

Patent Eligibility: Exploring the Intersection Between Patent Law and Biomedical Data

Erin A. Napoleon

Abstract

The world was fundamentally changed by the rampant spread of COVID-19 in 2020. This is not the first and will not be the last time the world is faced with a pandemic. Thus, it is essential to take the necessary steps now to be prepared in the future. This Note will address how patent law can protect inventions incorporating the biomedical data to prevent future pandemics. The Note compares U.S. and European Patent Regimes to determine which system is better at protecting biomedical data. Lastly, this Note proposes changes to the U.S. Patent Regime to help increase its compatibility with biomedical data.



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Patent Eligibility: Exploring the Intersection Between Patent Law and Biomedical Data

Erin A. Napoleon*

I. INTRODUCTION

We currently find ourselves in the middle of a global pandemic with no knowledge of its ultimate ramifications or scope. A year into this public health crisis, COVID-19 continues to reshape our lives.¹ The adverse impact on “people’s livelihood, their health, and our food systems” has resulted in unprecedented economic and social disruption.² Across the globe, there have been efforts to mitigate the detrimental effects of this invisible virus. Notwithstanding these efforts, those charged with developing and implementing mitigation strategies continue to come up short as COVID-19 has claimed the lives of millions of people.³ Given the unknown nature of COVID-19 and the spread of the virus, the world is functioning in a state of shock and frenzy, while searching for vaccines that will end the resulting devastation.⁴

As pathogens continue to move from animals to humans, new infectious viral outbreaks will occur.⁵ Despite additional viral outbreaks looming in the distance, including variant COVID-19 strains, the country’s leadership has failed to prepare

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¹ *Rolling updates on coronavirus disease (COVID-19)*, WORLD HEALTH ORG. (July 31, 2020), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen> (Declaring COVID-19 a pandemic on March 11, 2020).

² *Impact of COVID-19 on people’s livelihoods, their health and our food systems*, WORLD HEALTH ORG. (Oct. 13, 2020), <https://www.who.int/news/item/13-10-2020-impact-of-covid-19-on-people’s-livelihoods-their-health-and-our-food-systems>.

³ *CDC COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.

⁴ Prosper Junior Bakiny, *Amid the Coronavirus Frenzy, Novavax Remains a Risky Bet*, MOTLEY FOOL (Mar. 6, 2020, 10:45 AM), <https://www.fool.com/investing/2020/03/06/amid-the-coronavirus-frenzy-novavax-remains-a-risk.aspx>.

⁵ Pandemic Prediction and Forecasting Science and Technology Working Group, *Towards Epidemic Prediction: Federal Efforts and Opportunities in Outbreak Modeling*, NAT’L SCI. & TECH. COUNCIL (Dec. 2016), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/NSTC/towards_epidemic_prediction-federal_efforts_and_opportunities.pdf.

its citizens for the next surge and follow-on pandemics. In this era of great scientific and medical advances, the products of such advances should be used to combat not only the COVID-19 pandemic, but also future pandemics. The rise and accessibility of biomedical data⁶ can help further this goal through computer-based models and inventions protected by patent law. Incentivizing and motivating scientists and researchers to continue searching for strains of well-known viruses or new viruses through the protections afforded by patent law, will help ensure that the U.S. healthcare system is not surprised and ill-prepared when the next pandemic arrives.

This Note explores the concept of using both patent law and biomedical data emanating from new technologies, research and discoveries in efforts to prevent future pandemics. As a result, this Note seeks to provide a clearer understanding of the intersection between biomedical data and patent law. In addition, this Note seeks to address the question of how patent law can afford protections to inventions incorporating biomedical data used to prevent global viral and infectious outbreaks. In addressing this question, a comparison of the U.S. and European Patent Regimes will be provided to determine which system is better suited to protect biomedical data. Finally, this Note will analyze ways in which modifications to the American patent system can help increase its compatibility with biomedical data.

II. PANDEMICS AND PATENT LAW

The world has been plagued by pandemics for millennia. However, modern medicine and the implementation of pandemic response plans have mitigated the detrimental effects of recent viral outbreaks.⁷ In addition, the rise of patent law as a means for protecting the “architectural components” of vaccine discoveries has helped to prevent widespread global outbreaks.⁸ Such protections create a mechanism for motivating researchers to develop cures. This section provides an overview of modern pandemics and methods by which the public health community has sought to mitigate the detrimental effects of global viral outbreaks. This is done

⁶ See Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, STAN. TECH. L. REV. 3, 18 (2010) (defining biomedical data as “gene sequences, information about what a gene encodes, protein structures, research papers, and clinical trial results for pharmaceuticals); see also Sharona Hoffman & Andy Podgurski, *The Use and Misuse of Biomedical Data*, 39 AM. J.L. & MED. 497, 499 (2013) (defining biomedical data as the compilation of electronic health records and genomic data).

⁷ *CDC Pandemic Tools*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 20, 2020), <https://www.cdc.gov/flu/pandemic-resources/pandemic-resources.html>.

⁸ Eileen M. Kane, *Preparing for Pandemic Influenza: Achieving Clinical Equity in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1141–42 (2009).

by utilizing, in part, patent law as a means of protecting the research and methodologies used in developing vaccines and cures.

