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The Patentability of Antibodies for Use in Medications After *Amgen v. Sanofi*

By: Kaitlyn Taylor

Introduction

Taking medication is an important part of the daily routine of many individuals. For many, taking various medications, either prescription or over the counter, can prove to have a plethora of benefits such as fighting disease, managing chronic illness, and improving overall quality of life. Accordingly, a large number of medications enter the market every year. In 2020, 53 drugs received approval from the U.S. Food and Drug Administration (“FDA”),¹ and as of October 2021, 37 medications received FDA approval.² The process for researching and developing medications for approval and entrance into the market is incredibly long, arduous, and expensive.³ A critical step in this process is patenting the drug to protect the manufacturer's invention.

There are many different patent types that allow pharmaceuticals to be patented; however, a recent case has caused a shift in how one particular class of pharmaceuticals, proprotein convertase subtilisin kexin type 9 (“PCSK9”) inhibitors, are patented.⁴ In February 2021, the U.S. Court of Appeals for the Federal Circuit ruled on *Amgen v. Sanofi*, an important case that will drastically impact the patentability of PCSK9 inhibitors.⁵ This case centered around patents for medications utilizing antibodies, which are also known as immunoglobulins.⁶ The court invalidated two Amgen patents covering PCSK9 inhibitor monoclonal antibody drugs, used for lowering cholesterol.⁷ The antibodies utilized in Amgen’s drug, Repatha (generically known as evolocumab), lowers low-density lipoprotein (“LDL”) cholesterol.⁸

¹See Food & Drug Admin., Novel Drug Approvals for 2020 (Oct. 8, 2021), <https://perma.cc/6WGX-8LN7> (last visited Oct. 9, 2021).

²See Food & Drug Admin., Novel Drug Approvals for 2021 (Oct. 8, 2021), <https://perma.cc/7AEK-BRRT> (last visited Oct. 9, 2021).

³ Dani Kass, *Pharma Giants Tee Up Biologics Innovation Fight At Fed. Circ.* (Aug. 21, 2020) <https://perma.cc/2QNH-7J6D> (last visited Oct. 15, 2021).

⁴ *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1082 (Fed. Cir. 2021).

⁵ *Id.* at 1083.

⁶ See NEIL A. CAMPBELL ET AL., *CAMPBELL BIOLOGY* 953 (Beth Wilbur et al. eds., 10th ed. 2014).

⁷ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 9, 2021).

⁸ *Amgen*, 987 F.3d at 1082.

Repatha can lower LDL cholesterol by binding to the PCSK9 protein and blocking PCSK9 from binding to LDL receptors.⁹

In ruling on this case, the court stated that the functional claims within the patents for these antibodies were too broad.¹⁰ This ruling essentially eliminated the ability to define an antibody within the patent application purely based on the antibody's function.¹¹ This is a shift in the precedent previously governing the patentability of these monoclonal antibodies, which could impact and cause issues for applications and patents that were drafted several years ago, as well as future patents.¹² Therefore, due to this shift in precedent, *Amgen* has and will continue to substantially impact the patentability of antibodies for use in medications.

This article aims to discuss the impact that the *Amgen* decision has had, and will continue to have, on the process and patentability of antibodies for use in medications. Additionally, this article aims to discuss the impact that the *Amgen* decision could have on attempts to patent antibodies for use in new medications moving forward. This article is organized into five subsequent sections, the first of which will provide a brief overview of the United States patent system and background information regarding antibodies. After this, this article will provide an overview of the patentability of antibodies and the patent process regarding antibodies for use in medications prior to the *Amgen* decision. Then, this article will discuss and provide an overview of the *Amgen* case itself. Next, this article will discuss *Amgen's* impact on the patentability of antibodies for use in medications and the patent process itself. Finally, this article will conclude with a section detailing the impact that the *Amgen* decision could have on future attempts to patent antibodies for use in new medications moving forward.

Background

A Brief History of Patents in the United States

⁹ *Id.*

¹⁰ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 9, 2021).

¹¹ *Id.*

¹² *Id.*

To discuss the patentability of antibodies, one must understand the patent system and process within the United States. The Constitution of the United States laid out the initial framework for the governance of patents and patent law.¹³ “Congress shall have power . . . 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.” (the “Intellectual Property Clause”).¹⁴ England’s approach in the Statute of Monopolies was the initial basis for this concept, which granted limited monopolies for inventions.¹⁵

Although the Intellectual Property Clause initially set forth a basis for patent law, the first patent laws in the United States were not passed until the Patent Act of 1790 (“the 1790 Act”).¹⁶ The 1790 Act intended to promote the progress of the useful arts and grant a term of up to fourteen years of protection for inventions that could be deemed adequately important and useful.¹⁷ However, several years later, the 1790 Act was repealed and replaced with the Patent Act of 1793, which contains the definition for what constitutes subject matter that is patentable, and this definition has predominantly remained unchanged.¹⁸ There are four primary categories that define patentable subject matter: processes, machines, manufactures, and compositions of matter.¹⁹ Anything for which one is seeking patent protection must fall into at least one of these four categories.²⁰ Additionally, patentable subject matter does not include abstract ideas, laws of nature, and natural phenomena.²¹ Therefore, anything that can be defined as one of

¹³ A Brief History of Patent Law in the United States (May 7, 2014), <https://perma.cc/C75E-Q466> (last visited Oct. 9, 2021).

¹⁴ U.S. CONST. art. I, § 8.

¹⁵ A Brief History of Patent Law in the United States (May 7, 2014), <https://perma.cc/C75E-Q466> last visited Oct. 9, 2021).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ 2106 PATENT SUBJECT MATTER ELIGIBILITY [R-10.2019], <https://perma.cc/BXT7-XTW2> (last visited Oct. 15, 2021).

²⁰ *Id.*

²¹ *Id.*

these exceptions is not patentable subject matter, even if it falls into one of the four previously mentioned categories.²²

The current patent system dictates that any individual who creates or discovers something that is “new and useful” may obtain a patent for that new invention.²³ However, for a patent to be granted, an invention must satisfy three requirements.²⁴ It must: (1) be novel, (2) have utility, and (3) be non-obvious.²⁵ In a patent application, the claim defines the patentable subject matter for which one is seeking protection.²⁶ Claims function to describe and define precisely what would be protected if the patent application were to be granted so that it is clear exactly what is and what is not protected in regards to the patentable subject matter.²⁷ Additionally, all patent applications must contain a written description supporting the claim of the invention and the process in which it is made using specific, clear, and concise terms, along with all of the other additional specifications as they are laid out in the written description requirement.²⁸ In *Amgen*, the written description portion of the patents was the primary area of dispute and it is that portion where the court’s ruling had the greatest effect.²⁹

Another important aspect of the current patent system is the enablement requirement, which refers to a specific section of a patent application where one must describe how to make and use the invention.³⁰ For this requirement to be satisfied, one who is skilled in the art must be able to make and use the invention that is defined within the claim in that patent application.³¹ Therefore, if a patent applicant has sufficiently informed one who is skilled in that particular art how to make and use the invention within the patent application, then the enablement requirement is satisfied.³²

²² *Id.*

²³ 35 U.S.C.S. §§101-103 (2021).

