the practice of genus claiming.[139] As discussed in the preceding Part, no two antibodies are exactly the same, even if they are produced by the exact same method. Therefore, the question follows: how far should the patent protection extend to such antibodies? And to what extent should antibodies be considered as belonging to the same genus and thus be considered protectable under a patent?

A. TRADITIONAL ERA

Traditionally, an antibody was described by the antigen it binds to, as was clearly evidenced by the Trilateral study conducted by the Trilateral Patent Offices.[140] The start of this tradition can be seen in the case *Hybritech, Inc. v. Monoclonal Antibodies, Inc*, which was the first ruling on monoclonal antibody technology.[141] Although the character of a particular monoclonal antibody was not at issue in that case, the Federal Circuit ruled that monoclonal antibody technology is known in the art, and that the specification provided sufficient guidance for a PHOSITA to make and use the invention.[142] Therefore, the court decided, the claimed invention was enabled.[143] The court ruled that as long as the experimentation a PHOSITA has to undertake is not undue, such disclosure is considered to be enabling for a monoclonal antibody.[144]

The Federal Circuit continued this line of reasoning in *In re Wands*, an eponymous case that established the "*Wands* factors" to determine if the experimentation a PHOSITA would have to undertake to make and use the claimed invention is undue.[145] In *In re Wands*, the claimed invention was immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM subtype.[146] One of the issues in the

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139 *See generally* Karshtedt et al., *supra* note 133.

140 *See* TRILATERAL PROJECT B3B, *supra* note 81.

141 Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986).

142 *Id.*

143 *Id.*

144 *Id. (*stating that "there was not a shred of evidence that undue experimentation was required by those skilled in the art to practice the invention").

145 *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988) (see *Wands* factors, *supra* note 27).

146 *Id.* at 733.

case was whether the claim using monoclonal antibodies was adequately enabled by its disclosure of how to screen the desired monoclonal antibody.[147] The court ruled that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against the antigen were either well-known in the art or adequately disclosed and that the experimentation required of a PHOSITA is not undue.[148] Importantly, the court recognized that the nature of monoclonal antibody technology involves screening hybridomas to determine which ones secrete an antibody with the desired characteristics, that the specification discloses a method requiring only routine screening, and that the inventor was able to reproducibly obtain antibodies having the desired characteristics using the disclosed methods.[149] It also concluded that the experimentation a PHOSITA would have to undertake to make and use the claimed invention does not amount to undue experimentation, even if the amount of experimentation is considerable.[150] Accordingly, the court ruled that the claim at issue was enabled.[151]

This ruling is an example of a traditional analysis of a functionally claimed patent, which separately analyzes the teaching of the specification and undueness of experimentation to determine if the claims are enabled.[152] Functional claiming was an acceptable way of claiming antibodies when antibody biology and molecular biology were still in their infancy and identifying and describing the

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147 *Id.*

148 *Id.*

149 *Id.* at 740 (stating that,

> [t]his process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive.).

150 *Id.* at 740 (stating that a "considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed").

151 *Id.*

152 *Id.* at 735–36.

antigen required ingenuity of the inventor, which was more than what a PHOSITA could perform.[153] However, inherent in the functional claiming for antibodies is that such a claim will monopolize all future antibodies that may be raised against the described antigen.[154] As more and more techniques became available to describe the molecular structure of antibodies, courts started to recognize that functional claiming is not commensurate with the relevant disclosure.[155]

B. TRANSITION INTO ELEVATED STANDARD FOR DISCLOSURE REQUIREMENT

In the 1990s, with the advancement of techniques in high-throughput sequencing and structural analysis of proteins, defendants in biotechnology and chemistry cases started to use § 112(a) as a shield for infringement suits by using the overbreadth of functional claiming and early patenting as a defense.[156] This trend happened not only in the field of antibody biology but also in many areas that employ molecular biology techniques.[157]

One of the first cases that rejected the functional claiming appeared in the context of the written description requirement. In the case *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, the claimed invention was a method of detecting *N. Gonorrhoeae* using DNA probes.[158] The patent claimed a method by the ability (strength) of a DNA probe to hybridize to specific sequences, but not by the actual target sequence.[159] While recognizing that written description and enablement are separate requirements, the court in this case recognized that "biotechnology

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153 Lemley & Sherkow, *supra* note 90, at 998, 1014–15.

154 *Id.* at 1013.

155 *Id.* at 1020.

156 Karshtedt et al., *supra* note 133, at 22. Some of the cases that were found as not satisfying the disclosure requirement include the following: McRO, Inc. v. Bandai Namco Games Am., Inc., 959 F.3d 1091 (Fed. Cir. 2020); Wyeth & Cordis Corp. v. Abbott Lab'ys, 720 F.3d 1380 (Fed. Cir. 2013); *In re* Wright, 999 F.2d 1557 (Fed. Cir. 1993); Idenix Pharms. LLC v. Gilead Scis., Inc., No. 14-846-LPS, 2018 U.S. Dist. LEXIS 25663 (D. Del. Feb. 16, 2018); Morphosys AG v. Cambridge Antibody Tech., 193 F. Supp. 2d 125 (D.D.C. 2002); and Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999).

157 This trend is extensively discussed in renowned reviews, and readers are referred to these references; *see, e.g.*, Karshtedt et al., *supra* note 133, at 17–21; Lemley & Sherkow, *supra* note 90, at 1013–35.

158 Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 960 (Fed. Cir. 2002).

159 *Id.* at 961–62.

patents, in which a gene material has been defined only by a statement of function or result, . . . such a statement alone did not adequately describe the claimed invention."[160] However, in this decision, the court still recognized the antibody exception as set forth in the USPTO guidelines, stating:

> . . . the PTO would find compliance with § 112, P 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of "the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.[161]

Thus, in the early 2000s, while recognizing the accumulated knowledge of the antibody structure and antibody technology advances, the Federal Circuit continued to maintain the position that antibody patents should be treated differently from other patents directed to products or methods, carving out the so-called "antibody exception."[162] In other words, the court still upheld the functional claiming method as set forth in the USPTO guidelines.

C. RESTRICTION OF FUNCTIONAL CLAIMING IN ANTIBODY PATENTS

The cases *Amgen Inc. v. Sanofi*[163] and *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*[164] both put a clear end to the functional claiming of antibody patents. In *Amgen* and *Juno Therapeutics*, the Federal Circuit invalidated functional claiming of antibodies as not satisfying the enablement requirement and written description requirement, respectively.[165] As discussed below, the Supreme Court upheld the Federal Circuit's decision for *Amgen* in 2022[166] and denied *certiorari* for *Juno*

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160 *Id.* at 963–64.

161 *Id.* at 964.

162 *Id.*

163 Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1088 (Fed. Cir. 2021), *cert. granted in part sub nom.* Amgen Inc. v. Sanofi, 143 S. Ct. 399, (2022).

164 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1341 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022) *and reh'g denied*, 143 S. Ct. 631 (2023).

165 *Amgen*, 987 F.3d at 1088; *Juno Therapeutics*, 10 F.4th at 1342.

166 Amgen Inc. v. Sanofi, 598 U.S. 594, 616 (2023).

Therapeutics in 2021.[167] Thus, the Federal Circuit's decisions for both enablement and written description requirements in those cases remain valid today.

1. Amgen v. Sanofi at the Federal Circuit

In *Amgen*, the two patents at issue claimed monoclonal antibodies against PCSK9, which block PCSK9 from binding to LDL receptors, and made a blockbuster drug to treat hypercholesterolemia, REPATHA® (evolocumab).[168] Both patents described an isolated monoclonal antibody and claimed the antibody by describing the epitope (target) it binds to.[169] In 2014, Amgen asserted its patents against Sanofi's PRALUENT® (alirocumab).[170] In the trial court, the jury found that the patents were valid and issued a permanent injunction against the marketing of PRALUENT®.[171] Sanofi stipulated as to infringement but challenged the patent's validity on the grounds of written description, enablement, and obviousness.[172] The Federal Circuit agreed with the District Court's analysis of written description and found that the disclosure of the patents satisfied written description—however, the court disagreed with the lower court in terms of the enablement analysis.[173] In its opinion, we can see an important shift in the standards of both written description and enablement.

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167 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 143 S. Ct. 631, 631 (2023).

168 *Amgen*, 987 F.3d at 1083.

169 U.S. Patent No. 8,829,165 (filed Apr. 10, 2013), U.S. Patent No. 8,859,741 (filed Apr. 24, 2014).

170 Mark Cohen, *Amgen and Sanofi: What Does It Take to Patent an Antibody?*, LAW. MONTHLY (Oct. 1, 2019), https://www.lawyer-monthly.com/2019/10/amgen-and-sanofi-what-does-it-take-to-patent-an-antibody/ [https://perma.cc/DEP2-YBJZ].

171 *Id.*

172 Amgen Inc. v. Sanofi, 872 F.3d 1367, 1372 (Fed. Cir. 2017).

173 *Id.* at 1381–82.

a. The change in the written description standard.