A. *Modern Pandemics*

One of the first pandemics occurring in recent time is related to Severe Acute Respiratory Syndrome (SARS). SARS is a viral illness that attacks the respiratory system.⁹ Researchers believe that SARS originated in bats, which then transmitted the virus to small mammals handled by humans.¹⁰ This virus was first detected in China in February 2003 and eventually spread to four other countries.¹¹ While the spread of this virus was not long lasting, nearly 800 deaths resulted.¹²

The H1N1 virus (swine flu) was first detected in the United States in 2009.¹³ Even though other strains of influenza had existed both in the United States and globally, the strain that caused swine flu was due to a unique combination of genes not previously detected in humans or animals.¹⁴ The detrimental effects of this pandemic were felt not only domestically, but also internationally. The Centers for Disease Control (CDC) estimated that worldwide about 151,700,400 people died from the swine flu, with the United States making up about 0.008% of the total deaths.¹⁵ While the World Health Organization (WHO) officially declared the end of the H1N1 global pandemic on August 10, 2010, the virus still continues to circulate as the seasonal flu, resulting in hospitalizations and deaths yearly.¹⁶ The Food and Drug Administration (FDA) approved the Rapivab vaccine as a treatment for H1N1 on December 22, 2014.¹⁷

⁹ *SARS Basics Fact Sheet*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 6, 2017), <https://www.cdc.gov/sars/about/fs-sars.html>.

¹⁰ Chien-Te Tseng et al., *Immunization with SARS Coronavirus Vaccines Leads to Pulmonary Immunopathology on Challenge with the SARS Virus*, PLOS ONE (Apr. 20, 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3335060/>.

¹¹ *Severe Acute Respiratory Syndrome (SARS)*, WORLD HEALTH ORG. [WHO], https://www.who.int/health-topics/severe-acute-respiratory-syndrome#tab=tab_1.

¹² Tseng et al., *supra* note 10.

¹³ *2009 H1N1 Pandemic (H1N1pdm09 virus)*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 11, 2019), <https://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html>.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Charles Patrick Davis & Melissa Conrad Stöppler, *Swine Flu (Swine Influenza A [H1N1 and H3N2])*, MEDICINENET (Feb. 24, 2020), https://www.medicinenet.com/swine_flu/article.htm.

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The next notable viral outbreak occurred in 2014. The Ebola Virus Disease originated in West Africa and was characterized as the largest epidemic in African history.¹⁸ Ebola is primarily transmitted through direct contact with blood and bodily fluids of infected people.¹⁹ While Ebola was not deemed a pandemic due to its heavy concentration in Africa, the virus spread to other parts of the world including Italy, Spain, the United Kingdom, and the United States.²⁰ Ebola caused more than 11,000 deaths worldwide.²¹

Even though the Ebola outbreak occurred in 2014, the FDA did not approve a vaccination to treat this virus until 2019.²² Clinical studies and research led the FDA to approve Ervebo for the treatment of Ebola virus.²³ Subsequent to FDA approval, Merck sought patent protection for the Ervebo vaccine, which was granted on September 6, 2011.²⁴ Despite the minimal presence of Ebola virus today, “vaccination is essential to help prevent outbreaks and to stop the Ebola virus from spreading when outbreaks do occur.”²⁵ The research used to derive the vaccination can “help create a model for future studies under similar circumstances.”²⁶

Most recently, COVID-19 has proven to be one of the most lethal modern global pandemics. COVID-19 is an infectious viral disease caused by the respiratory pathogen, SARS-CoV-2.²⁷ The SARS-CoV-2 virus typically causes relatively mild infection, however the present strain, referred to as coronavirus, is novel and can lead

¹⁸ 2014–2016 Ebola Outbreak in West Africa, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 8, 2019), <https://www.cdc.gov/vhf/ebola/history/2014-2016-outbreak/index.html>.

¹⁹ First FDA-Approved Vaccine for the Prevention of Ebola Virus Disease, Marking a Critical Milestone in Public Health Preparedness and Response, U.S. FOOD & DRUG ADMIN. (Dec. 19, 2019), <https://www.fda.gov/news-events/press-announcements/first-fda-approved-vaccine-prevention-ebola-virus-disease-marking-critical-milestone-public-health>.

²⁰ CTRS. FOR DISEASE CONTROL & PREVENTION, *supra* note 18.

²¹ U.S. FOOD & DRUG ADMIN., *supra* note 19.