²⁴ *Id.*

²⁵ *Id.*

²⁶ 1824 THE CLAIMS [R-07.2015], <https://perma.cc/JS94-DQ3F> (last visited Oct. 15, 2021).

²⁷ *Id.*

²⁸ 35 U.S.C.S. § 112 (2021).

²⁹ *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1084 (Fed. Cir. 2021).

³⁰ 2164 THE ENABLEMENT REQUIREMENT [R-11.2013], <https://perma.cc/A6BH-XCN9> (last visited Oct. 15, 2021).

³¹ *Id.*

³² *Id.*

What is an Antibody?

To discuss the patentability of antibodies, one must understand antibodies themselves.

Essentially, an antibody is a protein component of the body's immune system that circulates throughout the bloodstream and works to recognize and neutralize a plethora of foreign substances (called antigens) such as viruses and bacteria.³³ Antibodies are proteins, and proteins are molecules that are made up of one or more polypeptides (a large group of amino acids) that are then folded and coiled into a three-dimensional structure.³⁴ Antibodies are produced and secreted by B cells which function as a part of the body's adaptive immune system.³⁵

Antibodies have a very distinct Y-shaped protein structure.³⁶ This structure is made up of four polypeptide chains grouped into two identical pairs, two heavy chains and two light chains.³⁷ These chains are linked together with disulfide bridges.³⁸ Due to the Y-shaped structure of antibodies, the two "hands" serve as antigen binding sites while the "tail" binds to various receptors on the surface of the cell.³⁹ The "tail" of an antibody cannot change, and thus is also known as its constant region; whereas, the hands of an antibody can change through the process of binding to antigens, and thus, are known as the variable region.⁴⁰ Additionally, the "tail" of the antibody serves as the identifier to determine the antibody's class.⁴¹ There are five different classes of antibodies: IgG, IgA, IgD, IgE, and IgM.⁴² Each antibody class serves a different purpose and has varying levels of frequency in the blood.⁴³ However, the

³³ *Antibody*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <https://perma.cc/47JH-CJQM> (last visited Sept. 24, 2021).

³⁴ See NEIL A. CAMPBELL ET AL., *CAMPBELL BIOLOGY* 953 (Beth Wilbur et al. eds., 10th ed. 2014).

³⁵ *Id.* at 953.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ LAUREN M. SOMPAYRAC, *HOW THE IMMUNE SYSTEM WORKS* 4 (4th ed. 2012)

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Mark Chiu et al., *Antibody Structure and Function: The Basis for Engineering Therapeutics*, MDPI, Dec. 3, 2019, at 1, 2.

⁴³ *Id.*

vast majority of antibodies in the blood are IgG antibodies.⁴⁴ The antibodies utilized in the drug Repatha, discussed in the *Amgen* case, are grouped in the IgG class of antibodies.⁴⁵

In medications, antibodies serve a wide variety of purposes and functions, working to treat and manage symptoms of many different illnesses and conditions.⁴⁶ Because of their high specificity in treating and managing illness, therapeutic antibodies used in medications have fewer adverse side effects when compared to traditional therapeutics.⁴⁷ Due to this, therapeutic antibodies have become the predominant class of new drugs developed over the past several years, with many of the best-selling drugs worldwide utilizing antibodies.⁴⁸ There are several different antibody engineering technologies used to develop these medications. However, the type of antibody in the medication at issue in *Amgen*, is a monoclonal antibody (“mAbs”).⁴⁹

Monoclonal antibodies are produced by B cells, and they work to specifically target antigens.⁵⁰ When used in medication, mAbs should have several essential biophysical properties such as high stability, high binding activity for antigens, and low immunogenicity.⁵¹ One example of a monoclonal antibody is in the drug Humira (generically known as Adalimumab), which is in the IgG class of antibodies and generates a significant immune response.⁵²

The monoclonal antibody whose patent was at issue in *Amgen* binds to PCSK9, which inhibits LDL cholesterol regulation.⁵³ An elevated LDL cholesterol can cause heart disease.⁵⁴ LDL receptors work to remove the amount of LDL cholesterol from the bloodstream, which serves as a regulatory method for

⁴⁴ LAUREN M. SOMPAYRAC, *HOW THE IMMUNE SYSTEM WORKS* 4 (4th ed. 2012).

⁴⁵ REPATHA PRESCRIBER INFORMATION, <https://perma.cc/63QC-5LZ2> (last visited Sept. 24, 2021).

⁴⁶ MONOCLONAL ANTIBODY DRUGS FOR CANCER: HOW THEY WORK, <https://perma.cc/8XGE-CGXB> (last visited Oct. 15, 2021).

⁴⁷ Ruei-Min Lu et al., *Development of therapeutic antibodies for the treatment of diseases*, J. Biomedical Sci., Jan. 2020 at 1, 1 <https://perma.cc/4U5Q-DGNL>.

⁴⁸ *Id.*

⁴⁹ *Amgen*, 987 F.3d at 1083.

⁵⁰ Ruei-Min Lu et al., *Development of therapeutic antibodies for the treatment of diseases*, J. Biomedical Sci., Jan. 2020 at 1, 1 <https://perma.cc/4U5Q-DGNL>.

⁵¹ *Id.* at 12.

⁵² *Id.*

⁵³ *Amgen*, at 1083.

⁵⁴ *Id.* at 1082.

LDL cholesterol.⁵⁵ PCSK9 works to regulate the degradation of LDL receptors by binding to the LDL receptors and mediating their degradation, which ultimately decreases the number of LDL receptors present on the surface of the cell.⁵⁶ Antibodies, such as those utilized in Amgen's drug Repatha, bind to PCSK9 and block it, allowing the LDL receptors to continue performing their regulatory function of LDL cholesterol.⁵⁷ In binding to PCSK9 and inhibiting the binding of PCSK9 to LDL, this antibody increases the number of available LDL receptors, thereby lowering LDL cholesterol.⁵⁸

The scientific definition, description, and understanding of antibodies are based primarily on the antibody's protein structure and primary function.⁵⁹ However, the legal definition and understanding of antibodies as it relates to patentability is slightly different.⁶⁰ When it comes to the patentability of an antibody, the legal system views that antibody merely as it is described and defined within the elements of its claim.⁶¹ With Repatha, scientifically, the antibodies in this medication would be described based upon their function, to bind to PCSK9 and thereby lower LDL cholesterol.⁶² However, legally, they would be defined based upon how they are described in the written claims portion of the patent pertaining to this drug: an isolated monoclonal antibody that when bound to PCSK9, binds to one of many residues.⁶³ This demonstrates a difference in the understanding, description, and definition of an antibody between the scientific and legal perspectives. The scientific understanding is based on the antibody's structure and function whereas the legal understanding is based upon the claims in the antibody's patent application. These differences could lead to a misunderstanding regarding what is actually claimed and therefore protected by a particular patent. This then leaves room for the United States Patent and Trademark Office,

⁵⁵ *Id.*

⁵⁶ *Id.* at 1083.

