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Navigating a Multi-Billion Dollar Industry: Protecting Drug-Related Inventions to Further Research and Development

Minal Patel

NAVIGATING A MULTI-BILLION DOLLAR INDUSTRY: PROTECTING DRUG-RELATED INVENTIONS TO FURTHER RESEARCH AND DEVELOPMENT

ABSTRACT

Even with advancements in science and technology, pharmaceuticals continue to find themselves tethered to patent protection guidelines that once ensured revenue would continue to flow and provide funding for the next blockbuster drug or antibodies. However, as the Federal Circuit appears to inch towards unpredictability in the realm of patent validity, challenges involving patenting are imminent. In fact, gaps are forming in the ability of pharmaceuticals to further research and develop drugs. This Note proposes a solution that encapsulates a more precise standard supported by economic and policy rationales to determine patent validity. It begins with the general requirements of patenting and reasons why trade secrecy may be more effective as investments in research and development increase. Next, policy rationales of patent protection versus trade secrecy will be explained using the Juno *case. Lastly, a solution will be proposed for how courts may consider patent validity cases to protect innovation. Overall, this Note aims to highlight the difficulties between choosing patent protection versus trade secrecy and how investment incentives may contribute to the decision, leaning towards the trade secrecy route.*

INTRODUCTION

The heart of a patent is fueled by the vessels of innovation and creativity. As a global leader in research and development (hereinafter, R&D), the United States is at the forefront of supporting and valuing innovation.[1] In fact, this value system manifests itself in the U.S. pharmaceutical industry. The industry spent $83 billion on R&D in 2019, which is nearly ten times as much spent in the 1980s.[2] This modern surge in R&D investment should come as no surprise, considering that the cost of developing a new drug can reach up to more than $2 billion, as seen between 2003 to 2013.[3]

1. Arthur Daemmrich, *Why Does America Prize Creativity and Invention?*, SMITHSONIAN (Nov. 12, 2015), https://www.smithsonianmag.com/innovation/why-does-america-prize-creativity-and-invention-180957256/.

2. *See* Pharmaceutical Research and Manufacturers of America, *2020 PhRMA Annual Membership Survey*, PHRMA (Sept. 14, 2020), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Membership_Survey_2020.pdf.

3. *See* Olivier J. Wouters, Martin McKee, and Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market,* JAMA NETWORK (Mar. 3, 2020), https://jamanetwork.com/journals/jama/fullarticle/2762311.

The finances needed to develop a drug are often justified by the ability to receive a patent to protect the invention.[4] Consequently, invalidating such patents can have serious financial implications. On August 26, 2021, the Federal Circuit reversed a $1.2 billion infringement judgment between Kite Pharma Inc. and Bristol-Myers's Juno Therapeutics, Inc., rendering Bristol-Myers's Juno Therapeutics and the Sloan Kettering Institute for Cancer Research's patent invalid.[5]

Given that a patent is valid for only twenty years from the filing date, the biopharmaceutical industry faces challenges when marketing its drugs for a limited amount of time.[6] When a patent is no longer protected, pharmaceuticals experience significant reductions in revenue from selling that particular drug.[7] This leads to a loss of revenue for R&D.[8] Consistent and continuous R&D is essential since only one in ten compounds makes it to market.[9] The invalidation of patents puts pressure on innovation and creativity since the "strength of intellectual property law is correlated with better economic outcomes."[10] Not only will the bottom line of pharmaceuticals be affected, but also the jobs, goods, and services that comprise the $1.3 trillion biopharma sector industry will be impacted.[11] Alternate methods are necessary to protect the intellectual property concerning antibodies and biomolecules, which are essential for drug development.

In the *Juno Therapeutics, Inc. v. Kite Pharma, Inc.* case and other similar cases, the Federal Circuit's decision revolved around the issues of written description and enablement, which are required in the patent specification.[12] The written description requirement states that the invention must be described sufficiently to the point where a person of ordinary skill in the art (PHOSITA) would understand that the inventor possesses the claimed

4. Susan Decker, *Gilead Wins Reversal of $1.2 Billion Bristol-Myers Decision*, BLOOMBERG (Aug. 26, 2021, 4:28 PM), https://www.bloomberg.com/news/articles/2021-08-26/gilead-wins-reversal-of-1-2b-patent-loss-to-bristol-myers.

5. *Id.*

6. Mark Terry, *Biopharma and Intellectual Property: Protecting One of America's Great Economic Engines*, BIOSPACE (July 24, 2019), https://www.biospace.com/article/biopharma-and-intellectual-property-protecting-one-of-america-s-great-economic-engines/.

7. Henry Grabowski, *Competition Between Generic and Branded Drugs*, *in* PHARMACEUTICAL INNOVATION, INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE, (Frank A. Sloan and Chee-Ruey Hsieh, eds., Cambridge Univ. Press 2007).

8. Henry Grabowski, *Evolving Brand-Name and Generic Drug Competition May Warrant A Revision Of The Hatch-Waxman Act*, HEALTH AFFAIRS (Nov. 30, 2011), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0270.

9. Terry, *supra* note 6.

10. *Id.*

11. *Id.*

12. Melissa C. Santos, Amanda K. Murphy, and Thomas L. Irving, *Be Careful Claiming Trees in the Middle of the Forest-and Be Sure You Win on a Dispositive Issue*, THE NAT'L L. REV. (Apr. 20, 2021), https://www.natlawreview.com/article/be-careful-claiming-trees-middle-forest-and-be-sure-you-win-dispositive-issue.

subject matter.[13] Distinct from the written description requirement is enablement, which states that the disclosure teaches a PHOSITA to make the claimed invention without undue experimentation.[14] It is essential to comply with these requirements separately as it can reduce potential litigation.[15] The Federal Circuit's decision held that the written description requirement was not met since it did not provide adequate details.[16] The Federal Circuit agreed with Kite in that the patent did not describe an invention and would prevent millions of potential patent applications.[17]

In the past decade, multiple cases decided by The Supreme Court of the United States (SCOTUS) and the Federal Circuit have highlighted the difficulty with patenting for biopharmaceutical companies.[18] For example, in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, SCOTUS held that a pharmaceutical company could not be granted the exclusive patent for a DNA gene sequence for simply identifying it.[19] In *Mayo v. Prometheus Labs*, SCOTUS held that the application of natural laws for patents related to the metabolism of a drug is not patent eligible subject matter under U.S. patent law.[20] As detailed in this Note, these rulings show the complexity with which scientific innovations must be handled.

In addition to patent protection, antibodies can also be protected by trade secrecy.[21] The intersection between patent protection and trade secrets is vital to understanding how to protect inventions, considering the recent Federal Circuit decisions.[22] The value of patent protection remains imperative in a society built on innovation, but trade secrecy may be a strong alternative for ensuring that the public is able to continue benefiting from the inventions of pharmaceuticals.[23] This Note argues that the written description standard as utilized by the Federal Circuit is rigid and unpredictable and that patent validity claims should be analyzed by looking at the reasonableness and burden of requiring such narrowness and specificity in antibody patents. This

13. 35 U.S.C. § 112.

14. *Id.*

15. Santos, *supra* note 12.

16. Dani Kass, *The Latest Fed. Circ. Antibody Rulings You Need to Know*, LAW360 (Sept. 2, 2021, 8:59 PM), https://www.law360.com/ip/articles/1418495/the-latest-fed-circ-antibody-rulings-you-need-to-know?spotlight=1.

