Reconsidering Conflicts over Gene Patents in View of Taiwan Patent Law

By LUNG-SHENG CHEN

ABSTRACT

This article discusses the legal and policy issues arising out of gene patents in light of the United States Supreme Court's *Myriad* decision. There are alternatives to an outright ban on all gene patents. This article proposes recommendations to accommodate the competing interests of patient access to beneficial technologies and gene patenting. In order to balance the competing interests of encouraging innovation while making gene-based medical treatment more accessible, a research exemption from patent infringement and compulsory licensing of a gene patent is suggested by referring to the Taiwan Patent Act. These solutions would ensure scientists and other groups the opportunity to use gene-related patents for the public interest or noncommercial purposes. The research exemption enables research on patented genes without the risk of being held liable for infringement, thereby promoting further advancement in the gene-related industry. The framework of a compulsory license ensures patient access to genetic treatment. These solutions, on the one hand, solve primary concerns surrounding gene patents, and on the other hand, maintain gene patent protection and the incentives needed to promote the progress of gene-related technologies.

I. INTRODUCTION

THE UNITED STATES SUPREME COURT'S 2013 *Association for Molecular Pathology v. Myriad Genetics, Inc.* decision¹ (hereinafter *Myriad*) has drawn the debate over patent eligibility of human genes.² Gene patents, or patents attempting to claim a DNA or nucleotide sequence,³ have always been controversial. Proponents advocate that gene patents give inventors powerful incentives in genetic research.⁴ Opponents, however, argue that gene patents can restrict patient access to genetic diagnostic tests and many other essential health services.⁵ Others object to gene patents

¹*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

²Andrew Pollack, *Justices Consider Whether Patents on Genes Are Valid*, N.Y. TIMES, Apr. 14, 2013, available at <https://reurl.cc/pDQyXe> (last visited Feb. 20, 2020); Adam Liptak, *Justices Seem Wary of Bold Action in Gene Patent Case*, N.Y. TIMES, Apr. 15, 2013, available at <https://reurl.cc/Naz6Ex> (last visited Feb. 20, 2020).

³See Code of Federal Regulations, United States Patent and Trademark Office, Department of Commerce, 37 C.F.R. § 1.821(a) (2005) ("Nucleotide and/or amino acid sequences ... are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides.").

⁴See Wolrad Prinz, *Research Tool Patents After Integra v. Merck—Have They Reached a Safe Harbor?*, 14 MICH. TELECOMM. & TECH. L. REV. 367, 372 (2008); Brian Murphy and Daniel Murphy, *Bilski's "Machine-or-Transformation" Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 760 (2010).

⁵Department of Health and Human Services, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Sec'y's Advisory Comm. on Genetics, Health, and Soc'y*, 3 (2010), http://oba.od.nih.gov/oba/sacghs/reports/sacghs_Patents_report_2010.pdf [hereinafter SAGCHS Report].

Keywords: gene patent, compulsory license, *Myriad*, research exemption, Taiwan Patent Act, patient access, patent eligibility

Lung-Sheng Chen is Associate Professor in the Department of Law at National Chung Hsing University in Taiwan. Mr. Chen holds an LLM from Washington University in St. Louis (United States) and National Chung Cheng University (Taiwan), and a JD from Washington University in St. Louis (United States). E-mail for Mr. Chen: lawchen@email.nchu.edu.tw

because such patents potentially impede the progress of future research.⁶

The Supreme Court has interpreted the patentable subject matter broadly to include “anything under the sun that is made by man.”⁷ Therefore, a natural substance such as a gene in its natural form is barred from patent protection because it is a product of nature.⁸ However, a patent application claiming a purified and isolated form of a gene or the protein it creates is patentable.⁹ Although there are criticisms of gene patent eligibility before the Supreme Court’s *Myriad* decision, the question was shortly put to rest after the United States Patent and Trademark Office (USPTO) issued its “Utility Examination Guidelines” (the “Utility Guidelines”) in 2001.¹⁰ Based on the Guidelines, a patent may contain claims directed to an isolated and subsequently purified genetic composition.¹¹ Therefore, gene patents typically cover the manifestation of genetic information in a physical form,¹² and genetic composition is broader than the scientific definition of a gene.

Myriad Genetics, a private biotechnology company, isolated the BRCA1 and BRCA2 genes associated with breast cancer and obtained patents in the U.S. and Europe.¹³ The breadth of the patents and the effects of preventing others from using these genes in medical research and patient care have triggered widespread criticism.¹⁴ The courts in the *Myriad* case have exemplified these concerns.¹⁵ In addition to these ethical arguments, another important patentability question is whether gene patents meet the nonobviousness requirements of patentability. For instance, in 2004, the European Patent Office Opposition Division revoked Myriad Genetics’ BRCA1 and BRCA2 patents because they lack an inventive step (nonobviousness criteria in the U.S.).¹⁶

This article will explore the legal and policy issues arising out of gene patents in light of the *Myriad* decision. Part II begins with a brief overview of gene patents and outlines the essential patentability requirement under the U.S. patent law. Part III analyzes the *Myriad* decisions and discusses their implications on gene patent eligibility. Part IV examines the alleged problems created by gene patents. This part will focus on the policy concerns of gene patent debates. Finally, Part V proposes recommendations to the competing interests of patient access to beneficial technologies and gene patenting. In this part, I suggest a research exemption from patent infringement and compulsory licensing of a gene patent by referring to the Taiwan Patent Act. These solutions would ensure scientists and other groups the opportunity

to use gene-related patents for public interests or noncommercial purposes.

