
STIFLING INNOVATION: DATA COLLECTING PATENTS IN THE MEDICAL
DEVICE INDUSTRY

Margaret A. Russell*

I. Introduction

For many companies, intellectual property (“IP”) is their most important asset. This is especially true in the medical device industry.¹ As the population ages, medical devices have become increasingly popular.² Many of these devices collect huge amounts of data

* J.D. Candidate, Suffolk University Law School, 2021; B.S. in Chemistry, Worcester Polytechnic Institute, 2017. Margaret can be reached at margaretrussell1@gmail.com.

¹ See Adam Moore & Ken Himma, *Intellectual Property*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Mar. 8, 2011), *archived at* <https://perma.cc/Y82D-PZLW> (noting that “[i]ntellectual property law protects a content-creator’s interest in her ideas by assigning and enforcing legal rights to produce and control physical instantiations of those ideas.”). Intellectual property generally includes copyright, trademark, patents, and trade secrets. *Id.* See also *IP priorities: five tips for medical device entrepreneurs*, TODAY’S MEDICAL DEVELOPMENTS (Mar. 7, 2015), *archived at* <https://perma.cc/E9K4-D476> (noting a strong IP position can be a medical device company’s strongest asset). Conversely, a weak or poorly defined IP portfolio can be a companies’ greatest liability. *Id.* Frank Becking, IP counsel and founder of Panthera MedTech, has explained how to create a strong IP portfolio, stating that “an effective IP portfolio must be managed actively with value-driven goals in mind throughout the development cycle – from idea conception to company acquisition and beyond.” *Id.*

² See *Systematic Review of Needs for Medical Devices for Ageing Populations*, 4 (World Health Organization, 2015), *archived at* <https://perma.cc/XTN2-D5KP> (reviewing the increase in medical devices among the older populations throughout the globe). See also *Active Implantable Medical Devices Market by Product (Implantable Cardioverter Defibrillators (Transvenous & Subcutaneous), Cardiac*

concerning the patient for use by doctors to personalize treatments.³ However, this information is also collected by corporations that hold and use the data for research and development of patentable devices, a fact most patients are ignorant of.⁴ Through a carefully curated and

Pacemaker, Ventricular Assist Device, Neurostimulator, Implantable Hearing Devices) - *Global Forecast to 2022*, MARKETANDMARKETS (Apr. 2017), archived at <https://perma.cc/766Z-WL7R> (noting one factor in the anticipated growth of the active implantable medical market is the gaining population). “The active implantable medical devices market is estimated to grow at a CAGR of 7.8% from 2017 to 2022 to reach USD 26.75 Billion by 2022.” *Id.* See also Mark Mather, et al., *Fact Sheet: Aging in the United States*, POPULATION REFERENCE BUREAU (July 15, 2019), archived at <https://perma.cc/84HY-95J7> (noting the percentage of aging adults in the United States is about to rapidly increase). “The number of Americans ages 65 and older is projected to nearly double from 52 million in 2018 to 95 million by 2060, and the 65-and-older age group’s share of the total population will rise from 16 percent to 23 percent.” *Id.* See also *Medical Device Overview*, FDA (Sept. 14, 2018), archived at <https://perma.cc/2DYG-MSEJ> (defining a medical device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article”). A medical device is “intended for the use in diagnosis of a disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals” but not through the means of “chemical action within or on the body of a man or other animals.” *Id.* See also Bill Siwicki, *Medical devices generate valuable data, so why aren’t providers using it?*, HEALTHCAREITNEWS (June 26, 2017), archived at <https://perma.cc/5JL2-S6W5> (explaining the data that medical devices can collect for procedures and how warning signs can be missed despite ample data). Warning signs of low quality or potentially unsafe care exists in this data, but it is often overlooked. *Id.* Resulting, this data should be revisited, “[r]ather than duplicate efforts and collect more data, healthcare leaders should renew their focus on making better use of available data. An example in which this is readily apparent involves the monitoring of medical devices.” *Id.*

³ See *The Rise of Integrated Medical Devices*, MEDIDATA, (Oct. 20, 2019), archived at <https://perma.cc/L57N-UMSE> (outlining recent trends in medical devices, including the type of data often collected). The data collected differs based on the type of medical device, “in the clinical trial industry, this approach can allow for traditional clinical trial data, electronic health records, imaging data, sensor data, and patient-provided data.” *Id.*

⁴ See *id.* (explaining how data generated from medical devices can be used in a number of different ways, including for research and development purposes).

For instance, Medtronic markets the MiniMed Connect, which offers diabetics mobile access to their insulin pump and continuous glucose monitoring data. A recent study found that more than seven million patients are using remote monitoring, and the use of remote monitoring is expected to continue to

manipulated intellectual property portfolio, a corporation can overtake a market, like the medical device industry.⁵ This market domination results in a decrease in innovation; and imposes higher prices on consumers, often for less effective devices.⁶

The curation of strategic IP portfolios can be used to create market monopolies, where a limited number of large corporations are the only entities developing and selling certain medical devices.⁷ A well-curated portfolio exerts protection over a range of different intellectual property assets.⁸ Patents are one of the most important assets of a well-curated portfolio, as they create limited monopolies that permit the owner exclusive rights to the invention by disclosing technical information.⁹ Similarly, trade secrets protect business information that a corporation secretly uses to obtain an economic

expand, and opportunities abound for innovations, including general platforms that can be adapted to a wide variety of cases specific to therapeutic areas.

Id.

⁵ See generally Michael Henry, *How to Launch a Patent Portfolio: 7 Strategic Steps*, HENRY PATENT FIRM (Nov. 16, 2017), archived at <https://perma.cc/ZL2L-54PA> (detailing how valuable and important a strategic patent portfolio is to any company). “[A] comprehensive portfolio can help your company expand and diversify revenue streams while developing meaningful protection for core intellectual property (IP) assets.” *Id.*

⁶ See Brenda M. Simon, et al., *Data-Generating Patents*, 111 NW. U. L. REV. 377, 377 (2017) (explaining the potentially negative effect a monopoly can have on innovation).

⁷ See *Definition of ‘Monopoly’*, THE ECONOMIC TIMES, (Nov. 18, 2019), archived at <https://perma.cc/Y6WA-QZ5M> (defining a market monopoly as “[a] market structure characterized by a single seller, selling a unique product in the market”). When a company creates a monopoly in a market “the seller faces no competition, as he is the sole seller of goods with no close substitute.” *Id.*

⁸ See Henry, *supra* note 5 (detailing that “a comprehensive portfolio can help your company expand and diversify revenue streams while developing meaningful protection for core intellectual property (IP) assets.”).

⁹ See generally 1 R. CARL MOY, *MOY’S WALKER ON PATENTS* § 1:1 (4th ed. 2017) (detailing how patents can be used to protect ideas and allow others to use it without diminishing its value). A patent allows the owner the right to exclude others from a number of activities, including: making, using, selling, offering or importing the claimed invention. *Id.* at n.7. This allows the holder to bring a suit for patent infringement against those who violate the claims of the patent. *Id.* at § 1:1.

edge over competitors.¹⁰ Medical devices that generate data are often patented in such a way that the data generated in relation to the purpose of the patent is disclosed to the United States Patent and Trademark Office (“USPTO”). The data generated is held as a trade secret and utilized by the corporation for any number of projects. Companies in the medical device industry often construct an IP portfolio, which includes patents and trade secrets in conjunction, to create a market monopoly. This results in an industry where a few corporations are able to drive up the price of their devices, stifle innovation, and prevent smaller entities from entering the market. As a result, less medical devices enter the market, with those that do being more expensive and less innovative. Further, data collecting patents can be used to collect large amounts of data, which can be held as a trade secret and used to further stifle innovation, causing more expensive and less effective products in the medical device industry.

II. History

IP law protects the products of human intellect by permitting multiple people to use the same invention without diminishing that invention’s value.¹¹ Out of the various IP assets, two important forms

¹⁰ See generally 1 MILGRIM ON TRADE SECRETS § 1.01:3 (2019) (explaining that a trade secret derives its economic value from not being known to the public or other entities who may benefit from its knowledge). This information is valuable because it is not known by others who could use it to their benefit. *Id.* A trade secret could be a propriety ingredient, formula, recipe. *Id.* To show that a piece of information is a trade secret the corporation must have taken steps to secure the information from the public. *Id.*

¹¹ See U.S. Const. art. I, § 8, cl. 8 (explaining congress has the power to protect intellectual property, specifically “to promote the progress of science and the useful arts.”). See also *Intellectual Property*, CORNELL LAW SCHOOL LEGAL INFORMATION INSTITUTE (Oct. 20, 2019), archived at <https://perma.cc/BP8D-H5JQ> (discussing the importance of intellectual property in general). The four main categories of intellectual property are: “patent, copyright, trademarks, and trade secrets.” *Id.* See also Gene Quinn, *Patents, Copyright and the Constitution, Perfectly Together*, IPWATCHDOG (Feb. 19, 2018), archived at <https://perma.cc/BK9J-2KKH> (detailing how the founding fathers hoped the protection of intellectual property, specifically that found in art. I, § 8, cl. 8, would help incentivize innovation). James Madison noted in the federalist papers, “The right to useful inventions seems with equal reason to belong to the inventors.” *Id.* Emphasizing the importance and intent of the framers to protect the rights of inventors. *Id.*

– patents and trade secrets – play crucial roles in protecting information and letting the owner exclude others from use.¹² A patent gives the owner the right to control the use of the innovative product or process.¹³ Similarly, a trade secret protects products or information that derive economic value from not being known or accessible to those who could gain value from its use.¹⁴ Patents and trade secrets are often considered economic substitutes to each other, because they are often capable of protecting the same information (e.g. methods of production, new ingredients).¹⁵ When used together as complements,

¹² See Michael R. McGurk & Jia W. Lu, *The Intersection of Patents and Trade Secrets*, 7 HASTINGS SCI. & TECH. L.J. 189, 190 (2015) (discussing the economic value of patents and trade secrets as similarly protecting intellectual concepts). See also *Patents*, CORNELL LAW SCHOOL LEGAL INFORMATION INSTITUTE (Oct. 20, 2019), archived at <https://perma.cc/E9PD-7C49> (detailing the fundamentals of patent law). The major goal of patent law is to grant “exclusive rights to the inventor,” which is “intended to encourage the investment of time and resources into the development of new and useful discoveries.” *Id.*

¹³ See 1 MOY’S WALKER ON PATENTS, *supra* note 9 §1:1 (explaining the inventor or relevant applicant is assumed to hold the rights to a patent and to its utilization). Patent rights can be assigned through contractual arrangements, similar to other forms of property. *Id.*

¹⁴ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining a trade secret “covers any information (which can be embodied in a physical thing, such as a pattern or device) used in business and lending the opportunity to attain a competitive advantage over others who do not know the information”). Unlike copyright and patent protection, where a matter must fall under a statutorily defined category, a trade secret can be just about anything so long as it’s economic value to the company comes from not being known to others. *Id.* Explaining that “[t]he essential rights of a trade secret owner are the right to use the trade secret and disclose it to employees and others standing in a confidential or contractual relationship with the owner subject to restrictions on unauthorized use or disclosure.” *Id.*

¹⁵ See McGurk, *supra* note 12, at 190 (defining trade secrets and patents as information). “Patents and trade secrets are the only two forms of intellectual property that protect information—patents protect patentable information (innovation), while trade secrets can protect patentable information and any other information providing economic value to the holder. Thus, the same information can often be protectable by patents or trade secrets.” *Id.* See also Simon, et al., *supra* note 6, at 383 (explaining trade secrets and patents are generally considered to be economic substitutes, such that inventors will often choose between one of the two). See also 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining trade secrets and patents have different benefits). Notably, upon the expiration of the patent term the invention falls into the public domain such that anyone can use it. *Id.* Trade secrets on the other hand do not have expiration dates,

trade secrets and patents can give the holder unfettered control over an industry, especially when it comes to data generating patents.¹⁶

A. *A Brief Description of Patents and Trade Secrets*

1. An Overview of Trade Secret Law

A trade secret is defined as any piece of information that is used in business to give the holder the opportunity to obtain an advantage over competitors, who do not know and cannot use that information.¹⁷ Trade secrets differ from other forms of secret business information, such as contract provisions and business proceedings, because they relate to a process or device that is in use in the operation of the business.¹⁸ Often contract law can be used to protect against the dissemination of secret information; but where contract law fails, trade secret law steps in.¹⁹

they last as long as they are secret, indicating they can have an incredibly long term. *Id.*

¹⁶ See Gideon Parchomovsky, et al., *Towards An Integrated Theory of Intellectual Property*, 88 VA. L. REV. 1455, 1494 (2002) (explaining patents and trade secrets protect the same type of information “as a substitute for patent protection, trade secrecy presents businesses with a choice between patent and trade secret protection. While firms can elect either option, they cannot employ both modes to protect the same information.”). See also Simon, et al., *supra* note 6, at 384 (explaining patents and trade secrets can be used as complements).