For the written description requirement, the Federal Circuit first confirmed its dicta in *Enzo Biochem* that, "functional characteristics when coupled with a known or disclosed correlation between function and structure may satisfy the written description requirement,"[174] and further stated that:

> the PTO would find compliance with 112, [¶] 1, for a claim to an isolated antibody capable of binding to antigen X, notwithstanding the functional definition of the antibody, in light of the well-defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.[175]

However, recognizing the advancement of antibody technology, the court raised the bar for the written description requirement. The court expressly stated that the "newly characterized antigen" test,[176] which was the touchstone for functional claiming of antibody patents, should no longer be used in determining whether there is adequate written description under 35 U.S.C. § 112(a) for a claim drawn to an antibody.[177]

Although in this particular case the Federal Circuit decided that the Amgen patents satisfied the written description requirement, the court made a clear switch from allowing to not allowing claims of a genus of antibodies that are described by function alone with respect to written description.[178] Soon after this decision, the USPTO issued a memorandum echoing *Amgen*, which announced that "adequate written description of a newly characterized antigen alone should not be considered adequate written description of a claimed antibody to that

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174 *Id.* at 1376 (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 960 (Fed. Cir. 2002)).

175 *Id.*

176 *See* Lemley & Sherkow, *supra* note 90, at 1034–35 (quoting Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341, 1352 (Fed. Cir. 2011)) (under the newly characterized antigen test, the written description for an antibody claim could be satisfied by the disclosure of a newly characterized antigen by its structure, formula, chemical name, or physical properties if the creation of the claimed antibody is routine).

177 *See* Cohen, *supra* note 170.

178 *Amgen*, 872 F.3d at 1381–82.

newly characterized antigen, even when preparation of such an antibody is routine and conventional," and started applying the heightened written description requirement in patent examination.[179] The effect of this switch was dramatic: allowance of antigen (epitope)-based patents dramatically decreased, and applicants were thrown into a dilemma of how much disclosure was needed to satisfy the new written description standard.[180]

b. Attempts to raise the bar for the enablement requirement.

With respect to the enablement standard, the jury sided with Amgen in both the initial and the new trial on remand, deeming the claims enabled.[181] However, the new verdict was overturned by the district court on a judgment as a matter of law,[182] and the Federal Circuit sided with the district court's analysis of the *Wands* factors, concluding that the experimentation was undue and the claims at issue were not enabled.[183] Importantly, the Federal Circuit adopted the

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179 Memorandum from Robert W. Bahr, Deputy Commissioner for Patent Examination Policy, to Patent Examining Corps on Clarification of Written Description Guidance for Claims Drawn to Antibodies and Status of 2008 Training Materials (February 22, 2018).

180 *See* Daisuke Tokushige, *Case Study: Recently Granted Epitope-Based Antibody Patents in the United States, Europe and Japan*, IPWATCHDOG (June 13, 2020, 12:15 PM), https://ipwatchdog.com/2020/06/13/case-study-recently-granted-epitope-based-antibody-patents-united-states-europe-japan/id=122432/ [https://perma.cc/XTW4-XV64].

181 Amgen Inc. v. Sanofi, 227 F. Supp. 3d 333, 337 (D. Del. 2017).

182 Amgen Inc. v. Sanofi, No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *51 (D. Del. Aug. 28, 2019).

183 This decision at issue was on the appeal after remand. *See id.* at *36. See, for procedural posture, *id.* at *2. The first suit tried issues of validity to the jury in March 2016. During the trial the Court granted JMOL of non-obviousness and no willful infringement. The Jury determined that the patents were valid. On appeal, the Federal Circuit affirmed the grant of Plaintiffs' JMOL of non-obviousness and the denial of Defendants' JMOL of no written description and enablement but reversed for errors made in evidentiary rulings and jury instructions and remanded the case for a new trial on written description and enablement. On remand, the jury found claim 7 of the '741 patent and claims 19 and 29 of the '165 patent valid, but invalidated claims 7 and 15 of the '165 patent for lack of written description. On appeal from this decision, Sanofi sought to overturn the jury verdict or get a new trial. While relying on the underlying factual determination of the jury, the

"heightened" enablement standard used by the district court, that the disclosure must be such that a PHOSITA can *practice the claims' full scope* without undue experimentation.[184] Under this heightened "practicing the full scope" standard, the Federal Circuit applied the *Wands* factors and concluded that the only ways for a person of ordinary skill to discover undisclosed claimed embodiments would be through either "trial and error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties," or else "by discovering the antibodies de novo" according to a randomization-and-screening "roadmap."[185] The Federal Circuit ruled that the district court's application of the *Wands* factors was consistent with the *Wands'* decision because "the scope of the claims encompasses millions of candidates claimed with respect to multiple specific functions, and that it would be necessary to first generate and then screen each candidate antibody to determine whether it meets the [] claim limitations."[186]

By requiring a patent specification to be such that a PHOSITA can practice the full scope of the claimed invention without undue experimentation, the *Amgen* court made it extremely hard to functionally claim biologics and hugely impacted pioneer companies that spend billions of dollars in research and discovery and the development of new drug targets.[187] Patent scholar Dimitry Karshtedt

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Delaware District Court considered the legal determination of the *Wands* factors *de novo* and concluded that the claims at issue are not enabled. *See generally, id.*

184 *See Amgen*, 987 F.3d at 1085, 1087. One of Amgen's contentions was that the *Wands* factors were not properly analyzed because no undue experimentation is required to obtain antibodies fully within the scope of the claims. *See id.* at 1086.

185 *Id.*

> (We do not hold that the effort required to exhaust a genus is dispositive. It is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance. The functional limitations here are broad, the disclosed examples and guidance are narrow, and no reasonable jury could conclude under these facts that anything but 'substantial time and effort' would be required to reach the full scope of claimed embodiments.).

186 *Id.* at 1088.

187 John H. Heithaus & Gerald M. Murphy, *Antibody Patents: Danger Ahead for Biologics*, LIFE SCIS. INTELL. PROP. REV. (May 20, 2019),

characterized that the fundamental and problematic shift in the Federal Circuit's § 112 case law was that the court changed the focus of the inquiry from "what information would be required to permit a PHOSITA to make and use species in the invention" to "what information is required to teach the PHOSITA which species in the genus work and which ones don't."[188] In other words, Karshtedt argued that the court was now requiring an inventor to explain to a PHOSITA what subset of the genus claims will work and what subset will not.[189] In Karshtedt's words, the court is therefore requiring an inventor to know the precise boundaries of the genus.[190] Amgen asserted that this decision was a clear attempt to depart from the traditional standard of enablement, which recognized that a PHOSITA may engage in some experimentation after learning how to make and use the claimed invention.[191]

c. Issues brought in front of the Supreme Court.

Amgen submitted a petition for a writ of certiorari in November 2021 and despite the recommendation against writ by the Solicitor General, the Supreme Court granted certiorari in November 2022 on the enablement issues.[192]

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https://www.lifesciencesipreview.com/contributed-article/antibody-patents-danger-ahead-for-biologics [https://perma.cc/L8R6-W733].

188 Karshtedt et al., *supra* note 133, at 56.

189 *Id.* at 57.

190 *Id.*

191 *See supra* Section III.1.; *see* Petition for Writ of Certiorari at 25–26, Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021) (No. 21-757), 2021 WL 5506421 at *11–12.

192 Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021), *cert. granted in part sub nom.* Amgen Inc. v. Sanofi, 143 S. Ct. 399, 399 (2022).

> The Supreme Court granted certiorari on question 2:
>
> Whether enablement is governed by the statutory requirement that the specification teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "*to reach the full scope* of claimed embodiments" without undue experimentation—*i.e.*, to cumulatively identify and make all or nearly all embodiments of the invention without substantial "'time and effort,'" Pet. App. 14a (emphasis added).

Subsequently, more than thirty amicus briefs were offered, showing a high interest of the patent community in the issue.[193] Before the court, Amgen argued that the shift of the enablement standard at issue posed problems both at the doctrinal level and the practical level.[194] As a doctrinal matter, requiring an inventor to disclose "which subset of the genus claims will work and what subset will not" brings in the consideration of "possession" or "subjective appreciation" of the invention into the determination of whether the enablement requirement is satisfied.[195] This argument resonates with the view of patent scholar Mark Lemley, that such inquiries were traditionally reserved for the written description inquiry, and that bringing such a standard into the enablement analysis is against the well-established case law that written description and enablement are distinct inquiries.[196] In addition, it is against the well-established case law that the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled.[197] Amgen further argued that the court's reasoning departed from the concept of "undue experimentation" that was established in *In re Wands* and subsequent cases, which recognized that a patent disclosure does not need to describe everything about the invention but can rely on a skilled artisan to conduct some optimizations or experimentations to make and use the invention.[198]

Petition for Writ of Certiorari at (i), 34, Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021) (No. 21-757), 2021 WL 5506421 at *i, *34.

193 *See* Linehan, *supra* note 5; *Divided Opinion:* Amgen v Sanofi*: Narrowing the Scope of Protection for Antibody Inventions?* PHARMATIMES MAG. (Apr. 13, 2021) http://magazine.pharmatimes.com/#/reader/38398/111789 [https://perma.cc/M44V-X36X].

194 Petition for Writ of Certiorari at 21, Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021) (No. 21-757), 2021 WL 5506421, at *19–21 (arguing that Federal Circuit departed from this Court's precedents and historical practice).

195 MOY, *supra* note 14, § 7.34.

196 Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010); *see also* Lemley & Sherkow, *supra* note 90, at 1020 (noting "after a long history of carefully trying to separate the two doctrines, the Federal Circuit's antibody jurisprudence has started to conflate enablement with written description").

197 Atlas Powder Co. v. E.I. du Pont De Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984) (noting that prophetic examples do not make the disclosure nonenabling).

198 *In re* Wands, 858 F.2d 731, 736–37 (Fed. Cir. 1988); Fields v. Conover, 443 F.2d 1386, 1390–91 (C.C.P.A. 1971).

