

2022

In the Midst of a Global Pandemic: Benefits of a Biomedical Patenting Regime

Amy Q. Nguyen
Southern Methodist University, Dedman School of Law

Recommended Citation

Amy Q. Nguyen, *In the Midst of a Global Pandemic: Benefits of a Biomedical Patenting Regime*, 25 SMU SCI. & TECH. L. REV. 63 (2022)
<https://scholar.smu.edu/scitech/vol25/iss1/5>

This Case Note is brought to you for free and open access by the Law Journals at SMU Scholar. It has been accepted for inclusion in SMU Science and Technology Law Review by an authorized administrator of SMU Scholar. For more information, please visit <http://digitalrepository.smu.edu>.

IN THE MIDST OF A GLOBAL PANDEMIC: BENEFITS OF A BIOMEDICAL PATENTING REGIME

*Amy Q. Nguyen**

ABSTRACT

There has long been a debate centered around genomic and biomedical data patenting. The opposition expresses concern that the patenting of genomic and biomedical data will hinder the manufacturing and distribution of medical and scientific discoveries to those who need them. On the other hand, supporters of patenting genomic and biomedical data explain that patents are beneficial. For example, genomic and biomedical patents allow pharmaceutical companies and research labs to recoup their massive investments in researching and developing new medical and scientific methodologies and technologies. Patents also incentivize these companies to make discoveries to prevent future pandemics and diseases.

In 2020, the COVID-19 pandemic broke out and left the world struggling to create more effective vaccines to combat the virus and its variants. At the center of this battle against the virus, various pharmaceutical companies, such as Pfizer, Moderna, BioNTech, and Arcturus, have been working endlessly to develop possible vaccine candidates for the COVID-19 vaccine. The question of whether these pharmaceutical companies will be allowed the protections afforded by genomic and biomedical patenting to spur more advances in the fields of science and medicine to combat new viruses has come to the forefront once again.

With two landmark Supreme Court cases that discuss the patenting of biomedical data and genomic processes, the U.S. Supreme Court has barred the patenting of isolated DNA and naturally occurring processes. However, amid a global pandemic, there are benefits to patenting biomedical data. The U.S. Patent Regime should allow genomic and biomedical data patenting to encourage innovation and incentivize researchers and scientists by taking measures to broaden the scope of patent-protected subject matters and by adopting aspects of foreign patent regimes, such as Japan's patent regime, to expand the treatment of patent protection and encourage innovation in biotechnology and medicine.

DOI: <https://doi.org/10.25172/smustr.25.1.5>

* Amy Nguyen is a 2023 Juris Doctor candidate from Southern Methodist University Dedman School of Law and is the Associate Managing Editor of SMU's Science and Technology Law Review. She graduated summa cum laude, receiving her Bachelor of Arts in Political Science from the University of Texas at Dallas in 2020. She would like to thank the editors of SMU Science and Technology Law Review for their careful attention and thoughtful improvements.

I. INTRODUCTION

In 2020, the COVID-19 virus, one of the most lethal modern global pandemics, spread to almost every country in the world.¹ In its wake, the COVID-19 pandemic left national economies and businesses crippled with costs, thousands unemployed, overwhelmed healthcare systems, and scrambling national governments trying to tackle the rampaging virus.² Today, almost two years later, the world continues to battle against the virus, which has changed life as we know it and has disturbed our social and economic dispositions.³ Despite the efforts taken to mitigate the harm caused by this global pandemic, millions have lost their lives to the continuously mutating virus.⁴ The world continues to operate in a state of desperation as it struggles to create more effective vaccines to combat the virus and defend against its variants.⁵ Various pharmaceutical companies, including Pfizer, Moderna, BioNTech, and Arcturus, have been developing candidates for the COVID-19 vaccine based on mRNA technology.⁶ For scientific and medical advances to prevent future pandemics, scientists and researchers must continue searching for strains of well-known viruses and new viruses through the protections afforded by genome patenting.⁷ However, in 2020, the Biden Administration announced its support for waiving the patent protections for the COVID-19 vaccines to increase the number of vaccines supplied around the world.⁸ In reaction to that decision, many patent advocates, including Pfizer's CEO, Albert Bourla, warned that waiving the patent protections would create sev-