²² *Id.*

²³ *Id.*

²⁴ MERCK, *Merck U.S. patent rights for products* (Dec. 16, 2020), <https://www.merck.com/research-and-products/patent/>.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Coronavirus disease (2019)*, WORLD HEALTH ORG. (Oct. 12, 2020), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19>.

to severe respiratory failure and ultimately death.²⁸ As of the time of this writing, there have been 3,295,681 deaths globally attributed to the coronavirus, with about 18% of those deaths occurring in the United States.²⁹

Knowledge of the patented SARS genomic sequence³⁰ and how the virus impacts the human body from the first SARS pandemic in 2003, gave scientists a great advantage when they began searching for cures for COVID-19.³¹ As of the date of writing this publication, the FDA has approved the Moderna and Pfizer vaccines for emergency use authorization, both of which employ the use of messenger RNA (mRNA).³² The FDA has also approved the emergency use of the Johnson and Johnson vaccine. The AstraZeneca and Novavax COVID-19 vaccines are currently in phase 3 clinical trials.³³ While the Pfizer and Moderna vaccines themselves are not patented, technologies used in the development of the vaccine are subject to patent protection.³⁴ For example, both Pfizer and Moderna hold a patent in lipid nanoparticle (NP) technology, which delivers mRNA to cells and instructs the cells to produce the SARS-CoV-2 spike protein.³⁵ Additionally, Pfizer holds patents in mRNA structure, formulations, and manufacturing.³⁶ Similarly, Moderna possesses 7 patents for COVID-19 related technologies and processes.³⁷ In combating modern pandemics, patent law and the protections it affords to biomedical data has played a

²⁸ Daniel DiMaio, Lynn W. Enquist & Terence S. Dermody, *A New Coronavirus Emerges, This Time Causing a Pandemic*, ANN. REV. VIROLOGY (Sept. 2020), <https://www.annualreviews.org/doi/10.1146/annurev-vi-07-042020-10000>.

²⁹ *Coronavirus Resource Center*, JOHNS HOPKINS U. & MED., <https://coronavirus.jhu.edu/>.

³⁰ U.S. Patent No. 7,897,744 (filed Apr. 28, 2004) (issued Mar. 1, 2011).

³¹ Jocelyn Solis-Moreira, *How did we develop a COVID-19 vaccine so quickly?*, MEDICAL NEWS TODAY (Dec. 15, 2020), <https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly#Funding-for-COVID-19-vaccine-research>.

³² *Understanding mRNA Covid-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 18, 2020), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>; see also *Messenger RNA*, National Human Genome Research Institute, <https://www.genome.gov/genetics-glossary/messenger-rna> (defining mRNA as “a single-stranded RNA molecule that is complementary to one of the DNA strands of a gene”).

³³ *Different COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 15, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>.

³⁴ See Mario Gaviria & Buruc Kilic, *BioNTech and Pfizer’s BNT162 Vaccine Patent Landscape*, PUBLIC CITIZEN (Nov. 16, 2020), <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>; Mario Gaviria & Buruc Kilic, *mRNA-1273 Vaccine Patent Landscape (for NIH Moderna Vaccine)*, PUBLIC CITIZEN, <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

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key role in incentivizing vaccine innovation and cures related to viral infections. As is evidenced by the numerous patents awarded for biomedical-related technologies and methodologies used in the development of cures for past pandemics, suggesting that biomedical data can in fact be successfully incorporated into patented inventions.

III. CAN PATENT LAW AND THE PROTECTION OF BIOMEDICAL DATA COEXIST?

Arguably, the potential protections afforded to biomedical data by patent law leads to the conclusion that patent law can serve as an incentivization tool to develop methodologies and technologies to prevent future pandemics. Biomedical data “traditionally [has] had a key role in [the] scientific process.”³⁸ Research and development of treatments utilizing such data “can yield patentable inventions and discoveries . . . such as newly identified genes [or] chemical entities that could eventually be marketed as drugs.”³⁹ In fact, many scholars believe that patenting and licensing inventions incorporating biomedical data facilitates innovation by “provid[ing] [a] basis for seeking the investment for further research and development.”⁴⁰ Additionally, biomedical data-driven patents help “accelerate exploration of particular paradigms” through the use of the best methods to create the invention claimed in the patent.⁴¹ Furthermore, these patents provide an effective means for scientists and researchers to use biomedical data to further the scientific process. This concept is addressed in some form in the U.S. and European patent law regimes as well as in international agreements and conventions—agreements and conventions to which the United States is a member. An overview of the U.S. and European patent law regimes is provided below, as well as an overview of international agreements. This overview seeks to highlight how different legal systems treat and protect inventions incorporating biomedical data under their respective patent law regimes.

³⁸ Raul Rodriguez-Esteban & Markus Bunschus, *Text mining patent for biomedical knowledge*, 21 DRUG DISCOVERY TODAY 997, 997 (2016), <https://www.sciencedirect.com/science/article/pii/S1359644616301520>.

³⁹ Josephine Johnston & Angela A. Wasunna, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, 37 THE HASTINGS CTR. REP. 2, 8 (2007), <https://www.jstor.org/stable/4625708>.

⁴⁰ *Id.* at 11.

⁴¹ See 35 U.S.C. § 112(a) (2018); see also Peter Lee, *Patents, Paradigms Shifts, and Progress*, 114 YALE L.J. 659, 676 (2004) (referring to 35 U.S.C. § 112(a) as the best mode requirement).