Amgen also asserted that the Federal Circuit made such an extreme doctrinal shift without providing any clear justification.[199]

At a practical level, as discussed above, due to the unique biology of antibodies—that no two antibodies are exactly the same at a molecular level, even if they are made using exactly the same method—such a shift in the requirement for enablement would make the protection of the first invention in the field very difficult, giving leeway to unauthorized copiers to avoid infringement allegations.[200] Amgen argued that, if an inventor is given protection only for antibodies they have disclosed under the "full-scope disclosure requirement," it gives very limited protection to the research and effort that went into discovering the claimed antibody because an antibody that a copier makes using the exact same method is necessarily different at a molecular level.[201] Amgen also asserted, as such, a copier would be able to freely use the full extent of disclosed information without worrying about infringing the patent of the first inventor.[202] Amgen further argued that the full-scope disclosure requirement would force the inventor to obtain a patent on every individual variation of a genus, which is impossible as well as waste of research resources.[203]Additionally, such a requirement would result in the patent rights of inventors with groundbreaking innovations being denied, based on speculation about embodiments that might (or might not) exist in the patent's extreme "corners," or because the inventor has not undertaken the "obviously impossible" task of specifying every potential embodiment.[204] Many amici echoed this argument in saying that such a prospect would disincentivize innovative companies from patenting useful inventions, and would rather incentivize keeping them as trade secrets.[205]

On the other hand, Sanofi and its amici argued if the first inventor is allowed to claim any antibodies that bind to a defined target sequence by

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199 Petition for Writ of Certiorari at 25, Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080 (Fed. Cir. 2021) (No. 21-757), 2021 WL 5506421, at *25 (Amgen argued that the Federal Circuit's "Reach the Full Scope" Requirement Defies Text, Precedent, and Policy).

200 *See supra* Section IV.D.

201 *See supra* Section IV.B.

202 Petition for Writ of Certiorari, *Amgen*, *supra* note 199, at 30.

203 *Id.*

204 *Id.* at 31–32.

205 Brief for Ass'n of Univ. Tech. Managers, Inc. et al. as Amici Curiae Supporting Petitioners at 7–8, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2021 WL 6140119, at *12–13.

functional claiming, such a claim would encompass all antibodies against that antigen that would be generated in the future. Sanofi asserted that such a claim is overbroad, as it would monopolize the entire functional genus of antibodies against the specific target.[206] If such claims were allowed, argued Sanofi, there would be "a chilling impact on innovation" as other companies would have no incentive to develop new therapeutics targeting the claimed epitope.[207]

At the time, it was clear that if the Court sided with Amgen, the decision would unproportionally benefit the pioneer inventor, while if the Court sided with Sanofi, it would unproportionally benefit the followers at the expense of the benefit of the pioneer inventor. The divide between the amicus briefs appeared to reflect such positions to some extent. For example, the amicus brief by Mark A. Lemley and Intellectual Property Professors strongly supported the practice of genus claims and argued that the current heightened enablement standard frustrates patenting and innovation in the chemical and life sciences.[208] Large leading companies such as Glaxosmithkline, Bristol-Myers Squibb, and Merck Sharp & Dohme also sided with the petitioners, raising strong concerns in the effect of disincentivizing the discovery of breakthrough drugs if the full-scope disclosure requirement is enforced.[209] In contrast, small or startup companies such as ABL Bio, Kiniksa, OPKO Health, and SK bioscience generally sided with Sanofi, and argued that if broad genus protection is allowed, it would disincentivize companies and investors to undertake risky new ventures for bringing such products to the market and particularly impact startups and small companies operating solely on capital supplied by investors.[210] However, some established large companies such as Pfizer Inc. also argued that broad antibody claims would

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206 Brief for Respondents at 21, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2023 WL 1864368, at *21.

207 *Id.* at 46.

208 Brief for Intellectual Property Professors as Amici Curiae Supporting Petitioners, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2021 WL 6140127, at *12.

209 Brief for GlaxoSmithKline PLC as Amici Curiae Supporting Petitioners at 3, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2021 WL 6140123, at *3 (noting "that sea change threatens to devastate the incentives for companies like GSK to invest billions of dollars and hundreds of thousands of research hours in discovering breakthrough drugs"); Brief of Amici Curiae Biogen Inc., et. al. in Support of Rehearing En Banc, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 20-1074), 2021 WL 1737453, at *6.

210 Brief for Small and Medium Biotechnology Companies as Amici Curiae in Support of Respondents, 2023 WL 2026564 (U.S.) at 25–27.

stifle innovation and sided with the respondent.[211] Thus, the divide in the opinion was not a simple leader-follower difference. Notably, several amici submitted briefs in support of neither party, with some offering alternative solutions.[212] This underscores the huge impact of the decision on the industry, and the difficulty of establishing a clear-cut standard to fairly protect all inventors.

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211 Brief for Amicus Curiae Pfizer Inc. in Support of Appellees, 2020 WL 3100506 (Fed. Cir.) (Pfizer had discontinued efforts to commercialize bococizumab, an anti-PCSK9 antibody, in 2016); Brief of Amicus Curiae Eli Lilly and Company. Supporting Defendants-Appellees; 2020 WL 3100507 (Fed. Cir.).

212 Brief of Amicus Curiae New York Intellectual Property Law Association in Support of Neither Party at 16, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2023 WL 119966 (U.S.) at *16 (proposing to determine undue experimentation at the time of infringement suit, *see infra* Section VII.B.); Brief of Amici Curiae Regenxbio Inc., et. al. Supporting Neither Party at 23, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2022 WL 120177 at *23 (arguing that not only large companies but small inventors would also be burdened); Brief for High Tech Inventors Alliance and the Computer & Communications Industry Association as Amici Curiae Supporting Neither Party at 3, 40, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2022 WL 130781 at *3, 40 (arguing that section 112 should not be disturbed and arguing that the Court should expressly circumscribe its opinion to apply solely to the claims and peculiar procedural posture before the court because any broader ruling risks serious harm to innovation across a broad range of industries and a vast swath of the American Economy); Brief of the Intellectual Property Law Association of Chicago as Amicus Curiae Supporting No Party at 1, 31, Amgen Inc., v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2022 WL 119961 at *1, 31 (arguing that the Court should follow the statutory and time-honored standard of enablement that was used for about 232 years and vacate and remand the case with instruction to follow the correct standard because only some of the recent cases deviated from the long-used standard and the court should not follow such deviation); Brief of Amicus Curiae Intellectual Property Owners Association Supporting Neither Party at 11–13, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757), 2022 WL 18142294 at *11–13 (arguing that more fact-finding and adherence to the controlling statutory requirements is necessary because enablement analysis should be conducted from the perspective of a person skilled in the art and the patent challenger in federal district court litigation must prove invalidity by clear and convincing evidence, however this proper analysis was not carried out).

In the end, the Supreme Court unanimously affirmed the Federal Circuit decision, and it became a huge victory for Sanofi and startup companies.[213] First, the Court disagreed with Amgen's contention that its broad claims were enabled because scientists can make and use every undisclosed but functional antibody if they simply follow the company's "roadmap" and "conservative substitution."[214] The Court likened this case to the "Incandescent Lamp" case, where the Court held that the broad claim by Sawyer and Man for every fibrous and textile material to be used as a filament in an incandescent lamp was not enabled, and that the "Edison lamp," invented by Thomas A. Edison, which uses a particular part of the stem of a bamboo as a filament of a lamp, does not infringe the patent of Sawyer and Man.[215] The Court reasoned that the "roadmap" or "conservative substitution" amounts to little more than two research assignments, and similar to Edison, who had to engage in the most careful and painstaking experimentation to find the best material for a filament, an inventor presented with a "roadmap" and "conservative substitution" would have to engage in painstaking experimentation.[216]

In response to Amgen's second argument that the bar for enablement had been raised, the Court agreed with the general principle that the Patent Act provides a single, universal enablement standard for all inventions.[217] However, it disagreed that the bar for enablement has been raised.[218] The Court agreed that the Federal Circuit recognized that the more a party claims for itself, the more it must enable.[219] However, the Court did not address whether the district court and the Federal Circuit applied the *Wands* factors[220] properly to determine whether undue experimentation is required to make and use the invention.

Finally, in response to Amgen's third argument that ruling against it risked destroying the incentives that lead to breakthrough inventions, the Court merely asserted that the proper balance between incentivizing inventors and

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213 Amgen Inc. v. Sanofi, 598 U.S. 594, 614 (2023).

214 *Id.*

215 Consol. Elec. Light Co. v. McKeesport Light Co., 159 U.S. 465, 476 (1895).

216 *Amgen*, 598 U.S. at 614.

217 *Id.* at 615.

218 *Id.* at 615–16.

219 *Id.* at 616.

220 *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

ensuring the public receives the full benefit of their innovations is achieved by the enablement requirement that has been implemented since 1790.[221]

What was conspicuously absent in this decision? As noted above, there was no reference to the *Wands* factors[222] in the Court's opinion. The Court decided that Amgen could not claim the entire genus of antibodies, and that there was only one standard of enablement—"the more a party claims for itself the more it must enable."[223] However, the Court did not provide guidance as to how to determine whether the experimentation required of an ordinary skilled person to make and use the invention is undue, which is determined by applying the *Wands* factors, and is well-established case law for determining whether the claimed invention is enabled.[224] This issue will be revisited in the sections below, in connection with the discussion of case decided after *Amgen*.[225]

2. Juno Therapeutics v. Kite Pharma

Juno Therapeutics is another case that dealt with the disclosure requirements of biological materials, but with respect to the written description requirement.[226] The patent at issue in *Juno Therapeutics* claimed a nucleic acid polymer encoding a chimeric T cell receptor containing a single-chain variable fragment (scFv) that can be used for therapeutics.[227] A T cell receptor, in its variable domain, has modular structures similar to antibodies, and its diversity is generated by *V(D)J* recombination similar to that utilized in generating the diversity of antibodies.[228] As such, T cell receptor patents containing scFv have

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221 *Id.*

222 *Id.*

223 Amgen Inc. v. Sanofi, 598 U.S. 594, 616 (2023).

224 *Id.*

225 *See infra,* Part VI.