1. Erin A. Napoleon, *Patent Eligibility: Exploring the Intersection Between Patent Law and Biomedical Data*, 21 U. PITT. J. TECH. L. & POL'Y 116, 117–20 (2021), <https://doi.org/10.5195/tlp.2021.246> [<https://perma.cc/A98R-YL8A>].
2. Lora Jones, Daniele Palumbo & David Brown, *Coronavirus: How the Pandemic Has Changed the World Economy*, BBC NEWS (Jan. 24, 2021), <https://www.bbc.com/news/business-51706225> [<https://perma.cc/N78C-EQLV>]; see also William A. Haseltine, *Overwhelmed U.S. Hospital Systems: A Look into the Future*, FORBES (July 26, 2021), <https://www.forbes.com/sites/williamhaseltine/2021/07/26/overwhelmed-us-hospital-systems-a-look-into-the-future/?sh=213850fc7c62> [<https://perma.cc/56AU-LHND>].
3. Napoleon, *supra* note 1, at 117.
4. *Id.*; *COVID Data Tracker*, CTS. DISEASE CONTROL & PREVENTION, <https://covid.cdc.gov/covid-data-tracker/#casescasesper100klast7days> [<https://perma.cc/P6E7-WXV2>].
5. Napoleon, *supra* note 1, at 117.
6. Mario Gaviria & Burcu Kilic, *A Network Analysis of COVID-19 mRNA Vaccine Patents*, 39 NATURE BIOTECHNOLOGY 546, 548 (2021), <https://doi.org/10.1038/s41587-021-00912-9> [<https://perma.cc/GX8K-UHK7>].
7. Napoleon, *supra* note 1, at 118.
8. Noah Baker & Amy Maxmen, *Coronapod: Waiving Vaccine Patents and Coronavirus Genome Data Disputes*, NATURE PODCAST (May 7, 2021), <https://nature.com/articles/d41586-021-01239-w> [<https://perma.cc/QLF7-LTP9>].

eral adverse consequences in the pharmaceutical industry, including a worldwide race for raw materials used in the production of the vaccines.⁹

There has long existed a debate on the patenting of genomic and biomedical data.¹⁰ Since the beginning of the COVID-19 global pandemic, healthcare advocates, governments, and scholars worldwide have expressed concern that patents would slow the manufacturing of medical supplies, vaccines, equipment, and therapies as well as distribution of supplies to those who really need them.¹¹ On the other hand, countless scientists and researchers have called for patent protection for genomic and biomedical discoveries because patents allow pharmaceutical companies to recoup the massive investments they put into researching and developing.¹² The potential patent protections of genomic and biomedical data act as incentives to spur the development of methodologies and technologies that can prevent future pandemics and foster innovation.¹³ In combating modern pandemics, patent law and protections for genomic and biomedical data have played a significant role in incentivizing vaccine innovation and cures related to viral infections.¹⁴ While many assume that limiting patent protection allows for more vaccines to be produced, this assumption fails to recognize that being allowed to produce vaccines is starkly different from having the ability to produce vaccines to the same degree of effectiveness and safety.¹⁵ Creating clean and safe vaccines requires a high degree of knowledge, experience, and technological infrastructure.¹⁶ Having this knowledge, experience, and technological capability is especially important when producing vaccines based

9. Kevin Breuninger, *Pfizer CEO Opposes U.S. Call to Waive Covid Vaccine Patents, Cites Manufacturing and Safety Issues*, CNBC, (May 7, 2021, 3:55 PM), <https://www.cnbc.com/2021/05/07/pfizer-ceo-biden-backed-covid-vaccine-patent-waiver-will-cause-problems.html> [<https://perma.cc/5WCV-VC5S>].
10. See Timothy Caulfield, E. Richard Gold & Mildred K. Cho, *Patenting Human Genetic Material: Refocusing the Debate*, 1 NATURE REV. GENETICS 227, 227 (2000).
11. Jorge L. Contreras, *COVID-19 as an Example of Why Genomic Sequence Data Should Remain Patent Ineligible*, in COVID-19 LAW AND POLICY PLAYBOOK: LEGAL RECOMMENDATIONS FOR A SAFER, MORE EQUITABLE FUTURE, 137, 137–41 (S. Burris et al. eds., 2021), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3808319 [<https://perma.cc/PB8M-8SRH>].
12. Baker & Maxmen, *supra* note 8.
13. See Napoleon, *supra* note 1, at 118–19.
14. See *id.* at 118.
15. Christoph J. Crützen & Maximilian Kücking, *The Waiver of Patent Protection for COVID-19 Vaccines—on Practicability and Purpose of Such Measure*, MAYER BROWN (July 7, 2021), <https://www.mayerbrown.com/en/perspectives-events/publications/2021/07/ger-the-waiver-of-patent-protection> [<https://perma.cc/TMH8-ME2E>].
16. *Id.*