A. U.S. Patent Law Regime

Under the U.S. patent law regime, rights are granted to the first inventor to file and allow the inventor “the right to exclude others from making, using, offering for sale or selling the invention.”⁴² However, to be granted a patent under the U.S. patent law regime, an invention must fall into one of the statutorily prescribed categories: process, machine, manufacture, or composition of matter.⁴³ In addition, the invention must be novel, useful, and nonobvious.⁴⁴ Further, the specification of the patent application must contain a written description which enables a person having ordinary skill in the art to make the invention, and the best mode for making such invention.⁴⁵

Patent protection has been granted for a wide array of scientific discoveries. More specifically, pharmaceutical patents have been granted for drug compounds, methods of use, and production process.⁴⁶ Similarly, U.S. drug compound patents have been granted both for the active ingredient of pharmaceutical products and the method by which such products are used to treat specific illnesses.⁴⁷

B. European Patent Law Regime

While many countries in Europe have their own patent offices and patent systems, a little more than half of the European countries’ patent systems are subject to the rules of the European Patent Convention (the “Convention”).⁴⁸ The Convention establishes a Unitary Patent System among 25 European Union (EU) member states, which makes it possible for a patent applicant to obtain patent protection by submitting a single request to the European Patent Office.⁴⁹ Prior to the implementation of the Unitary Patent System in 2013, the only approach to obtaining rights in Europe was to acquire rights through each country’s respective

⁴² 35 U.S.C. § 154(a)(2) (2018).

⁴³ 35 U.S.C. § 101 (2018).

⁴⁴ 35 U.S.C. §§ 102, 103 (2018).

⁴⁵ 35 U.S.C. § 112(a) (2018).

⁴⁶ Eileen M. Kane, *Preparing for Pandemic Influenza: Achieving Clinical Equality in an Influenza Pandemic: Patent Realities*, 39 SETON HALL L. REV. 1137, 1142 (2009).

⁴⁷ *Id.*

⁴⁸ Geertrui Van Overwalle, *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches*, 1 U.C. IRVINE L. REV. 433, 438 (2011).

⁴⁹ *European Route*, EUROPEAN PATENT OFFICE (Mar. 8, 2015), <https://www.epo.org/applying/european.html>.

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patent office.⁵⁰ This approach was disfavored by many because of the fragmented patent law protection it would produce.⁵¹ Prior to the Convention, patent applicants not only had to apply for protection in the each European Country, it had to enforce those protections on a country-by-country basis as well, incurring significant filing and litigation costs.⁵² However, many patent applicants now opt to file a patent through the European Patent Office where their patent rights are subject to the protections of the Convention.⁵³ Such a filing prevents different interpretations by different countries of a patent applicant's rights.⁵⁴ The establishment of the unitary patent also led to the creation of the Unified Patent Court (UPC), which was granted exclusive jurisdiction to adjudicate unitary patent disputes.⁵⁵ However, the UPC's jurisdiction over European patents is not exclusive, allowing litigants to protect their patent rights in their respective national courts.⁵⁶ This method is less favorable as the UPC allows for more consistency and predictability in patent litigation and protection.⁵⁷

Under the Convention, patents filed in member nations are granted in all fields of technology for inventions that are “new, involve an inventive step and [are] susceptible of [or used in] industrial application.”⁵⁸ While the Convention prohibits patents for “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods,” it allows patents for substances or compositions used in surgical, therapeutic, or diagnostic methods.⁵⁹ In addition, the EU

⁵⁰ Stuart J.H. Graham & Nicolas Van Zeebroeck, *Comparing Patent Litigation Across Europe, A First Look*, 17 STAN. TECH. L. REV. 655, 665 (2014).

⁵¹ Michael J. Crowley, *Restoring Order in European Patent Law: A Proposal for the Reintroduction of the Substantive Patent Provisions of the Unitary Patent Package into EU Law*, 4 N.Y.U. J. INTELL. PROP. & ENT. L. 197, 200 (2015).

⁵² *Id.*

⁵³ Overwalle, *supra* note 48, at 438.

⁵⁴ Kevin P. Mahne, *A Unitary Patent and Unified Patent Court for the European Union: An Analysis of Europe's Long Standing Attempt to Create a Supranational Patent System*, 94 J. PAT. & TRADEMARK OFF. SOC'Y 162, 164 (2012).

⁵⁵ Crowley, *supra* note 51, at 202.

⁵⁶ *Id.*

⁵⁷ Joseph Kenneth Yarsky, *Hastening Harmonization in European Patent Law Through Preliminary Reference Power*, 40 B.C. INT'L & COMP. L. REV. 167, 168 (2017).

⁵⁸ *The European Patent Convention*, EUROPEAN PAT. OFF., <https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html> (last visited Apr. 19, 2021).

⁵⁹ *Id.*

Biotechnology Directive⁶⁰ states that biological material isolated from its natural environment or produced by technical processes is patentable.⁶¹ Discovery of DNA sequences and the related methodology for discovery, on the other hand, is not eligible for patent protection.⁶²

C. *International Agreements and Conventions*

The introduction of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994 created new protections and mutual recognition of intellectual property rights among the 164 member countries.⁶³ Such recognition is achieved through providing member countries intellectual property rights protection through respecting domestic laws, providing enforcement of such rights, and agreeing to handle disputes arising from the violation of patent rights through the World Trade Organization (WTO) dispute settlement system.⁶⁴ While the TRIPS Agreement seeks to afford these protections, it does not mandate that member countries create identical or similar intellectual property regimes.⁶⁵ Rather, countries maintain sovereignty with regard to intellectual property protection domestically.