⁵⁷ *Id.*

⁵⁸ REPATHA PRESCRIBER INFORMATION, <https://perma.cc/63QC-5LZ2> (last visited Sept. 24, 2021).

⁵⁹ *Antibody*, NATIONAL HUMAN GENOME RESEARCH INSTITUTE, <https://perma.cc/47JH-CJQM> (last visited Sept. 24, 2021).

⁶⁰ MONOCLONAL ANTIBODY PATENTS: EVOLVING LAW & STRATEGIES, (Oct. 1, 2012) <https://perma.cc/BC96-CWY7> (Oct. 15, 2021).

⁶¹ *Id.*

⁶² REPATHA PRESCRIBER INFORMATION, <https://perma.cc/63QC-5LZ2> (last visited Sept. 24, 2021).

⁶³ *Amgen*, at 1083.

as well as the court system, to deal with these discrepancies and disputes as they arise, clarifying for scientists exactly what they have and have not claimed in regard to the antibodies they are attempting to patent.

How were Antibodies Patented in the Past?

To discuss the changes to antibody patentability following the decision in *Amgen*, one must also understand the process of patenting antibodies prior to this decision. As mentioned previously, all inventions to be patented must meet three criteria: (1) novelty, (2) utility, and (3) nonobviousness, and this includes antibodies for use in medications.⁶⁴ Additionally, all inventions to be patented must adhere to the written requirements and disclosures of 35 U.S.C. § 112.⁶⁵ However, satisfying this written requirement is often the primary focus of litigation in patent suits where individuals claim infringement of antibody patents as used in medication.⁶⁶ In these suits, courts must determine what level of specificity must be listed within the claim to adequately satisfy the written requirement laid out in 35 U.S.C. § 112.⁶⁷ This discussion of the written requirement, specifically the enablement requirement, and whether or not these requirements are satisfied, is the primary focus of the litigation in the *Amgen* case.⁶⁸

Georges J. F Köhler and César Milstein were the first individuals who introduced a technique that allowed for the creation of monoclonal antibodies in large amounts.⁶⁹ However, the pair of scientists were not able to obtain a patent for their techniques, given that their work had been featured in an article in *Nature*, and British patent law prevents any work that has been previously disclosed in a medium such as a publication from being included in an application for a patent.⁷⁰ Additionally, they did not obtain a patent in the United States, as they took no action to file for a patent.⁷¹ The first patents in the United

⁶⁴ 35 U.S.C.S. §§ 101-103 (2021).

⁶⁵ 35 U.S.C.S. § 112 (2021).

⁶⁶ Laura Labeots, *The Written Description Requirement*, Healthcare Law Insights, Dec. 17, 2014, <https://perma.cc/M379-GUDF> (last visited Oct. 15, 2021).

⁶⁷ *Id.*

⁶⁸ *Amgen*, 987 F.3d at 1083.

⁶⁹ Ruei-Min Lu et al., *Development of therapeutic antibodies for the treatment of diseases*, J. Biomedical Sci., Jan. 2020 at 1, 1 <https://perma.cc/4U5Q-DGNL>.

⁷⁰ *A Missed Opportunity? The Patent Saga*, WHAT IS BIO TECHNOLOGY (2017), <https://perma.cc/SAC4-N2GT>.

⁷¹ *Id.*

States for monoclonal antibodies used in a clinical setting (to fight tumors and influenza virus antigens) were awarded a few years later in late 1979 and early 1980 to Koprowski, Croce, and Gerhard.⁷² This was controversial in Britain as well as the scientific community at large given that many individuals felt as though they were merely copying Köhler and Milstein's technique.⁷³ After this patent was granted, claims shifted from patenting the process of creating the antibody utilized in a particular medication, to claims that were instead focused on patenting the antibody itself.

There is a substantial body of law that relates either to the patenting of antibodies or the written requirement portion of the patent application process. Given that this body of law is so large, this article will highlight only a few significant cases that provide important background and precedent on these issues before the ruling in *Amgen*. The following four cases will provide insight and understanding into the process of patenting antibodies as well as the court's understanding and interpretation of the written requirement portion of the patent application process.

This first case provides a general insight into the patenting of monoclonal antibodies. In a 2015 case before the U.S. District Court for the Eastern District of Virginia, the plaintiff, UCB, brought suit against Yeda Research & Development Company, stating that UCB's monoclonal antibody drug, Cimzia, did not infringe on Yeda's patent and that Yeda's patent was invalid.⁷⁴ The court held that in the written description, using the term "monoclonal antibody" limited the term to an antibody that was generated in a specific manner and not through other processes.⁷⁵ The court further defined a monoclonal antibody as a grouping of a single type of antibody that was generated in that specific manner.⁷⁶ This case essentially set up the court's interpretation of a monoclonal antibody as it was defined through the written requirement of a patent application.⁷⁷ This interpretation by the court provided a standardized method of

⁷² *Id.*

⁷³ *Id.*

⁷⁴ UCB, Inc. v. Yeda Research & Dev. Co., 117 F. Supp. 3d 755, 759 (E.D. Va. 2015).

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *Id.*

determining exactly what a monoclonal antibody is so that it does not need to be continuously defined in future applications.⁷⁸

Regents of Univ. of Cal. v. Eli Lilly & Co., provides a baseline analysis and understanding regarding the courts' interpretation of the written requirement of the patent application. 119 F.3d 1559 (Fed. Cir. 1997). In this case, the Regents of the University of California brought action against Eli Lilly & Company alleging infringement on several patents for the manufacture of human insulin.⁷⁹ The court cited several different specifications for adequately fulfilling the written description requirement in a patent application.⁸⁰ First, the court stated that a patent application must describe an invention in sufficient detail to conclude that "the inventor invented the claimed invention."⁸¹ This "sufficient detail" is satisfied through a plethora of descriptive means such as words, structures, diagrams, formulas, chemical names, or physical properties.⁸² When it comes to deoxyribonucleic acid ("DNA") that codes for a specific protein, the court stated that in order to claim DNA in a patent application, a very precise definition is required.⁸³ This definition should be precise because the disclosure of the amino acid sequence of a protein does not necessarily make the DNA molecules that are encoding the protein apparent. The DNA molecules that encode the protein are not apparent because the genetic code is redundant and could generate a large number of DNA sequences that code for the protein.⁸⁴ Additionally, the court noted that a definition by function does not define the genus itself, as it describes what it does as opposed to what it is.⁸⁵ Ultimately, this case indicates that in order to satisfy the written requirement, a definition by function is usually not sufficient and neither is a disclosure of an amino acid sequence of a protein.⁸⁶

⁷⁸ *Id.*

⁷⁹ *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1562 (Fed. Cir. 1997).