17. Decker, *supra* note 4.

18. *See generally* Kass, *supra* note 16.

19. *Case Study: Association for Molecular Pathology v. Myriad Genetics, Inc.*, WASH. UNIV. IN ST. LOUIS SCHOOL OF L. (July 24, 2014), https://onlinelaw.wustl.edu/blog/case-study-association-for-molecular-pathology-v-myriad-genetics-inc/.

20. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

21. Nicholas J. Landau, *Court Decision Means that Antibody Patenting Is Not Getting Easier*, THE NAT'L L. REV. (June 30, 2021), https://www.natlawreview.com/article/court-decision-means-antibody-patenting-not-getting-easier.

22. Anatole Krattiger, *Intellectual Property Management in Health and Agricultural Innovation: a handbook of best practices*, MIHR, (2007), https://www.ipmall.info/sites/default/files/hosted_resources/IP_handbook/iphandbook_volume_2.pdf.

23. *Id.*

Note emphasizes the necessity of aligning economic and policy rationales with the function of patents to encourage innovation.

This Note begins with Part I, which explains the general requirements of patenting set forth by the United States Patent and Trademark Office (USPTO), focusing on the written description and enablement requirements to show its recent evolution and impact on decisions in biopharmaceutical cases. Further, Part I will explain the advantages and disadvantages of trade secrecy, along with the criteria relied on by the courts. Part II will delve into greater detail surrounding the *Juno* case to show the difficulty drug companies will face going forward for similar patent protections. Part III will highlight the policy rationales of patent protection versus trade secrecy. It will also show the investment incentives underlying these policies to explain how trade secrecy may serve as a better alternative to patent protection. Part IV will propose a solution for how courts should treat patent validity cases and offer a new standard based on policy rationales, the principles of trade secrecy, and the risk to investments in innovation.

I. BACKGROUND ON INTELLECTUAL PROPERTY LAW

A. THE INNER WORKINGS OF PATENT PROTECTION

A patent granted by the USPTO is valid for a term of twenty years from the date on which the patent application was filed.[24] This Note focuses on utility patents that are granted to inventors of any new and useful process, article of manufacture, the composition of matter, or any new and useful improvement.[25] To receive a patent for an invention, it must be useful, novel, nonobvious, and sufficiently disclosed in a patent application.[26] Upon satisfaction of these initial requirements, enablement, written description, and the best mode of carrying out the invention must also be met.[27]

The enablement requirement states that the specification will include the manner and process of making and using the invention.[28] Concerns with enablement are evident in the *Amgen v. Sanofi* case, where Sanofi argued that "there are millions of antibody candidates within the scope of the claims, the disclosures do not provide sufficient guidance, antibody generation is unpredictable, and practicing the full scope of the claims requires substantial

24. *General information concerning patents*, U.S. PAT. AND TRADEMARK OFF., https://www.uspto.gov/patents/basics/general-information-patents (last visited Oct. 7, 2021).

25. *Id.*

26. Christopher A. Michaels, *Biotechnology and the Requirement for Utility in Patent Law*, 76 J. PAT. & TRADEMARK OFF. SOC'Y 247 (1994).

27. 35 U.S.C. § 112, *supra* note 13. Although not analyzed in this Note, the best mode requirement asks if at the time of filing the application, the inventor possessed a best mode for practicing the invention. If the inventor did possess a best mode, the question becomes whether the written description details the best mode so that a PHOSITA would be able to practice the invention.

28. *Id.*

trial and error."[29] Additionally, the written description requirement is especially crucial in the biotechnology (hereinafter, biotech) sector since its purpose is to ensure that claims do not "overreach the scope of the inventor's contribution to the field of art as described in the patent specification."[30] Courts have interpreted the written description requirement to mean inventions involving a chemical genus must contain a precise definition, which may include a structure, formula, or chemical name.[31]

B. THE INNER WORKINGS OF TRADE SECRET PROTECTION

An alternative to patent protection with the USPTO is trade secrecy. Trade secret is defined by the Uniform Trade Secrets Act (UTSA) as information that derives independent economic value from being unknown to others who can obtain economic value from its disclosure and is the subject of reasonable efforts under the circumstances to maintain its secrecy.[32] Courts have turned to factors such as: (1) the extent to which information is known outside of the business and to employees and others in the business; (2) measures taken to guard the information's secrecy; (3) the value of the information; (4) amount of effort or money expended in developing the information; and (5) the ease or difficulty with which the information could be acquired or duplicated.[33] Since trade secret protection is no longer available once the trade secret is known to the public, including if a competitor reverse engineers or ascertains the trade secret on its own, companies are constantly weighing whether patent or trade secret protection are appropriate paths to take.[34]

Protection for pharmaceutical trade secrets can cover an extensive list of information. Categories include testing procedures and protocols, manufacturing methods, test results, product designs, customized client lists, market analyses, pricing and marketing information, and business strategies.[35] Due to the nature of the pharmaceutical industry, partnerships with other companies, hospitals, and research organizations often lead companies to share proprietary information to assist in manufacturing and distributing their drugs.[36] This can cause difficulties in keeping the

29. Amgen Inc. v. Sanofi, 987 F.3d 1080, 1085 (Fed. Cir. 2021).

30. Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1337 (Fed. Cir. 2021) (quoting Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1353–54 (Fed. Cir. 2010)).

31. *Id.* at 1335.

32. UNIF. TR. SECRETS ACT § 1(4), 14 U.L.A. 372 (1985).

33. Krattiger, *supra* note 22.

34. Mike Fuller, *Trade Secrets or Patents?*, LIFE SCIENCE LEADER (May 1, 2020), https://www.lifescienceleader.com/doc/trade-secrets-or-patents-0001.

35. Laurie Carr Mims and Maya Perelman, *Trade-Secret Vulnerabilities: Recent Hacking Schemes Highlight the Need to Protect Proprietary Pharmaceutical Information*, BIOPROCESS INT'L (Apr. 16, 2021, 7:40 PM), https://bioprocessintl.com/business/intellectual-property/recent-hacking-schemes-highlight-the-need-to-protect-pharmaceutical-trade-secrets/.

36. *Id.*

information secret, especially in countries where protections for pharmaceutical trade secrets are not as widespread.[37] Countries vary in their trade secrecy level of protection for pharmaceutical trade secrets.[38] In fact, the U.S. Department of Justice has stated that the trade secrets of American companies are affected by theft and has "called attention to both the 'misuse of information submitted by trade secret owners to government entities in other countries and the difficulty in obtaining effective remedies following such misuses."[39] When dealing with international countries, it is valuable to keep in mind the pharmaceutical trade secret protections that are offered and the strength of their protection.

The idea of reverse engineering is a major disadvantage of trade secret protection.[40] The Defend Trade Secrets Act (DTSA) states that reverse engineering is allowed under federal trade secret law.[41] However, if the invention was stolen or obtained through improper means, then trade secret misappropriation may exist, and reverse engineering may be deemed impermissible.[42]

Under trade secret protection, owners are given the right to prevent the information from being disclosed, acquired, or used by competitors in a way that is against honest commercial practice.[43] This may include industrial or commercial espionage, breach of contract, breach of confidence, or inducement to breach.[44] Trade secret law provides a deterrent and remedy against competitors taking a company's research and using it to their advantage, which allows companies to secure the investments it has made in R&D.[45]

Trade secrets are often protected using nondisclosure agreements (NDAs).[46] This legally binding contract between the pharmaceutical and company employees explicitly enumerates what must not be disclosed.[47]

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37. *Id.*

38. *Id.*

39. *Id.*

40. *See* Fuller, supra note 34.