226 Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1330 (Fed. Cir. 2021), *cert. denied*, 143 S. Ct. 402 (2022) *and reh'g denied*, 143 S. Ct. 631 (2023); *see generally* Jonathan B. Fitzgerald, *Navigating Claim Scope for Functionally Claimed Biological Compounds After* Amgen v. Sanofi, OUTSOURCED PHARMA (Mar. 14, 2023), https://www.outsourcedpharma.com/doc/navigating-claim-scope-for-functionally-claimed-biological-compounds-after-amgen-v-sanofi-0001 [https://perma.cc/94EC-HGU4].

227 *Juno Therapeutics*, 10 F.4th at 1334.

228 *See supra* Section IV.B.

similar issues as antibody patents.[229] In *Juno Therapeutics*, the scFv was claimed according to its function of being capable of binding to its targets.[230] Juno Therapeutics's patent disclosed two working embodiments of scFvs, and the issue was what level of disclosure was required to satisfy the written description requirement.[231]

The Federal Circuit confirmed that a genus can be sufficiently disclosed by either (1) "a representative number of species falling within the scope of the genus," or (2) "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the member of the genus."[232] Recognizing that whether a patent specification satisfies the written description requirement is a fact-specific inquiry, the court stated that the two disclosed examples of scFvs in *Juno Therapeutics*, without a rationale as to why these two examples were not representative of the species, did not sufficiently describe the claimed invention.[233] The court also ruled that a knowledge of common structural features of scFvs was insufficient to show structural features that are common to the genus.[234] Thus, even though the *Juno Therapeutics* court indicated that two embodiments do not satisfy the written disclosure requirement, it fell short of providing clear guidance as to what amount or kind of disclosure is sufficient to satisfy the written description requirement for a functionally claimed genus of biological materials.[235] As the Supreme Court declined to review this case, the minimum requirement for written description remains vague at this point. Nevertheless, it is worth noting that the focus of *Juno Therapeutics* was about the disclosure of the claimed scFvs, not the target it binds to.[236] Thus, the Federal Circuit took a position that functionally claimed antibody-like molecules should

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229 E.g., that there are millions of scFv molecules in the genus, that no two scFv molecules are exactly the same unless they are cloned, that a screening step is necessary to make and use the invention, and a copier can follow a disclosure of a scFv patent and obtain a new scFv molecule that has the same functions but is molecularly different from the claimed scFv molecule. *See* Lemley & Sherkow, *supra* note 90, at 1002–03.

230 *Juno Therapeutics,* 10 F.4th at 1334.

231 *Id.* at 1336.

232 *Id.* at 1335 (*quoting Ariad*, 598 F.3d at 1350).

233 *Id.* at 1336.

234 *Id.* at 1338–39.

235 Fitzgerald, *supra* note 133.

236 *See generally Juno Therapeutics*, 10 F.4th at 1330.

be defined by the description of the molecules themselves, and not by the target they bind to.[237]

VI. COMPARATIVE STUDY OF *AMGEN V. SANOFI* & RELATED DECISIONS

Amgen's product Repatha® "is approved in more than 60 countries, including the U.S., Japan, Canada, and in all 28 countries that are members of the European Union."[238] The total sales of Repatha® in 2022 was almost 1.3 billion U.S. dollars, and it is estimated that over 1.5 million patients have been prescribed Repatha® since its launch.[239] By contrast, Sanofi's product Praluent® is approved in more than 60 countries worldwide, including the European Union, United States, Japan, Canada, Switzerland, Mexico and Brazil.[240] The net sales of Praluent® in 2022 was 376 million Euro (approximately 396 million USD).[241] The global market of this important cholesterol-lowering drug will necessarily be profoundly impacted by patent court decisions. In this Part, I compare how the disclosure requirements of antibody patents were dealt with in Europe (i.e.,

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237 *Id.* at 1335 (noting "a genus can be sufficiently disclosed by 'either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus'").

238 Amgen, *Amgen Receives NMPA Approval for Repatha® (evolocumab) In China to Reduce the Risk of Cardiovascular Events*, PR NEWSWIRE (Jan. 24, 2019, 4:00 PM), http://www.prnewswire.com/news-releases/amgen-receives-nmpa-approval-for-repatha-evolocumab-in-china-to-reduce-the-risk-of-cardiovascular-events-300783979.html [https://perma.cc/XW95-FN34] [hereinafter *Amgen Receives NMPA Approval*].

239 Press Release, Amgen, Amgen Reports Fourth Quarter and Full Year 2022 Financial Results (Jan. 31, 2023), https://www.amgen.com/newsroom/press-releases/2023/01/amgen-reports-fourth-quarter-and-full-year-2022-financial-results [https://perma.cc/FPF9-UVPF] [hereinafter Amgen Reports].

240 Press Release, Sanofi, European Patent Office Rules in Favor of Sanofi and Regeneron Concerning Praluent® (alirocumab) (Oct. 29, 2020), https://www.sanofi.com/assets/dotcom/pressreleases/2020/2020-10-29-13-50-00-2117063-en.pdf [https://perma.cc/EWC8-UVWS] [hereinafter European Patent Office Rules in Favor of Sanofi].

241 *2022 Form 20-F*, SANOFI, https://www.sanofi.com/assets/dotcom/content-app/publications/annual-report-on-form-20-f/2022-01-01-form-20-f-2022-en.pdf [https://perma.cc/UCB7-DC7P].

Germany and the United Kingdom) and in Japan, centering on the cases related to *Amgen.*

A. CENTRAL CLAIMING & PERIPHERAL CLAIMING METHODS

The differences in disclosure requirements in different jurisdictions have great relevance to the difference in the interpretation of patent claims. The United States and the U.K. are almost the only countries in the world which use the "peripheral claiming" method, while the rest of the world uses the method called "central claiming."[242] Peripheral claiming is a method of defining the inventor's contribution directly through the lingual meanings of the claim words themselves.[243] Claims are therefore understood by assigning meanings of the individual words of the claim and then assembling those meanings according to the accepted rules of grammar.[244] As the claim language can be interpreted to be broader than what is disclosed, this method gives ample notice to the public; however, it can lack or be low in the accuracy of the definition of the claimed subject matter.[245]

In central claiming, the assumption is that the legal meaning is the scope of the teaching in the specification.[246] Under central claiming, the patent claim identifies the part of the disclosure that sets out the subject invention, and distinguishes that part from the background or ancillary parts.[247] Thus, the identified part of the disclosure is used to determine the "scope that covers all the specific forms in which the inventive concept can be embodied, in particular the equivalents of the embodiments."[248] In terms of the degree of notice and definitional accuracy, central claiming can therefore provide a more accurate definition of the claimed invention—however, it provides poor notice to the public.[249] We can see from the examples of Germany and Japan, both central claiming jurisdictions, that their approaches were different from that of the United

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242 MOY, *supra* note 14, §§ 4.8, 4.9 n.2 (4th ed. 2023).

243 *Id.* § 4.8.

244 *Id.*

245 *Id.* § 4.9.

246 *Id.* § 4.8.

247 *Id.*

248 *Id.*

249 *Id.* § 4.9.

States courts towards addressing the issues of antibody patents and functional claiming.

B. EUROPE (GERMANY)

In Europe, Amgen launched the Repatha®/Praluent® battle in 2016, suing Sanofi for patent infringement in six countries, including Germany.[250] In Europe, to enforce their patent rights, a European patent holder must seek remedies in each country where they allege infringement.[251] In July 2019, the Regional Court of Düsseldorf ruled in favor of Amgen and issued an injunction against Sanofi and Regeneron.[252] However, this turned out to be a short victory for Amgen. Sanofi and Regeneron countered by filing a challenge of invalidity of Amgen's patent EP2215124 directly at the EPO.[253] Subsequent to the invalidation judgment, the Higher Regional Court of Düsseldorf dismissed Amgen's application at second instance, meaning that the first-instance judgment of 2019 is without objection.[254] As a result, Amgen lost the rights to injunctive relief, provision of information, accounting, recall, destruction, and damages that were granted in the first-instance for Sanofi's infringement of the German part of European Patent EP2215124, and Sanofi regained the right to distribute Praluent® in Germany.[255]

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250 *See generally* Mathieu Klos, *EPO Decision Clears Way for Sanofi Blockbuster Drug Praluent,* JUVE PAT. (Nov. 6, 2020), https://www.juve-patent.com/news-and-stories/cases/epo-decision-clears-way-for-sanofi-blockbuster-drug-praluent [https://perma.cc/T4LV-KJX7]; *see also* Sam Habein, *The United States Stands Alone: A Divergence in the Treatment of Genus Claims in Pharmaceutical Patents*, 22 UIC REV. INTELL. PROP. L. 97, 105 (2022).