¹⁷ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01:3 (defining what constitutes a trade secret and how the term is used in the industry). A trade secret may include: a recipe, an algorithm, a client list. *Id.* See also RESTATEMENT OF THE LAW, TORTS § 757 CMT. B (AM. LAW INST. 1939) (defining a trade secret as “any formula, pattern, device or compilation of information which is used in one’s business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.”).

¹⁸ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (detailing how a trade secret differs from other kinds of secret business information).

¹⁹ See generally Sharon Sandeen, *The Evolution of Trade Secret Law and Why Courts Commit Error When They Do Not Follow the Uniform Trade Secrets Act*, 33 HAMLINE L. REV. 493, 512 (2010) (noting that contract law is often used to protect trade secrets, allow the holders of trade secrets to share the information while making it clear the expectation of privacy). Before and after the USTA “[t]he existence of secret information coupled with an express or implied

Many states have adopted the Uniform Trade Secrets Act (“UTSA”), as a way of uniformly regulating trade secrets.²⁰ The USTA outlines factors courts often use to determine if a piece of information qualifies as a trade secret.²¹ These factors include, but are

agreement of confidentiality made it easy for common law courts to impose liability on individuals or companies who were parties to the agreement because breach of contract and breach of trust were well-recognized wrongs.” *Id.* at 497. In litigating trade secret protection under contract law, courts would often have difficulties distinguishing between secret information and “public information, general skill, and knowledge.” *Id.* at 498. Defendants could then argue that the information was not secret but instead required to work in the trade, meaning the contract was invalid as it would prevent the individual from working in the field at all. *Id.* at 500. An action of this sort is often referred to as restraint of trade, wherein defendant argues the plaintiffs action prevents them from working in the market. *Id.* at 499. *See also* Cincinnati Bell Foundry Co. v. Dodds, 10 Ohio Dec. Rep. 154 (Super. Ct. 1887) (detailing a restraint of trade argument).

There can be no property in a process, and no right of protection, if knowledge of it is common to the world. It would be a violation of every right of an employee of a manufacturer to prevent the former from using, in a business of his own, knowledge which he acquired in the employ of the latter when he might have acquired such knowledge in the employ of other manufacturers. Indeed, a contract not to do so would probably fail of enforcement because of a restraint of trade.

Id. at 84.

²⁰ *See* Ernie Linek, *A Brief History of Trade Secret Law, Part 1*, BIOPROCESS INT’L (Oct. 2004), archived at <https://perma.cc/9LMS-Q7LG> (noting trade secret litigation often occurred in states with “large commercial centers” and “it rarely occurred in less populous and more agricultural jurisdictions”). This discrepancy in litigation lead to differing laws and remedies based on the state. *Id.* Additionally, the 1978 Restatement of Torts removed definition of a trade secret which had worked as a “legal guide for trade secret protection since 1939.” *Id.* at 1–2. In an attempt to stop confusion many states adopted, with some modifications, the USTA in the 1980s, in an attempt to streamline regulation. *Id.* at 2.

²¹ *See id.* at 4 n.4 (explaining which states have adopted the USTA). *See also* 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining the USTA outlines 6 factors courts should use to determine if a piece of information used by a business is a trade secret).

(1) the extent to which information is known outside a trade secret claimant’s business and (2) by employees and others involved in the business, (3) secrecy measures, (4) the value of the information to the claimant and his competitors, (5) the effort or investment to develop the information and (6) the ease or

not limited to: (1) efforts to maintain secrecy; (2) value of the information to the holder and their competitors; and (3) ease at which the information can be reverse engineered.²² There are no restrictions on what qualifies as a trade secret.²³

Generally, there are three elements that need to be proven in a trade secret claim: (1) the information was a trade secret; (2) the holder took reasonable efforts under the circumstances to protect that secret; and (3) the information was misappropriated.²⁴ Misappropriation is defined by the UTSA as including unauthorized acquisition, use, and disclosure.²⁵ Third-party use of the trade secret will not be deemed

difficulty with which the information could be properly acquired or duplicated by others.

Id.

²² See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (defining UTSA and the factors, listed above, used to determine if a piece of information is a trade secret). See also 2012 Cal. Stat. 22 § 126042 (West) (outlining an example of a state inaction of the UTSA). See also *Trade Secret Policy*, USPTO (Feb. 7, 2019), archived at <https://perma.cc/XB5G-NDRC> (explaining many states have adopted the UTSA and those who have not have similar laws).

²³ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining the difference between patent and trade secret law). Patents, unlike trade secrets, have specific subject matter eligibility requirements. *Id.* Patents and trade secret protection often overlap, but differ in ways such as: term length, type of assets that can be protected, and potential remedy upon infringement. *Id.* Patent subject matter eligibility includes specific subject matter and novelty requirements. *Id.*

²⁴ See Restatement (Third) of Unfair Competition §1 (Am. Law Inst. 2009) (explaining misappropriation of a trade secret is a form of unfair competition). See also *Trade secret*, CORNELL LAW SCHOOL LEGAL INFORMATION INSTITUTE (Oct. 20, 2019), archived at <https://perma.cc/NQA8-RAUN> (explaining the elements of a trade secret claim). Generally, the three elements of a trade secret claim are: “(1) [t]he subject matter involved must qualify for trade secret protection . . . (2) [t]he holder of the subject matter must establish that reasonable precautions were taken to prevent disclosure of the subject matter; (3) [t]he trade secret holder must prove that the information was misappropriated or wrongfully taken.” *Id.* See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (noting that while there are six factors to determine if information qualifies as a trade secret, courts usually look to see if a business has (1) efforts in place to maintain secrecy; (2) how high the value of the information is to the holder and their competitors; and (3) the ease at which the information can be reverse engineered to determine if the information is a trade secret).

²⁵ See generally 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining the UTSA generally defines misappropriation as including “unauthorized acquisition, use and disclosure”).

illegal if the information has been acquired by lawful measures such as reverse engineering, independent discovery, or inadvertent disclosure.²⁶ Interestingly, the UTSA does not require the trade secret to be used by the owner's business in order to be entitled to protection.²⁷ Although trade secrets are often created by similar means to patentable inventions, they are protected in a different way.²⁸

'Misappropriation' means: (i) acquisition of a trade secret of another by a person who knows or has reason to know that the trade secret was acquired by improper means; or (ii) disclosure or use of a trade secret of another without express or implied consent by a person who (A) used improper means to acquire knowledge of the trade secret; or (B) at the time of disclosure or use, knew or had reason to know that his knowledge of the trade secret was (I) derived from or through a person who had utilized improper means to acquire it; (II) acquired under circumstances giving rise to a duty to maintain its secrecy or limit its use; or (III) derived from or through a person who owed a duty to the person seeking relief to maintain its secrecy or limit its use; or (C) before a material change of his position, knew or had reason to know that it was a trade secret and that knowledge of it had been acquired by accident or mistake.

Id. Two claims are often asserted in a misappropriation case: a breach of contract and of confidence. *Id.* Under the UTSA, trade secret owners can also bring a claim for misappropriation. *Id.* In addition to USTA misappropriation claims, a plaintiff can also "assert other tort claims, including conversion, restraint of trade and unfair competition." *Id.*

²⁶ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining the misuse and acquisition of a trade secret will not include use of a trade secret that was acquired by lawful measures such as reverse engineering, independent discovery, or inadvertent disclosure).

²⁷ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining trade secret protection does not end because the trade secret is not actively in use, taking reasonable security steps and having value in the secret are enough to secure protection).

²⁸ See *Trade Secret Policy*, *supra* note 22 (explaining the difference between patent and trade secret protection). Noting that "unlike trade secrets, patents may protect against independent discovery. Patent protection also eliminates the need to maintain secrecy. While most anything can be kept secret, there are limitations on what can be protected by a patent." *Id.* See also *How are Trade Secrets Protected??*, WIPO (Jan. 31, 2020), archived at <https://perma.cc/C3BU-9GEN> (describing the difference between trade secrets and patents). Unlike patent protection, "trade secrets are protected without registration, that is, trade secrets are protected without any procedural formalities. Consequently, a trade secret can be protected for an unlimited period of time." *Id.*

Unlike patents the value of a trade secret does not come from novelty, but instead from its secrecy.²⁹

2. An Overview of Patent Law

As stated in the U.S. Constitution, the purpose of a patent is to “promote the progress of science and the useful arts” by giving inventors exclusive rights to their inventions.³⁰ Therefore, Congress has the ability to grant limited monopolies to patent holders by allowing them exclusive economic rights to their claimed invention for a limited amount of time.³¹ After the patent expires, the invention becomes a part of the public domain and the public can use the technology to invent better, more efficient, and cost effective inventions.³² By granting a limited monopoly, the patent system

²⁹ See Michael Risch, *Why Do We Have Trade Secrets?*, 11 INTELL. PROP. L. REV. 1–29, 11–13 (2007) (explaining the difference between trade secrets and patents). See MPEP § 2760 (9th ed. Rev. 2018) (noting that revealing a trade secret may be required in order to receive a patent). The MPEP notes that trade secrets can be expunged from patents upon request. *Id.*

³⁰ See U.S. CONST. art. I, § 8, cl. 8. (“To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries”). See also Patents, *supra* note 12 (explaining how patents derive their economic value, specifically by giving the owner exclusive rights to do a number of things). The patent owner has “the exclusive right to prevent others from making, using, offering for sale, or selling the patented invention.” *Id.*

³¹ See Moy, *supra* note 9, at § 1:13 (explaining how upon the expiration of the patent the information enters into the public domain). Once the information pertaining to the invention that is protected in the patent enters into the public domain any member of the public is free to use it. *Id.*

³² See generally Moy, *supra* note 9 (explaining the lifecycle of a patent). Upon the expiration of the patent term the invention falls into the public domain. *Id.* See also Reanne Young, *Patents and the Public Domain: Improving Patent Quality Upon Reexamination*, ELECTRONIC FRONTIER FOUNDATION (June 13, 2008), archived at <https://perma.cc/93DM-ZSBD> (explaining that goal of the patent system was to promote innovation and “manage the public domain.”). A limited monopoly over the invention “encourage[es] other inventors to work around the patent to create improved, alternative technologies that might not have otherwise been developed, patents encourage creativity and innovation in society.” *Id.* These alternative technologies can also be rewarded by limited monopolies, “reward[ing] inventors for their hard work and ingenuity by giving them the right to control the manufacture and sale of their invention.” *Id.*

creates an economic incentive that also encourages the dissemination of knowledge for the benefit and use of the general public.³³

i. How to Obtain a Patent

To obtain a patent in the U.S., the inventor must file an application with the USPTO describing the invention through claims, technical specifications, and best mode enablement.³⁴ This application is then reviewed by a patent examiner (“examiner”) from the USPTO.³⁵ The examiner looks to see if the patent meets the requirements outlined by Congress, such as ensuring the claimed invention: constitutes patent-eligible subject matter, has not previously

³³ See Young, *supra* note 32 (noting there are positive and negative qualities to the public domain).

By granting the inventor a limited monopoly on their inventions, the US patent system also requires inventors to disclose their innovations into the public domain to give others the opportunity to improve on them and to contribute the invention to the public record. In this way, the patent system, while spurred by economic incentive, can also encourage the dissemination of knowledge for the benefit and use of the public.

Id.