41. Katherine Prescott and Qiuyi Autumn Wu, *Is "Reverse Engineering" Misappropriation of Trade Secrets?*, JDSUPRA (July 31, 2020), https://www.jdsupra.com/legalnews/is-reverse-engineering-misappropriation-96161/.

42. *Id.*

43. *Frequently Asked Questions: Trade Secrets*, WORLD INTELL. PROP. ORG., https://www.wipo.int/tradesecrets/en/tradesecrets_faqs.html (last visited Sept. 21, 2022).

44. *Id.*

45. Mark F. Schultz, *Trade Secrecy and COVID-19*, GENEVA NETWORK (Jun. 22, 2022), https://geneva-network.com/wp-content/uploads/2021/09/Trade-secrets-and-Covid-19-1.pdf.

46. Brian Farkas, *Trade Secret Basics FAQ: What every business owner should know about trade secret law.*, NOLO, https://www.nolo.com/legal-encyclopedia/trade-secret-basics-faq.html (last visited Sept. 21, 2022).

47. *See* Mims, *supra* note 35. To mitigate the risk that a trade secret will be revealed, especially in the pharmaceutical industry, it is crucial to advise and train employees, partners, and vendors on how critical it is to secure confidential information, ensure that company insiders and former employees do not disclose unauthorized information, establish confidentiality policies, monitor

NDAs must be detailed to ensure that there are no misunderstandings regarding what must be kept a secret under the agreement.[48] Since trade secrets are often used to protect internal information as opposed to patents, which are used for external protection, trade secret protection may not be as beneficial as patent protection to prevent competitors from stealing information.[49]

If a trade secret is stolen, an injunction to stop a competitor from using the information for profit may be obtained.[50] An injunction allows legal action to be taken against the competitor for theft.[51] Taking legal action in a trade secrecy case can be costly and may negatively impact the publicity surrounding a company.[52] Courts value the weight a company gives to protecting its own trade secrets, which is why companies must act with promptness and diligence in these types of cases.[53] A decision by the court can include gaining an award for damages, lost revenue, attorney fees, and possibly punitive damages.[54]

C. TWO COMPLEX ROUTES: PATENT PROTECTION OR TRADE SECRECY

Considering that both patents and trade secrets protect inventions worth billions of dollars, choosing which route to take may prove to be extremely difficult. Often generic competition does not arise even after the patent exclusivity period ends.[55] The reason for this is that the pharmaceutical company is able to keep its process undisclosed through trade secrecy.[56] If a competitor does claim to have succeeded in creating a drug or process held under trade secret protection, the pharmaceutical can launch an investigation, resulting in the court issuing a judgment against the competitors to halt using

employee access and use of confidential documents, and prepare to take action through legal remedies for the trade secret that is threatened. *Id.*

48. Jean Murray, *How to Protect Your Business's Trade Secrets*, LIVEABOUT (July 21, 2021), https://www.liveabout.com/how-to-protect-your-trade-secrets-4590019.

49. *Id.* (demonstrating that patenting is helpful in cases where one thinks that their information has been stolen which provides the leverage to file a lawsuit).

50. *Id.*

51. *Id.*

52. Ben Natter, *The Defend Trade Secrets Act: An Overview and Key Developments*, JDSUPRA (July 16, 2020), https://www.jdsupra.com/legalnews/the-defend-trade-secrets-act-an-39692/.

53. Murray, *supra* note 48.

54. *Id.*

55. Orly Lobel, *Filing for a Patent Versus Keeping Your Invention a Trade Secret*, HARV. BUS. REV, (Nov. 21, 2013), https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret.

56. *Id.* A simplified example of this is the creation of the Coca-Cola formula. The recipe has been kept a secret for more than 100 years and is only accessible to a handful of people. Essentially, keeping the formula hidden as a trade secret allows the company to continue using it without competitors receiving access to the formula after what would have been 20 years if it were filed as a patent. *Id.*

the trade secret.[57] If the invention has been useful for more than twenty years, it may be beneficial to take the trade secrecy route.[58] However, this must be weighed against the possibility that competitors can reverse engineer it.[59] Since it is difficult in antibody patent cases and other drug-related inventions to be exceedingly specific, filing a patent gives inventors the advantage of patenting the broad concept (however, as evident in recent antibody patent cases, this can lead to patent invalidation) as compared to trade secrecy which focuses on the production details.[60] The issue with deciding which route to take is further complicated by the fact that it is uncertain which invention will make billions of dollars in profit until after a patent application is filed or it is kept as a trade secret.[61]

II: RECENT PRECEDENT

A. THE *JUNO* DECISION

The recent Federal Circuit decision in *Juno* highlighted the importance of the written description requirement.[62] In this case, in which a $1.2 billion damage award for patent infringement was reversed, the court found that without sufficient additional information in the disclosure of the patent, "no reasonable jury could find the inventors satisfied the written description requirement."[63] The patent claim at issue involved a nucleic acid polymer encoding a three-part chimeric antigen receptor (CAR) for a T cell.[64] Kite used CAR to target lymphoma and leukemia cancer cells, which led Juno to sue Kite for infringement of their patent.[65] Kite filed a counterclaim stating that the claim was invalid for failing to satisfy the written description requirement.[66] According to the court, the written description requirement is satisfied in the patent specification when it demonstrates to a PHOSITA that the particular species of single-chain antibody variable fragments (scFVs) would bind to a representative number of targets.[67] The Federal Circuit's standard for determining whether the written description requirement is satisfied is for the patent to (1) affirm a correlation between structure and function, or (2) disclose "a number" of species representative of the entire

57. *Id.*
58. *Id.*
59. *Id.*
60. *Id.*
61. Orly Lobel, *Filing for a Patent Versus Keeping Your Invention a Trade Secret*, HARV. BUS. REV, (Nov. 21, 2013), https://hbr.org/2013/11/filing-for-a-patent-versus-keeping-your-invention-a-trade-secret.
62. *Juno Therapeutics, Inc.*, 10 F.4th at 1334.
63. *Id.*
64. *Id.* at 1333.
65. *Id.* at 1334.
66. *Id.* at 1336.
67. *Id.*

genus.[68] Here, the court found that the Juno patent did not include the required representative number of species in the genus needed for validity.[69]

The *Juno* case shows the painstaking process of protecting biological inventions through patents.[70] Recently, courts have rejected even narrow claims due to their invalidity under the written description requirement.[71] Patents for biological sequences may meet the written description requirement by ensuring that numerous representative species of the generic biological sequence are disclosed, and the structural feature within the sequence gives rise to the function identified.[72] This requirement for biological sequences is seen in patents for antibodies.[73] Biotech companies who were previously granted patents that covered the group of antibodies that attached to a particular target, instead of a specific antibody by the USPTO, face the issue of narrowing their antibody patent claims.[74] In fact, the recent changes in science and technology have resulted in this requirement for narrower claims to retroactively harm biotech companies with existing antibody patents. The issue arises out of the fact that antibodies are structurally complicated, and a patent based on an antibody's sequence can be slightly altered to create a new antibody with the same function.[75] This gives competitors an opportunity to use the slightly changed antibody to their advantage.[76]

B. ANTIBODY CASES: IMPACT ON FUTURE PATENT PROTECTION

The U.S. Court of Appeals for the Federal Circuit invalidated Amgen's antibody patent, which began the recent backlash in the legal community over this major antibody patentability decision.[77] The Amgen patent was too broad since it covered antibodies that were not actually invented.[78] The claim defined the antibodies in broad functional terms instead of by their molecular

68. Krisha Yadav-Rajan, *Patenting Antibodies: A Complication in Written Description Jurisprudence*, 21 DEPAUL J. HEALTH CARE L. 21, 24 (May 2020), https://via.library.depaul.edu/cgi/viewcontent.cgi?article=1381&context=jhcl.