251 Habein, *supra* note 250, at 105; *see also generally* EPO, *Patent Litigation in Europe: An Overview of National Law and Practice in the EPC Contracting States*, 3 (July 31, 2019), https://documents.epo.org/projects/babylon/eponot.nsf/0/05B84848CBCF7338C1257833003C2531/$FILE/patent_litigation_in_europe_2019_en.pdf [https://perma.cc/27JL-QEFK].

252 Klos, *supra* note 250. Regeneron and Sanofi developed Praluent® in collaboration. Regeneron is the U.S. distributor of Praluent® and Sanofi is the distributor outside the U.S. *Id.*

253 Habein, *supra* note 250, at 105 (noting "[T]he 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.").

254 Klos, *supra* note 250.

255 *Id.*

This decision in the Higher Regional Court's was preceded by the decision by the Technical Board of Appeal at the EPO. At the Technical Board of Appeal, the scope of Amgen's European patent EP2215124 was significantly limited after opposition and appeal proceedings.[256] In the EP2215124 patent, the claims that covered Sanofi's Praluent® were defined in functional terms but more narrowly than the U.S. claims: they required the claimed antibody compete for binding to PCSK9 with either evolocumab or another specific antibody; and have neutralizing activity, that is the ability to reduce the binding of PCSK9 to the LDL receptor.[257] These claims were found to meet the enablement requirement in the Technical Board of Appeal; however, their scope was substantially limited to cover only the active ingredient in Repatha®, namely evolocumab.[258] As a result, the claims were subsequently invalidated by the Board of Appeal for lack of inventive step.[259] As the patent no longer had the claims that would be the basis of the Düsseldorf infringement action, the judgment for Amgen was reversed.[260]

It is noteworthy that the EPO never ruled whether a functionally worded claim lacked enablement. However, the fact that the claims were not invalidated for lack of enablement by the EPO does not necessarily mean that it would have been found to be enabled by a national court in a European jurisdiction.[261] This development including the narrow construction of the claims appears to reflect the central claiming method adopted in Europe, in which the patent claim is used as a pointer to identify the part of the disclosure that sets out the subject invention, and the equivalence of the invention is measured from there.[262] It is yet to be seen

256 Linehan, *supra* note 5.

257 *Id.*

258 Habein, *supra* note 250, at 105–06.

259 *Id.*

260 Klos, *supra* note 250.

261 Habein, *supra* note 250, at 106.

262 MOY, *supra* note 14, § 4.8

how European courts will decide how far the ring of equivalents would extend in case of functionally defined antibody claims for the purposes of enablement.

C. JAPAN

Japan is another centrally claiming country—however, its Repatha®/Praluent® litigation developed differently from those in the United States and Europe. Claim 1 of Amgen's Japanese patent 5,705,288 was directed to a neutralizing antibody binding to PCSK9 and LDLR proteins and recited that it is a monoclonal antibody that can compete with the 21B12 antibody (a reference antibody) with respect to the binding to PCSK9.[263] As such, the claim was functionally claimed by its activity, namely its blocking activity and competition activity.[264] In 2017, Sanofi sued Amgen in the District Court of Tokyo as the patent lacking inventive step, support, and enablement.[265] The court found for Amgen, and Sanofi appealed.[266] In April 2020, the Intellectual Property (IP) High Court also ruled for Amgen, finding that "[t]he enablement requirement was met because the

> (under central claiming the patent claim identities the part of the technical disclosure that sets out the subject invention, and thereby distinguishes that part from the parts of the disclosure that provide information that is background or otherwise ancillary. Once this is done, central interpretation examines this identified part of the disclosure and uses it to determine the underlying inventive concept that the disclosure has contributed to the art. It then assigns the patent right a technological scope that covers all the specific forms in which the inventive concept can be embodied, in particular those equivalent to the embodiments disclosed.).

263 Japanese Patent No. 5,705,288.

264 *Id.*

265 Tōkyō Chihō Saibansho (東京地方裁判所) [Tokyo Dist. Ct.] January 17, 2019, Hei 29 (waワ) no. 16468, 7 (Japan), https://www.courts.go.jp/app/hanrei_jp/detail7?id=88330 [https://perma.cc/E62S-MW8C].

266 Chiteki Zaisan Kōtō Saibansho (知的財産高等裁判所) [Intellectual Prop. High Ct.] Dec. 27, 2017, Hei 29 (gyō ke) no. 10225, 83 (Japan), https://www.ip.courts.go.jp/app/hanrei_jp/detail?id=5080 [https://perma.cc/H864-6M9Z]; Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Oct. 30, 2019, Hei 31 (gyō ne) no. 10014, (Japan), https://www.ip.courts.go.jp/app/hanrei_jp/detail?id=5258 [https://perma.cc/E5TN-22ZQ].

specification taught how to obtain an antibody with the required functions, and it was not necessary for the specification to disclose how every suitable antibody may be obtained."[267] Sanofi appealed, but the Supreme Court of Japan denied Sanofi's petition for final appeal, finalizing the decision of the IP High Court.[268] This decision resulted in Sanofi ceasing manufacturing, distributing, importing, or offering to distribute Praluent® in the Japanese market.[269] Notably, here, the Japanese IP High Court used the standard similar to the traditional U.S. enablement standard (teaching plus undue experimentation analysis) and ruled that the functionally defined antibody claims were enabled.[270]

However, this case took a dramatic turn in 2023, when Sanofi's collaborator Regeneron sued Amgen to invalidate the 5,705,288 patent for not satisfying the requirements for (1) support, (2) enablement, (3) inventive step, (4) clarity, and (5) subject matter eligibility.[271] The IP high court took up the two related cases and agreed with Regeneron that the patent did not satisfy the support requirement.[272] In this case, the court looked into the mechanisms for an antibody

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267 Linehan, *supra* note 5.

268 *See* Chiteki Zaisan Kōtō Saibansho, [Intellectual Prop. High Ct.], no. 10225, at 83; Chiteki Zaisan Kōtō Saibansho, [Intellectual Prop. High Ct], no. 10014, at 54–55.

269 *See* Fubuki, Sanofi ga Praulent® no hanbaiteishi Happyou, Amgen tono tokkyoshingaisoshō de saikousaijyoukoku kikyakukettei uke (サノフィがプラルエント®の販売停止発表　アムジェンとの特許侵害訴訟で最高裁上告棄却決定受け) [Sanofi Announces Discontinuation of Praulent® Sales in Response to Dismissal of Final Appeal] (May 8, 2020), https://www.tokkyoteki.com/2020/05/sanofi-alirocumab.html [https://perma.cc/H7FU-53T7]; Amgen Perspectives, PCSK9 Tokkyo shingai soshō no saikousai ketteinitsuite (PCSK9特許侵害訴訟の最高裁決定について) [Comments with Respect to the Supreme Court Decision Regarding PCSK9 Infringement Suit] (May 8, 2020), https://www.amgen.co.jp/media/Amgen-Perspectives/20200508 [https://perma.cc/YS59-VAKR].

270 *See* Chiteki Zaisan Kōtō Saibansho, [Intellectual Prop. High Ct.], no. 10225, at 19; Chiteki Zaisan Kōtō Saibansho, [Intellectual Prop. High Ct], no. 10014, at 4.

271 *See* Invalidation case No. 2020-800011 (無効2020-800011号事件), Request date: February 12, 2020; Invalidation case No. 2020-800012 (無効2020-800012号事件), Request date: February 12, 2020.

272 *See* Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Jan. 26, 2023, Rei 3 (gyō ke) no. 10093, 4 (Japan), https://www.ip.courts.go.jp/app/hanrei_jp/detail?id=5909

blocking molecular interactions and considered whether the specification supports all forms of the blocking activity and competing activity as recited in claim 1.[273] The court defined the technical significance of the invention to be that if an antibody competes with the reference antibody 21B12, the antibody functions as a neutralizing antibody for the interaction of PCSK9 and LDLR proteins by a mechanism similar to that of the 21B12 antibody.[274] However, the court found that the specification does not provide evidence that if an antibody competes with the reference antibody 21B12, such an antibody always neutralizes the binding of PCSK9 and LDLR protein in a similar way that antibody 21B12 does.[275] Specifically, the court pointed out the possibility that there are antibodies that compete with the 21B12 antibody by steric hindrance but not by binding to the interaction surface of PCSK9 and LDLR proteins, and ruled that such antibodies are not supported by the specification.[276]

It is notable that this decision placed emphasis on the disclosure and support it provided, which reflects the interpretation of the claims by the central claiming method. Further, it should be noted that this ruling was based on the support requirement, and the 2020 ruling that the enablement requirement is satisfied for this patent is still undisturbed.[277] The court also specifically recognized the different rulings in the European and U.S. courts with respect to enablement.[278] However, it confirmed that the decision of other jurisdictions would not immediately affect the outcome of the case.[279]

[https://perma.cc/6S8G-DJ65]; Chiteki Zaisan Kōtō Saibansho [Intellectual Prop. High Ct.] Jan 26, 2023, Rei 3 (gyō ke) no. 10094, 4 (Japan) https://www.ip.courts.go.jp/app/hanrei_jp/detail?id=5911 [https://perma.cc/4PVV-MYQN]. As these two cases are similar, the difference being using different monoclonal antibodies, case 10093 will be discussed here.

273 Rei 3 (gyō ke) no. 10093, *supra* note 272, at 14–19. The court first ruled that even if Sanofi and Regeneron are co-developers of Praluent®, they are different entities, and the claim exclusion does not apply. *Id.*

274 *See id.* at 52.

275 *See id.* at 55.

276 *See id.*

277 *Id.* at 79.

278 *See id.* at 79–80.