³⁴ See *Patent process overview*, USPTO (Mar. 18, 2019), *archived at* <https://perma.cc/7NPF-J7LX> (noting the steps required to receive a patent). See also 35 U.S.C. § 111 (2020) (detailing the sections required to submit an application). A written nonprovisional application must include: a specification, oath or description, drawing and fee. *Id.* A provisional application, a shorter application which holds a filing date until a later nonprovisional patent application is filed, must include a specification or drawing. *Id.* See generally MPEP § 600 (9th ed. Rev. 8, Aug. 2017) (outlining the parts and forms required to submit a provisional and nonprovisional patent application). See also 35 U.S.C. § 101 (2020) (describing the categories of inventions that qualify for patents as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof”). See also MPEP §§ 2100, 2165 (9th ed. Rev. 8, Aug. 2017) (explaining application of 35 U.S.C. § 112, often called “best mode” enablement). 35 U.S.C. § 112 requires the patent application include a specification that “shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.” *Id.*

³⁵ See *Patent process overview*, *supra* note 34 (noting a patent examiner from the USPTO will review the patent application).

been patented, and has met the various specifications.³⁶ If a requirement is not met, the examiner will send an office action—a rejection for not meeting the requirements of the USPTO or the relevant patent laws.³⁷ The applicant will then work with the examiner to respond appropriately, such that the examiner is satisfied and allows the patent to issue.³⁸ Once issued, the applicant will have exclusive rights over the invention for a set amount of time.³⁹

ii. Patent Subject Matter Eligibility

In order to obtain a patent, the invention must be subject matter eligible.⁴⁰ Determining subject matter eligibility involves a two part inquiry: first, the patent must fall into one of the four statutory categories; and second, the claimed invention must be directed towards

³⁶ See MPEP § 2103 (9th ed. Rev. 8, Aug. 2017) (noting that subject matter eligibility is just one part of the patent application process, other qualifications are required in order for a patent to grant).

The patent eligibility inquiry under 35 U.S.C. [§] 101 is a threshold inquiry. Even if a claimed invention qualifies as eligible subject matter under 35 U.S.C. [§] 101, it must also satisfy the other conditions and requirements of the patent laws, including the requirements for novelty (35 U.S.C. [§] 102), nonobviousness (35 U.S.C. [§] 103), and adequate description and definite claiming (35 U.S.C. [§] 112).

Id. See also MPEP § 608.01 (9th ed. Rev. 8, Aug. 2017) (explaining the claims define what the patent is and covers). The claims are key in determining if another party has infringed, the courts will look to the claims to determine what the patent covers. *Id.* The specification is the whole application, excluding the first page information and the claims. *Id.* The specification includes the summary, background, and various descriptions. *Id.*

³⁷ See MPEP § 2103 (9th ed. Rev. 8, Aug. 2017) (explaining an examiner may state in an office action “all reasons and bases for rejecting claims in the first Office action. Deficiencies should be explained clearly, particularly when they serve as a basis for a rejection.”).

³⁸ See *id.* (advising examiners that “[w]henver practicable, examiners should indicate how rejections may be overcome and how problems may be resolved.”).

³⁹ See *Moy, supra* note 9, at § 13.40 (noting that the patent allows for an exclusive right over the invention, upon the expiration of said monopoly the invention falls into the public domain).

⁴⁰ See *Patent process overview, supra* note 34 (explaining the invention must fall under 35 U.S.C. § 101 in order to be patent eligible). See also 35 U.S.C. § 101 (outlining the categories of inventions that shall qualify for patents, in accordance with the constitution, as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof”).

eligible subject matter or amount to significantly more than any judicial exception it encompasses.⁴¹ To have subject matter eligibility, the invention must first fall into one of the four following statutory categories: process, machine, manufacture, or composition of matter.⁴² Machine, manufacture, and composition of matter define the type of tangible “things” that Congress felt was appropriate to patent.⁴³ Process, as defined by the Supreme Court, “is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.”⁴⁴ This kind of patent is most often used to protect business methods, which involves the patenting of a new

⁴¹ See MPEP § 2106.04 (9th ed. Rev. 8, Aug. 2017) (explaining there is a two-step test for determining subject matter eligibility).

First, the claimed invention must be to one of the four statutory categories. 35 U.S.C. [§] 101 defines the four categories of invention that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter ... second, the claimed invention also must qualify as patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.

Id.

⁴² See 35 U.S.C. § 101 (categories of inventions that shall qualify for patents, in accordance with the constitution, include: “process, machine, manufacture, or composition of matter”). See also MPEP § 2106.04 (9th ed. Rev. 8, Aug. 2017) (stating the two-part test required for subject matter eligibility). The first inquiry in determining subject matter eligibility is to identify which of the four statutory categories the claimed invention falls into. *Id.*

⁴³ See MPEP § 2106.03 (9th ed. Rev. 8, Aug. 2017) (explaining the categories of subject matter, “[t]he other three categories (machines, manufactures and compositions of matter) define the types of physical or tangible ‘things’ or ‘products’ that Congress deemed appropriate to patent”).

⁴⁴ See MPEP § 2106.03 (9th ed. Rev. 8, Aug. 2017) (detailing what a process is, in comparison to the other types of statutory subject matter categories). See also *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972) (italics added) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, (1876)) (defining “[a] process defines “actions”, i.e., an invention that is claimed as an act or step, or a series of acts or steps. As explained by the Supreme Court, a “process” is “a mode of treatment of certain materials to produce a given result. It is an *act, or a series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing.”). See also *In re Nuijten*, 500 F.3d 1346, 1501 (Fed. Cir. 2007) (explaining that the Supreme Court has “consistently interpreted the statutory term ‘process’ to require action”). See also *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1319 (Fed. Cir. 2005) (“[A] process is a series of acts.”).

way of conducting business.⁴⁵ Business methods can be challenging to patent and are often rejected by the USPTO as having nonpatent-eligible subject matter.⁴⁶ Specifically, the USPTO often rejects business method patents under the as directed towards patent ineligible subject matter, specifically the “judicial exception” of abstract ideas.⁴⁷ Over the years, there have been a number of different articles of legislation and Supreme Court cases regulating patent activity, including what is considered to be patentable subject matter.⁴⁸

To determine if the claimed invention is patentable, the examiner considers if it falls within the categories outlined in § 101 of chapter 35 of the United States Code and is not directed towards a judicial exception.⁴⁹ It has long been held that Congress intended patentable

⁴⁵ See Brette Sember, *What a Business Method Patent Is*, LEGALZOOM (Sept. 2018), archived at <https://perma.cc/8QA2-T82H> (explaining that “A business method patent is another type of patent” that “usually patents a business method that is combined with technology, resulting in a new way of doing business”).

⁴⁶ See *Business Method Patents*, IPWATCHDOG (Feb. 29, 2020), archived at <https://perma.cc/3PYZ-N4RJ> (noting there has been changes over the years in the law that allowed for a business method exception to patentability, because business methods were seen as a type of abstract idea). Since 1998 business method patents have been allowed, the Federal Circuit has noted “‘business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.’” *Id.* However, courts have noted that in order for the business method to be patentable it is necessary for the invention to have some sort of practical application. *Id.* “In other words, in order for a business method to be patentable it must produce a ‘useful, concrete and tangible result.’” *Id.* The purpose of this requirement is to limit patent protection to inventions that possess a certain level of ‘real world’ value, as opposed to subject matter that represents nothing more than an idea or concept (which is not patentable), or is simply a starting point for future investigation or research.” *Id.*

⁴⁷ See generally *id.* (noting business method patents are often rejected for lacking patentable subject matter under the judicial exception of abstract idea). See also MPEP §2106.04 (9th ed. Rev. 8, Aug. 2017) (describing the steps to determine subject matter eligibility).

⁴⁸ See generally Moy, *supra* note 9, at §1:26 (explaining what the America Invents Act is and its effect on patent law). §101 subject matter eligibility involves looking at the invention itself to ensure it is novel, not a judicial exception, and patentable. *Id.* at §5:1. See also MPEP § 2106 (9th ed. Rev. 8, Aug. 2017) (outlining patentable subject matter and the specific requirements resulting from various Supreme Court cases).

⁴⁹ See 35 U.S.C.A. § 101 (West, Westlaw through Pub. L. No. 116–158) (describing the categories of patentable inventions). See generally MPEP §2106 (9th ed. Rev. 8, Aug. 2017) (explaining that in order for a patent to “qualify as

subject matter to “include anything under the sun made by man.”⁵⁰ However, this broad purpose has since been refined by various cases such as *Alice v. CLS* (“*Alice*”), wherein the Supreme Court outlined three categories of subject matter that would not qualify for patents called judicial exceptions: laws of nature, abstract ideas, and natural phenomenon.⁵¹ The patent application will be rejected as being directed towards a judicial exception, unless the claimed invention as a whole has additional aspects that amount to “significantly more than the exception” at issue.⁵² The Court reasoned these exceptions “are basic tools of scientific and technological work” and monopolizing these tools would deter innovation.⁵³ As a result, to determine if the claimed invention satisfies the criteria for subject matter eligibility it must fall under one of the statutory categories of invention and if directed towards a judicial exception, it must amount to “significantly more than the exception.”⁵⁴

patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.”). *See also* MPEP §2106.03 (9th ed. Rev. 8, Aug. 2017) (outlining the four categories of statutory subject matter and how to determine which category the claimed invention falls under).

⁵⁰ *See* *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (noting that Congress intended patentable subject matter “to include anything under the sun that is made by man,” indicating the intention to cover a large amount of subject matter limited only by what is man-made).

⁵¹ *See* *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66, 71 (2012) (detailing how judicial exceptions include laws of nature, abstract ideas, and natural phenomena). *See also* *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217–18 (2014) (explaining those inventions who as a whole are directed at a judicial exception do not have the appropriate subject matter to be eligible for a patent); MPEP § 2106.03 (9th ed. Rev. 8, Aug. 2017) (outlining the four categories of statutory subject matter: “processes, machines, manufactures and compositions of matter”).

⁵² *See generally* MPEP §2106 (9th ed. Rev. 8, Aug. 2017) (explaining that “. . . the claimed invention also must qualify as patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception”). *See also* MPEP §2106.04 (9th ed. Rev. 8, Aug. 2017) (detailing how to determine if a claim is direct to a judicial exception).

⁵³ *See* *Mayo*, 566 U.S. at 71 (explaining that allowing these patents would monopolize “basic tools of scientific and technological work,” which would prevent innovation).

⁵⁴ *See* MPEP §2106 (9th ed. Rev. 8, Aug. 2017) (outlining a flowchart to showing patent examiners how to perform the subject matter eligibility analysis). *See also*

iii. Additional Requirements

To satisfy the requirements of patentability, the patent application must also include a specification detailing the embodiment the inventor prefers and the best mode of carrying out the invention.⁵⁵ 35 U.S.C. § 112, also known as best mode enablement, requires disclosure of the best mode the inventor knows at the time of making or using the entire invention.⁵⁶ Best mode is designed to prevent the inventor from obtaining patent rights if retaining trade secret protection over information related to the patent.⁵⁷ However, in 2011, Congress passed the American Invents Act (“AIA”) that overhauled the patent system.⁵⁸ The AIA removed the best mode requirement by declaring that failure to disclose best mode was no longer a basis to

MPEP §2106.04(a) (9th ed. Rev. 8, Aug. 2017) (explaining that business methods could be considered a type of abstract idea, but court rulings have declared business methods are a type of method that can in some circumstances be patent eligible).

⁵⁵ See 35 U.S.C.A §112 (2012) (detailing what is required to include in the specification of the patent application). See also Moy, *supra* note 9, at §7:1 (explaining best mode enablement and the evolution of what must be disclosed in the specification).

⁵⁶ See MPEP §§2100, 2165 (9th ed. Rev. 8, Aug. 2017) (noting the application of 35 U.S.C. 112, often called “best mode,” and the guidelines for compliance with the written description requirement). Best mode requires disclosure of the best mode the inventor knows of (at the time of filing) making or using the entire invention. *Id.* at §2107. If an application has not appropriately disclosed best mode, they will receive an ‘indefiniteness’ rejection under 35 U.S.C. 112. *Id.* at §2173.

⁵⁷ See *id.* at §2165 (9th ed. Rev. 8, Aug. 2017) (defining best mode and the requirements to comply). *Id.* at §2103 (9th ed. Rev. 8, Aug. 2017) (noting that to determine compliance with best mode there is a two pronged inquiry: “(1) at the time the application was filed, did the inventor possess a best mode for practicing the invention; and (2) if the inventor did possess a best mode, does the written description disclose the best mode such that a person skilled in the art could practice it”). See also Moy, *supra* note 9, at §7:1 (explaining best mode is intended to prevent trade secrets protection over related information).

⁵⁸ See generally Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) [hereinafter AIA] (explaining the goal of AIA was to amend title 35 U.S.C. to provide for patent reform). The AIA went into effect in March of 2013 and dramatically overhauled patent law. *Id.* Codifying much of the court created patent law, AIA also did away with a number of well understood basics of patent law. *Id.* Some of the more common hallmarks no longer considered in validating and litigating patents include best mode and first to file. *Id.*

invalidate a patent.⁵⁹ Often when a patent holder sues for patent infringement, the accused will argue there was no infringement because the patent issued is invalid as it has not satisfied the requirements of patentability.⁶⁰

3. Patents and Trade Secrets as Compliments

Due to their similarities, patents and trade secrets have often been seen as economic substitutes, however, when used as compliments they can act as a powerful tool.⁶¹ Recently, many corporations have started using both patents and trade secrets to curate a tactful IP portfolio.⁶² Patents can be used to protect the invention, allowing the corporation to collect a large array of data from users and prevent competitors from using the claimed invention.⁶³ These

⁵⁹ See 35 U.S.C.A § 282 (2012) (detailing what the presumption of validity defense is). See also AIA §15 (explaining best mode is no longer a requirement and not a basis to show patent invalidity).