69. *Juno Therapeutics, Inc*., 10 F.4th at 1334.

70. Douglas J. Bucklin, *$1.1 Billion Dollars Washed Down the Written Description Drain*, VOLPE KOENIG L. (Aug. 27, 2021, https://www.vklaw.com/ImagineThatIPLawBlog/1-1-billion-dollars-washed-down-the.

71. *Id.*

72. *Id.*

73. Heidi Ledford, *Rush to protect billion-dollar antibody patents*, NATURE (May 31, 2018), https://media.nature.com/original/magazine-assets/d41586-018-05273-z/d41586-018-05273-z.pdf.

74. *Id.*

75. *Id.*

76. *Id.*

77. Kass, *supra* note 16.

78. Sheena Linehand, *Amgen v. Sanofi: narrowing the scope of protection for antibody inventions?*, PHARMATIMES MAGAZINE (Apr. 2021), https://www.pharmatimes.com/magazine/2021/april_2021/divided_opinion.

structure.[79] The enablement requirement came into play in this case.[80] Amgen argued that a skilled practitioner could create all the antibodies within the scope of the patent by following a roadmap or by making slight changes to the examples defined structurally.[81] Sanofi claimed that within Amgen's patent, there are millions of antibody candidates, which would entail undue experimentation to establish if they satisfy the claimed functions. The court found that Amgen's patent claims did not meet enablement standards due to being too broad, especially because it would involve undue experimentation to ascertain the limits of the patents' claim.[82]

The outcome of these cases has pointed to the risks and uncertainties surrounding antibody patents.[83] Recommendations for ensuring that antibody patents are upheld emphasize including as much detail and data about the structure and function of the antibodies in the patent specification.[84]

Patenting innovation can be complex, especially in terms of receiving protection for genetic research where similar complications seen in patenting antibodies arise.[85] In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the court held that simply identifying a certain DNA gene sequence does not adequately grant the inventor an exclusive patent for the sequence.[86] Essentially, Myriad Genetics was granted patents related to the BRCA1 and BRCA2 genes, which increase the risk of women developing cancer.[87] Since validating these patents would indicate that Myriad Genetics owned the genes, scientific progress would be hindered.[88] Therefore, SCOTUS held that nothing was created.[89] It stated that separating the gene from the genetic material is not an act of an invention.[90] This case shows that only inventions that result from human innovation and creation should be patentable.[91] In fact, a crucial takeaway from this case is that innovations which are created for the public good should be patentable in comparison to those simply made for private gain.[92]

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79. *Id.*
80. *Id.*
81. *Id.*
82. Kass, *supra* note 16.
83. Cristopher E. Loh, *Antibody Claims: Patent Eligibility and Written Description Issues*, LEXISNEXIS (Mar. 10, 2020), https://www.lexisnexis.com/lexis-practical-guidance/the-journal/b/pa/posts/antibody-claims-patent-eligibility-and-written-description-issues.
84. *Id.*
85. *Case Study: Association for Molecular Pathology v. Myriad Genetics, Inc.*, *supra* note 19.
86. *Id.*
87. *Id.*
88. *Id.*
89. Tobin Klusty and Richard Weinmeyer, *Supreme Court to Myriad Genetics: Synthetic DNA is Patentable but Isolated Genes Are Not*, AMA J. ETHICS (Sept. 17, 2015), https://journalofethics.ama-assn.org/article/supreme-court-myriad-genetics-synthetic-dna-patentable-isolated-genes-are-not/2015-09.
90. *Id.*
91. *Id.*
92. *Id.*

In a similar SCOTUS case, the court held that patents that are related to the metabolism of a drug, essentially the application of natural laws, were not patent eligible subject matter under U.S. patent law.[93] *Mayo v. Prometheus Labs* was one of the earlier cases that began changing how the patent eligible subject matter was treated.[94] After *Mayo* was decided, there were concerns that various pharmaceutical inventions would be invalidated, considering that many treatments and methods are, at the core, natural phenomena.[95]

III: POLICY RATIONALES AND INCENTIVES TO INVEST IN INVENTING

A. POLICY RATIONALES: PATENT PROTECTION VS. TRADE SECRECY

Patents are unique in that they are often seen as offensive weapons. For twenty years, a competitor is unable to make, use, or sell the invention.[96] However, at what cost is patent protection achieved? Due to the technical nature of patent applications, the process is expensive and time consuming.[97] Despite this, patents provide strong protection since they can prevent competitors from reverse engineering and using the invention to their own advantage.[98] A disadvantage of patents is that they can discourage inventors from additional research on an already existing patent since it cannot be commercialized if it infringes on the first patent.[99]

Various scholars have argued that patent rights should be significantly weakened.[100] Scholars argue that given the evolving nature of new technology, the research, development, and innovation costs involved with patenting are drastically reducing.[101] In fact, they assert that the need for the patent system itself has decreased.[102] In terms of pharmaceutical drugs, it is argued that computer-based technologies can help identify principal

93. *Mayo Collaborative Servs.*, 566 U.S. 66 (2012).

94. Geoff Biegler, Megan Chacon, Dalia Kothari, *Life Sciences Patent Eligibility "101": Mayo at Five*, FISH & RICHARDSON (Sept. 2017), https://www.fr.com/wp-content/uploads/2017/09/Life-Science-Patent-Eligibility-101.pdf.

95. *Id.*

96. Fuller, *supra* note 34.

97. *Trade Secrets vs Patents: Which Approach Is Right For You?*, MORNINGSIDE, (Feb. 18, 2021), https://www.morningtrans.com/trade-secrets-vs-patents-which-approach-is-right-for-you/.

98. *Id.*

99. Lucas S. Osborn, Joshua M. Pearce & Amberlee Haselhuhn, *A Case for Weakening Patent Rights*, 89 ST. JOHN'S L. REV. 1185 (2015).

100. *Id.*

101. *Id.*

102. *Id.* (looking at the issue from a technological standpoint, in that innovation has allowed people to work quicker and faster in areas that were previously more complex and time consuming).

compounds for potential future drugs, resulting in cost reductions associated with patents and ultimately, the diminished value of the patent itself.[103]

Trade secrets, on the other hand, can cover any information that has potential economic value and can have an infinite lifespan, if never known to the public.[104] A trade secret does not have filing, legal, or patent translation fees.[105] Unlike patents, no government agencies regulate trade secrets.[106] Given that the value of trade secrets for U.S. publicly traded companies is five trillion dollars, this type of protection makes up a large portion of a company's intangible assets.[107]

Trade secrecy may also be a push in the right direction since it shows that competitive behavior should be discouraged, and it dissuades from acting in bad faith.[108] This type of protection may be problematic since it is beneficial only for developing information that is able to be kept secret.[109] Despite this issue, keeping a secret does not necessarily mean that no one can know about the invention.[110] In fact, trade secrecy emphasizes the importance of being selective about who has access to the information.[111] Essentially, trade secrecy can prove beneficial if it is used in a collaborative and selective way.[112]

It is necessary to balance policy rationales because pharmaceuticals develop their strongest inventions when there is competition [113] Scholars have argued that allowing companies to hide behind the twenty-year exclusivity period prevents increased competition and innovation from occurring.[114] However, this is not evident for patents that already exist since pharmaceuticals have spent exorbitant amounts of capital to further research.[115] Pharmaceuticals are motivated to maximize the value of their patent regardless of whether it can be taken by competitors.[116] Therefore, it appears that for future protections, trade secrecy may be a strong option since

103. Thomas Watson, *Carbons Into Bytes: Patented Chemical Compound Protection in the Virtual World*, 12 DUKE L. & TECH. REV. 26, 40 (2014).