While the TRIPS Agreement expands intellectual property protections, it has created tensions between member countries' intellectual property standards.⁶⁶ The Agreement requires governments to grant patent rights in fields, such as generics and pharmaceuticals, that were deemed unpatentable in other regimes.⁶⁷ In addition, the Agreement imposes more stringent compliance mechanisms than those enforced by individual member countries.⁶⁸ Despite these tensions, the TRIPS Agreement has continued to protect both patent and other intellectual property rights effectively and has continued to foster innovation.

⁶⁰ See Directive 98/44/EC of the European Parliament and of the Council, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044> (a 1998 directive harmonizing patent law among 27 member countries while providing for the legal protection of biotechnological inventions).

⁶¹ Overwalle, *supra* note 48, at 445.

⁶² *Id.*

⁶³ Marney L. Check, *The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime*, 33 GEO. WASH. INT'L REV. 277, 287 (2001).

⁶⁴ *Id.* at 292.

⁶⁵ *Id.*

⁶⁶ Laurence R. Helfer, *Regime Shifting: The Trips Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 26 (2004).

⁶⁷ *Id.*

⁶⁸ *Id.*

Similarly, the Paris Convention requires member states to extend the same protection granted to its own citizens to nationals of other member states.⁶⁹ Under the Paris Convention, the grant of a patent in one member state does not preclude the inventor from obtaining a subsequent patent in another member state even if both patents claim the same or similar inventions.⁷⁰ This ensures that “foreigners could not be excluded from obtaining patents in foreign countries” and “provide[s] assurances to inventors from one country that they could protect their invention in other countries as well.”⁷¹ Additionally, the Paris Convention creates a “uniform one-year rule of priority,” allowing inventors a grace period between filing in various member countries.⁷²

The Patent Cooperation Treaty (PCT) serves as an alternative to the Paris Convention⁷³ and allows inventors to simultaneously file patent applications in all member states.⁷⁴ The PCT system implements an official international prior art search,⁷⁵ which aids in the examination of the patentability of the claimed invention.⁷⁶ Such search concludes with a written opinion detailing whether the application complies with the patentability criteria of the PCT.⁷⁷ However, the non-binding nature of the written opinion does not require members of the PCT to grant or deny a patent application in compliance with the opinion.⁷⁸ The “final decision of granting a patent remains . . . at the sole discretion of the national or regional patent

⁶⁹ *Summary of the Paris Convention for the Protection of Industrial Property (1883)*, WORLD INTELLECTUAL PROP. ORG., https://www.wipo.int/treaties/en/ip/paris/summary_paris.html (last visited Apr. 2, 2021).

⁷⁰ *Id.*

⁷¹ Brice C. Lynch, Note, *International Patent Harmonization: Creating a Binding Prior Art Search Within the Patent Cooperation Treaty*, 44 GEO. WASH. INT’L L. REV. 403, 412 (2012).

⁷² *Id.*

⁷³ Juan Lapenne, *Patent Cooperation Treaty (PCT)*, 92 J. PAT & TRADEMARK OFF. SOC’Y 192, 194 (2010).

⁷⁴ *Patent Cooperation Treaty*, U.S. PATENT & TRADEMARK OFF., <https://www.uspto.gov/patents-getting-started/international-protection/patent-cooperation-treaty>.

⁷⁵ *What is Prior Art?*, EUROPEAN PATENT OFF. (Sept. 15, 2015) (defining prior art as “any evidence that your invention is already known”).

⁷⁶ Lapenne, *supra* note 73, at 195.

⁷⁷ *Id.*

⁷⁸ Lapenne, *supra* note 73, at 196.

offices.”⁷⁹ Thus, the PCT provides applicants with predictability in regards to the likelihood of their inventions being patented.⁸⁰

The Paris Convention and PCT are two distinct agreements. However, they can be used together to provide patentees greater protection.⁸¹ Both the Paris Convention and Patent Cooperation seek to “streamline the acquisition of international patent rights.”⁸² While the main goal of the Paris Convention and the PCT is to harmonize filing between member states, these agreements do not prohibit the filing of inventions incorporating biomedical data or naturally occurring phenomena. Rather, the decision of patentability is placed with the individual member nations. Thus, nations that are part of either agreement and the Convention can still afford patent protection to inventions claiming isolation of DNA or genomic sequences, as well as chemicals and compounds used to treat viral illnesses and diseases.

IV. PATENTING BIOMEDICAL DATA

The U.S. and European Patent Regimes treat patenting biomedical data in two different ways. The U.S. patent system is more restrictive than the European patent system, declining to afford patent protection to inventions incorporating biological processes despite the potential utility of such inventions. The U.S. patent system requires inventions to fall into one of the statutorily prescribed categories. Those inventions that may potentially fall outside of the prescriptions are less likely to receive patent protection. However, in Europe, inventions do not have to explicitly fall into a statutorily prescribed category. Rather, as long as inventions are technical and have utility, they will be awarded patent protection.⁸³ The distinction between the treatment of inventions incorporating biomedical data in the United States and European patent regimes is indeed stark.