⁶⁰ See 1 MOY'S WALKER ON PATENTS, *supra* note 9, at §17:1 (defining various defenses to a patent infringement suit, including the noninfringement and invalidity defense). See also AIA §15 (explaining a number of different changes to the process of getting a patent). Patents are not awarded based on the first to file, instead of the first to invent. *Id.*

⁶¹ See Michael R. McGurk, et al., *The Intersection of Patents and Trade Secrets*, 7 HASTINGS SCI. & TECH. L.J. 189, 190 (2015) (discussing the economic value of patents and trade secrets as similarly protecting intellectual concepts). See also *Patents*, CORNELL LAW SCHOOL LEGAL INFORMATION INSTITUTE (Oct. 20, 2019), archived at <https://perma.cc/E9PD-7C49> (detailing the fundamentals of patent law). The major goal of patent law is to grant “exclusive rights to the inventor,” which is “intended to encourage the investment of time and resources into the development of new and useful discoveries.” *Id.*

⁶² See McGurk, *supra* note 12, at 190 (detailing how “[p]atents and trade secrets are the only two forms of intellectual property that protect information—patents protect patentable information (innovation), while trade secrets can protect patentable information and any other information providing economic value to the holder. Thus, the same information can often be protectable by patents or trade secrets.”). See also Gideon Parchomovsky, et al., *supra* note 16, at 1494 (explaining patents and trade secrets are often treated as economic substitutes). “As a substitute for patent protection, trade secrecy presents businesses with a choice between patent and trade secret protection. While firms can elect either option, they cannot employ both modes to protect the same information.” *Id.*

⁶³ See *Patents*, *supra* note 12 (explaining how patents derive their economic value, specifically by giving the owner exclusive rights to do a number of things). The patent owner has “the exclusive right to prevent others from making, using,

databases can then be protected as trade secrets, lasting long after the patent expires and usable in a number of different and productive ways.⁶⁴ These portfolios give corporations a powerful leg up against competitors in everything from research and development, to expanding into unforeseen markets and preempting potential competition.⁶⁵ Consequently, a curated IP portfolio that uses patents and trade secrets as compliments is a powerful tool corporations can use in a number of different ways.⁶⁶

B. Association for Molecular Pathology v. Myriad Genetics, Inc

The intersection of patent law and trade secret law was exemplified in the landmark Supreme Court case *Association for Molecular Pathology v. Myriad Genetics, Inc.*⁶⁷ In 1994, Myriad Genetics, Inc. (“Myriad”) discovered the exact location of genes, that when mutated, significantly increased an individual’s chance of

offering for sale, or selling the patented invention.” *Id.* See also Simon, *supra* note 6, at 378 (outlining the type data that Myriad generated and the database it created). The data generated by Myriad’s test was kept as a trade secret. *Id.*

⁶⁴ See 1 MILGRIM ON TRADE SECRETS, *supra* note 10, at §1.01 (explaining a trade secret “covers any information (which can be embodied in a physical thing, such as a pattern or device) used in business and lending the opportunity to attain a competitive advantage over others who do not know the information”). See also Simon, *supra* note 6, at 379 (explaining the databases Myriad’s data created can be mined for information that is not accessible to competitors, including small startups, and is near impossible to recreate). “The value of trade secrets obtained through data-generating patents is particularly evident in the area of genetic testing, particularly the generation of proprietary databases of patients’ genetic information derived from patented diagnostic tests.” *Id.* at 393. See also Facts *infra* section B.

⁶⁵ See generally Simon, *supra* note 6, at 378 (explaining that “[b]y leveraging its patents, Myriad has managed to extend its exclusivity, even after its patents were invalidated by the Supreme Court for lack of patentable subject matter. What began with patent protection over genetic information now includes trade secret protection for Myriad’s databases of patients’ full genetic sequences and phenotypic information, as well as the correlations and algorithms resulting from access to that wealth of data.”). *Id.* at 409. See also Facts *infra* section B.

⁶⁶ See Analysis *infra*.

⁶⁷ See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 576 (2013) (outlining the facts of the case).

developing certain cancers.⁶⁸ Myriad obtained a number of patents that same year focusing on the isolation of specific genes and tests to determine if the individual had an increased risk for certain cancers.⁶⁹ The Supreme Court unanimously ruled against Myriad, invalidating their patents and holding that a naturally occurring gene is not patentable simply because it has been isolated.⁷⁰

Before the patents were invalidated, Myriad was the exclusive provider of genetic testing for certain cancers.⁷¹ As the provider of

⁶⁸ *See id.* (explaining the test for the BRCA genes included isolating the specific BRCA gene). The court identified four claims that were representative of the nine compositional claims at issue. *Id.* at 584. An example of the claims at issue in the case: “The first claim asserts a patent on ‘[a]n isolated DNA coding for a BRCA1 polypeptide,’ which has ‘the amino acid sequence set forth in SEQ ID NO:2.’ App. 822. SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes . . . claim 1 asserts a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO:2.” *Id.*

⁶⁹ *See id.* (explaining what the patents held by Myriad were for). “Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can dramatically increase an individual’s risk of developing breast and ovarian cancer.” *See Ass’n for Molecular Pathology*, 569 U.S. at 582–3. “Myriad’s patents would, if valid, give it the exclusive right to isolate an individual’s BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual’s genome.” *Id.* at 585.

⁷⁰ *See* MPEP §2106.03 (9th ed. Rev. 8, Aug. 2017) (explaining a method is synonymous with a process). The MPEP defines a process as a set of “‘actions,’ i.e., an invention that is claimed as an act or step, or a series of acts or steps.” *Id.* As explained by the Supreme Court, a “process” is “a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.” *Id.* *See also Ass’n for Molecular Pathology*, 569 U.S. at 583 (explaining no method claims were before the court, only “compositional” claims). The method claims detailed in the patents Myriad owned were not at issue in the Supreme Court case. *Id.*

⁷¹ *See Ass’n for Molecular Pathology*, 569 U.S. at 584 (describing Myriad’s most popular products as their genetic testing kit, specifically the kit that tested for mutations in the BRCA1 and BRCA2 gene, which is accepted as the indicator of a heightened risk for breast cancer). *See also* Simon, *supra* note 6, at 393–94 (stating “Most notably, Myriad Genetics had been the sole provider in the United States of testing for the BRCA1 and BRCA2 genes, which are markers for breast cancer. Myriad collects and stores information from its patients about variations, phenotypes, populations, and family histories. Over 1.5 million patients have used and contributed data to Myriad’s BRCA testing services.”). *See also Investor Relations*, MYRIAD GENETICS (Oct. 5, 2019), *archived at*

these genetic testing services, Myriad amassed large amounts of clinical data on the genetic composition of the patients who went in for testing.⁷² Through these patents, Myriad disclosed the best mode for identifying and isolating the specific gene, but their patents had failed to mention that the testing generated data for the entire genome⁷³ The resulting database generated by Myriad's testing contained data on both the specific gene and on the patients entire genetic make-up, which was kept as a trade secret and could be used for research and development purposes.⁷⁴

Although Myriad's patents have been effectively invalidated through the Court's decision, the corporation still gained a market advantage through its ability to use its database of patient information for research and development purposes.⁷⁵ Patent protection gave Myriad an exclusive time lead to mine these databases to develop new products, an advantage that extends beyond the usefulness of the patent

<https://perma.cc/HF7Y-2VVC> (outlining investor relations and the profits of the company before the Supreme Court decision). Myriad's stock was traded \$26.46 per share before the ruling. *Id.*

⁷² See Investor Relations, *supra* note 71 (explaining Myriad's company revenue before the Supreme Court decision). See also Simon, *supra* note 6, at 378 (outlining the amount and type data that Myriad collected).

⁷³ See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. at 584 (noting Myriad's patents identified the exact location and grouping of BRCA genes). The patents at issue in the *Myriad* case included: U.S. Patent No. 5,747,282A (filed Aug. 12, 1994); U.S. Patent No. 5,837,492A (filed Dec. 18, 1995); U.S. Patent No. 6,033,857A (filed Dec. 18, 1995). *Id.*

⁷⁴ See Simon, *supra* note 6, at 378 (outlining the type data that Myriad generated and the database it created). The data generated by Myriad's test was kept as a trade secret. *Id.* See also *Patient Access to Health Records*, HEALTHIT.GOV (Sept. 2019), archived at <https://perma.cc/QZ7V-VZ7Y> (explaining that patients can request their health records and the results from tests).

⁷⁵ See Simon, *supra* note 6, at 378 (explaining the databases Myriad's data created).

The value of trade secrets obtained through data-generating patents is particularly evident in the area of genetic testing, particularly the generation of proprietary databases of patients' genetic information derived from patented diagnostic tests. Most notably, Myriad Genetics had been the sole provider in the United States of testing for the BRCA1 and BRCA2 genes, which are markers for breast cancer.

Id. at 393. See also *Myriad Genetics*, TRADINGVIEW (Oct. 5, 2020), archived at <https://perma.cc/DNS6-5PZC> (explaining Myriad's stock growth over the years).

term.⁷⁶ Myriad's extensive databases filled with patient information will be challenging for competitors to recreate, while Myriad can use this data for the research and development of new products that will put competitors out of business.⁷⁷ Myriad used its patents to obtain exclusive rights over their data-generating inventions and trade secrets to create databases of information.⁷⁸ By curating its IP to use trade secrets and patents as complements, Myriad was able to create a portfolio that gave it an exclusive monopoly over the genetic testing industry.⁷⁹ Myriad's strategic IP portfolio was made possible by the

⁷⁶ See Simon, *supra* note 6, at 380 (explaining these databases can be mined for information that is not accessible to competitors, including small startups, and is near impossible to recreate). See also John M. Conley et al., *Myriad After Myriad: The Proprietary Data Dilemma*, 15 N.C. J.L. & TECH. 597, 614–15 (2014) (noting that “Myriad has used its patent-based monopoly as the sole BRCA 1 and 2 test provider to develop, at its own cost, an extensive database that relates VUSs to phenotypes, details the frequency of VUSs in various populations, and includes genetic studies on patient families. There is no comparable public database.”). See also Angela M. Oliver, *Personalized Medicine in the Information Age: Myriad's De Facto Monopoly on Breast Cancer Research*, 68 SMU L. REV. 537, 549 (2015) (explaining that if researchers could recreate Myriad's database then the trade secret protection would be rendered moot). “If researchers could create a comparable database through such efforts, it would strip Myriad of trade secret protection for its database.” *Id.* at 551–52.

⁷⁷ See Simon, *supra* note 6, at 380 (outlining how the data, specifically the genetic makeup of the users, could be mined for research and development purposes). These databases can create time lead that gives the company the advantage of having a large database of information to use for research and development purposes. *Id.*

⁷⁸ See Simon, *supra* note 6, at 378 (outlining how Myriad created their database, including their refusal to share their findings).

Myriad effectively stopped contributing to public databases almost a decade ago, when it decided to maintain its users' data as a trade secret. Although Myriad has published articles on its findings, it has not provided its interpretive algorithms or data supporting its conclusions. Any company that wants to compete with Myriad can only interpret variations based on limited public data using incomplete analytic algorithms.

Id. at 409. “What began with patent protection over genetic information now includes trade secret protection for Myriad's databases of patients' full genetic sequences and phenotypic information, as well as the correlations and algorithms resulting from access to that wealth of data.” *Id.*

⁷⁹ See generally Simon, *supra* note 6, at 378 (explaining Myriad's intellectual property portfolio).

structure of patent laws in the United States, a structure of which faces changes in the upcoming years.