104. Fuller, *supra* note 34.

105. *Trade Secrets*, *supra* note 97.

106. *Obtaining IP Rights: Trade* Secrets, WORLD INTELLECTUAL PROP. ORG, https://www.wipo.int/sme/en/obtain_ip_rights/trade_secrets.html (last visited Sept. 21, 2021).

107. Leonard I. Nakamura, *Intangible Assets and National Income Accounting: Measuring a Scientific Revolution*, (Fed. Rsrv. Bank of Phila., Working Paper No. 09-11, 2009).

108. JOHN R. THOMAS, CONG. RSCH. SERV., R41391, THE ROLE OF TRADE SECRETS IN INNOVATION POLICY (2014).

109. Michael P. Simpson, *The Future of Innovation: Trade Secrets, Property Rights, and Protectionism—An Age-Old Tale*, 70 BROOK. L. REV. 1121 (2005).

110. Schultz, *supra* note 45.

111. *Id.*

112. *Id.*

113. Osburn, *supra* note 99.

114. *Id.*

115. *Id.*

116. *Id.*

pharmaceuticals would still try to gain the fruits of the investment regardless of whether there is competition.

B. INVESTMENT INCENTIVES UNDER PATENTS AND TRADE SECRETS

The core of the patent system is that it provides inventors with the incentive to invent.[117] Scholar Edmund Kitch proposes that patents provide owners with the "incentive to make investments to maximize the value of the patent without fear that the fruits of the investment will produce unpatentable information appropriable by competitors."[118] Essentially, patents are valuable even after they expire.[119] In addition to this reasoning, there are many economic justifications for the patent system.[120]

Patent inventions are seen as markers of industrial progress.[121] The protection the patent system provides allows pharmaceuticals to invest in the invention process because the end creation will not be easily copied by competitors.[122] The patentee pays the price of disclosure through their patent specification, but in exchange receives twenty years of exclusivity.[123] This amount of time aligns with the economic consequences resulting from losing exclusivity after the patent protection expires, because it gives pharmaceuticals enough time to profit from their invention to justify what was initially invested in the process.[124] The temporary monopoly of a patent is warranted by the extraordinary profits that pharmaceuticals and inventors expect.[125]

Patents are imperative as fundamental drivers of discovery and investment within the economic ecosystem of biopharmaceuticals.[126] A typical R&D process can take more than ten years to accomplish, with only 1 in 8 drug contenders passing clinical testing.[127] Biopharmaceuticals must

117. *Id.*

118. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 276 (1977).

119. Osborn, *supra* note 99.

120. *Id.*

121. *Justification for the patent system*, EUROPEAN PATENT ACADEMY (May 7, 2018), https://e-courses.epo.org/wbts_int/litigation/Justification.pdf.

122. *Id.*

123. *Id.*

124. *Id.*

125. Economists from the early 1900's have understood anticipated profit to be one of the reasons that inventors take on research and experimentation at such a great magnitude. The risk factor is rationalized by the fact that inventors must have the chance to gain profits that overwhelmingly surpass their investments. *See* Adam Karbowki & Jacek Prokop, *Controversy over the economic justifications for patent protection*, ECONSTOR (Sept. 19, 2013), https://www.econstor.eu/bitstream/10419/127476/1/ICOAE_Karbowski.pdf.

126. Henry G. Grabowski, Joseph A. DiMasi, & Genia Long, *The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation*, HEALTH AFFAIRS (Feb. 2015), https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2014.1047.

127. THOMAS, *supra* note 108.

take advantage of the patents received for the top selling drugs and market them strategically over the twenty-year patent term because there is a great risk of failure.[128] In support of the Federal Circuit's decisions, it may appear rational that awarding an inventor too broad a scope of rights for a patent can lead to an economically unjustified patent protection. However, this is only applicable to poorly created patent protections that do not encompass innovation.[129] If the patent is impeding the development of a certain area of the market or industry, it is economically beneficial to invalidate the patent.[130]

Similarly, trade secrets provide an incentive to innovate since companies can immediately reap the benefits of their investments.[131] Trade secret law can be economically justified given that the loss is essentially encompassed by only accidental disclosure, undetected misappropriation, and loss due to insufficient protection.[132] Therefore, protecting a patent with reasonable efforts will have lower economic costs than if there was no trade secret law.[133] Companies can invest in preventing accidental disclosure, resulting in less money spent on protecting secrets.[134] As a result, trade secrecy is aligned with the justification that patent protection provides a means of internalizing the benefits of innovation.[135] The price of drugs is often the result of patent thickets.[136] There is evidence that pharmaceuticals have filed around 125 patent applications for a single drug to further extend their monopoly of it beyond the exclusivity period under patent law.[137] In fact, patent laws have been used to receive investments far more than what their initial investment in the research process required, which is attributed to the patent thicket tactic.[138] However, scholars have argued that pharmaceutical industries do not have a patent thicket issue.[139] This is because these companies do not

128. *Id.*
129. Karbowki, *supra* note 125.
130. *Id.*
131. THOMAS, *supra* note 108.
132. Michael Risch, *Why Do We Have Trade Secrets?*, 11 INTELL. PROP. L. REV. 1 (2007).
133. *Id.*
134. *Id.*
135. David D. Friedman, William M. Landes, & Richard A. Posner, *Some Economics of Trade Secret Law*, 5(1) J. OF ECON. PERSP., 61–72 (1991).
136. Patricia Kelmar, *Hacking through thickets of drug patents to get to affordable medicine*, U.S. PIRG (Mar. 31, 2021), https://pirg.org/articles/hacking-through-thickets-of-drug-patents-to-get-to-affordable-medicine/. A patent thicket can be defined as "a dense web of overlapping intellectual property rights that a company must hack its way through to actually commercialize new technology." *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, U.C. AT BERKELEY (Jan. 2021), https://www.nber.org/system/files/chapters/c10778/c10778.pdf.
137. *Id.*
138. *Id.*
139. Stefan Wagner, *Are 'Patent Thickets' Smothering Innovation?*, YALE INSIGHTS (Apr. 22, 2015), https://insights.som.yale.edu/insights/are-patent-thickets-smothering-innovation.

have to obtain access to inventions patented by others when their product can be protected by simply one patent, such as in the case of a single molecule.[140]

IV. REACHING A SOLUTION

A. A LOOK FORWARD

The *Juno* case opened Pandora's box and the uncertainty of biotech patents. After the case was decided, Juno Therapeutics asked the full Federal Circuit to reconsider its reversal of the $1.1 billion judgment against Kite Pharma.[141] Juno's argument was that the written description requirement was too rigidly applied by the panel.[142] Juno argued that the rigid requirement goes against public policy and the statutory text's pursuit to promote the progress of the useful arts.[143] In 2019, when Juno originally sued Kite for allegedly infringing the patent, a California jury rejected Kite's argument that the patent was overly broad.[144] The difficulty of meeting the panel's standard in the Federal Circuit's decision appears to increase with each similarly factual case. Therefore, going forward, a line should be drawn between a patent that is overly broad and one that is specific, meeting the Federal Circuit's standard as recited in the decision.