⁸⁰ *Id.*

⁸¹ *Id.* at 1566.

⁸² *Id.*

⁸³ *Id.* at 1567.

⁸⁴ *Id.*

⁸⁵ *Id.* at 1568.

⁸⁶ *Id.*

The next case discussed, *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341 (Fed. Cir. 2011), provides insight into a portion of the written requirement of a patent application that is often referred to as “the antibody exception.” In this case, Centocor brought suit against Abbott Labs alleging infringement on a medication that utilized antibodies to treat arthritis.⁸⁷ The court referenced the description guidelines from the U.S. Patent and Trademark Office (“USPTO”) discussing the “antibody exception.”⁸⁸ These guidelines indicated that a claim referencing an isolated antibody capable of binding to a specific protein is described adequately if the specification fully characterizes the protein and that this claim does not need to include working or detailed example(s) of actual antibodies that bind to the protein.⁸⁹ The court then elaborated that this example (which is often referred to as the antibody exception), assumes that the patent applicant is first disclosing a new protein and then claiming both the antibody that binds to it and the protein itself.⁹⁰ Finally, the court indicated because precedent implies the written description requirement for antibody claims can be satisfied through the disclosure of an antigen that is well-characterized, so can antigens that are newly characterized, so long as the antibody creation that is claimed is routine.⁹¹

The *Centocor* case set forth the precedent for the “antibody exception,” which led to many broad antibody claims regarding the written requirement. In the area of patent law, a traditional interpretation of the written description requirement would have required a characterization of the antibody that was more specific than the broad claims permitted because of *Centocor*. However, the antibody exception set forth the precedent that if the applicant can characterize the structure of an antigen, then the applicant can claim an antibody against the antigen.⁹² The “antibody exception” doctrine, as first defined in *Centocor*, described the relationship like a “lock and key” mechanism, to mean that if an antigen can be

⁸⁷ *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1343 (Fed. Cir. 2011).

⁸⁸ *Id.* at 1351.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.* at 1352.

⁹² *Monoclonal Antibody Patents: Evolving Law & Strategies*, FENWICK INSIGHTS, (Oct. 1, 2012) <https://perma.cc/5ZPJ-L5TV>.

characterized to a certain level of detail, then the creation of an antibody that would bind to that antigen would be straightforward.⁹³

AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., provides insight into patenting antibodies generally, as well as patenting a genus or group of antibodies. 759 F.3d 1285 (Fed. Cir. 2014). In this case, AbbVie sued Janssen Biotech, alleging infringement on several patents that Janssen possessed on a human IL-12 neutralizing antibody drug that was marketed under the name Stelara.⁹⁴ AbbVie's patent claimed a class of antibodies defined by their high affinity and neutralizing activity to a known antigen, human IL-12.⁹⁵ The court had to determine if the patents at issue sufficiently described the representative species to support the entire genus of the antibodies.⁹⁶ The court concluded that AbbVie's patents described only one type of antibody that was structurally similar, not an entire genus.⁹⁷ However, the court noted that claims that functionally define a genus can be vulnerable to a challenge for lack of written support, especially in fields where the technology claimed is highly unpredictable.⁹⁸ This vulnerability exists because it can be difficult to establish that a correlation exists between the function and structure for an entire genus and precisely what the functionally claimed genus would cover.⁹⁹

Importantly, the *AbbVie* case served to narrow the "antibody exception" for the written disclosure requirement, as it indicated that in order for this requirement to be satisfied and an applicant have the ability to claim a genus, that applicant would need to disclose all of the potential antibody structures that the patent intends to cover.¹⁰⁰ This narrowing of the antibody exception led to a shift where many companies would include the amino-acid sequences in their disclosure, labeled as residues of the target antigen of the antibody, which was the case for the patent application in *Amgen*.¹⁰¹

⁹³ *Id.*

⁹⁴ *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1289,1292 (Fed. Cir. 2014).

⁹⁵ *Id.* at 1299.

⁹⁶ *Id.*

⁹⁷ *Id.* at 1300.

⁹⁸ *Id.* at 1301.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1083-84 (Fed. Cir. 2021).

Amgen v. Sanofi

The *Amgen* case had a long history of ongoing litigation beginning October of 2014 when Plaintiffs, Amgen, Inc., Amgen USA Inc., and Amgen Manufacturing, Ltd., filed suit in the U.S. District Court for the District of Delaware, alleging that Defendants, Sanofi, Sanofi-Aventis U.S. LLC, Regeneron Pharmaceuticals, Inc., and Aventisub LLC infringed several of the plaintiffs' U.S. patents.¹⁰² These patents were then tried based on their validity in front of a jury in March of 2016, where the district court granted judgement as a matter of law based upon nonobviousness and a lack of willful infringement.¹⁰³ Notably, the jury found that the patents were not invalid due to a lack of written description.¹⁰⁴ Sanofi appealed, and the U.S. Court of Appeals for the Federal Circuit found that the district court erred in finding that the patents were valid.¹⁰⁵ As a result, the U.S. Court of Appeals for the Federal Circuit remanded back to the lower court for a new trial on the issues surrounding Sanofi's defense that the patents in question lack both the enablement and written description requirements.¹⁰⁶ On remand, the district court found that Sanofi's claims were invalid for a lack of both written description and enablement, which the Federal Circuit Court ultimately affirmed.¹⁰⁷

Amgen owns the two patents at issue in this case: U.S. Patent No. 8,829,165¹⁰⁸ (commonly referred to as the "165 patent") and U.S. Patent No. 8,859,741¹⁰⁹ (commonly referred to as the "741 patent").¹¹⁰ These patents describe the antibodies utilized in Repatha, where antibodies lower LDL levels by binding to PCSK9 and preventing it from binding to LDL receptors.¹¹¹ They share a common written description, specifying that the antibody to be patented is an isolated monoclonal antibody, and that when

¹⁰² *Amgen Inc. v. Sanofi*, Civil Action No. 14-1317-RGA, 2019 U.S. Dist. LEXIS 146305, at *2 (D. Del. Aug. 28, 2019).

¹⁰³ *Amgen*, 987 F.3d at 1083-84.

¹⁰⁴ *Id.* at 1084.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 1084, 1088.

¹⁰⁸ U.S. Patent No. 8,829,165 (issued Sept. 9, 2014).

¹⁰⁹ U.S. Patent No. 8,859,741 (issued Oct. 14, 2014).