III. Facts

A. *Proposed Changes to 35 U.S.C. §101*

Congress's proposed changes to the patent laws could drastically change the way companies approach developing their IP portfolios. Members of Congress have proposed a bipartisan bill to change patent laws, which would lower the bar for patent eligibility.⁸⁰ Lowering the bar for patent eligibility would potentially increase the number of companies utilizing a complementary IP portfolio to generate data.⁸¹

This proposed bill would construe the provisions of 35 U.S.C. § 101 in favor of eligibility.⁸² The proposed bill would also do away with the *Alice* decision that created judicial exceptions to subject matter eligibility, including those for "abstract ideas," "laws of

By leveraging its patents, Myriad has managed to extend its exclusivity, even after its patents were invalidated by the Supreme Court for lack of patentable subject matter. What began with patent protection over genetic information now includes trade secret protection for Myriad's databases of patients' full genetic sequences and phenotypic information, as well as the correlations and algorithms resulting from access to that wealth of data.

Id. at 409.

⁸⁰ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, THOM TILLIS U.S. SENATOR FOR NORTH CAROLINA (May 22, 2019), archived at <https://perma.cc/K77D-7HZT> (explaining the proposed changes to 35 USC § 101, including how the revised section § 101 would be construed in favor of eligibility). Senator Tillis explained the goal of the bill "[w]e believe this draft framework represents a true balance that will restore integrity, predictability, and stability to our nation's patent system, while also preventing the issuance of overly broad patents." *Id.*

⁸¹ See Stuart Meyer, *Still No Shortage of Viewpoints as Eligibility Debate Moves to the Hill*, FENWICK & WEST (June 27, 2019), archived at <https://perma.cc/8E8R-U5DN> (detailing different companies testifying in support of the reform, including: IBM, Qualcomm, Nokia, and Clearing House Payments Company, among others).

⁸² See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (describing the new presumption of validity, which would require examiners to presume an application is patent eligible).

nature,” and “natural phenomena.”⁸³ It would also define “useful” as “any invention or discovery that provides specific and practical utility in any field of technology through human intervention.”⁸⁴ Finally, §101 eligibility would be determined “without regard to” how the invention was made, meaning to determine if the patent passes the §101 eligible material bar, there would be no inquiry into obviousness, prior art, or best mode.⁸⁵

The proposed changes would effectively reverse the Supreme Court’s *Alice* decision, which narrowed 35 U.S.C. §101 eligibility.⁸⁶ *Alice* raised the standard for patent eligibility, especially in the business methods category.⁸⁷ Following *Alice*, there was a large jump in § 101 rejections from the USPTO, a decrease in patent litigation,

⁸³ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (removing judicially created exceptions on subject matter eligibility and abrogating the relevant case law).

⁸⁴ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (explaining that the rewritten § 101 would do away with previous accepted understandings of utility and impose a new definition of the term).

⁸⁵ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (detailing that the rewritten § 101 would require eligibility to be considered without regard to sections 35 U.S.C § 102 (prior art), 35 U.S.C. § 103 (obviousness), or 35 U.S.C. § 112 (best mode)). See also Michael Borella, *Congress Proposes Draft Bill to Change 35 U.S.C. 101*, JD SUPRA, (May 24, 2019), *archived at* <https://perma.cc/LDY5-EH6Q> (explaining many judges are confused and frustrated by the subject matter eligibility requirements created by recent Supreme Court cases, quoting Paul Michel, a former chief judge of the federal circuit as saying the Supreme Court “create[d] a standard that is too vague, too subjective, too unpredictable and impossible to administer in a coherent consistent way in the patent office or in the district courts or even in the federal circuit”).

⁸⁶ See *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. at 217 (explaining their interpretation of § 101). See also *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (explaining the new § 101 rule would do away with the judicially created exceptions on subject matter eligibility, including those for “abstract ideas,” “laws of nature,” or “natural phenomena”).

⁸⁷ See Austin Underhill, *Who Is Alice And Why Is She Driving Patent Attorneys Mad as Hatters?*, ABOVE THE LAW (Feb. 19, 2016), *archived at* <https://perma.cc/5H59-XSGC> (explaining the number of business method patents the USPTO allowed rapidly decreased following the *Alice* decision). “Prior to *Alice*, section 101 made up about 31% of all rejections in this area. After *Alice*, that percentage increased to nearly 82%.” *Id.* Following, between 2014 and 2016 “[t]he percentage of section 101 rejections increased by 51 percentage points.” *Id.*

and an increase in research and development.⁸⁸ The proposed changes would drastically change patent prosecution, making it much easier to acquire subject matter eligibility.⁸⁹

B. The Rise in Patent and Trade Secret Misuse

1. Google's Preemption of Potential Competition in the Search Engine Market

The use of trade secrets and patents as complements to accumulate data has become an increasingly relevant issue. Many internet companies, including Google, have used this curated IP portfolio strategy to preempt competition and expand into new markets.⁹⁰ Google began as a search engine that ranked web pages by

⁸⁸ See *id.* (detailing the affect the Alice decision had on the patent industry). See also Sridhar Srinivasan, *Do Weaker Patents Induce Greater Research Investments?* (Dec. 22, 2018) (Ph.D. dissertation, Northwestern University) (SSRN) (explaining the effect a higher bar for patent eligibility had on research and development). See also *The State of Patent Eligibility in America: Part I: Hearing Before the Subcomm. on Intell. Prop. of the Comm. On the Judiciary*, 116th Cong. 1–12 (2019) (testimony of Alex H. Moss, Staff Attorney, Electronic Frontier Foundation) (explaining the effect Alice had on business method patents). Noting one effect Alice had was: “helping achieve balance by weeding out low value patents that offer nothing that could plausibly qualify as inventive while leaving space for claims that at least arguably advances beyond the addition of well-known expedients to basic concepts.” *Id.* at 5. See also James Cosgrove, *Alice: Three Years On*, JURISTAT (July 19, 2017), archived at <https://perma.cc/T9A4-FWFN> (explaining a number of different statistics detailing the affect Alice had on business method patents). “[I]f an applicant receives a § 101 rejection, there is a 63.9% chance that that rejection will cite Alice. Overall, applicants who receive § 101 rejections have a 60.8% chance of overcoming them. However, if the rejection cites Alice, that chance drops to 49.7%.” *Id.* See also Joe Mullin, *Experts Warn Congress: Proposed Changes to Patent Law Would Thwart Innovation*, ELEC. FRONTIER FOUND. (June 12, 2019), archived at <https://perma.cc/6LY4-769W> (explaining the proposed changes to §101 would have a disastrous effect on innovation in a number of different industries).

⁸⁹ See Underhill, *supra* note 87 (noting the profound impact Alice had on the patent prosecution industry).

⁹⁰ See Brad Smith, *A new IP strategy for a new era of shared innovation*, MICROSOFT (Apr. 4, 2018), archived at <https://perma.cc/D2CS-ARPV> (exploring Microsoft extensive Shared Innovation Initiative aimed at reshaping their IP strategy to adapt for future competition and change). The seven core principals of their initiative include: (1) respect for ownership of existing technology; (2)

how many other web pages linked back to them.⁹¹ As their popularity grew, Google reinvented themselves and patented their novel techniques, including: a method for improved text searching, a technique for extracting patterns from scattered databases like the world wide web, and a way of mapping and tagging the data their algorithms generated.⁹² Through patents like these, Google generates data about the similarities and differences of the material available on the internet.⁹³ This data can then be efficiently organized to enable the consumer to conveniently find information to make the website incredibly user friendly.⁹⁴

assuring customer ownership of new patents and design rights; (3) support for open source; (4) licensing new IP rights back to Microsoft; (5) software portability; (6) transparency and clarity; and (7) learning and improvement. *Id.* See also Julia Justusson, *Exploring Intellectual Property at Apple: A Study of Strategy and Patterns*, KTMINE (Jul. 25, 2018), archived at <https://perma.cc/HZ5U-55JL> (explaining Apple's extensive IP strategy, including copyrights, trademarks, trade secrets, and patents).

⁹¹ See Matt Weinberger et al., *Google's cofounders are stepping down from their company. Here are 43 photos showing Google's rise from a Stanford dorm room to global internet superpower*, BUS. INSIDER (Dec. 4, 2019), archived at <https://perma.cc/LCR9-P2ZM> (detailing the beginning of google and its growth from 'backrub' to 'google'). See also *From the garage to the Googleplex*, GOOGLE (Nov. 2, 2019), archived at <https://perma.cc/4XLT-8CSD> (outlining the initial idea behind the company that we now recognize as Google was to rank different internet web pages by the number of other web pages that linked back).

⁹² See Bill Slawski, *Google's First Semantic Search Invention was Patented in 1999*, SEO BY THE SEA, (Sept. 16, 2014), archived at <https://perma.cc/KBU5-6243> (explaining that the provisional and nonprovisional patents Google, then Backrub, originally filed for could be used to develop a website that could map the internet through tracking how and what web pages linked to other web pages). See also Weinberger, et al., *supra* note 91 (explaining Google's evolution from Backrub to Google).

⁹³ See Slawski, *supra* note 92 (explaining how Google's technology gathered and mapped data on the world wide web, and how Google's intellectual property portfolio initially began).

⁹⁴ See Michael Borella, *Data Engine Technologies LLC v. Google LLC (Fed. Cir 2018)*, PATENT DOCS (Oct. 17, 2018), archived at <https://perma.cc/9376-9KKW> (explaining that the data organization techniques used by Google and other search engines are not patent eligible under 35 U.S.C. § 101, because they fail the two step Alice analysis falling under the (1) abstract idea and (2) not claiming something 'significantly more' than the abstract idea). See also Kristine Laudadio Devine, *Preserving Competition in Multi-Sided Innovative Markets: How Do you Solve a Problem Like Google?*, 10 N.C. J. L. & TECH. 59, 107 (2008) (describing the rise of Google and its crushing effect on the market).

Over the years Google has become immensely popular among search engine users, and through data generating algorithms protected under patents, Google can monitor search patterns, social networking statistics, and even user location.⁹⁵ Google maintains this vast database of user information as a trade secret, which it mines to create and improve its search capacities and target advertising to specific users.⁹⁶ These abilities allow Google unparalleled control over the search engine market.⁹⁷ In 2009, Google commanded 66.8 percent of the global search market, that number grew to 90.8 percent in 2019.⁹⁸ Google's patented data generating technologies have developed large quantities of data, which Google has kept as a trade secret.⁹⁹ Through the use of this data Google has generated new technology and improved advertising, effectively eliminating competition in the search engine market.¹⁰⁰

⁹⁵ See Simon, *supra* note 6, at 378 (explaining the data Google generates from their users, including location, social media tracking, and search history, and how this data is kept as a trade secret).

⁹⁶ See Simon, *supra* note 6, at 379 (noting that Google used patents and trade secrets as complements to create a database of information about their consumers).

⁹⁷ See Jeff Desjardins, *How Google retains more than 90% market share*, BUS.INSIDER (Apr. 23, 2018), archived at <https://perma.cc/HH3X-MWA3> (showing that in 2019 Yahoo accounted for only 2.4 percent of the global search market). In 2016, Bing made a total of \$5.3 billion, compared to Google's \$80 billion in earnings from just advertising alone that same year. *Id.*

⁹⁸ See Manish Agarwal et al., *The Emergence of Global Search Engines: Trends in History and Competition*, 7 COMPETITION POL'Y INT'L 115, 122 (2011) (detailing Google's growth and global share of the search engine market). See also Desjardins, *supra* note 97 (explaining the various search market shares of relevant companies in the year 2019). See also J. Clement, *Google: annual advertising revenue 2001–2019*, STATISTA (Feb. 5, 2020), archived at <https://perma.cc/SY6V-233E> (outlining Google's advertising income from 2001 to 2018). See also Antonio Regalado, *Google's Growing Patent Stockpile*, MIT TECHNOLOGY REVIEW (Nov. 29, 2013), archived at <https://perma.cc/5HLS-HBL7> (explaining that Google has stockpiled a number of different patents in recent years, increasing from 38 patents in 2007 to 1,800 in 2013 alone).

⁹⁹ See generally Simon, *supra* note 6, at 378 (outlining Google's use of its databases to generate new and better services).

¹⁰⁰ See Devine, *supra* note 94, at 59 (explaining the overwhelming effect Google had, resulting in a lack of competition in the U.S. search engine market).

2. Myriad's Use of Patents to Expand into Unforeseen Medical Markets

Similar to Google, Myriad curated their IP portfolio to use trade secrets and patents as complements, allowing them to expand into new markets.¹⁰¹ Over 1.5 million patients have used Myriad's testing services.¹⁰² This database of information is valuable and costly to reproduce.¹⁰³ Myriad utilized this database to research and develop new products not just for genetic testing, but for other types of personalized medicine.¹⁰⁴ Myriad's new products include new methods of genetic testing, algorithms to identify genetic changes, and devices to monitor disease progression.¹⁰⁵ Through these products, Myriad was able to expand into new markets that would not have been accessible without access to this data.¹⁰⁶ Even with the company's

¹⁰¹ See Simon, *supra* note 6, at 378 (outlining Myriad's approach to IP, including obtaining patents and protecting their trade secrets).