on the new mRNA technology, such as those produced by Pfizer, Moderna, and others.¹⁷ The new mRNA-based vaccines are significantly more expensive and complex to manufacture than the established vector vaccine.¹⁸ For example, the vaccines are extremely sensitive to variations in temperatures and mostly require a constant set temperature.¹⁹ Due to the unique challenges of manufacturing a COVID-19 vaccine, simply releasing patents will not guarantee that previously inexperienced pharmaceutical manufacturers worldwide will be suddenly able to produce clean and safe vaccines.²⁰

Additionally, a single drug costs about \$1.3 billion to \$2.8 billion to produce.²¹ The government-initiated restriction on patent protections does not consider the complicated and cost-intensive development of drugs.²² It also fails to consider that the research and development of a medicine do not guarantee success.²³ In the worst-case scenario, pharmaceutical manufacturers are expending billions of dollars to gain nothing in return.²⁴ In the face of these multibillion-dollar R&D costs, pharmaceutical companies rely on patents to incentivize them to embark on costly and time-consuming research and development of new, breakthrough drugs.²⁵

Currently, the U.S. Supreme Court has barred patents claiming isolated DNA and other naturally occurring processes.²⁶ However, the Supreme Court has not clearly defined what is and is not included under such a label.²⁷ Therefore, the U.S. patent regime must be modified to grant patents in genomic and biomedical data, encourage innovation, and provide incentives to researchers and inventors.²⁸ This can be accomplished by taking measures to broaden the scope of patent-protected subject matters, specifically, overturning the two landmark Supreme Court cases that discuss the patenting of biomedical data and genomic processes and taking on aspects of other countries' patent regimes.²⁹ This action may result in a more expanded treat-

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*

21. Crützen & Kücking, *supra* note 15.

22. *See id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. Napoleon, *supra* note 1, at 131.

27. *Id.*

28. *Id.*

29. *See id.*

ment of patent protection and encourage innovation in biotechnology and medicine.³⁰

II. HISTORY AND BACKGROUND

The U.S. patent regime does not allow patent protection for inventions that incorporate biological processes even though such inventions might be helpful.³¹ The topic of whether biological processes should be allowed to be patented continues to be hotly debated.³² In 2012 and 2013, the Supreme Court concluded that patents incorporating biological processes must be rejected.³³

In 2012 the Supreme Court, in *Mayo Collaborative Services v. Prometheus Labs., Inc.*, dealt with one of the long-established judicial exceptions of patentability—the laws of nature.³⁴ In a 9-0 decision, the Court answered the question of whether certain types of diagnostic medical tests could be patented.³⁵ The Court established that because the laws of nature are not patentable themselves, natural processes are also not patentable unless they have additional characteristics that “provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations.”³⁶ Additionally, the Court decided that “purely ‘conventional or obvious’ ‘pre-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”³⁷ Things such as “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”³⁸

In 2013, in another landmark case, *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court addressed whether human genes could be patented.³⁹ Writing for the Court, Justice Thomas stated that “laws of nature, natural phenomena, and abstract ideas are not patentable” but are just “basic tools of scientific and technological work that lie beyond the do-

30. *Id.*

31. *Id.*

32. Napoleon, *supra* note 1, at 127.

33. *Id.* at 128.

34. *What Are Mayo and Myriad?*, FISH & RICHARDSON, <https://www.fr.com/what-are-mayo-and-myriad/> [<https://perma.cc/EZP2-2MUB>].

35. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, OYEZ, <https://www.oyez.org/cases/2011/10-1150> [<https://perma.cc/R2SF-PDN2>].

36. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 67 (2012).

37. *Id.* at 79 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

38. *Id.* at 71 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

39. *Association for Molecular Pathology v. Myriad Genetics*, OYEZ, <https://www.oyez.org/cases/2012/12-398> [<https://perma.cc/9M2J-CBE4>].

main of patent protection.”⁴⁰ Patents are designed to promote creation, and patenting such things would inhibit further innovation in science and technology.⁴¹ In arriving at this conclusion, Justice Thomas applied the “markedly different characteristic” test from the case of *Diamond v. Chakrabarty*.⁴² Under the *Diamond* test, the Court concluded that if a subject matter is “‘a product of human ingenuity having a distinctive name, character, and use’” and has “‘markedly different characteristics from any found in nature,’” it is patentable.⁴³

In the cases of *Mayo* and *Myriad*, the Supreme Court created some distinctions between artificial and natural processes by outlining what could and could not be patented regarding genomic DNA, medical techniques, and biomedical data.⁴⁴ These decisions, however, in the landmark cases of *Mayo* and *Myriad* fail to cover every aspect of the question of the patentability of biomedical data—specifically, how much genes have to be modified before they can be patent-eligible and whether the chemical structure or the encoded information of the DNA should be considered for patent eligibility.⁴⁵ The Supreme Court’s decisions sparked protests from advocates of stronger patent protections who now push for the overturning of *Mayo* and *Myriad* in favor of a broader scope of patent-eligible subject matters.⁴⁶

In 2019, two senators, Chris Coons and Thom Tillis, introduced legislation that would have canceled any “implicitly or judicially created exceptions to [patent] subject matter eligibility including ‘abstract ideas,’ ‘laws of nature,’ or ‘natural phenomena’” which would have allowed undiscovered natural substances or genomic sequences to be patented again.⁴⁷ Despite the Coon-Tillis proposal failing to gain legislative support, the outbreak of the COVID-19 global pandemic in 2020 led to renewed calls for increased patent protection of biomedical discoveries, and advocates for increased patent protections blamed lax patents for the lack of reliable diagnostic tests, vaccines, and treatments for COVID patients.⁴⁸ The U.S. Patent and Trademark Office (“USPTO”) created new programs to speed up the examination and issuing of patents covering COVID-19 related inventions.⁴⁹ Senator Sasse introduced

40. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (citing *Mayo Collaborative Servs.*, 566 U.S. at 71).

41. *Id.* at 589–90.

42. Napoleon, *supra* note 1, at 128; *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980).

43. *Myriad*, 569 U.S. at 590–91 (quoting *Diamond*, 447 U.S. at 309–10).

44. Napoleon, *supra* note 1, at 129.

45. *Id.* at 130.

46. Contreras, *supra* note 10, at 137–38.

47. *Id.* at 138.

48. *Id.*

49. *Id.*

legislation that would add ten years to the term of COVID-related patents.⁵⁰ In early 2021, when the Biden Administration first took office, new legislative proposals to strengthen patents began percolating on Capitol Hill.⁵¹

III. THE PROBLEM: CAN PATENTS AND PANDEMICS COEXIST?

Opponents to increased patent protection of biomedical data argue that there is ample evidence to suggest that increased patent protections would be counterproductive.⁵² They also argue that genomic sequence data is an essential research tool that should be broadly available for researchers to address different research questions.⁵³ Making this primary research tool available to researchers will allow for speed and international collaboration when needed.⁵⁴ Additionally, reversing the Supreme Court's holdings in *Mayo* and *Myriad* would enable patent holders to control all uses of a particular genomic sequence, creating significant bottlenecks to effective research and development.⁵⁵ Next, opponents argue that patents discourage advancements, as the lack of competition created by patents leaves patent holders unmotivated to improve their diagnostic tests once a patent is issued, giving the patent holder a monopoly over the subject matter.⁵⁶ Additionally, patents are not needed to incentivize the discovery of genomic sequences because there is extensive support from government philanthropic funding sources.⁵⁷ Private incentives such as patent royalties and procurement payments exist to promote the development of needed technologies.⁵⁸ Finally, opponents argue that patents on genomic sequences increase costs and reduce access to medical innovations because patents enable private firms to have legal exclusivity to increase patient costs, burden healthcare systems, and exclude those in need from critical medical innovations.⁵⁹

Proponents of patenting biomedical data argue that patents give companies that patent genes time to look at the genes without competition from other companies.⁶⁰ Smaller companies, especially those that make significant

50. *Id.*

51. *Id.*

52. *See* Conteras, *supra* note 11, at 139.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. Conteras, *supra* note 11, at 139.