279 *See id.*

D. *REGENERON V. KYMAB* IN THE UNITED KINGDOM

The Supreme Court of the United Kingdom considered a question on the requirement of sufficiency of disclosure in the case *Regeneron v. Kymab*.[280] In this case, the central issue is very similar to that of *Amgen v. Sanofi*.[281] The claimed invention in *Regeneron* was a transgenic mouse that produces hybrid antibody molecules that have human antigen binding domain (variable regions) and mouse constant regions.[282] This mouse containing a so-called "Reverse Chimeric Locus" was groundbreaking because the mouse did not suffer immunological sickness due to the presence of human immunoglobulin molecules in the body, and the B cells in the mouse proliferated and produced "matured" immunoglobulins that have gone through a normal "affinity maturation" process.[283] Regeneron's patent, however, had a similar disclosure issue to *Amgen*: the patent described the method of making such mice with a Reverse Chimeric Locus, describing the mouse by what it does (the nature of the mouse) and disclosed only a limited number of examples—however, the number of actual possible antibodies was enormous due to the *V(D)J* recombination.[284] Setting out eight principles of insufficiency,[285] the

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[280] *See* Regeneron Pharms. Inc. v. Kymab Ltd. [2020] UKSC 27 (appeal taken from Eng.); *see generally* Ben Millson & Dr. Robert Burrows, *Regeneron v Kymab: UK Supreme Court finds Regeneron's Transgenic Mouse Patents Insufficient*, BRISTOWS LLP (Apr. 2021), www.bristows.com/app/uploads/2021/04/Regeneron-v-Kymab-AIPPI-Japan-Journal-23-April-2021.pdf [https://perma.cc/SL9B-QQRK].

[281] *See Amgen*, 872 F.3d at 1372.

[282] *See Regeneron*, [2020] UKSC 27 at 5, para. 13.

[283] *Id.* at 4–5, paras. 9–12.

[284] *See supra* Section IV.B.

[285] *See Regeneron*, [2020] UKSC 27 at 23–24, para. 56. This principle will likely guide future determination of sufficiency requirement:

> i) The requirement of sufficiency imposed by article 83 of the EPC exists to ensure that the extent of the monopoly conferred by the patent corresponds with the extent of the contribution which it makes to the art.
>
> ii) In the case of a product claim, the contribution to the art is the ability of the skilled person to make the product itself, rather than (if different) the invention.

iii) Patentees are free to choose how widely to frame the range of products for which they claim protection. But they need to ensure that they make no broader claim than is enabled by their disclosure.

iv) The disclosure required of the patentee is such as will, coupled with the common general knowledge existing as at the priority date, be sufficient to enable the skilled person to make substantially all the types or embodiments of products within the scope of the claim. That is what, in the context of a product claim, enablement means.

v) A claim which seeks to protect products which cannot be made by the skilled person using the disclosure in the patent will, subject to de minimis or wholly irrelevant exceptions, be bound to exceed the contribution to the art made by the patent, measured as it must be at the priority date.

vi) This does not mean that the patentee has to demonstrate in the disclosure that every embodiment within the scope of the claim has been tried, tested and proved to have been enabled to be made. Patentees may rely, if they can, upon a principle of general application if it would appear reasonably likely to enable the whole range of products within the scope of the claim to be made. But they take the risk, if challenged, that the supposed general principle will be proved at trial not in fact to enable a significant, relevant, part of the claimed range to be made, as at the priority date.

vii) Nor will a claim which in substance passes the sufficiency test be defeated by dividing the product claim into a range denominated by some wholly irrelevant factor, such as the length of a mouse's tail. The requirement to show enablement across the whole scope of the claim applies only across a relevant range. Put broadly, the range will be relevant if it is denominated by reference to a variable which significantly affects the value or utility of the product in achieving the purpose for which it is to be made.

British Supreme Court held by a 4:1 majority that because the claims of the Regeneron Patents were not enabled across their entire range, they did not satisfy the disclosure requirement.[286] Thus, the U.K., a peripheral claiming jurisdiction, took a position similar to the Federal Circuit in *Amgen*, that an enabling specification must be such that a PHOSITA can practice the entire scope of the claimed invention without undue experimentation (the "practicing the full scope standard"[287]).

VII. AVENUES FOR SOLUTION – HOW DO WE PROMOTE INNOVATION & SUPPORT THE PHARMACEUTICAL INDUSTRIES?

As is discussed in the preceding Sections, courts in the U.S, Germany, Japan, and the U.K. have all decided the issues of functional claiming of antibodies very differently. Each jurisdiction has recognized that the natural diversity of antibodies can cause enablement, written description, or support issues—however, they all took different approaches. How does the *Amgen* decision in the United States fit into this spectrum? Is there any possibility that a unified disclosure standard could be developed across the world?[288] What is the prospect for functionally claiming antibodies given the current *Amgen* and *Juno Therapeutics* decisions? This Part discusses the aftermath of *Amgen* and the case *Baxalta Inc. v.*

> viii) Enablement across the scope of a product claim is not established merely by showing that all products within the relevant range will, if and when they can be made, deliver the same general benefit intended to be generated by the invention, regardless how valuable and ground-breaking that invention may prove to be.

See id.

286 *See id.* at 60.

287 *See supra* Section IV.D.

288 Efforts were made in WIPO from late 1980s to 2006 to draft a Substantive Patent Law Treaty (SPLT). Article 10 of SCP/9/2 published by the Standing Committee on the Law of Patents, ninth session, in 2003 contained a provision on enablement disclosure, and Rule 10 of SCP/10/5 published in 2004 contained a provision on sufficiency, which recited factors similar to the *Wands* factors to determine undue experimentation. However, SPLT negotiations were put on hold in 2006 due to difficulties in terms of reaching agreement and SPLT never came into effect. *See Draft Substantive Patent Law Treaty*, WIPO, https://www.wipo.int/patent-law/en/draft_splt.htm [https://perma.cc/3XYU-RWGV].

Genentech, Inc.,[289] which is the first antibody case decided on enablement after *Amgen*, and how antibody patents might be dealt with in the future.

A. THE AFTERMATH OF *AMGEN V. SANOFI*

The Supreme Court's decision in *Amgen* limits the rights of a pioneer inventor of an antibody targeting a specific antigen, and encourages followers to develop similar antibodies.[290] It effectively limits patent protection of a pioneer developer to those antibodies that the developer characterized and disclosed, and prevents the first inventor from monopolizing the field.[291] Additionally, it encourages competitors to innovate over the first inventor's patents.[292] The Supreme Court's decision appears to be sensible in terms of promoting innovation and is consistent with the fundamental principle of the patent system that an inventor gets protection for what they have disclosed. As Justice Gorsuch delved in detail in the opinion, it also appears to be in line with the long-established case law since *O'Reilly v. Morse* that an inventor cannot monopolize the entire class of things that are defined by their function.[293]

However, the fact that the protection for pioneer inventors has been significantly reduced should not be disregarded. Pioneer companies may consider giving up protection of their invention by patents and resort to trade secrets instead, which would work against the pro-patent policy and economy.[294] Foreign innovators may hesitate to enter the U.S. market when the protection available is minimal. In addition, it has been pointed out that United States will be prevented from arguing that some countries failed to satisfy their TRIPS obligations for denying protection to pharmaceutical patents if the United States itself fails to

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289 *See* Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023).

290 *See supra*, Section V.C.1.c.

291 *See id.*

292 *See id.*

293 *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).

294 *See* U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"). In addition, trade secret protection would not be a very effective way to protect intellectual property rights of antibodies, as a PHOSITA would be able to repeat generally routine experimentation and obtain their own antibodies.

protect its own pharmaceutical patents.[295] On the other hand, this decision, requiring "full scope" enablement appears to be generally in line with the decisions in Germany, Japan, and the U.K. in a broad sense. Although the approaches and reasonings are different, the rulings in these jurisdictions all tended to limit the broad functional claiming of antibody patents by looking at the factual details of the inventions.[296] In terms of achieving unified patent effects across jurisdictions, the Court's ruling in favor of Sanofi was probably more in line with the decisions in other jurisdictions than if they had ruled in favor of Amgen.[297]

What was absent in this Supreme Court's decision? As discussed in the preceding Sections, conspicuously absent was whether the factual determination and analysis by the district court and the Federal Circuit of enablement using the *Wands* factors were proper.[298] The Court's opinion did not even reference the eight *Wands* factors, and did not provide guidance as to how to determine whether a PHOSITA is necessitated to engage in undue experimentation.[299] The opinion

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295 *See* Habein, *supra* note 250, at 108–09 (discussing jurisdictions that do not follow TRIPS Agreement on minimum protection requirements by easily issuing compulsory licenses, taking India as an example).

296 *See supra* Part VI.

297 *See* Habein, *supra* note 250; Chiteki Zaisan Kōtō Saibansho (知的財産高等裁判所）[Intellectual Prop. High Ct.] Dec. 27, 2017, Hei 29 (gyō ke) no. 10225, 79 (Japan), https://www.ip.courts.go.jp/app/hanrei_jp/detail?id=5080 [https://perma.cc/H864-6M9Z]; Regeneron Pharms. Inc. v. Kymab Ltd. [2020] UKSC 27 (appeal taken from Eng.); *see generally* Ben Millson & Dr. Robert Burrows, *Regeneron v Kymab: UK Supreme Court finds Regeneron's Transgenic Mouse Patents Insufficient*, BRISTOWS LLP (Apr. 2021), www.bristows.com/app/uploads/2021/04/Regeneron-v-Kymab-AIPPI-Japan-Journal-23-April-2021.pdf [https://perma.cc/SL9B-QQRK]. Note that this is regarding the effects of narrowing the scope of antibody protection; Japanese Intellectual Prop. High Ct. still allows functional claiming of antibodies; *see supra* Section III.B.