¹⁰² See *Myriad Corporate Presentation*, MYRIAD GENETICS (Sept. 10, 2019), archived at <https://perma.cc/T2JJE9WW> (outlining Myriad's current users and planned expansions into new markets, including a number of new countries).

¹⁰³ See Simon, *supra* note 6, at 378 (outlining the type data that Myriad generated and database of patient genetic information it created). See also *Myriad Corporate Presentation*, *supra* note 102 (showing greater than 95% of U.S. payers are in-network to use Myriad's products). Myriad has over 100,000 doctors who prescribe their products and 143 countries who have order their products. *Id.*

¹⁰⁴ See *Myriad Corporate Presentation*, *supra* note 102 (explaining Myriad's new products and their uses).

¹⁰⁵ See Simon, *supra* note 6, at 378 (outlining the type of data that Myriad generated and how this data was used to create new products). See also *Myriad Corporate Presentation*, *supra* note 102 (showing new products in development in 2019). Myriad genetics has developed personalized medicines such as cancer treatments, melanoma detection, and various methods of measuring the progress of diseases. *Id.*

¹⁰⁶ See *Myriad Corporate Presentation*, *supra* note 102 (outlining Myriad's plan to expand into new markets, including further expanding into personalized medicine). One of Myriad's critical success factors used to achieve their goals is building upon their "hereditary cancer foundation," meaning they are using the data and resources from their genetic testing products to research and develop new products. *Id.* See also *Myriad RBM Launches New Immunoassay Services Based on the Ultrasensitive Simoa (TM) Platform*, MYRIAD GENETICS (Mar. 5, 2015), archived at <https://perma.cc/9ZC9-5TAF> (describing Myriad's new immunotherapy product). Simoa measures protein biomarkers in blood samples. *Id.* Myriad used this technology to create a new immunoassay services, expanding upon Simoa's capacities the new technology can now measure multiple proteins simultaneously. *Id.*

emphasis on expanding into unforeseen markets, Myriad remains a powerhouse in the genetic testing marketplace.¹⁰⁷ Many consumers grew to trust and rely on Myriad's products; and even though new genetic testing services are now available—many consumers still use Myriad's genetic testing products.¹⁰⁸

C. *Medical Device Market*

Changes to the patent statute could have a drastic effect on a number of different markets that rely on patent protection, once such market is the industry that has been built around medical devices.¹⁰⁹ Medical devices include devices made for the working purpose of providing medical assistance to the user.¹¹⁰ The Food & Drug

¹⁰⁷ See Simon, *supra* note 6, at 394 (explaining Myriad was a household name in the genetic testing market and used their research and development, stemming from their databases of user data, to create new products outside of the genetic testing market). See also *Myriad Corporate Presentation*, *supra* note 102 (discussing “new indications” that show an additional 175,000 patients per year available in the U.S. and Japan would be eligible to use Myriad's genetic testing products).

¹⁰⁸ See *Myriad Corporate Presentation*, *supra* note 102 (outlining the large volume of the relative global market each of Myriad's new products has, which could dominate especially considering the growing and planned expansion into international markets). Projecting 75% of volume in fiscal year 2019 will come from new products. *Id.* See also Simon, *supra* note 6, at 395 (explaining that, for a time, Myriad was the exclusive provider of genetic testing for the BRCA1 and BRCA2 genes). During this time, patients became comfortable with Myriad's tests and many began to exclusively use Myriad's for all of their genetic testing. *Id.* After Myriad's patents were invalidated and other BRCA1 and BRCA2 testing options were available, many consumers continued to use Myriad's because they trusted the results. *Id.*

¹⁰⁹ See Kate Gaudry et al., *Patent Trends Study Part Six: Medical Devices Industry*, IPWATCHDOG (May 8, 2019), archived at <https://perma.cc/L9A7-BA7F> (noting the U.S. is the largest medical device market, making up 50% of the global market). “As reported in [the] initial patent-trends article, filings for the industry had been dramatically increasing (from approximately 22,400 in 2007 to approximately 34,400 in 2018) until 2015 (the year after Alice), after which filings dropped (to approximately 10,400 in 2018).” *Id.* See also *Saved by Alice*, ELEC. FRONTIER FOUND., archived at <https://perma.cc/3HD7-TY2N> (noting the effect of Alice on patent rulings).

¹¹⁰ See *Is the Product a Medical Device?*, FOOD & DRUG ADMIN. (Mar. 22, 2018), archived at <https://perma.cc/2KPV-ZQSG> (defining a medical device).

Administration (“FDA”) breaks these device into three categories.¹¹¹ Class I devices make up 47 percent of U.S. medical devices: they are low risk, simple in design, and often do not require FDA approval.¹¹² Class II devices make up 43 percent of U.S. medical devices, they pose a moderate level of risk and require 510(k) submissions.¹¹³ The

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: 1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, 2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or 3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Id. See also Gerald Donahue, *Estimates of the Medical Devices Spending in the United States*, ADVAMED (Nov. 2018), archived at <https://perma.cc/JE6B-LREE> (outlining 8 categories of medical devices: electromedical and electrotherapeutic apparatus, irradiation apparatus, surgical and medical instruments, surgical apparatus and supplies, dental equipment and supplies, dental laboratories, and ophthalmic goods). See also *Report to the Congress: Medicare and the Health Care Delivery System*, MEDPAC (June 2017), archived at <https://perma.cc/XN2Q-SV84> (describing the medical device industry). See also *Software as a Medical Device (SaMD)*, FOOD & DRUG ADMIN. (Dec. 4, 2018), archived at <https://perma.cc/MR5X-MBZG> (explaining how software, used not as hardware, can be used as a medical device).

¹¹¹ See *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, FOOD & DRUG ADMIN. (Dec. 29, 2017), archived at <https://perma.cc/AKK7-ERX6> (outlining three classes of medical devices).

¹¹² See *id.* (explaining that class I devices are the most common, pose minimal risk to the user, and are often exempt from FDA approval). “Examples include enema kits and elastic bandages.” *Id.*

¹¹³ See *id.* (defining a class II medical device and the 510(k) notification). “Examples of Class II devices include powered wheelchairs and some pregnancy test kits.” *Id.* See also *510(k) Clearances*, FOOD & DRUG ADMIN. (Sept. 4, 2018), archived at <https://perma.cc/99UZ-HDP3> (defining 510(k) clearance and the process a medical device goes through to achieve 510(k) status). Medical device manufacturers can market their device so long as they can prove the device is “substantially similar” to its predecessor, most 510(k) devices do not require clinical data. *Id.*

purposes of a 510(k) submission is to show the device is “substantially equivalent” to the previous version of the device.¹¹⁴ Class III devices make up 10 percent of U.S. medical devices and are usually high-risk complex devices that sustain or support life and require premarket approval.¹¹⁵

Both Class II and Class III devices are expensive to bring into the market, the average cost to bring a Class II product from conception to market is approximately \$31 million and the price rises to \$94 million for a Class III device.¹¹⁶ Many medical device manufacturers are looking to reduce product costs to adapt to increasingly price conscious hospitals.¹¹⁷ In the past, manufactures could charge high prices for new products that had only minor improvements over their predecessors.¹¹⁸ But due to falling profit margins, many hospitals are hesitant to purchase new devices that are not substantially better than the ones in use.¹¹⁹ On top of this,

¹¹⁴ See *510(k) Clearances*, *supra* note 113 (explaining 510(k) devices are approved by the FDA by a showing by the manufacturer that the device is “substantially similar” to its predecessor). See also Jason Smith & Stephen Barrett, *What are 510(k) Clearance and Premarket Approval?*, DEVICE WATCH (Apr. 12, 2008), archived at <https://perma.cc/TN9S-WZCM> (explaining that 510(k) devices must be “substantially similar” to the previous device in order to be approved by the FDA). Additionally, it is not legal to advertise 510(k) devices as “FDA-approved.” *Id.*

¹¹⁵ See *Learn if a Medical Device Has Been Cleared by FDA for Marketing*, *supra* note 111 (defining a class III device as a device that imposes a high risk onto users and requires premarket approval). “Examples of Class III devices include implantable pacemakers and breast implants.” *Id.*

¹¹⁶ See Josh Makower et al., *FDA Impact on U.S. Medical Technology Innovation*, AVAMED (Nov. 2010), archived at <https://perma.cc/U6VK-LJR7> (finding in the 2010 study that the average cost to bring a class II product from conception to market cost approvability \$31 million and \$94 million for a class III device).

¹¹⁷ See Brian Buntz, *5 Reasons Why Medical Device Innovation Is So Tough*, MED. DEVICE AND DIAGNOSTIC INDUS. (Apr. 4, 2016), archived at <https://perma.cc/6E4S-LHCW> (explaining many medical device manufacturers are looking to cut costs in response to “increasingly cost-conscious” hospitals). See also Chris Newmarker, *2. Medical Device Company Merger Frenzy Could Continue*, MED. DEVICE AND DIAGNOSTIC INDUS. (Jan. 13, 2016), archived at <https://perma.cc/UUL9-A66P> (explaining many hospitals are reducing their costs in response to changes in Medicare).

¹¹⁸ See Buntz, *supra* note 117 (explaining that previously manufactures could make small unnoticeable changes to their devices and charge consumers large amounts for these new devices, despite the fact the previous device worked practically the same).

¹¹⁹ See Buntz, *supra* note 117 (outlining how falling profits and budgets at many hospitals have cause more cost-conscious purchasing).

developing maintenance and risk management programs to prevent potential quality issues is costly.¹²⁰ A single non-routine quality event, such as a recall, can cost the manufacturer as much as \$600 million and could result in as much as a 13 percent stock price drop across the industry.¹²¹ Due to these high costs and significant risks, manufacturers have looked for new ways to cut costs.¹²² Consequently, in recent years, the medical device industry has consolidated, with many entities purchasing or merging with competitors in an attempt to “offer better economies of scale” and provide access to different products and services.¹²³ Changes in technology, competitors, and regulations could have a disastrous effect on companies already struggling to keep up in the current medical market.

¹²⁰ See Buntz, *supra* note 117 (explaining the risks associated with medical devices, including the risk of malfunction, that could lead to high costs in both regulation, recall, and user fear). See also Ted Fuhr et al., *The Business Case For Medical Device Quality*, MCKINSEY & CO. (Oct. 2013), archived at <https://perma.cc/9KLV-BVJG> (outlining how the cost for manufactures to upkeep a maintenance program and risk management for various devices can be costly).

¹²¹ See Fuhr, *supra* note 120, at 10 (showing the cost for a “single non-routine quality event, like a major recall” could result in a medical device company losing as much as \$600 million and the overall industry stock dropping 13%). See also Tejva Pettinger, *Factors affecting the Stock Market*, ECONS. HELP (May 4, 2017), archived at <https://perma.cc/RMM9-GFYL> (explaining various factors that could influence the stock market).

¹²² See Buntz, *supra* note 117 (detailing how many manufacturers have looked to cut costs over increasing manufacturing, development, and maintenance costs).

¹²³ See Newmarker, *supra* note 117 (noting how in recent years to adapt to consumer needs and to “offer better economies of scale” many medical device companies have merged). See also Tejvan Pettinger, *Benefits of Mergers*, ECONOMICS HELP (Nov. 28, 2012), archived at <https://perma.cc/L5TT-H3P5> (describing the benefits of mergers, including the possibility for increased investment in research and development). Mergers also decrease the competition between businesses, as there are less companies competing for consumers. *Id.* See also *Benefits of a Merger or Acquisition*, MINORITY BUS. DEV. AGENCY, U.S. DEP’T OF COM. (Nov. 18, 2019), archived at <https://perma.cc/F68T-CWEE> (noting that mergers allow for better access to different resources, which each company alone may not be able to offer or can offer the other party).

IV. Analysis

A. *The Affect the Proposed Changes to §101 Will Have on the Medical Device Industry*

Congress's proposed changes to 35 U.S.C. §101 will be detrimental to innovation in the medical device industry. The proposed changes will lower the bar for patent eligibility by construing provisions of § 101 in favor of eligibility.¹²⁴ This change would obliterate the *Alice* decision and require § 101 eligibility to be considered without deference to prior art or obviousness.¹²⁵ Without these defenses, more patents could be acquired for various medical device inventions, including software used as a medical device in its own right, or used to ensure optimal performance of a particular device.¹²⁶

¹²⁴ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (describing the new presumption of validity, that would require examiners to presume an application is patent eligible). "Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation." See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80. "The provisions of section 101 shall be construed in favor of eligibility." *Id.*

¹²⁵ See *Sens. Tillis and Coons and Reps. Collins, Johnson, and Stivers Release Draft Bill Text to Reform Section 101 of the Patent Act*, *supra* note 80 (detailing how §101 eligibility will now be decided without consideration of obviousness (§103), prior art (§102), or the various *Alice* requirements).