59. *Id.*

60. *Patenting Genes: Pros and Cons*, GENETICS GENERATION, <https://knowgenetics.org/patenting-genes-pros-and-cons/> [<https://perma.cc/2V2Y-6LEW>].

discoveries but lack the financial resources to compete with larger, more established companies, are concerned about increased patent protections.⁶¹ Additionally, patents motivate companies and individuals to invest in patented biomedical discoveries.⁶² Investments provide financial support for the development of valuable innovations.⁶³ It can take millions of dollars to introduce a new drug or biomedical technology to the market.⁶⁴ Most companies do not have this financial resource and have to rely on investors for financial assistance.⁶⁵

The current state of the U.S. patent regime regarding patenting biomedical data and genomic processes and the announcement from the Biden Administration to waive patent protection for COVID-19 vaccines is a problem according to many in the pharmaceutical industry and other patent advocates.⁶⁶ It is especially harmful with the current global pandemic.⁶⁷ First, genomic and biomedical data patents encourage innovation and provide inventive protection to researchers and inventors who seek to introduce new methods of identifying and curing viral infections.⁶⁸ The pharmaceutical industry needs to be motivated by making profits when they make huge investments upfront and it can take many years to continue creating effective vaccines that combat the COVID-19 virus and its variants.⁶⁹ The pharmaceutical industry needs to have sufficient guidance and a more substantial grasp on what is considered patent-eligible and broaden the scope of medical patents in times of increased technology and biomedical innovation and experimentation.⁷⁰ Such changes are essential to encouraging these companies to realize some gain that incentivizes the continuation of such innovation for researching the COVID-19 vaccines and other viruses for future pandemics.⁷¹ The policy decision to waive patent protections on the COVID-19 vaccines raises fear of a dangerous, unwanted precedent.⁷² There is difficulty in providing incentives for the future because patent protections were created to incentivize via short-term monopoly profits so that firms and individuals can

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *See Baker & Maxmen, supra* note 8.

67. *See id.*

68. Napoleon, *supra* note 1, at 131.

69. *See* Napoleon, *supra* note 1, at 122.

70. Napoleon, *supra* note 1, at 131.

71. *Id.*

72. Baker & Maxmen, *supra* note 8.

invest in innovation.⁷³ In the face of a public emergency, this temporary waiver sets a scary precedent that makes firms and individuals doubt whether they will want to invest next time there's an emergency.⁷⁴

IV. THE SOLUTION

It is essential to modify the grant of patents in biomedical data, encourage innovation, and provide inventive protection to researchers and developers to introduce new methods of identifying and curing viral diseases.⁷⁵ This can be accomplished by broadening the patent-eligible subject matter and adopting policies from thriving international innovation centers such as Japan's patent regime.

First, to broaden the scope of patent eligibility, the U.S. Supreme Court should implement the standard that it set out in *Diamond v. Chakrabarty*.⁷⁶ In the 1980 case, in a 5-4 decision, the Supreme Court decided on a landmark case that would impact the biotechnology industry forever.⁷⁷ The Court found that patentable subject matter included "anything under the sun that man makes."⁷⁸ The holding in that case allowed a micro-organism to be patented for being "a product of human ingenuity having a distinctive name, character, and use."⁷⁹ Various genomic processes were patentable under the standard set by *Diamond*.⁸⁰ *Diamond* transformed the biotechnology industry by spurring the advancements of inventions that are beneficial to human life.⁸¹ Applying the *Diamond* Standard would broaden what the Court currently considers patent-eligible, allowing biomedical data and other genomic processes to be qualified as patentable as they are made by man and a product with distinctive characteristics.⁸² Despite the revolutionary effects of *Dia-*

73. Farasat Bokhari, *US-backed vaccine patent pros and cons explained*, CONVERSATION (May 6, 2021, 12:08 PM), <https://theconversation.com/us-backed-vaccine-patent-waiver-pros-and-cons-explained-160480> [<https://perma.cc/K42M-GYAU>].