298 *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); see *supra* note 27 for the eight *Wands* factors.

299 Professor Dennis Crouch points out that the jury in *Amgen* considered the *Wands* factors and found that claims are enabled, but this pro-patentee verdict was overturned by the district court on JMOL and was subsequently affirmed by both the Federal Circuit and the Supreme Court. Professor Crouch notes "the Supreme Court seems to reassess the Wands factors de novo without acknowledging the jury's verdict," which marks a significant oversight by the court. *See* Dennis Crouch, *The Silent Echo: Supreme Court's*

categorically ruled that giving a "roadmap" or "conservative substitution" was like two research assignments, because a person of ordinary skill would be forced to engage in "painstaking experimentation" to see what works.[300] Citing the Brief for Intellectual Property Law Professors and Scholars as Amici Curiae, the Court likened antibody screening to a combination lock with 100 tumblers, each of which can be set to 20 different positions.[301] It argued that it is like when an inventor instructs others "to randomly try a large set of combinations and then record the successful ones."[302] The Court continued, "[s]ure enough, that kind of "roadmap" would produce functional combinations. But it would not enable others to make and use functional combinations; it would instead leave them to "random trial-and-error discovery."[303]

However, the amount of experimentation necessary discussed by the Court is only one of the eight *Wands* factors.[304] The Court also failed to address whether ingenuity of the PHOSITA is required to make and use the invention. The analogy to a combination lock by the Court categorically determined that a combination lock would require undue amount of trial-and-error to find a key,[305] which is not necessarily true. For example, if a lock has only a handful of combinations, trying all possible combinations is not undue. Also, finding a combination of a lock may not be undue to a skilled person: the readers are referred to the famous episode of Richard Feynman habitually breaking codes of combination locks that secured national secrets.[306] In sum, the *Amgen* opinion did

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Non-Engagement with the Federal Circuit in Amgen v. Sanofi, PATENTLY-O (May 26, 2023), https://patentlyo.com/patent/2023/05/supreme-engagement-federal.html [https://perma.cc/EC2T-X79F].

300 Amgen Inc. v. Sanofi, 598 U.S. 594, 1245, 1254 (2023) (internal citations omitted).

301 *See id.* at 1257.

302 *Id.*

303 *Id.*

304 *See In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988); *see also supra* note 27.

305 *See Amgen*, 598 U.S. at 614–15 ("Imagine a combination lock with 100 tumblers, each of which can be set to 20 different positions.").

306 Reference to a famous episode of a Nobel Prize winner Physicist Richard Feynman who cracked codes of safety cabinets containing all the secrets to the atomic bomb to amuse himself out of boredom at the Los Alamos National Laboratory during World War II. Feynman later disclosed how he cracked combination codes by his logic. This episode poses a good example that even superficially unsurmountable task such as cracking a combination

not provide guidance to the factual analysis of the *Wands* factors, which requires considering not only the quantity of experimentation necessary, but also the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.[307]

Related to this omission of a *Wands* analysis is the lack of appreciation of the unique problems of antibody patents.[308] The "roadmap" and "conservative substitution" argument presented by Amgen relates to the fact that a PHOSITA can always obtain a novel (molecularly distinct) antibody that recognizes an antigen of interest by repeating the same procedure as disclosed in a patent specification, using a routine technique—in other words, that an intellectual input or ingenuity that amounts to invention may not be needed to obtain a non-infringing antibody.[309] However, this aspect was not emphasized in the oral argument or in Amgen's brief enough to invoke the *Wands* analysis. In the opinion, the Court referenced several historical enablement cases, such as *Holland Furniture Co. v. Perkins Glue Co.* and *The Incandescent Lamp Patent* and *O'Reilly v. Morse*, and compared *Amgen* with those cases.[310] However, there is a critical difference in the intellectual input required to obtain a non-infringing product between the cited precedents and *Amgen*.

For example, the Court discussed "The Incandescent Lamp" at length and argued that while Sawyer and Man disclosed an "electric lamp" with an "incandescing conductor" made of "carbonized fibrous or textile material," Thomas Edison discovered only through "painstaking experimentation"' that

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code cannot be categorically classified as requiring undue trial-and-error. *See* Mike Springer, *Learn How Richard Feynman Cracked the Safes with Atomic Secrets at Los Alamos*, OPEN CULTURE (Apr. 17, 2013), https://www.openculture.com/2013/04/learn_how_richard_feynman_cracked_the_safes_with_atomic_secrets_at_los_alamos.html [https://perma.cc/673H-U8BX].

307 *See In re Wands*, 858 F.2d at 737 (listing eight Wands factors to be considered in determining whether a disclosure would require undue experimentation).

308 *See supra* Part IV (highlighting the uniqueness of the problem of patenting antibodies due to antibody's diverse nature).

309 *See* Transcript of Oral Argument at 3–8, Amgen Inc. v. Sanofi, 598 U.S. 594 (2023) (No. 21-757) 2023 WL 9375472, *3–8.

310 *See Amgen*, 598 U.S. at 614.

bamboo fiber was suited for his improved incandescent lamp.[311] As the Court recognized, Edison dispatched men across the globe to collect specimens of bamboo and found that one sample from Japan worked brilliantly because its fibers ran more nearly parallel than in other species of wood.[312] Edison did not have any guidance from Sawyer and Man that a bamboo fiber would be suited for the conductor, nor that he should test bamboo from across the world, much less a specimen of bamboo from a particular area of Japan that was particularly suited for this purpose.[313] Thus, Edison went through "painstaking experimentation" and used his intellect to search for a conductor material, which made his invention distinct from the Sawyer and Man patent.[314] In contrast, in the case of obtaining a non-infringing antibody under the *Amgen* standard, what is needed of a PHOSITA is to repeat what is disclosed and to screen a large number of antibodies using standard techniques.[315] Admittedly, the amount of work may be large and may be as extensive as the original experimentation that was used to make the invention. However, unlike Edison, a PHOSITA is taught where to go and how to find a new antibody. The obtained antibody will therefore almost certainly be novel because of the unique nature of the mechanisms of antibody generation.[316]

As illustrated by the comparison above, it is clear the amount of intellectual input required of a PHOSITA to make and use the invention should be considered to determine whether an experimentation is undue. This concept was already recognized in cases preceding *In re Wands*. For example, in *Fields v. Conover*, the U.S. Court of Customs and Patent Appeals ("CCPA") stated that "a disclosure complies with the how-to-make requirement of 35 U.S.C. § 112 even though 'some experimentation, provided it is not an undue amount' (and provided that it does not require ingenuity beyond that to be expected of one of ordinary skill in the art), is still required to adapt the invention to particular settings (emphasis added)."[317] Subsequent to *Fields*, the *Wands* court, in setting forth the eight *Wands* factors, specifically noted that routine work with sufficient directions is not undue, even if the amount of effort is large.[318] Thus, under the

311 *Id.*; *see also supra* Section V.C.1.c.

312 *Amgen*, 598 U.S. at 614.

313 *See id.*, at 608–09.

314 *See id.*

315 *See supra* Part IV.

316 *Id.*

317 Fields v. Conover, 443 F.2d 1386, 1390–91 (C.C.P.A. 1971).

318 *See In re* Wands, 858 F.2d 731, 731, 740 (Fed. Cir. 1988).

case law, screening an antibody should not be considered undue experimentation if the antigen and the procedure for screening is known, even if the amount of effort to perform the screening is immense. It appears that the technical sophistication and labor intensiveness of biological science became mistakenly equated to "ingenuity beyond that to be expected of one of ordinary skill in the art" in recent cases related to biologics, including *Amgen*.[319] As discussed above, the *Amgen* opinion did not refer to how a *Wands* analysis should be applied to antibodies in view of such a unique nature, nor did it discuss the Federal Circuit cases that shaped the interpretation and application of the *Wands* factors.[320]

B. *BAXALTA INC. V. GENENTECH INC.*

Baxalta was the first Federal Circuit case considering the enablement of antibody-related claims after *Amgen*, and attempted to address the "ingenuity requirement" discussed in the preceding Section. [321] Baxalta tried to distinguish its case from *Amgen* based on the amount of guidance it provides for a PHOSITA.[322] In this case, Baxalta's U.S. Patent No. 7,033,590 ("the '590 patent) regarded genetically engineered antibodies to treat a blood clotting disorder, generated using a prior art method known as the hybridoma technique.[323] Baxalta sued Genentech alleging Genentech's Hemlibra® (emicizumab) product infringed the '590 patent, and Genentech moved for summary judgment of the claims as being invalid for lack of enablement.[324] In its relevant part, the '590 patent described the antibody by the target it binds to—however, it disclosed in detailed specificity how to obtain the desired antibodies.[325] Baxalta argued that this case was distinguishable from *Amgen* because skilled artisans can make and identify new claimed antibodies (with new variable regions) using the routine hybridoma-and-

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319 *See supra* text accompanying notes 305–306.

320 *See* Crouch, *supra* note 299.

321 *See Baxalta*, 81 F.4th 1362 (Fed. Cir. 2023).

322 *Id.* at 1367 (Baxalta argues "the hybridoma-and-screening process . . . does not require trial and error but instead predictably and reliably generates new claimed antibodies every time it is performed.").