¹¹⁰ *Amgen*, 987 F.3d at 1083.

¹¹¹ *Id.*

bound to PCSK9, the antibody binds to at least one (or more) of a list of 15 amino acids (described as residues).¹¹² The written description also includes amino acid sequences for 26 antibodies, one of which is the antibody utilized in Repatha.¹¹³ Additionally, the written description discloses the three-dimensional structures for two antibodies and the location where those two antibodies bind to PCSK9.¹¹⁴

The primary area of the court's analysis in *Amgen* is in determining if the claim at issue satisfies the requirements in 35 U.S.C. § 112.¹¹⁵ The court initially focused on the enablement requirement, stating that to prove the invalidity of a claim due to a lack of enablement, one must present clear and convincing evidence that a person of ordinary skill in the art would have to undergo "undue experimentation" to practice this claimed invention.¹¹⁶

The court then turned to the eight *Wands* factors, which establish a factual method of analyzing whether undue experimentation is necessary.¹¹⁷ The *Wands* factors are: (1) the amount of necessary experimentation, (2) the amount of either guidance or discretion that is presented, (3) the existence (or lack thereof) of working examples, (4) the nature of the invention itself, (5) the state of similar preexisting art, (6) the skill of those who are in the art, (7) the predictability (or lack thereof) of the art, and (8) the breadth of the claims at stake.¹¹⁸ *Amgen* argued that under these factors, no undue experimentation is necessary to obtain the antibodies that are within the scope of the claims, whereas Sanofi argued that undue experimentation is necessary.¹¹⁹

The court stated that applying the *Wands* analysis requires the concrete identification of some or all of the embodiments asserted to not be enabled.¹²⁰ This must occur in order to concretely demonstrate breadth as opposed to an abstract possibility regarding the level of experimentation necessary to make or

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.* at 1084.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

¹¹⁹ *Amgen*, 987 F.3d at 1085.

¹²⁰ *Id.*

use the product or processes in question.¹²¹ The court also held that, “while functional claim limitations are not necessarily precluded in claims that meet the enablement requirement, such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language.”¹²² The court essentially indicated that it is incredibly difficult to fulfill the enablement requirement in claims where broad function language is used.¹²³ This broad functional language is like the language used to describe the antibodies to be patented in this case.¹²⁴ The court highlighted that the claims in this case are defined by functional limitations as opposed to structure, indicating that the functional breadth of the antibodies in question was a major source of concern.¹²⁵ Ultimately, the court agreed with the district court that the level of specification present in these claims did not enable preparation without undue experimentation.¹²⁶ The court highlighted that in limiting the claims to how and what the antibodies bind to, this factor alone would be sufficient to require one of ordinary skill to experience undue experimentation.¹²⁷

Notably, the court did mention one mitigating factor although it did not have a drastic impact on the decision itself.¹²⁸ The court recognized that the field of science where several patents were at issue is unpredictable in terms of satisfying the full scope of functional limitations necessary under 35 U.S.C. § 112.¹²⁹

Ultimately, the court held that undue experimentation would be necessary to practice the full scope of the claims at issue in this case.¹³⁰ The court stated that the primary reasoning for this decision was that the evidence demonstrated that the scope of the claims at issue encompassed millions of potential candidates that are claimed with respect to a multitude of specific functions.¹³¹ As a result, generating and

¹²¹ *Id.* at 1086.

¹²² *Id.* at 1087.

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.* at 1088.

¹³¹ *Id.*

screening each antibody candidate would be necessary to determine if that candidate adheres to the necessary limitations set forth by the claim stating the dual-function of each antibody.¹³² Additionally, the court stated that the *Wands* factors do not indicate that the screening of antibodies never requires undue experimentation.¹³³

Essentially the ruling in *Amgen* indicated that broad functional language would no longer be acceptable to satisfy the enablement requirement as laid out in 35 U.S.C. § 112, since language such as this would require “undue experimentation” by a person having ordinary skill in the art to practice or use the claimed invention.¹³⁴ The court’s reasoning came from its analysis of the *Wands* factors, which indicated that Amgen’s broad functional patent claims, given the breadth of those claims, set the bar too high under the enablement requirement.¹³⁵ The court indicated that had the claims been based upon structure as opposed to function, the outcome could have been different.¹³⁶ The court noted that the analysis using the *Wands* factors in and of itself did not indicate that antibodies never require undue experimentation.¹³⁷ In *Amgen*, the Federal Circuit held that in order for one to obtain broad patent coverage for a class of antibodies that perform a specific function and bind to a specific antigen, one must meet one of two criteria.¹³⁸ A company must disclose an adequate number of antibodies that are representative of this function across the genus one is attempting to claim, or establish that a clear relationship exists between the antibody’s function and the genus of the antibody that is present in the company’s specification.¹³⁹ Ultimately, the ruling in *Amgen* provided a stark contrast to claims where antibodies used in medications had been patented in the past, given that broad functional claims had previously been considered acceptable in satisfying the enablement requirement.¹⁴⁰ This raised the bar for

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ Joanna Brougher, *Reaching The Post-Amgen High Bar For Antibody Patents* (Apr. 6, 2021), <https://perma.cc/P6AK-UTFM> (last visited Oct. 15, 2021).

¹³⁹ *Id.*

¹⁴⁰ *Amgen*, 987 F.3d at 1088.

protecting antibody inventions as the amount of data required when disclosing and claiming antibodies has significantly increased with the court's decision in *Amgen*.¹⁴¹

How Has/Will the *Amgen* Decision Impact the Process and Patentability of Antibodies?

As the *Amgen v. Sanofi* decision indicated that broad functional claims are no longer acceptable or sufficient to satisfy the enablement requirement of a patent application for antibodies, this begs the question: how has and how will this decision impact both the process and patentability of antibodies for use in medications? In the United States, six of the top ten drugs, when ranked by revenue, are drugs utilizing antibodies in some way.¹⁴² Due to the *Amgen* decision, it is estimated that there will likely continue to be patentability issues surrounding antibody patents and patent applications that were drafted several years prior to the court's decision in *Amgen*.¹⁴³ As the decision in *Amgen v. Sanofi* shifted how antibodies are patented and what antibody claims are sufficient to satisfy both the written and enablement requirements, this could endanger the patent protection of not only those medications, but others that are currently patented as well as those that have yet to be patented.¹⁴⁴ This shift in what is considered sufficient to satisfy the necessary requirements to patent an antibody drug has already and will likely continue to impact the process of patenting antibodies, as well as encourage companies to get creative in searching for alternative methods for protecting their antibody medications.