74. *Id.*

75. Napoleon, *supra* note 1, at 131.

76. *Id.*

77. Matthew Jordan et al., *Forty Years Since Diamond v. Chakrabarty: Legal Underpinnings and its Impact on the Biotechnology Industry and Society*, CTR. FOR PROT. INTELL. PROP. 1 (Jan. 2021), <https://cip2.gmu.edu/wp-content/uploads/sites/31/2021/01/Forty-Years-Since-Diamond-v-Chakrabarty.pdf> [<https://perma.cc/DS9S-SES2>]; *Diamond v. Chakrabarty*, 447 U.S. 303, 304–05 (1980).

78. Jordan, *supra* note 77, at 1.

79. Napoleon, *supra* note 1, at 132.

80. *Id.*

81. Jordan, *supra* note 77, at 1.

82. Napoleon, *supra* note 1, at 132.

mond on the growth of biotechnology in the U.S., the Supreme Court's distinction between manufactured and naturally occurring phenomena in the case of *Mayo* and *Myriad* narrowed the scope of what could be considered patent-eligible.⁸³ When the world struggles to find cures and vaccines for a global pandemic, patenting scientific methods and discoveries would further incentivize companies to research and develop treatments and vaccines.⁸⁴

The second strategy to broaden the scope of patent-eligible subject matter is to reverse the decisions of *Mayo* and *Myriad* in favor of returning to the standard outlined in *Diamond*.⁸⁵ The Supreme Court's decisions in *Mayo* and *Myriad* greatly hinder the possibility of further incorporating biomedical and genetic discoveries into patent-eligible inventions because they limit the potential to patent such discoveries.⁸⁶ Allowing these decisions to remain will negatively impact the motivation of firms and individuals to invest in the research and development that companies are attempting, which will then affect the researchers' incentive to innovate.⁸⁷

Many thriving innovation centers worldwide have patent regimes conducive to rapid yet lucrative developments in science and technology.⁸⁸ Specifically, the U.S. patent regime would greatly benefit from adopting similar policies currently at play in the Japanese patent regime regarding the patenting of biotechnology. Japan stands as the world's current second-largest national pharmaceutical life sciences market, thanks to the Japanese courts cultivating a pro-patent application environment in the life sciences.⁸⁹ The clear industrial applicability in Japan employs a requirement similar to that established in the U.S. case of *Diamond v. Chakrabarty*, which states that anything that can be manufactured and sold is a patentable subject matter.⁹⁰ Therefore, compounds, compositions, and methods of making such products are patentable.⁹¹ In the U.S., opponents of increased patent eligibility argue that strengthened patent protections hinder the diffusion of the discoveries and create a bottleneck from the patent holder maintaining a monopoly over the discovery.⁹² However, in Japan, the patent system serve as a mechanism

83. Jordan, *supra* note 77, at 1.

84. Napoleon, *supra* note 1, at 118.

85. *Id.* at 132.

86. *Id.*

87. *Id.*

88. See John A Tessensohn, *Japan's Patent Issues Relating to Life Science Therapeutic Inventions*, EXPERT OP. ON THERAPEUTIC PATS. 953 (Aug. 4, 2014), <https://doi.org/10.1517/13543776.2014.944161> [<https://perma.cc/A9JG-ZSP4>] (discussing Japan's patent regime).

89. *Id.*

90. *Id.* at 954.