Fearing that the panel's ruling will impact revolutionary innovation, behemoth biotech company Amgen has decided to back Juno's efforts to restore its $1.1 billion patent judgment.[145] Amgen has stated that it is being forced to perform wasteful and time-consuming work through further scientific experimentation to prevent its patents from being deemed invalid.[146] By calling the court's test unpredictable, Amgen highlights the risk to innovation and states that the standard "needs some adjustment."[147] Biotech innovators are not alone in sharing Amgen's concerns.[148] Nonprofit hospitals such as St. Jude Children's Research Hospital call the standard impossible, stating the difficulty of filing lawsuits over their inventions in the future.[149]

SCOTUS recently declined to hear cases surrounding Section 112, meaning that it is unlikely that decisions in antibody cases will dramatically

140. *Id.*
141. Tiffany Hu, *Juno Urges Fed. Circ. To Undo 'Mischief' In Wiping $1B IP Win*, LAW360 (Oct. 28, 2021, 5:02 PM), https://www.law360.com/articles/1435512/juno-urges-fed-circ-to-undo-mischief-in-wiping-1b-ip-win.
142. *Id.*
143. *Id.*
144. *Id.*
145. Andrew Karpan, *Amgen Backs Juno's Fed. Circ. Bid to Revive $1.1B Judgment*, LAW360 (Nov. 12, 2021, 5:00 PM), https://www.law360.com/articles/1439889/amgen-backs-juno-s-fed-circ-bid-to-revive-1-1b-judgment.
146. *Id.*
147. *Id.*
148. *Id.*
149. *Id.*

change.[150] This most likely means that finding a new way to protect innovations will become necessary. Juno's decision to ask the full Federal Circuit to reconsider its reversal may not be successful, given that the Federal Circuit usually has the last say. In fact, the past fifteen years have consistently seen invalidation of antibody patents based on the written description requirement.[151] Amgen had previously petitioned SCOTUS to remove the written description requirement altogether, but this proved unsuccessful.[152] Given the uncertainty of Section 112, it would appear beneficial for the Federal Circuit to confront patent invalidity claims from a different perspective.

In July 2022, a series of amici were filed by Juno Therapeutics Inc. and Sloan Kettering Institute for Cancer Research, requesting SCOTUS to consider a Bristol-Myers Squibb CAR-T patent case to revive the $1.2 billion verdict against Gilead.[153] Amgen emphasizes that the Federal Circuit has strayed from the law and created a series of subtests without clear instructions on how to pass those tests.[154] Leading medical research institutions and pharmaceutical and biotechnology field leaders continue to warn of the "unfeasible standard" that will threaten the life sciences industry.[155]

B. THE SOLUTION

The decisions by the Federal Circuit requiring narrower claims retroactively harm biotech companies with existing antibody patents. It causes economic disadvantages and contradicts the well-established policy rationale that patent protection incentivizes innovation. Trade secrets are problematic in that if a competitor is able to reverse engineer or reproduce the project, there is no protection available.[156] A recent example of reverse engineering arose when Stanford scientists published a previously unknown mRNA sequence for the Moderna COVID-19 vaccine.[157] The scientists were able to reverse engineer the mRNA sequence of the mRNA for SARS-CoV-2's spike protection that is used in the COVID-19 vaccine from droplets remaining in the used vials.[158] This exemplifies how crucial it is to have a

150. Yadav-Rajan, *supra* note 68.

151. *See generally* Gaston Kroub, *Mending A Fallen Kite*, ABOVE THE LAW (Aug. 31, 2021, 5:47 PM), https://abovethelaw.com/2021/08/mending-a-fallen-kite/.

152. Yadav-Rajan, *supra* note 68.

153. Dani Kass, *Drug Cos., Researchers Back Juno's 'Possession' Petition*, LAW360 (July 18, 2022, 9:19 PM), https://www.law360.com/articles/1512215/drug-cos-researchers-back-juno-s-possession-petition.

154. *Id.*

155. *Id.*

156. *Trade Secrets vs Patents: Which Approach is Right For You?*, *supra* note 97.

157. Jan-Diederik Lindemans, *Reverse Engineering of Trade Secrets: An important issue you should consider when setting up your innovation protection strategy*, CROWELL MORING (Apr. 30, 2021), https://www.crowelltradesecretstrends.com/2021/04/reverse-engineering-of-trade-secrets-an-important-issue-you-should-consider-when-setting-up-your-innovation-protection-strategy/.

158. *Id.*

proper innovation protection strategy, which can include assessing the likelihood of an invention being reverse engineered.[159] Therefore, from the patent perspective, if courts uphold the validity of existing patents by using evidence that a patent could be reengineered or reproduced, this could prevent antibody or biomolecule patents from being invalidated for just the written description or enablement requirements. This rationale can also prove useful for future inventions. Pharmaceuticals should continue to weigh whether they should patent their invention or protect it as a trade secret.

The Federal Circuit has stated that the purpose of patents is to incentivize the creation of actual inventions.[160] The biomedical industry has realized costs in excess of $500 million in a single year for R&D for antibody therapies.[161] This does not include the increasing social and economic costs of creating innovative biomedical technology.[162] In her analysis of the written description requirement, Krisha Yadav-Rajan argues that it would be practical for the legislature to address the written description issue by "enacting a new provision to Title 35 of the U.S. Code to carve out a special exception for written description of antibody patents."[163] While Yadav-Rajan recognizes that the tests for antibody patents lead to inconsistent application of the law, reducing the pressure on courts may be better served by directly implementing the change through the court's approach in patent invalidity claims.

Courts should uphold patents, especially to avoid detrimental impacts on innovation and research, which may threaten incentives to invest in drug discovery for the protection of antibody and other biomolecular patents.[164] Since patents are extremely valuable, especially in driving innovation in the U.S., it may be beneficial for the Federal Circuit to use the *Juno* case to reevaluate how the written description standard is applied for antibody patents.[165] If the case is evaluated by the Federal Circuit in the same way it has been for the past fifteen years, innovation and research incentives will plummet. Before understanding how to use trade secrecy to navigate future patents, courts must formulate a new standard for challenging the validity of patents previously filed with the USPTO.

159. *Id.*
160. Yadav-Rajan, *supra* note 68.
161. *Id.*
162. *Id.*
163. *Id.*
164. Krattiger, *supra* note 22.
165. Yadav-Rajan, *supra* note 68. Yadav-Rajan discusses how the court's decision in *Amgen* changed the way antibody patents are evaluated and how a different case, *MorphoSys*, may be used to determine the written description adequacy standard for antibody patents. Since this note was published before *Juno v. Kite* and the Federal Circuit has not changed the way they think about the written description requirement- perhaps thinking even more narrowly than a few years ago- the *Juno* case may be a step forward in evaluating the standard from a different perspective.