Any major decision in a particular area of law is bound to impact future analysis or thought within that area. Therefore, the same can be said regarding the process of patenting antibodies for use in medications. The decision by the Federal Circuit in *Amgen* substantially "raised the bar" for obtaining broad patent protections of monoclonal antibodies used in therapeutics to satisfy the enablement

¹⁴¹ Joanna Brougher, *Reaching The Post-Amgen High Bar For Antibody Patents* (Apr. 6, 2021), <https://perma.cc/P6AK-UTFM> (last visited Oct. 15, 2021).

¹⁴² Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁴³ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, *BioPharma Rep.* (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 15, 2021).

¹⁴⁴ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

requirement of a patent application.¹⁴⁵ Additionally, the standard regarding the patent's specification as a part of the written description requirement was also increased because of *Amgen*.¹⁴⁶ This higher bar for both the written description and enablement requirement from the *Amgen* decision creates a list of additional demands that those seeking patent protection of antibodies must meet, which will likely create some challenges in regards to the process and patentability of monoclonal antibodies used in therapeutics.¹⁴⁷ For example, because of the *Amgen* decision, it is likely that patent examiners will become much more conservative when it comes to their grants.¹⁴⁸ As a result of this, patent examiners are likely to reject these broader claims for the patenting of antibodies.¹⁴⁹ Therefore, individuals who are seeking to patent an antibody would have to fight for their application through the Patent Trial and Appeal Board, and eventually, the Federal Circuit.¹⁵⁰ This higher bar for antibody medication patent protection would ultimately make it more difficult for those seeking patent protection to obtain an antibody patent, as it would require additional time, money, and research in order to satisfy the new antibody patenting requirements following the *Amgen* decision.¹⁵¹

Although *Amgen* created its own set of difficulties and issues moving forward, there are clear positive impacts that may come about. One positive impact is the increase in competition because the *Amgen* decision suggests that there are ways that companies will be able to either invent around or challenge a claim that prevents them from inventing around a patent for a given antibody patent that achieved the same goal first.¹⁵² This will then lead to an increase in competition, which is not inherently a

¹⁴⁵ Joanna Brougher, *Reaching The Post-Amgen High Bar For Antibody Patents* (Apr. 6, 2021), <https://perma.cc/P6AK-UTFM> (last visited Oct. 15, 2021).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ Dani Kass, *Pharma Giants Tee Up Biologics Innovation Fight At Fed. Circ.* (Aug. 21, 2020) <https://perma.cc/2QNH-7J6D> (last visited Oct. 15, 2021).

¹⁵² *Id.*

negative outcome from this decision as currently there is not a significant amount of competition when it comes to biologics, such as medications that utilize antibodies.¹⁵³

Not only could the *Amgen* decision lead to an increase in competition, it could also lead to an increase in innovation.¹⁵⁴ Had the *Amgen* decision allowed broad functional claims to continue to remain valid, it could have prevented other companies from making improvements within that class of antibodies in the future.¹⁵⁵ Often when a particular class of antibodies is being developed for therapeutic drug use, each subsequent antibody created within that class has one, if not more, additional or enhanced feature(s).¹⁵⁶ If the broad functional claims over an antibody class, like those in *Amgen*, were upheld, this could prevent these incremental improvements within a particular antibody class from being developed due to infringement as they would still be present within the same antibody class.¹⁵⁷ Therefore, the *Amgen* decision could lead to an increase in innovation as subsequent incremental improvements on a class of antibodies would not constitute infringement on a patent for the entire class.¹⁵⁸ This would be beneficial for patients as it would allow for the creation of more effective medications that were able to treat and manage illness and symptoms more effectively. Therefore, the *Amgen* decision will likely lead to an increase in innovation as it will create an incentive for companies to be more innovative in their development of antibody medications, but this incentive comes from the inability to secure patent claims that are broad and purely functional, failing to adequately describe the structures disclosed.¹⁵⁹

Additionally, although the *Amgen* decision will pose some difficulties and challenges for those companies who are trying to obtain an antibody patent for a particular medication, this prevents those seeking antibody patents from claiming more than they have actually discovered.¹⁶⁰ Getting rid of the

¹⁵³ *Id.*

¹⁵⁴ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 15, 2021).

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

ability to broadly claim more than what one has truly discovered could lead to the lowering of the price of medications utilizing antibodies, which could prove to greatly benefit patients.¹⁶¹ In obtaining a large number of extremely broad patents, companies are able to pile on protections of the new drug they are creating.¹⁶² Obtaining a large number of broad patents will keep competitors who would be able to produce the same drug for a lower cost out of the market for a significant period of time.¹⁶³ This leads to a substantial amount of income for the companies that hold these broad antibody patents.¹⁶⁴ In making it far more difficult, if not impossible, to obtain these patents, competition will be increased within the market for medications that utilize antibodies, thus lowering prices for patients.¹⁶⁵

Ultimately, the *Amgen* decision has altered the way antibodies for use in medication are patented, through preventing broad functional claims from continuing to satisfy the enablement requirement. Although this will inevitably make it more difficult for companies to obtain patents for antibody drugs, it also will likely have several positive effects that will ultimately help patients, such as, those relating to competition, innovation, and lowering prices for patients. As a result of these difficulties created in the wake of the *Amgen* decision, it is possible that some companies will instead turn to alternative methods in order to avoid these difficulties caused by the *Amgen* decision.

Alternative Methods of Antibody Protection

Given that it is unclear how antibodies claimed at the genus level for use in medications can be patented following the *Amgen v. Sanofi* decision, companies may turn to alternative methods outside of the patent process of claiming an entire genus of antibodies to seek protection over their antibody drugs that perhaps would otherwise have a low patentability. There are a plethora of various methods that could be utilized to help protect antibody drugs that are not patentable due to broad functional claims following

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

the *Amgen* decision.¹⁶⁶ The top three methods include: trade secret protection, attempting to patent the antibody based on homology, and accession deposits, among many others.¹⁶⁷ Each of these methods has benefits as well as drawbacks, and the costs and risks associated with these options compared to the process in which antibodies were patented in the past will need to be weighed carefully by each company seeking protection over a particular antibody drug.¹⁶⁸

There are several alternative methods of antibody drug protection that still involve the patent process yet avoid the broad functional claims that are no longer permitted under the *Amgen* decision. These methods, if utilized by companies seeking protection of their antibody drugs, could still allow for patent protection, although the claims within the patent application would not be broad or merely functional. One example of an alternative method of antibody drug protection utilizing the patent system would be to patent a specific antibody sequence and antibody sequences that share a certain level or similarity or homology with those original antibody sequences.¹⁶⁹ This process of patenting through homology could provide a method of protecting the sequence that creates the antibody itself.¹⁷⁰

Another option would be for companies to obtain a patent that protects everything except the antibody itself.¹⁷¹ This patent could include methods of manufacturing the medication, the pharmaceutical composition of the antibody drug, and other aspects of the medication that do not include the antibody itself.¹⁷² However, this alternative is not without flaw, as it too could raise several questions regarding functional claims which could potentially cause issues rooted in the court's decision in *Amgen*.¹⁷³