U.S. courts, for example, have hotly debated the patent eligibility of inventions incorporating biological processes.⁸⁴ Notwithstanding this debate, the Supreme Court has held that “[granting] patents on medical relationships and isolated DNA

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² John Gladstone Mills III, *A Transnational Patent Convention for the Acquisition and Enforcement of International Patent Rights*, 88 J. PAT. & TRADEMARK OFF. SOC’Y 958, 961 (2006).

⁸³ *Guidelines for Examination*, EUR. PATENT OFF., https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_i_1.htm.

⁸⁴ Overwalle, *supra* note 48, at 445.

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risk tying up the tolls of future innovation due to their broad scope.”⁸⁵ This conclusion was the basis for rejecting patents incorporating biological processes in the Supreme Court’s *Mayo* and *Myriad* decisions.

In *Mayo Collaborative Services v. Prometheus Labs Inc.*, (“*Mayo*”), the Supreme Court tackled the question of whether the processes set forth in certain claims and which describe natural relations emanating from certain processes are patent eligible. The Court, in evaluating a process that assisted physicians in determining the appropriate dosage of thiopurine drugs to treat patients with autoimmune diseases, concluded that such a process did not adequately transform natural laws into patent eligible subject matter.⁸⁶ In its conclusion, the Court held that “purely conventional or obvious presolution activity is normally not sufficient to transform an unpatentable law of nature into a patent eligible application of such law.”⁸⁷ In the Court’s view, this is exactly what Mayo Collaborative Services sought to achieve in its patent application. The Court, in its decision, further noted that “phenomena of nature, though discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”⁸⁸

Similarly, in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (“*Myriad*”), the Supreme Court addressed the question of the validity of gene patents covering isolated DNA sequences. The Court determined that isolated naturally occurring DNA is not patent eligible.⁸⁹ In its review, the Court analyzed whether the isolation of the cancer causing BRCA1 and BRCA2 genes were patent eligible under 35 U.S.C. § 101. The Court’s determination was aided by the application of the “markedly different characteristics” test enumerated in *Diamond v. Chakrabarty* (“*Chakrabarty*”).⁹⁰ Markedly different characteristics include “non-naturally

⁸⁵ Johnathon Liddicoat, Kathleen Liddell & Mateo Aboy, *The Effects of Myriad and Mayo on Molecular-Test Development in the United States and Europe: Interviews from the Frontline*, 22 VAND. J. ENT. & TECH. L. 785, 789 (2020); see, e.g., *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 556 U.S. 66 (2012); *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576 (2013); but see *Diamond v. Chakrabarty* 447 U.S. 303 (1980).

⁸⁶ *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 556 U.S. 66, 72 (2012).

⁸⁷ *Id.* at 79.

⁸⁸ *Id.* at 70.

⁸⁹ *Association for Molecular Pathology v. Myriad Genetics*, 569 U.S. 576, 580 (2013).

⁹⁰ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (where a scientist sought patent protection related to his discovery of a method for developing a human-made genetically engineered bacterium that could break down multiple components of crude oil; the court holding that patents cannot protect laws of nature or physical phenomena; naturally occurring organisms to be patent eligible must have “markedly different characteristics from any found in nature and one having the potential for significant utility”).

occurring manufactures or composition of matter, a product of human ingenuity “having distinctive name, character [and] use.”⁹¹ Applying this test, the Court reasoned that isolating DNA from its genetic material did not make it “markedly different” from its natural composition.⁹² The Court further justified its determination by noting that § 101 “contains an important implicit exception: [L]aws of nature, natural phenomena, and abstract ideas are not patentable”⁹³ because granting patents in this area would “tie up the use of such tools and thereby inhibit future innovation premised upon them.”⁹⁴

The Court in these cases have outlined the scope of what constitutes patent eligible subject matter with regard to genomic DNA, medical techniques, and biomedical data.⁹⁵ Academic studies have revealed the precedent setting value of these decisions on courts and agencies. For example, a study conducted by Professor Mateo Aboy, a visiting scholar in precision medicine, artificial intelligent, and law at Harvard University, revealed the United States Patent and Trademark Office routinely used the holding in *Myriad* to reject patents involving peptides, proteins, antibodies, cells, and pharmaceutical compositions.⁹⁶ Lower courts have used the holdings and reasoning in both *Mayo* and *Myriad* to invalidate patents claiming the application of conventional molecular DNA isolation techniques and technologies.⁹⁷ Notwithstanding this trend, the Federal Circuit in 2018 determined that companion diagnostics⁹⁸ or non-natural biologic processes are patent eligible if the drug claimed is unconventional or if the steps claimed “amount to more than merely diagnosing a patient and instructing a doctor to generically treat it.”⁹⁹

⁹¹ *Id.* at 310.

⁹² *Myriad Genetics*, 569 U.S. at 591.

⁹³ *Id.* at 589 (quoting *Mayo*, 566 U.S. at 70).

⁹⁴ *Id.*

⁹⁵ Liddicoat, Liddell & Aboy, *supra* note 85, at 787.