323 U.S. Patent No. 7,033,590 (filed Sept. 14, 2000).

324 *Baxalta*, 81 F.4th at 1364.

325 *Id.* (Claim 1 recites: "An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.").

screening process disclosed in the '590 patent, and that such routine screening did not amount to undue experimentation.[326]

However, the Federal Circuit disagreed. The court ruled that the facts of *Baxalta* were materially indistinguishable from *Amgen,* and rejected the argument that the hybridoma-and-screening process disclosed in the '590 patent predictably and reliably generated new claimed antibodies every time it is performed.[327] The court interpreted *Amgen* to say that 35 U.S.C. § 112(a) requires inventors to enable the "full scope" of the claimed invention without unreasonable experimentation.[328] The court also stated, "it is undisputed that to practice the full scope of the claimed invention, skilled artisans must make candidate antibodies and screen them to determine which ones perform the claimed functions . . . This is the definition of trial and error and leaves the public no better equipped to make and use the claimed antibodies than the inventors were when they set out to discover the antibodies over which they now have an exclusive right. Under *Amgen*, such random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a)."[329]

In this decision, the Federal Circuit closely adhered to the *Amgen* analysis in finding lack of enablement for a claim defining an antibody by its function.[330] It also failed to consider the "ingenuity requirement" that was missing in the *Amgen* analysis. Following the Supreme Court's silence regarding the *Wands* factors in *Amgen*, the Federal Circuit did not indicate what level of experimentation may be considered reasonable or unreasonable, and the court appeared to consider any level of experimentation as undue, at least in the field of antibody science.

As much as this decision was disappointing to pioneer inventors, there were some signs of hope for them: the Federal Circuit does not appear to be blindly following *Amgen*'s rather simplistic decision. The questions asked at the oral argument showed the Federal Circuit's struggle to reconciliate *Amgen* with past Federal Circuit decisions, as well as its concerns about the changing standards of what is "undue" in accordance with advancement of technology.[331] The issue of

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326 *Id.* at 1365.

327 *Id.* at 1367.

328 *Id.*

329 *Id.*

330 *Baxalta*, 81 F.4th at 1367.

331 Transcript of Oral Argument at 69, Amgen Inc. v. Sanofi 598 U.S. 594 (2023) (No. 21-757) 2023 WL 9375472, *69 (The first concern of the court is whether the Supreme Court disturbed the *Wands* factors. Further, Judges Moore and Chen ask questions about the situation when computing techniques is

how a *Wands* analysis should be applied, or even whether the *Wands* factors should be applied at all, to antibodies in view of its unique diversity will continue to be debated.[332] As it currently stands, the protection of inventions related to antibodies in the U.S. patent system is very narrow and limited to those that are described by structure (i.e. sequences) in the specification of a patent.

VIII. CONCLUSION

This Article reviews the historical changes of disclosure requirements under 35 U.S.C. §112(a) and discusses *Amgen v. Sanofi* and related cases in different jurisdictions with an emphasis on the unique biology of antibodies.[333] The U.S. patent system has gradually elevated the bar for the requirements of disclosure, as seen in Part V.[334] As discussed in Part VI, although the reasonings and approaches are different, the general trend of different jurisdictions is to narrow the scope of antibody patent protection and to limit patents to what is disclosed.[335] This trend co-evolved with the advancement of technology, especially the advancement of the ability of researchers to precisely describe the invention, such as defining an antibody molecule by sequence.[336] However, as discussed in Part VII, there are still unsolved issues in antibody claiming, and the unique issues arising from antibody

advanced and the screening of millions of antibodies becomes routine or conventional.).

[332] After completion of this manuscript, the USPTO published guidelines titled "Guidelines for Assessing Enablement in Utility Application and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al." Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563 (Jan. 10, 2024). In this publication, the USPTO director Kathi Vidal confirmed that the USPTO will continue to use the *Wands* factors to ascertain whether the amount of experimentation required to enable the full scope of the claimed invention is reasonable. *Id.* at 1563.

[333] *See supra* Parts V and VI.

[334] *See supra* Part V. Shift in the enablement and written description requirements related to antibody patents in the US. Although the Supreme Court states that there is and has been only one enablement standard, Amgen Inc. v. Sanofi, 598 U.S. 594, 615–16 (2023), the way the enablement standard is applied has changed over time as discussed in Part V.

[335] *See supra* Part VI (comparative study of *Amgen v. Sanof*i and related decisions).

[336] *See supra* Part V.

diversity and the laborious nature of antibody research were not fully recognized in the *Amgen* and the subsequent *Baxalta* decisions.[337] Additionally how to apply the *Wands* factors to antibody patents remains unanswered at this time.[338]

While the *Amgen* decision appears to be consistent with the principle of "*quid-pro-quo*" to not allow a monopoly of the field by allowing a patent claiming the entire field by function, the current case law offers a very narrow scope of protection for antibody patents. The *Amgen* decision was a huge setback for pioneer inventors like Amgen, and it will certainly impact patenting and marketing strategies of innovators that are developing truly novel biologics-based drugs. As emphasized throughout this paper, the ease of obtaining a new antibody with sufficient roadmap and/or conservative substitution (albeit immense labor) should not be ignored nor considered settled by the *Amgen* and *Baxalta* decisions, but the courts and the legislatures should continue looking for ways to protect the pioneer innovators. As discussed above in Part VII, the ingenuity requirement set forth in *Fields*, *Wands*, and preceding cases should be revisited.[339] Courts should not hesitate to delve into the technical intricacies and biological complexities to determine if there is ingenuity of a PHOSITA required to make and use the claimed invention. Referring more to expert opinions about the technical nature might be necessary. As discussed in the *Baxalta* oral argument, courts should also make clear distinctions between the amount of experimentation required (which becomes inevitably large in biological inventions) and the inventiveness of such experimentation.[340] Only when the experimentation requires more than a person of ordinary skill can conceive or perform with sufficient direction, the experimentation should be considered undue.

Another avenue the courts or the legislature might take to protect pioneer inventors might be to use the doctrine of equivalents and define how far the ring

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337 *See supra* Part VII.

338 Guidelines for Assessing Enablement in Utility Applications and Patents in View of the Supreme Court Decision in Amgen Inc. et al. v. Sanofi et al., 89 Fed. Reg. 1563, 1565 (Jan. 10, 2024). The guidelines states that what is reasonable with respect to the amount of experimentation will depend on the nature of the invention and the underlying art. *Id.*

339 Fields v. Conover, 443 F.2d 1386, 1390–91 (C.C.P.A. 1971); *In re* Wands, 858 F.2d 731, 740 (Fed. Cir. 1988).

340 Oral Argument at 45:46-46:27, Baxalta Inc. v. Genentech, Inc., 81 F.4th 1362 (Fed. Cir. 2023) (No. 22-1461), https://oralarguments.cafc.uscourts.gov/default.aspx?fl=22-1461_07122023.mp3 [https://perma.cc/PL7Z-XE3X].

of protection would extend from a disclosed invention.[341] For example, if a scientist altered one amino acid in a disclosed antibody, such change may not alter the functionality of the antibody, but the mutated antibody is yet structurally different from the disclosed antibody because it has a new amino acid sequence. If this antibody has exactly the same efficacy and functional property as the claimed antibody, does it infringe the claimed antibody? The current case law likely would say no if the new antibody was obtained through screening millions of antibodies. Under the current case law, a follower would be able to make an antibody following a well-defined "roadmap" provided by the pioneer inventor without themselves providing any inventive input and claim that the antibody is a new, uninfringing antibody. Clearly, some protection of near equivalents would be necessary, and defining the "ring of protection" may be one avenue to achieve this purpose.

As discussed above and throughout this paper, it is this author's view that despite the Supreme Court's decision, many issues remain as to how to properly protect the rights of inventors of antibody patents. For a patent applicant, at this moment, without any specific guidance from the courts as to how to apply the *Wands* factors and how big a ring of protection the applicant would be granted, disclosing as much information as possible appears to be the strategy to increase the likelihood of allowance and protection. It appears to be prudent to provide in the specification as much information as possible characterizing the antibodies by their sequences, preferably in combination with the 3D structure of the antibody itself and the function (e.g. binding ability, effects of antibody binding etc.).

While courts and legislatures have many issues left to address, solutions for the issues discussed above may also come from the innovators themselves. As we have seen from the historical considerations in Part V,[342] the issues of disclosure requirements in antibody patenting arose with the advancement of biological technology. Functional claiming of antibodies was a well-accepted claiming method before sequencing techniques were available.[343] With the maturation of such technologies of high throughput sequencing, structural analysis, and cloning, and general advancement in our understanding of immunology, patent offices around the world began to think that a monopoly should no longer be given to all antibodies defined by function.[344] Likewise, the next shift in enablement standard

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341 5B DONALD S. CHISUM, CHISUM ON PATENTS § 18.04a (2024), Lexis+.

342 *See supra* Part V (Shift in the enablement and Written description requirements related to antibody patents in the US).

343 *Id.*

344 *Id.*

might again be triggered by further advancement of technologies. After *Amgen*, U.S. patent applicants are likely to take all measures possible to prevent their patent from being invalidated. The inventors would likely start describing and testing all of their claimed antibodies and their permutations to obtain strong patents that will withstand the challenges in litigation. Thus, the norm of disclosure will inevitably become more extensive. However, with the continuous development of technologies, including Artificial Intelligence and computer modeling, such exhaustive descriptions may become conventional. Experimentations that are considered undue today may not be considered undue in the future. This author is watching with great interest how newly developing technologies will co-evolve with the wobbling Section 112(a) standards.