No implicit or other judicially created exceptions to subject matter eligibility, including 'abstract ideas,' 'laws of nature,' or 'natural phenomena,' shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated. The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.

Id.

¹²⁶ See *Is the Product a Medical Device?*, *supra* note 110 (outlining various medical devices). See also *Software as a Medical Device (SaMD)*, *supra* note 110 (explaining that some medical devices require the use of software in order to be

Software of this nature often falls under the business method exception, which was regulated by the *Alice* decision.¹²⁷ Business method patents have become popular with non-practicing entities, who would file for various patents then seek profit off those rights by threatening companies with licensing demands.¹²⁸ These suits are incredibly expensive and divert funds set aside for patenting towards defending the patents.¹²⁹ Resources used for patenting usually come out of the research and development budget and are typically those used for patent litigation.¹³⁰ Currently, patent holders can use the *Alice* decision as a defense, arguing the non-practicing entity's patent was invalid.¹³¹ Following the *Alice* decision, the percentage of business method patents rejected under §101 increased from 31 percent to 82 percent in just two years.¹³² An *Alice* argument would force a settlement before the case continued, as neither side would want to

operational or to perform optimally). This software is different than the hardware of the medical device. *Id.*

¹²⁷ See *Alice Corp. Pty. Ltd v. CLS Bank Int'l*, 573 U.S. 203, 217–18 (2014) (explaining software patents are generally evaluated under the business methods standard). See also MPEP §2106 (9th ed. Rev. 8, Aug. 2017) (explaining what a method patent is).

¹²⁸ See Testimony of Alex H. Moss, *supra* note 88, at 4 (explaining how business method patents became popular with patent trolls “. . . and others seeking to profit off otherwise useless patent rights by threatening companies with licensing demands far beyond the cost of proving a patent is invalid or isn't being infringed”). See also Mullin, *supra* note 88 (explaining that a non-practicing entity is often referred to as a “patent troll,” a growing problem in the patent industry).

¹²⁹ See Testimony of Alex H. Moss, *supra* note 88, at 5 (explaining how resources can be diverted to protect the IP of the defendant company).

¹³⁰ See Mullin, *supra* note 88 (explaining the high cost of patent litigation usually affects the research and development budget of the responding company).

¹³¹ See Testimony of Alex H. Moss, *supra* note 88, at 4 (explaining patent litigation can be costly and dip into the research and development fund of the company). “That will drain resources from innovation by small companies.” *Id.* at 7. See also Mullin, *supra* note 88 (explaining the cost of patent prosecution and litigation usually affects the research and development budget).

¹³² See Cosgrove, *supra* note 88 (outlining the increase in USPTO rejections of business method patents following the *Alice* decision).

spend time and money in litigation.¹³³ A settlement would thus save the defending company from large costs associated with trial.¹³⁴

Often a decrease in patent litigation results in a decrease in the overall cost of patenting, this means that more money, often set aside for patenting, can be spent on research and development.¹³⁵ This trend was seen post *Alice*, a number of different companies were able to increase their research and development budget as they were able to spend substantially less money on litigation costs.¹³⁶ *Alice* was able to save a number of small companies from excessive patent litigation, in some cases even saving the company from going out of business.¹³⁷

¹³³ See Testimony of Alex H. Moss, *supra* note 88, at 4 (explaining how the *Alice* decision could be used as a defense to force a settlement, saving the defending company huge amounts of money).

For small companies, independent developers, and makers of all kinds, the difference between winning a case early under Section 101 and trying to win on other grounds of invalidity or non-infringement at later stages cannot be overstated. Trying to win a case on any other basis requires incurring the exorbitant costs of discovery and expert witnesses on practically every issue.

Id. at 6. “The effects of *Alice* have been powerful and positive. It has led district courts to reject baseless lawsuits early enough to save parties from the staggering costs of discovery and trial.” *Id.* at 4.

¹³⁴ See Testimony of Alex H. Moss, *supra* note 88, at 4–5 (explaining this money can be better spent in research and development).

Trying to win a case on any other basis requires incurring the exorbitant costs of discovery and expert witnesses on practically every issue: the meaning of a patent’s claims (claim construction), written description and enablement (invalidity under Section 112), invalidity for anticipation or obviousness in view of prior art (Sections 102 and 103, respectively), and infringement.

Id. at 6.

¹³⁵ See Srinivasan, *supra* note 88 (explaining the effect of *Alice* on research and development). The *Alice* decision allowed “firms to increase their investment in R&D while simultaneously reducing their patenting.” *Id.* at 24.

¹³⁶ See Srinivasan, *supra* note 88, at 24 (explaining the effect *Alice* had on the patent litigation expenses of a number of different companies). Following, these companies were able to spend the money they previously would have spent defending their patents on research and development. *Id.*

¹³⁷ See *generally Saved by Alice*, *supra* note 109 (noting that *Alice* saved a number of different companies from frivolous patent litigation that threatened to put the company out of business). See also Testimony of Alex H. Moss, *supra* note 88, at 9 (detailing the plight of one small business: “Over a two-year period, Ordrx spent as much on litigation expenses as it did on employee salaries. David cut his own

The *Alice* case acts as a defense for frivolous patent litigation, allowing companies to spend more money on research and development.¹³⁸

Lowering the bar for patent eligibility and doing away with *Alice* would increase the number of patents the USPTO would allow.¹³⁹ *Alice* has had a profound effect on § 101 for if a patent application receives a § 101 rejection there is a 63 percent chance the rejection will cite *Alice*.¹⁴⁰ While applications that receive § 101 rejection usually have a 60.8 percent chance of overcoming them, if the rejection cites *Alice*, the chance drops to 49.7 percent.¹⁴¹ Doing away with *Alice* would mean more companies would file and receive

salary entirely during that time. Ultimately, these litigation costs caused Ordrx to fold, and David had to lay off 40 employees.”).

¹³⁸ See Testimony of Alex H. Moss, *supra* note 88, at 9 (explaining that the *Alice* decision greatly decreased the number of frivolous patent suits).

Section 101 is critical to ensuring the patent law fosters the productive and innovative efforts of people and businesses that the Constitution’s authors expected the patent system to promote. It limits what can be patented to ensure the power that patents confer the power to stop others from using whatever a patent claims as its invention does not deprive the public of access to basic research tools and aspects of nature that no person could have invented. No other provision of patent law has the same purpose or effect.

Id. at 3. *Alice* plays an important part in patent law, helping to uphold the high standards of §101. *Id.* at 5. “[T]he *Alice* decision is helping achieve balance by weeding out low value patents that offer nothing that could plausibly qualify as inventive while leaving space for claims that at least arguably advances beyond the addition of well-known expedients to basic concepts.” *Id.* at 5.

¹³⁹ See Cosgrove, *supra* note 88 (outlining the increase in USPTO rejections of business method patents following the *Alice* decision). See Underhill, *supra* note 87 (explaining the number of patents the USPTO allowed decreased following the *Alice* decision, especially in the area of business methods).

¹⁴⁰ See Cosgrove, *supra* note 88 (noting that applications that receive §101 rejections fare worse if the rejection will cite *Alice*). “[I]f an applicant receives a § 101 rejection, there is a 63.9% chance that that rejection will cite *Alice*.” *Id.*

¹⁴¹ See Cosgrove, *supra* note 88 (noting that “[o]verall, applicants who receive § 101 rejections have a 60.8% chance of overcoming them. However, if the rejection cites *Alice*, that chance drops to 49.7%. Of course, these statistics are mere averages.”). Rates of success in responding to § 101 rejections are affected by the type of response. *Id.* “When it is time to respond to an *Alice* rejection, the vast majority of applicants choose a request for continued examination (RCE), at 65.1%. The second most frequent response is abandonment, at 18.4%.” *Id.* “[T]he most advantageous response to an *Alice* rejection is an interview, with a 59.1% success rate. RCEs, meanwhile, are only successful at overcoming *Alice* rejections 37.9% of the time.” *Id.*

patents, causing an increase in litigation costs.¹⁴² Increased patenting costs would divert resources away from research and development, causing a decrease in innovation.¹⁴³ As more patents are issued the number of companies utilizing complementary IP portfolios to generate user data would potentially likewise increase.¹⁴⁴ Using patents to collect user data, which is then kept as a trade secret creates databases of information that companies can use to create new products and establish a monopoly, stifling innovation in the medical device industry.

B. *Economic Effect on Innovation*

1. Preempting Potential Competition

The use of trade secrets and patents as complements is an incredibly effective way to preempt potential competition. By utilizing an IP portfolio that obtains patents to develop consumer information, a corporation is able to keep the resulting data as a trade secret.¹⁴⁵ The corporation can then analyze that data to develop new products or improve existing capacities.¹⁴⁶ By tailoring products to better fit the consumers' needs, the corporation attracts new users and

¹⁴² See Srinivasan, *supra* note 88 (explaining that an increase in patent regulation lead to a decrease in patent litigation resulting in an increase in research and development spending).

¹⁴³ See generally Srinivasan, *supra* note 88 (noting that a decrease in patent litigation lead to an increase in research and development spending). Often costs associated with patenting were folded in under the budget of research and development. *Id.*

¹⁴⁴ See Cosgrove, *supra* note 88 (outlining the increase in USPTO rejections following the *Alice* decision). See Underhill, *supra* note 87 (explaining the number of patents the USPTO allowed decreased following the *Alice* decision). See generally *Saved by Alice*, *supra* note 109 (noting that *Alice* saved a number of different companies from frivolous patent litigation).

¹⁴⁵ See 1 MILGRIM ON TRADE SECRETS §1.01 (2019) (outlining how a trade secret can be used to create product information a corporation may find valuable). See also *Trade Secret Policy*, *supra* note 22 (detailing what constitutes a trade secret).

¹⁴⁶ See Simon, *supra* note 6, at 378 (outlining the database Myriad created with data they collected from their patented technology). The data generated by Myriad's test was kept as a trade secret. *Id.* at 378. This data can be mined for consumer information that is not accessible to competitors and is near impossible to recreate without access to the patented technology. *Id.* at 379.

ensures existing consumers continue using the product.¹⁴⁷ Without a corresponding database of user data, competitors have a hard time developing products that perform as effectively.¹⁴⁸ Through the use of their databases, corporations are able to develop new and more effective products that attract consumers and can put their competitors out of business.¹⁴⁹

Developing new products is incredibly expensive, without databases of client data to effectively bring a product to market, a manufacturer risks a huge financial loss.¹⁵⁰ On average, to bring a new class III product to market costs around \$100 million and around \$31 million for a class II product.¹⁵¹ Without proper development major defects can occur, which could injure consumers and damage the market overall.¹⁵² A single quality issue such as a major recall, could result in the medical device company losing as much as \$600 million

¹⁴⁷ See Investor Relations, *supra* note 71 (outlining Myriad's expected revenue from 2012). See also *MYRIAD GENETICS*, *supra* note 75 (detailing Myriad's stock portfolio over the years). In March 2015, Myriad's stock increased. See *id.* See also *Myriad RBM Launches New Immunoassay Services Based on the Ultrasensitive Simoa (TM) Platform*, *supra* note 106 (announcing the new Simoa based product on March 5, 2015). See also Pettinger, *supra* note 123 (explaining a perceived increase in demand for a good or service could increase share prices).

¹⁴⁸ See *The Rise of Integrated Medical Devices*, *supra* note 3 (explaining how user data can be used to develop new products). See also Simon, *supra* note 6, at 379 (explaining the databases of user data can be mined for information that is not accessible to competitors, including small startups, and is near impossible to recreate without access to the underlying patents).

¹⁴⁹ See Devine, *supra* note 94, at 59 (explaining the affect google had in the U.S. search engine market, resulting in a lack of competition).

¹⁵⁰ See Buntz, *supra* note 117 (detailing the costs that go into developing a new medical device). See also Makower, *supra* note 116, at 10 (explaining the U.S. medical device industry accounts for \$123 billion in products, \$21.5 billion in salaries to over 357,000 employees).

¹⁵¹ See Makower, *supra* note 116, at 10 (explaining it can cost on average around \$100 million to bring a PMA product to market and around \$31 million for a 501(k) product). See also Medpac, *supra* note 110, at 209 (noting that medical devices account for approximately 4% to 6% of total U.S. spending on health care).