¹⁶⁶ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

The patent system provides another option for those seeking robust patent protection of a monoclonal antibody medication, the layering process.¹⁷⁴ The concept and process of layering involves both the filing of multiple patents and multiple claim scopes temporarily.¹⁷⁵ Protecting antibody drugs and obtaining patent protections could be achieved in several different ways.¹⁷⁶ For example, the subject matter of each patent “layered” should be claimed using a variety of different formulas which create differences in scope.¹⁷⁷ This way, even if some of the claims are invalidated as a result of a post-grant challenge, the other claims that were presented within the patent application would remain valid.¹⁷⁸ Furthermore, the patent portfolio could be staggered chronologically so that a range of different patent claims are included within the portfolio, thus extending the term in which the patent application was initially filed.¹⁷⁹

Additionally, adding back up claims is another method that can be utilized within the patent process to help increase the patentability of antibodies following the court’s decision in *Amgen* where broad functional claims were deemed to be insufficient to secure patent protection for antibody medication would be adding backup claims.¹⁸⁰ When a patent applicant adds backup claims, they are essentially also including a set of narrower claims within the patent application.¹⁸¹ These narrower claims include various aspects of the antibody such as portions of the antibody’s sequence or combining functional and structural elements within the same claim, which will increase the patent’s chance of withstanding a challenge, and therefore the patentability of the antibody.¹⁸² In adding these backup claims

¹⁷⁴ Joanna Brougher, *Reaching The Post-Amgen High Bar For Antibody Patents* (Apr. 6, 2021), <https://perma.cc/P6AK-UTFM> (last visited Oct. 15, 2021).

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

to the patent application for an antibody drug, companies would be increasing the patentability of that drug as it would magnify the chances that the entire patent is invalidated in a post-grant challenge.¹⁸³

Another example of an alternative method would be to utilize trade secret protection.¹⁸⁴ The U.S. Food and Drug Administration provides twelve years of exclusivity through the trade secret process, and companies may simply hold on to their inventions as trade secrets for this time, skipping the patent process entirely.¹⁸⁵ Although this solution would avoid the risks associated with disclosing information through the patent process in regards to how their antibody medications achieve the desired result, it also presents its own challenges.¹⁸⁶ However, utilizing trade secret protection as an alternative solution to claiming patent protection could raise questions regarding the Biologics Price Competition and Innovation Act, as well as questions regarding biosimilar competition.¹⁸⁷ These questions present a problem as without a patent disclosing exactly what the antibody is designed to bind to, it would then need to be determined if that information regarding the antibody's function, which would potentially be protected as a trade secret, would need to be disclosed through the Biologics License Application approval process.¹⁸⁸ Additionally, it would require a determination of whether or not biosimilars would or should have access to that potentially protected information or not.¹⁸⁹ Protecting antibody medications through trade secret protection presents a problem as it could prevent the dissemination of information and advancements in regard to future antibody medication developments. Preventing information about future antibody medications from being shared would go against the further production of science and the overall goal of improving medications for future use. The issues caused by protecting antibodies with trade secret protection demonstrates that although the patent process regarding antibody medications will prove to cause difficulties for companies looking to patent medications in the future, alternative solutions

¹⁸³ *Id.*

¹⁸⁴ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

may not prove to be the best solution for combating these difficulties, as they could create a variety of additional problems.

One final alternative method outside of the patent process of claiming an entire genus of antibodies to seek protection over an antibody drug that perhaps would otherwise have a low patentability is an accession deposit. An accession deposit occurs when a company takes a sample of the antibody for which they are seeking protection and deposits this sample at an accession deposit organization.¹⁹⁰ Then, the company would use that deposit at the accession deposit organization as a reference for their patent claims in the process of patenting the antibody.¹⁹¹ This process is rarely done and, likely would not occur; however, it still is a potential option that a company could use when seeking an alternate method of antibody medication protection following the *Amgen* decision.¹⁹²

Ultimately, these alternative methods to the new standards for monoclonal antibody medication patent protection in the wake of the *Amgen* decision all have benefits as well as downsides, and each method of protection is associated with varying levels of risk. Although some companies may choose to seek alternative methods or layer in additional protections to their patent applications so that their antibody drugs will have an increased likelihood of patentability due to the changes and increased difficulties caused by the *Amgen* decision, it is highly unlikely that these changes in patent protections will cause pharmaceutical companies to stop making antibody drugs.¹⁹³ As mentioned previously, antibody drugs are massively profitable, with some bringing in tens of billions of U.S. dollars a year.¹⁹⁴ Although these alternative methods may provide a way for companies to obtain additional patent protection or avoid some of the difficulties of the changes caused by *Amgen*, companies will likely still seek to create and obtain protection for these antibody medications, regardless of their patentability.

How Will the *Amgen* Decision Impact Future Attempts to Patent Antibodies?

¹⁹⁰ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *Id.*

¹⁹⁴ *Id.*

Now that a thorough discussion has occurred in regard to the impact that the *Amgen v. Sanofi* decision has had and will continue to have on the process and patentability of antibodies, one question still remains: how will this decision impact future attempts to patent antibodies for use in medications? As mentioned previously, the debate over whether antibodies can be claimed and protected by a patent broadly at the genus level has been ongoing.¹⁹⁵ Those in support of claiming antibodies at a genus level have based their argument around the idea that since scientists have a tendency to define antibodies based on what they bind to.¹⁹⁶ However, the Federal Circuit, in the *Amgen* decision has strongly indicated, so much so that it can no longer be questioned, that there is no longer an exception present for antibodies, indicating that antibodies can no longer be claimed or under patent protection at the genus level in the way that they were previously.¹⁹⁷ Ultimately, this shift will make it more difficult for patent applicants to obtain patent protection for their monoclonal antibody drugs. However, this increase in difficulty will also help to avoid some of the previously mentioned problems that can occur as a result of permitting genus level patent claims.

As a result of the Federal Circuit's decision in the *Amgen* case, future attempts to patent antibodies will be affected by this shift.¹⁹⁸ Following the *Amgen* decision, companies will no longer be able to define and claim antibodies purely based on function alone.¹⁹⁹ Those looking to patent antibodies moving forward will have to tie their patent claims to the antibody's structure to some degree.²⁰⁰ Including the antibody's structure within a patent claim could be satisfied in a variety of ways, such as identifying particular amino acids that might be substituted within the protein sequence disclosed in the patent application, an exact description of an amino acid sequence, or a percent identity to an amino acid sequence.²⁰¹ Additionally, the antibody's structure could be listed in the claim through the inclusion of the

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 15, 2021).