Courts are right to use the written description requirement when the patentee attempts to overclaim in their patent. However, courts should strongly consider exempting antibody patents from the rigidity of this requirement. Antibody patents are extremely complex and, therefore, cannot be specific to the point where they can meet the harsh standards courts require. In fact, since patenting a "claim for 'an antibody capable of binding enzyme X'" is extremely challenging, patenting a method of diagnosis or treatment is much easier, such as a patent for "'a method of detecting enzyme X comprising binding enzyme X to an antibody.'"[166] Therefore, because of this complexity, patenting antibodies continues to be complicated.[167] To evaluate whether a different standard to antibody patents applies, the courts should look to whether requiring (1) affirming a correlation between structure and function or (2) disclosing "a number of species representative of the entire genus" is *reasonable*. This reasonability can be evaluated based on similar antibody patents and the patent's ability to be specific without excluding an important part of the specification. If it is reasonable for the patent to meet either of these written description requirements, the court should proceed to ask whether this patent could have been better served being protected as a trade secret. If it is a patent that could be reengineered or reproduced without difficulty or undue hardship, it is a patent that would best be served under the protection of patent law, since patent law is best suited to protect such patents.[168] Based on this line of reasoning, the Federal Circuit should uphold the patent as valid.

If it is a patent that cannot be easily reengineered or reproduced, it would have been better served to be protected as a trade secret. However, since the patent is already filed with the USPTO, evaluating this patent for validity requires an additional step. This next step would involve asking whether there would be an undue burden on the patentee to have submitted a narrower patent application by investing in further scientific experimentation weighed against the costs of competitors taking the narrow patent, identifying a non-patented species of the invention, and using it without royalties.[169] If the costs

166. Landau, *supra* note 21.

167. Laura Smalley, *Recent District Court Decisions Provide Guidance on Written Description Requirement for Antibodies*, JDSUPRA (May 7, 2019), https://www.jdsupra.com/legalnews/recent-district-court-decisions-provide-98472/ (stating that in *Amgen v. Sanofi*, the jury only found that the claims were not invalid for lack of adequate written description because the claims were extremely narrow where a small number of antibodies bonded to the particular amino acids specified in the claims but were later found invalid upon appeal).

168. Since this reasonability standard would require the court to participate in implementing it, there may be negative implications. Applying this standard may lead to it being applied rather broadly and upholding patents that necessarily should not be patent protected. However, this standard may prove useful in alleviating courts from flooding since challengers can evaluate for themselves prior to litigating the reasonability standard based on previous challenges to patent validity.

169. Karpan, *supra* note 145. This was a concern brought up by the City of Hope National Medical Center, who stated that if research centers were forced to write narrow patent applications,

of requiring a narrower patent are higher than the benefits the patent provides, the patent should be upheld as valid.

The benefits of patent protection should be kept in mind because the *Juno* decision threatens the fundamental importance of being able to protect research and innovation through a patent. Keeping in perspective the policy reasons behind upholding patents, it may be beneficial to look at who exactly the business model of the drug is benefitting.[170] For example, women who were at risk of breast cancer were the target audience of Myriad Genetics when acquiring the patents related to the BRCA1 and BRCA2 genes.[171] Myriad's genetic testing allowed for identifying these genes in women to detect if they were more likely to contract the disease.[172] Before Myriad's work in this field, BRCA testing was uncommon.[173] In this sense, it can be seen as a public good on behalf of Myriad's work. The patent in the *Juno* case was once recognized as one of the most valuable single patents ever issued.[174] In fact, Juno claimed the invention is "capable of curing patients with just months (or weeks) to live."[175] Therefore, it may be beneficial for courts to look at the policy implication of upholding the patent in terms of whether it is for the public good or for the private gain of the pharmaceutical company. It is beneficial for the court to take the steps outlined above, by asking whether there would be an undue burden on the patentee to submit a narrower patent application by investing in further scientific experimentation weighed against the costs of competitors taking the narrow patent, identifying a non-patented species of the invention, and using it without royalties,[176]

licensees would not be interested in buying them, since they would face competition from labs which could "conduct 'routine experimentation to identify a non-patented species [of a biologic invention] that can be used royalty free.'"

170. Implementing policy reasons with consistency requires balancing the purpose the drug will serve with the private gain of the pharmaceutical. The public good should be greater than the private gain.

171. E. Richard Gold and Julia Carbone, *Myriad Genetics: In the eye of the policy storm*, OFFICIAL JOURNAL OF THE AMERICAN COLLEGE OF MEDICAL GENETICS (Apr. 2010), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3037261/.

172. *Id.*

173. *Id.*

174. Kroub, *supra* note 151.

175. Britain Eakin, *Fed. Circ. Wipes Out $1.1B Juno IP Win On Cancer Drug*, LAW360 (Aug. 26, 2021, 12:25 PM), https://www.law360.com/articles/1416605/fed-circ-wipes-out-1-1b-juno-ip-win-on-cancer-drug.

176. A royalty is a compensation to the owner of intellectual property for the right to use or profit from the property. *See Royalty*, LEGAL INFORMATION INSTITUTE CORNELL LAW, (July 2021), https://www.law.cornell.edu/wex/royalty. In the pharmaceutical industry, royalty rates are set by looking at comparable pharmaceutical royalties set in comparable pharmaceutical licensing deals. The significance of royalties arises from the fact that drugs are often licensed to other companies who develop, manufacture, and commercialize them. This allows for the pharmaceutical to make a profit. Narrow patents threaten the ability of pharmaceuticals to receive royalties for inventions that they have discovered but were forced to exclude in their specification due to the Federal Circuit's strict written description requirement. *See How to set pharmaceutical royalty rates*, ROYALTYRANGE (May 2019), https://www.royaltyrange.com/home/blog/how-to-set-pharmaceutical-royalty-rates.

because it provides predictability, ensuring that time and resources guided by these policy rationales are not wasted by invalidating patents based on a rather unpredictable test of the written description.[177]

Scholars have argued that based on the industry a patent is found in, such as technology, pharmaceuticals, or software engineering, the length of the patent should vary.[178] However, the issue is not with reducing or increasing the patent life, considering that pharmaceutical companies continue to benefit economically as seen in Part III, despite the patent length being only twenty years. The real issue lies in how the Federal Circuit and SCOTUS interpret patent validity claims. The solution proposed above may serve as a beneficial step forward in ensuring that the economic and social benefits remain at the forefront.

C. PREFERRING TRADE SECRECY

A policy reason in support of trade secrecy is that it provides an incentive to innovate since companies can immediately take advantage of the benefits of their investments.[179] Unless the court's standard changes with the *Juno* case, biopharmaceuticals should be ready to gear themselves towards the protection trade secrecy provides. As the global race continues to generate the next top selling drug in the form of a monoclonal antibody or other antibody-derived compounds continues, the need to protect antibody manufacturing and production will remain at the forefront.[180] A critique of trade secrecy is that it prevents knowledge from being dispersed and that providing access to research more broadly could allow greater production or innovation to take place.[181] However, this is a misconception.[182] Trade secrets may be shared or licensed selectively and continue to be legally protected.[183] Therefore, collaboration with other research institutions or companies is not prohibited, and trade secrecy remains a strong option to protect commercially valuable proprietary information.[184]

Going forward, biopharmaceuticals should strongly consider using trade secrecy for inventions that are unable to be easily reengineered or

177. Karpan, *supra* note 145. (showing that the methodology used by the court in recent antibody cases is unpredictable and undermines investment-backed expectations according to biopharmaceuticals, hospitals, and research universities).