¹⁵² See *501(k) Clearances*, *supra* note 113 (explaining that under the FDA 501(k) approval process medical device manufacturers can market their device so long as they can prove the device is "substantially similar" to its predecessor, and that most 501(k) devices do not require clinical data). See also Buntz, *supra* note 117 (explaining the risks associated with medical devices, including the risk of malfunction). A malfunction in a device could lead to fear among other consumers that their device may fail resulting in a similar injury. *Id.*

and the overall industry stock dropping as much as 13 percent.¹⁵³ These jarring figures make it all the more important to invest in early stages.¹⁵⁴ Additionally, government regulation such as testing, preventative maintenance, and approval also contribute to the high costs of developing new medical devices.¹⁵⁵

Understanding what the consumer is looking for and what new products would fill existing needs can ensure a device will be successful.¹⁵⁶ Corporations can use their databases to mine information about what common issues consumers have.¹⁵⁷ By understanding this information, corporations will be more likely to fund products because they know long term the device will be successful.¹⁵⁸ Without the knowledge of how a product will likely perform in the market, it will be harder to get funding from investors, who will be weary to take a chance on a new device.¹⁵⁹

¹⁵³ See Buntz, *supra* note 117 (showing the cost for a “single non-routine quality event, like a major recall” could result in a medical device company losing as much as \$600 million and the overall industry stock dropping 13%). See also Medpac, *supra* note 110, at 218 (noting that “OIG found \$1.5 billion in Medicare payments and \$140 million in beneficiary copayments and deductibles for services and procedures associated with seven recalled or failed devices”).

¹⁵⁴ See Medpac, *supra* note 110, at 214 (outlining the affect a non-routine medical device failure can have on a patient). In 2016, the FDA recalled about 2,900 products, of which 4% could have caused major medical risk to the user. *Id.*

¹⁵⁵ See Makower, *supra* note 116, at 7 (noting that the 2010 study found that the average cost to bring a class II product from conception to market cost approvability \$31 million and \$94 million for a class III device). See also Buntz, *supra* note 117 (outlining the various costs associated with bringing a new medical devices product to market).

¹⁵⁶ See Buntz, *supra* note 117 (explaining the costs associated with developing new medical devices).

¹⁵⁷ See Simon, *supra* note 6, at 379 (explaining the databases of user data Myriad collected could be mined for information that is not accessible to competitors and is near impossible to recreate). This data could be used to understand what other issues consumers often had by analyzing their genetic data to identify other diseases. *Id.* This data could then be used to create new devices. *Id.* See also *Myriad RBM Launches New Immunoassay Services Based on the Ultrasensitive Simoa (TM) Platform*, *supra* note 106 (announcing a new genetic testing platform that expanded upon a previous genetic test).

¹⁵⁸ See Medpac, *supra* note 110, at 217 (explaining how an improved understanding of a devices long term costs can help in estimating future expenses).

¹⁵⁹ See generally *id.* (explaining how this estimation can help both consumers and the medical device company understand what the device will cost long term). Understanding the long-term costs can ensure the consumer receives the

Smaller medical device companies often look to venture capital firms for funding.¹⁶⁰ Some of these companies will spend the majority of their money on research and development and may be unprofitable for years before developing a viable product.¹⁶¹ From 2007 to 2009, the total amount of venture capital funding in medical device companies declined from \$3.7 billion to \$2.6 billion.¹⁶² With funding from venture capital firms decreasing, smaller companies may have a harder time developing products and will be more likely to go out of business.¹⁶³

These practices contribute to chances being taken on innovative new products, making it easier for larger corporations to halt competition in their existing markets.¹⁶⁴ Medical device companies with revenues placing them in the top one percent of the industry accounted for 82 percent of total assets.¹⁶⁵ Smaller corporations without access to the infrastructure, funding, and databases these larger companies utilize will have a harder time improving and developing new products.¹⁶⁶ In recent years, these

appropriate device. *Id.* Through an understanding of what device is most appropriate for the consumer, a medical device company can better create products that meet consumer needs. *Id.*

¹⁶⁰ See *id.* at 210 (explaining that smaller medical device companies often look to venture capital firms for seed funding).

¹⁶¹ See *id.* (noting that smaller companies will often spend large amounts of money on research and development and may be unprofitable for years before developing a viable product).

¹⁶² See *id.* (noting that “between 2007 and 2009, the total amount that venture capital firms invested in medical device companies declined from \$3.7 billion to \$2.6 billion”).

¹⁶³ See Medpac, *supra* note 110, at 211 (noting that without funding smaller corporations will go out of business).

¹⁶⁴ See Simon, *supra* note 6, at 382 (explaining the ways companies can preempt potential competition to drive competitors out of business).

¹⁶⁵ See Medpac, *supra* note 110, at 210 (noting a CRS study found “the top 1 percent of firms in the medical device industry accounted for 82 percent of total assets, with the top 0.2 percent of firms alone accounting for 56 percent of overall assets”).

¹⁶⁶ See generally Buntz, *supra* note 117 (detailing the various costs that go into developing a new medical device). See also Medpac, *supra* note 110, at 210 (noting 83 percent of companies had less than \$1 million in assets, and 95 percent had less than \$10 million in assets). Most companies in the medical device industry would qualify as ‘small.’ *Id.* See also Makower, *supra* note 116, at 37 (noting that the 2010 study found that the average cost to bring a class II product from conception to market cost approvability \$31 million and \$94 million for a

smaller inventors have been bought up by the larger corporations.¹⁶⁷ Merging with or buying out competitors gives these larger corporations access to new companies' capacities, devices, and IP.¹⁶⁸ However, these companies may not wish to continue development on unfinished devices in the overtaken company's portfolio.¹⁶⁹ Likely these new products will be scratched and the capacities merged into other departments to better fit the larger corporation's needs.¹⁷⁰ By utilizing the data collected from the patented technology, a medical device company can preempt potential competition by developing better products and putting their competition out of business.

2. Expanding into New Markets

Databases of consumer information gives the holding corporation an understanding of not only how their existing products function, but also what new products are needed. In addition to helping the corporation understand their market, this data can illuminate other consumer needs potentially leading to new products.¹⁷¹ This was seen

class III device). Most of these small companies would not be able to pay these high prices. *Id.* at 38. David Cassak, managing director of Windhover information, explains ““We’ve already hit that point where innovators and investors look at the regulatory pathway and say, “This new technology could be meaningful and could be helpful to patients, but we just can’t even take a chance on it.””” *Id.*¹⁶⁷ See Newmarker, *supra* note 117 (noting a large number of medical device manufacturers have merged in recent years as a response to changing demands in the industry). In recent years, to adapt to consumer needs and to “offer better economies of scale” many medical device companies have merged or bought out competitors. *Id.*

¹⁶⁸ See generally *Benefits of a Merger or Acquisition*, *supra* note 123 (noting mergers allow for better access to different resources, including the two companies' existing facilities, IP, etc.).

¹⁶⁹ See Pettinger, *supra* note 123 (detailing how mergers can decrease competition in a market, because there are less companies competing for consumers).

¹⁷⁰ See Pettinger, *supra* note 123 (noting how mergers can decrease competition).

¹⁷¹ See Simon, *supra* note 6, at 378 (outlining the database Myriad created with data they collected from their patented technology). Myriad's databases can be mined for information that is not accessible to competitors, that could be used in the initial stages of developing new products. *Id.* See also *Investor Relations*, *supra* note 71 (outlining Myriad's expected revenue from 2012). See also *Myriad Genetics, Inc.*, *supra* note 75 (detailing Myriad's stock portfolio over the years). In March 2015, Myriad's stock increased following the release of their new Simoa based product. *Id.* See also *Myriad RBM Launches New Immunoassay Services*

in the *Association for Molecular Pathology v. Myriad Genetics, Inc.* case, where the invention detected abnormalities in the BRCA gene, but also collected data on the entirety of the patient's genome.¹⁷² Myriad could mine this data for other abnormalities and develop testing kits to find changes in the genome that would show other genetic abnormalities.¹⁷³ From this, Myriad proceeded to develop tests for various other genetic abnormalities.¹⁷⁴ Ultimately, these databases of consumer information gave Myriad an opportunity to expand into new markets and extract profits from existing entities.¹⁷⁵

Without competition prices will increase, as singular corporations will become the only sellers of certain devices.¹⁷⁶ Lacking fear of being outmatched by a competitor, corporations can

Based on the Ultrasensitive Simoa (TM) Platform, supra note 106 (announcing the new Simoa based product on March 5, 2015). *See also* Pettinger, *supra* note 123 (explaining that a perceived increase in demand for a good or service could increase share prices).

¹⁷² *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (outlining the facts, specifically the patents at issue, of the Myriad Genetics case). Myriad's most popular product was their genetic testing kits, specifically the kit that tested for mutations in the BRCA1 and BRCA2 gene, which is accepted as the indicator of a heightened risk for breast cancer. *Id.* *See also* Simon, *supra* note 6, at 378 (explaining that Myriad's genetics tests collected data about the consumers' entire genome, which was kept as a trade secret).

¹⁷³ *See* Simon, *supra* note 6, at 378 (explaining these databases can be mined for information to create new products and give the corporation an advantage against competitors).

¹⁷⁴ *See* Myriad RBM Launches New Immunoassay Services Based on the Ultrasensitive Simoa (TM) Platform, *supra* note 106 (describing Myriad's new immunotherapy product Simoa, which measures protein biomarkers in blood samples). Myriad used this technology, which can now measure multiple proteins, to create new immunoassay services. *Id.*

¹⁷⁵ *See* Myriad Corporate Presentation, *supra* note 102 (detailing Myriad's plan to expand into new markets, including further expansion into the personalized medicine market). One of Myriad's critical success factors used to achieve their goals is building upon their "hereditary cancer foundation," meaning they could potentially be using the resources from their genetic testing products to research and develop new products in new markets. *Id.*

¹⁷⁶ *See* Simon, *supra* note 6, at 379 (explain how Google used an IP portfolio, including both trade secrets and patents, to take over the search engine market by developing better products that attracted more users). *See also* Desjardins, *supra* note 97 (explaining that Google currently holds a 90% share of the global search engine market). *See also* Devine, *supra* note 94, at 88 (explaining the overwhelming affect google had, resulting in a lack of competition in the U.S. search engine market).

set prices as they wish.¹⁷⁷ Devices will not be improved upon and new devices will be produced at a lower rate because there is no incentive to get these products to market.¹⁷⁸ Overall this negatively effects consumers, who will now have to pay more for devices and will receive less effective and innovative products.

V. Conclusion

IP protection is crucial to ensuring a company is successful in its market, this is especially true in the medical device industry. Curated IP portfolios made up of data-collecting patents produce databases of patient information, which is protected by trade secrets. These databases can be used to conduct research and development, expand into unforeseen markets, and preempt potential competition. This strategic IP portfolio enables companies to create a market monopoly, wherein they can drive up the price of their devices, stifle innovation, and prevent smaller entities from entering the market. Patients will see their options for medical devices decrease, while the products they have access to become more expensive and less innovative.

Relaxing of the patent statute would allow more patents to issue, causing a higher cost of patenting coupled with a decrease in spending on research and development. Without this spending, many smaller entities will likely go out of business causing a decrease in innovation throughout the medical device industry. Congress's proposed changes to the patent statute would remove longstanding protections against this kind of patent curation—doing away with the

¹⁷⁷ See Pettinger, *supra* note 123 123(explaining that mergers decrease competition between businesses, as there are less companies competing for consumers). See also *Report to the Congress: Medicare and the Health Care Delivery System*, *supra* note 110, at 237 (explaining that without competition prices for consumers may increase).

¹⁷⁸ See Makower, *supra* note 116, at 15 (outlining how the high cost of bringing new devices to market disincentives innovation). Bringing a fully new devices to market is costly compared to minutely improving a previous device. *Id.* See also Buntz, *supra* note 117 (explaining that manufactures can make small unnoticeable changes to their devices and charge consumers large amounts for these new devices, despite the fact the previous device worked practically the same). See also *510(k) Clearances*, *supra* note 113 (explaining that 510(k) devices are approved by the FDA by a showing by the manufacturer that the device is “substantially equivalent” to its predecessor).

Alice decision, and requiring § 101 eligibility to be considered without deference to prior art or non-obviousness. Data collecting patents can be used to collect large amounts of data, which can in turn be held as a trade secret and used to further stifle innovation, meaning patients will see more expensive and less effective products in the medical device industry.