⁹⁶ *Id.* at 792 (citing Mateo Aboy et al., *Was the Myriad Decision a “Surgical Strike” on Isolated DNA Patents, or Does it Have Wider Impacts?*, 36 NATURE BIOTECHNOLOGY 1146 (2018)).

⁹⁷ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1371 (Fed. Cir. 2015).

⁹⁸ *Companion Diagnostics*, U.S. FOOD & DRUG ADMIN. (Dec. 7, 2018), <https://www.fda.gov/medical-devices/vitro-diagnostics/companion-diagnostics> (defining companion diagnostics as a medical device providing information essential for the safe administration of a corresponding drug or biological product).

⁹⁹ Liddicoat, Liddell & Aboy, *supra* note 85, at 795–95; *see also* *Vanda Pharmaceuticals, Inc v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1135–36 (Fed. Cir. 2018); *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (holding that “the natural ability of subject matter to undergo the process does not make the claim ‘directed to’ that natural ability”).

INSERT PATENT ELIGIBILITY

Given its attempt to definitively determine the patentability of biomedical data, the Court in *Mayo* and *Myriad* left a gap by leaving open the question as to the patentability of genetic information. More specifically, the courts “failed to answer exactly how much researchers can modify a gene before it becomes patent eligible.”¹⁰⁰ Additionally, the Court left open the question as to “whether the legal system should [consider the patent eligibility of] DNA based on its chemical structure or based on the information it encodes.”¹⁰¹

However, European law has taken a different approach to ensure that inventors understand the limits of patenting biomedical data-related inventions. In efforts to increase innovation implementing biomedical data, the EU implemented the Biotech Directive, which sought to affirmatively define the bounds of patenting biotech inventions.¹⁰² Under this directive, in order for subject matter to be patent eligible it must be technical in nature or have utility.¹⁰³ More specifically, the directive states that

[S]uch an element isolated from the human body or otherwise produced is not excluded from patentability since it is . . . the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.¹⁰⁴

Thus, DNA, RNA, and other genetic materials are eligible for patent protection under the European Patent Law Regime because their isolation “make[s] something available to the public that previously was not.”¹⁰⁵

As a result, the European patent regime affords broader protection for inventions incorporating biomedical data. In fact, “European equivalents of the patents considered in *Myriad* [and] *Mayo* were treated differently than in the U.S.”¹⁰⁶ The standard by which the European patent system evaluates patent eligible subject

¹⁰⁰ Carrie Arnold, *Gene Patents Remain Controversial in Biomedical Research*, THE LANCET (Aug. 10, 2013), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)61698-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)61698-0/fulltext).

¹⁰¹ *Id.*

¹⁰² Jessica C. Lai, *Myriad Genetics and the BRCA Patents in Europe: The Implications of the U.S. Supreme Court Decision*, 5 U.C. IRVINE L. REV. 1041, 1044 (2015).

¹⁰³ *Id.* at 1046.

¹⁰⁴ EU Biotech Directive, EUR-Lex (July 6, 1998), <https://eur-lex.europa.eu/eli/dir/1998/44/oj>.

¹⁰⁵ Lai, *supra* note 102, at 1064.

¹⁰⁶ Timo Missen & Robert M. Schwartz, *Separating Sheep from Goats: A European View on the Patent Eligibility of Biomedical Diagnostic Methods*, 3 J.L. BIOSCIENCES 365, 365 (2016).

matter is more conducive to ensuring that inventions seeking to help prevent viral outbreaks are patented. This is evidenced by various patents awarded to inventions encompassing biomedical data throughout Europe. For example, the European Patent Office awarded to the University of Utah a patent claiming the creation of the method for diagnosing a predisposition for breast and ovarian cancer.¹⁰⁷ Additionally, a European patent was awarded to the University for the identification of the naturally occurring genetic mutations linked to increasing a patient's susceptibility of ovarian and breast cancer.¹⁰⁸ Further, in 2017, the German Federal Court of Justice (Bundesgerichtshof—Germany's highest patent court) concluded that the “disclosure of how to create a [DNA] sequence through a technical process such as isolation” is patentable.¹⁰⁹

V. MODIFICATION OF THE UNITED STATES PATENT REGIME

Prior to the *Mayo* and *Myriad* decisions, isolated DNA was patentable under the United States patent regime. However, U.S. Supreme Court jurisprudence barred patents claiming isolated DNA and other naturally occurring processes. Despite the rulings in *Mayo* and *Myriad*, the Supreme Court did not clearly define a “natural product.” This left patent seekers without sufficient guidance as to what is considered patent eligible and limited the scope of medical patents, despite the rise in both technology and biomedical data. Thus, it is essential to modify the grant of patents in the field of biomedical data and encourage innovation and provide inventive protection to researches and inventors who seek to introduce new methods of identifying and curing viral infections. This can be done through the Supreme Court's revisit and implementation of the standard set forth in *Diamond v. Chakrabarty*. Additionally, overturning *Mayo* and *Myriad* would expand the patent eligible subject matter to include biomedical data. Lastly, taking on the policies of international trade agreements and conventions may result in more expanded treatment of patent protection and encourage innovation.