²⁰⁰ *Id.*

²⁰¹ *Id.*

variable domains of the heavy and light chains.²⁰² These structural claims have always been useful in protecting antibodies that are innovative.²⁰³ It is highly likely that structural claims will continue to be useful in the future for those seeking to patent antibody medications following the *Amgen* decision, as using structural claims eliminates patentability for those who do not adequately disclose the antibody's structure within the patent application and instead base their claims on the antibody's function.²⁰⁴

Moving forward with future attempts to patent antibodies, it has become significantly more important for patent applications to analyze each antibody on a case-by-case basis.²⁰⁵ Antibodies should be analyzed in this way so that patent applicants can determine which features should be claimed, and how the claims can be most effectively made based upon the amount of investment, data, and research pertaining to the antibody available.²⁰⁶ In carefully selecting and analyzing the features to be claimed, companies seeking patent protection in the future can increase the likelihood that at least some, if not all, of the claims made within their patent applications will remain patentable even when the patent faces invalidation.²⁰⁷

Additionally, the court's decision in *Amgen* will make the process of patenting antibodies for use in medications in the future far more expensive than they were previously. The process of developing antibody drugs is incredibly complex and very expensive.²⁰⁸ On average, medications that utilize antibodies cost around 2.6 billion dollars to bring to the market.²⁰⁹ In narrowing how antibodies can be patented with the *Amgen* decision, this process will likely become even more expensive for companies looking to develop new antibody biologics as more research and information is required to satisfy the

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

²⁰⁶ *Id.*

²⁰⁷ *Id.*

²⁰⁸ Dani Kass, *Pharma Giants Tee Up Biologics Innovation Fight At Fed. Circ.* (Aug. 21, 2020) <https://perma.cc/2QNH-7J6D> (last visited Oct. 15, 2021).

²⁰⁹ *Id.*

written and enablement requirements post *Amgen*.²¹⁰ Furthermore, in the process of developing these medications, it is possible that a company may have over 50 promising candidates at a time, which makes it more difficult for that company to know when to file a patent application.²¹¹ This is because the *Amgen* decision requires additional research and information to be presented to satisfy the written and enablement requirements, and if a company waits until they have that much information and have narrowed the promising antibody candidates to only a few, it is possible that someone else may have already filed an application overlapping with those antibody candidates.²¹² If someone had already filed an application overlapping with those candidates, this would lead to a waste of both time and money, making the process of developing antibody based medications more expensive. This increase in cost is simply another hurdle that those attempting to patent antibody drugs in the future will have to overcome.

The *Amgen* decision drastically changed the antibody patenting process and created a plethora of questions that have yet to be answered. These questions have already made it much more difficult for attorneys working within patent law to know or understand exactly what to advise their clients who are hoping to patent antibodies to be used in various medications.²¹³ The process of patenting antibodies is more difficult for attorneys following the *Amgen* decision because, although the Federal Circuit has said that it is theoretically possible to patent an antibody genus, the Federal Circuit has yet to provide an example of where the necessary requirements would be met in order for an antibody genus to be patented.²¹⁴ Instead, the Federal Circuit has provided several instances where the written description and enablement requirements were not satisfied, such as stating that the 26 examples present in the *Amgen* decision and the 300 examples present in the *AbbVie* decision were not sufficient to satisfy these requirements.²¹⁵ Therefore, as the Federal Circuit has not made it clear what is necessary to satisfy the

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

²¹³ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

²¹⁴ *Id.*

²¹⁵ *Id.*

written description and enablement requirements for those seeking patent protection of antibodies to be used in medication, this lack of clarification from the Federal Circuit creates a wide variety of problems for those companies that spend a substantial amount of money creating these medications.²¹⁶ These problems and unanswered questions pose additional hurdles for patent applicants seeking protection over antibody medications. However many of these questions will likely be answered and some of these concepts will continue to receive attention from the court in the future, as issues with antibody drug patent claims continue to arise.²¹⁷

Conclusion

In conclusion, the *Amgen* decision in 2021 drastically changed the U.S. patent system regarding the patentability of antibodies. In *Amgen*, the Federal Circuit held that broad functional claims were not sufficient to satisfy the enablement requirement.²¹⁸ Ultimately, this decision provided a stark contrast to claims where antibodies used in medications had been patented in the past, given that broad functional claims had previously been considered acceptable in satisfying the enablement requirement.²¹⁹ In providing this contrast, the *Amgen* decision raised the bar for protecting antibody inventions as the amount of data required when disclosing and claiming antibodies has significantly increased with the court's decision in *Amgen*.²²⁰ The *Amgen* decision has and will continue to vastly impact the process and patentability of antibodies. inevitably making it more difficult for companies to obtain patents for antibody drugs. As a result of these difficulties created in the wake of the *Amgen* decision, some companies will instead turn to alternative methods to avoid these difficulties. However, the *Amgen* decision also will likely have several positive effects that will ultimately help patients, such as, those relating to competition, innovation, and lowering prices for patients. Moving forward, those looking to

²¹⁶ *Id.*

²¹⁷ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 15, 2021)

²¹⁸ *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1083-84 (Fed. Cir. 2021).

²¹⁹ *Id.* at 1088.

²²⁰ Joanna Brougher, *Reaching The Post-Amgen High Bar For Antibody Patents* (Apr. 6, 2021), <https://perma.cc/P6AK-UTFM> (last visited Oct. 15, 2021).

patent antibodies in the future will instead have to tie their patent claims to the antibody's structure to some degree.²²¹ Additionally, companies seeking patent protection will need to carefully select and analyze the antibody features to be claimed to increase the likelihood that at least some, if not all, of the claims made within their patent applications will remain patentable even when the patent faces invalidation.²²² The *Amgen* decision will also likely increase the cost to companies seeking to develop antibody drugs due to the additional research and information that are now required as a part of the patent application due to *Amgen*.²²³ However, despite these additional difficulties caused by *Amgen* and the shift that it has caused in the process and necessary requirements for patenting antibodies used in medications, pharmaceutical companies will likely still develop and create new antibody medications for years to come. Ultimately, drugs utilizing antibodies are some of the highest grossing drugs in the United States and why would a biologic company stop producing and creating new drugs that gross billions of dollars each year?²²⁴

²²¹ Jane Byrne, *Amgen v. Sanofi ruling: It is time to kiss goodbye to broad, functional patent claims for antibodies*, BioPharma Rep. (Mar. 25, 2021), <https://perma.cc/4WHH-ETCD> (last visited Oct. 15, 2021).

²²² Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).

²²³ Dani Kass, *Pharma Giants Tee Up Biologics Innovation Fight At Fed. Circ.* (Aug. 21, 2020) <https://perma.cc/2QNH-7J6D> (last visited Oct. 15, 2021).

²²⁴ Dani Kass, *Biologics Face Tougher Patent Scrutiny After Amgen Ruling* (Feb. 18, 2021) <https://perma.cc/C9JY-6PPQ> (last visited Oct. 15, 2021).