91. *Id.*

92. Contreras, *supra* note 11, at 139.

for technology diffusion in the economy.⁹³ Features of the Japanese patent system, specifically, the narrow claim requirements and a pre-grant disclosure rule, promote technological diffusion.⁹⁴ In turn, this positively impacts technical progress, encouraging more research and development that produce more discoveries and innovations.⁹⁵ In Japan, the application for utility models is the primary channel for diffusion.⁹⁶ Application for utility models allows for incremental inventions to build on prior fundamental technical knowledge embodied in patent applications and commercial uses.⁹⁷

In Japan, discoveries and innovations must have novelty, utility, and an inventive step, and such requirements set the bar for earning exclusive rights to a patent.⁹⁸ However, the conditions do not have to be significantly met, as having low novelty standards and recognizing only narrow claims encourage small and incremental inventions in Japan.⁹⁹ Firms in Japan get protection and design patents on technologies that are only slightly modified from the original invention.¹⁰⁰ Suppose a similar aspect is adopted in the U.S. In that case, it will counter the fear that patent holders will have little incentive to improve upon their discoveries because they hold monopolies over discoveries, as competition will remain to motivate innovation.¹⁰¹

Additionally, the patent systems require disclosure of patentable technologies through public media in Japan.¹⁰² The earlier the disclosure and the more detailed the technical specifications, the simpler it is for competing firms to learn technologies and develop patentable improvements.¹⁰³ Thus, liberal disclosure rules also promote technology diffusion.¹⁰⁴ With the narrow patent claims and rapid disclosure requirements that encourage large applications for slightly different products, substantial cross-licensing among indus-

93. See Keith E. Maskus & Christine McDaniel, *Impacts of the Japanese Patent System On Productivity Growth*, 11 JAPAN AND WORLD ECON. 557, 559 (1999), [https://doi.org/10.1016/S0922-1425\(99\)00012-2](https://doi.org/10.1016/S0922-1425(99)00012-2) [https://perma.cc/27GL-M2EK].

94. *Id.* at 558.

95. *Id.*

96. *Id.*

97. *Id.*

98. See *id.* at 559.

99. See *id.*

100. *Id.* at 559–60.

101. Contreras, *supra* note 111, at 139.

102. Maskus & McDaniel, *supra* note 92, at 561.

103. *Id.*

104. *Id.*

try groups and rival firms promotes another avenue for speedy and widespread diffusion of innovation and discoveries.¹⁰⁵

In the face of the COVID-19 pandemic, applying these aspects of the Japanese patent regime and widening the scope of patent eligibility for biomedical and genetic technology will allow firms and individuals to be motivated to invest in biotechnology and pharmaceutical companies.¹⁰⁶ In turn, this creates an incentive to continue research and development for potential cures and vaccines for not only the COVID-19 virus but future viruses as well.¹⁰⁷ The increased accessibility of biomedical data can help advance this objective through inventions protected by patent law.¹⁰⁸ Without it, not as many resources will go into biomedical research.¹⁰⁹

V. CONCLUSION

Contrary to some beliefs that increased patent protection of biomedical data and genomic processes are not beneficial to the diffusion and availability of scientific and medical discoveries, biomedical data and patent law can coexist. They can work in parallel and eventually intersect to prevent future pandemics. However, the current patent regime in the U.S. restricts the patenting of genomic and biomedical data, which works against the world's current demand for discoveries in the face of the COVID-19 pandemic. The theories proposed in this Note do not cover all the possible methods and points that potentially exist to create greater interactions between the fields of genomic and biomedical data and patent law. However, these theories can be used as potential starting points to see how the U.S. patent regime can mitigate the current pandemic and stop future pandemics. To reconcile the wants of patent protection opposition and patent protection support, the U.S. patent regime should first broaden the scope of subject matters that are allowed patent protection. The current Supreme Court precedence disqualifies genetic DNA processes and medical techniques for patent eligibility. At the same time, there has been an undeniable growth in biotechnology that urgently calls for scientific advancements to be patent-eligible. Second, the U.S. should consider adopting aspects of Japan's patenting regime regarding biotechnology. Currently, the Japanese patent regime allows for the patenting of biomedical data without compromising the diffusion and availability of scientific and medical discoveries. Such modifications, allowing the increase of patent-eligible subject matter in the U.S. patent regime, will enable American inventors and researchers to use biomedical data to find cures and preventive

105. *Id.*

106. *See e.g.*, Maskus & McDaniel, *supra* note 92, at 559-61; *see* Contreras, *supra* note 11, at 139.

107. Napoleon, *supra* note 1, at 122.

108. *Id.* at 118.

109. *Id.*

measures for pandemics such as the COVID-19 pandemic and future pandemics.