178. Osburn, *supra* note 99.

179. Thomas, *supra* note 108.

180. Noel Courage and Phil Goldbach, *IP for Ig: Protection for Antibody-Based Assets in the Canadian Market and Beyond*, BERESKIN & PARR LLP (Jun. 4, 2018), https://www.bereskinparr.com/doc/pdf/ip-for-ig-protection-for-antibody-based-assets-in-the-canadian-market-and-beyond.

181. Schultz, *supra* note 45. (showing that the COVID-19 pandemic has aggravated concerns that rival manufacturers are unable to make high-quality generic versions of vaccines because of trade secrecy and a lack of access to important components and manufacturing methods of the vaccines).

182. *Id.*

183. *Id.*

184. *Id.* (revealing that forcing companies to share trade secrets would disrupt partnerships made on a selective basis).

reproduced. However, based on the outcome of *Juno*, it may be prudent to continue using patent protection for antibody inventions that go beyond protecting research results, experimental data, and manufacturing processes.[185] Since information protected by trade secrecy could result in a patentable invention, it is beneficial to keep as much information at the beginning stages of research of a trade secret before patent protection is necessary.[186] In his policy brief, Schultz highlights a study he published for the Organization for Economic Cooperation and Development, where a positive relationship was found between the effectiveness of a country's trade secret protection and investment in innovation.[187] As the biopharmaceutical industry becomes more complicated, especially in the shift to biologics such as monoclonal antibodies, it is crucial to remember that development and manufacturing is a collaborative effort that can be maximized by trade secret protection.[188] Therefore, it is important for companies to weigh the benefits that trade secrecy can provide especially given that it can help further innovation and research, but still protect the investments in R&D.[189] In a country where R&D spending continues to increase, trade secrecy allows for positive economic advantages.[190]

The protection patents provide have also allowed companies to continue investing in R&D.[191] However, how can sales from drugs continue to lead to more R&D when patents lose their protection after twenty years?[192] In fact, 80% of revenue produced by pharmaceuticals from selling "blockbuster" drugs is lost when the patent is no longer protected.[193] Upon losing patent protection, generic competition threatens these companies financially, but becomes beneficial to the public given their low cost and extensive availability.[194] This leads to a loss of revenue for R&D resulting from patent expirations and generic competition.[195] Since trade secrets have no time limit, antibody inventions may be better served by this protection because they are

185. *Id.* (stating that the two broad categories that can be a trade secret are technical information and business and financial information).

186. *Id.*

187. Mark F. Schultz, *Trade Secrecy and COVID-19*, GENEVA NETWORK (Jun. 22, 2022), https://geneva-network.com/wp-content/uploads/2021/09/Trade-secrets-and-Covid-19-1.pdf.

188. *Id.*

189. *Id.*

190. *Id.*

191. CONG. RSCH. SERV., R42399, DRUG PAT. EXPIRATIONS: POTENTIAL EFFECTS ON PHARM. INNOV. (2012).

192. *Id.*

193. Grawboski, *supra* note 7. Blockbuster drugs are popular drugs that generate at least a billion dollars of sales for the pharmaceutical company. Common examples include Lipitor, Humira, and Plavix. *See* James Brumley, *The 15 All-Time Best-Selling Prescription Drugs*, KIPLINGER (Dec. 5, 2017), https://www.kiplinger.com/slideshow/investing/t027-s001-the-15-all-time-best-selling-prescription-drugs/index.html.

194. Grabowski, *supra* note 8.

195. *Id.*

commercially viable for much longer than compared to inventions that are not profitable beyond twenty years.[196]

Many scholars have noted how the change in technology and increasing research and innovation costs have lessened the need for the patent system has decreased.[197] Those scholars have argued that society could be more innovative without patents.[198] Yet, society continues to benefit from sectors that have long lead-times for development and require more R&D funding.[199] The pharmaceutical industry is a prime example of this.[200] People invest in the industry because there are profits to be made; without this benefit, there would be very little incentive to discover new medicines.[201] Considering that the patent system has evolved over the past decade, it has the potential to be used in a more constructive and economical way. Importantly, patent rights prevent competitors from utilizing any research independently discovered or developed.[202] Therefore, antibody and drug-related patents can continue to be of great value and provide security that, unlike trade secret protection,[203] informs competitors they will be brought to court if they are found to be infringing on a patent. The written description standard utilized by the Federal Circuit threatens this benefit provided by patent protection.

The costs of litigating trade secrecy and patent cases have increased dramatically over the past four years.[204] Cases from 2015 to 2019 had inventions with valuations from $1 million to $25 million at risk.[205] Since proving damages is more difficult in trade secrecy cases, they continue to be expensive cases to litigate.[206] Therefore, the specificity required in patent law

196. Hart David Carson LLP, *When to Use Trade Secrets Rather than Patents*, HART DAVID CARSON LLP (Sept. 1, 2020), https://www.hartdavidcarson.com/news/when-to-use-trade-secrets-rather-than-patents/.

197. Osburn, *supra* note 197. These scholars look at the issue from a technological standpoint, in that innovation has allowed people to work quicker and faster in areas that were previously more complex and time consuming.

198. Scholars have stated that the pace of innovation has slowed down due to the increased need to patent all research for companies to receive a profit off their inventions. This does not appear to be the case given that the patent system has allowed for the pharmaceutical industry to become more diversified and has increased competition to allow for the pace of innovation to expand exponentially. *See The Great IP Debate: Do patents do more harm than good?*, SCIENCE BUSINESS (July 28, 2016), https://sciencebusiness.net/news/79887/The-Great-IP-Debate%3A-Do-patents-do-more-harm-than-good%3F (providing the example that Steve Jobs did not think about patents while developing Apple computers, and if he had paid royalties on all the software he worked with, innovation in this area would not have grown at the pace that it did).

199. *Id.*

200. *Id.*

201. *Id.*

202. Schultz, *supra* note 45.

203. *Id.*

204. Dimas Ardian, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, BLOOMBERG (Sept. 10, 2019, 8:01 AM), https://news.bloomberglaw.com/ip-law/costs-soar-for-trade-secrets-pharma-patent-suits-survey-finds.

205. *Id.*

206. *Id.*

can also be seen as applying in trade secrecy cases, where a party must prove exactly what the competitor stole. Despite these costs and difficulties in obtaining evidence in trade secrecy cases, biopharmaceuticals continue to use trade secrets because protecting broad inventions is not stifled by requirements to be specific when protection is initially sought.

In the past year, the Federal Circuit has invalidated several antibody patents.[207] Upholding a patent that requires the written description and enablement standard to be met according to the court's standard has caused difficulties for the pharmaceutical industry.[208] Patenting antibodies and biomolecules, is a complicated process, notwithstanding the complexity of understanding how a molecule's structure contributes to binding the target.[209] Therefore, even if the standard is changed by the court, understanding how to write a patent antibody claim will remain a challenge since the court's decision will continue to rely heavily on the information laid out in the specification.[210]

CONCLUSION

In conclusion, the standard used by the Federal Circuit is unpredictable and should be replaced by the solution proposed above, which aligns with the economic, innovation, and policy rationales shaping society today. If the Federal Circuit does not reevaluate the currently written description requirement on appeal, the protections afforded by trade secrecy will be more effective going forward, especially as investments in R&D continue to rise. The next decade will shape advancements in R&D and choosing ways to navigate the world of protecting inventions will continue to be at the forefront of the largest pharmaceuticals as profitability remains a key consideration.

Minal Patel[*]

207. Kass, *supra* note 16.
208. *Id.*
209. Landau, *supra* note 21.
210. *See generally* Kass, *supra* note 16.

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