¹⁰⁷ European Patent No. T 0080/05 (Method of diagnosis/University of Utah) (decided Nov. 19, 2008), <https://www.epo.org/law-practice/case-law-appeals/recent/t050080eu1.html>.

¹⁰⁸ European Patent No. T 1213/05 (Breast and ovarian cancer/University of Utah) (decided Sept. 27, 2007), <https://www.epo.org/law-practice/case-law-appeals/recent/t051213eu1.html>.

¹⁰⁹ *Case law from the Contacting States to the EPC*, EUROPEAN PATENT OFF. (Dec. 15, 2017), <https://www.epo.org/law-practice/legal-texts/official-journal/2017/etc/se6/p12.html>; see also Mateo Aboy et al., *How does emerging patent case law in the US and Europe affect precision medicine*, 37 NATURE BIOTECHNOLOGY 1118, 1122 (2019), <https://www.nature.com/articles/s41587-019-0265-1>.

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A. *The Diamond v. Chakrabarty Standard*

The United States Supreme Court was tasked with interpreting 35 U.S.C. § 101 in *Diamond v. Chakrabarty* in 1980. The Court held that Congress intended statutory subject matter to include “anything under the sun that is made by man.”¹¹⁰ Thus, respondent’s micro-organism qualified as patentable subject matter because it was “a product of human ingenuity having a distinctive name, character and use.”¹¹¹ Under this standard, the United States provided the broadest protection for biomedical inventions, ranging from gene isolation to other genetic treatments and processes.¹¹² Implementing the *Chakrabarty* standard would render inventions incorporating biomedical data patent eligible because they would be the product of “human ingenuity” through manipulation, isolation, and testing. More specifically, implementing this standard would allow for scientific methods and discoveries used to develop new vaccines and cures for viral infections to be awarded patent protection.

B. *The Supreme Court Should Reverse Mayo and Myriad to Expand Patent Eligible Subject Matter*

The decisions in both *Mayo* and *Myriad* significantly limit the potential to incorporate genetic and biomedical discoveries into patent eligible inventions. As the use of technology in science expands, the holdings in these two cases could potentially adversely impact patenting methodologies and medicines used in curing and preventing viral infections and addressing pandemics now and in the future. These decisions could have a chilling effect on innovation to the extent that inventors may no longer be incentivized to innovate, knowing their inventions will not be protected. Such an adverse impact on innovation may require the Supreme Court to overturn *Mayo* and *Myriad* and revert back to the *Chakrabarty* standard.

C. *Implementing the Policies of International Trade Agreements*

Even though the United States is a party to the Paris Convention, the TRIPS Agreement, and the Patent Cooperation Treaty it still fails to treat inventions incorporating biomedical data the way other countries that are parties to those agreements do. For example, under the Japanese Patent Regime, inventions with

¹¹⁰ *Chakrabarty*, 447 U.S. at 309.

¹¹¹ *Id.* at 309–10.

¹¹² Jasmine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT’L L. REV. 223, 226 (2002).

industrial applicability are patent eligible.¹¹³ However, activities that are normally attributable to doctors such as surgery, therapy, or diagnoses fall outside of patent eligible subject matter.¹¹⁴ Despite this exception, inventions that can be manufactured and sold, including compounds, compositions, and methods of making such inventions, are patent eligible.¹¹⁵ Thus, inventions incorporating biomedical data to assist in isolating viruses or creating new vaccines to cure viruses would be eligible for patent protection in Japan. Similarly in Europe, inventions incorporating biomedical data are patent eligible if they are produced via a technical process.¹¹⁶ Even if substances and compositions are part of the prior art, if they are used for a surgical, therapeutic, or diagnostic purpose for the first time, patent protection can be granted.¹¹⁷ If the United States Patent Regime adopts policies similar to Japan and Europe, inventions using biomedical data to find cures and prevent future pandemics would be patent eligible subject matter. There would be no need for the United States Patent Office or the courts to scrutinize inventions created to help prevent global public health crises.

VI. CONCLUSION

Biomedical data and patent law can work in parallel and eventually intersect to prevent future pandemics. The theories proposed in this Note do not cover all of the possible methods that potentially exist to create greater interaction between the fields of biomedical data and patent law. However, these theories can be used as starting points in analyzing how the two fields can work in conjunction with one another to prevent future pandemics. While current Supreme Court precedent disqualifies genetic DNA isolation processes and medical techniques as patent eligible subject matter, the shift in biomedical data for scientific advancement may result in an altered interpretation of 35 U.S.C. § 101. In contrast to the United States, patent systems in Europe and Japan, for example, afford broader protection to inventions encompassing biomedical data. Key international agreements to which the United States is a party, follow this trend. Therefore, American inventors and researchers may find protection through the TRIPS Agreement, the EU Biotech Directive, the Paris Convention, and the Patent Cooperation Treaty, until patenting inventions involving biomedical data becomes normalized in the U.S. patent law regime.

¹¹³ John A. Tessensohn, *Japan's Patent Issues Relating to Life Science Therapeutic*, 24:9 EXPERT OPINION ON THERAPEUTIC PATENTS 953 (2014).

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ Overwalle, *supra* note 48, at 445.

¹¹⁷ *Id.* at 453.

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