II. GENE PATENTS AND PATENTABILITY

Gene patents have grown in recent decades.¹⁷ Before addressing the issues raised in the *Myriad* case, one should understand the concepts of genes and the patentability requirements. This part provides a brief overview of genetics and biotechnology, as well as the U.S. patent law background.

A. Overview of genes

Broadly speaking, biotechnology is “the manipulation of living organisms or their components to produce useful, usually commercial, products (as pest-resistant crops, new bacterial strains, or novel pharmaceuticals).”¹⁸ Biotechnology uses biological techniques to advance the development or manufacture, or both, of a product for the industry.¹⁹ As such, the advancement in biotechnology has broad

⁶See Christopher M. Holman, *Trends in Human Gene Patent Litigation*, 322 SCIENCE 198, 198 (Oct. 2008); Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U.J. SCI. & TECH. L. 1, 50 (2005).

⁷*Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

⁸See Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 299 (2007).

⁹John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689, 689–90 (May 1 1998). In order for DNA sequences to be distinguished from their naturally occurring counterparts, the patent application must state that the invention has been purified or isolated or is part of a recombinant molecule or is now part of a vector.

¹⁰U.S. Patent and Trademark Office (USPTO), *Utility Examination Guidelines*, 66 Fed. Reg. 1092 (Jan. 5, 2001).

¹¹*Id.*

¹²*Id.*

¹³Aljalian, *supra* note 6, at 53.

¹⁴*Id.* 53–54.

¹⁵See *infra* Part III.

¹⁶See Alison Abbott, *Clinician Win Fight to Overturn Patent for Breast-Cancer Gene*, 429 NATURE 329, 329 (2004).

¹⁷Sirpa Soini, Ségolène Aymé, and Gret Matthijs, *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 EUR. J. HUM. GENETICS S10, S10 (2008).

¹⁸See *Biotechnology*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/biotechnology> (last visited Feb. 20, 2020).

¹⁹See *Biotechnology*, ENCYCLOPEDIA BRITANNICA, <http://www.britannica.com/search?query=Biotechnology&ct=&fuzzy=N> (last visited May 14, 2019). Biotechnology is defined as “the application to industry of advances made in the techniques and instruments of research in the biological sciences.”

and significant impacts on the industry.²⁰ For instance, the discovery of DNA structure in 1953 by James D. Watson and Francis H.C. Crick²¹ brought about the subsequent development of recombinant DNA technology in the 1970s, and such technology has been widely used to manipulate the DNA of bacteria and other organisms to manufacture biological products such as industrial materials and drugs.²²

DNA, which stands for deoxyribonucleic acid, consists of two long polymers of nucleotides.²³ These two strands, in the shape of a double helix, are formed by linking together four different nucleotides called bases.²⁴ There are four types of nucleotides in a DNA molecule: adenine (A), thymine (T), cytosine (C), and guanine (G).²⁵ The nucleotide bases A and T form a bond, and so do the bases C and G.²⁶ It is the sequence of these four bases along the backbone that encodes information that is read using the genetic code. Except for some RNA (ribonucleic acid) viruses, most organisms use DNA to carry genetic information.²⁷ A gene is a specific sequence of nucleotides and the basic physical and functional unit of heredity, and a naturally occurring DNA molecule generally comprises more than one gene.²⁸ The term “gene” refers to “a locatable region of genomic sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions and/or other functional sequence regions.”²⁹ However, increasingly, except for the concept of protein-encoding genetic sequences, the term “gene” is also broadly used to encompass other functional regions of the genome as well.³⁰

B. Patent law background

The U.S. Constitution authorizes Congress 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.”³¹ Based on this authority, Congress has enacted the U.S. patent law,³² and the law authorizes the USPTO to examine patent applications and to issue patents.³³ To be patented, an invention must meet several requirements. The claimed invention must be patentable subject matter³⁴ and satisfy the patentability requirements, which include utility,³⁵ novelty,³⁶ and nonobviousness.³⁷

Section 101 of the patent law provides that “whoever invents or discovers any new or useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor”³⁸ The Supreme Court has recognized that patentable subject matter should “include anything under the sun that is made by man.”³⁹ The scope of patent eligible subject matter

is limited, however, as the Court has held that “laws of nature, principles, physical phenomena, and abstract ideas” are not patentable.⁴⁰

Once an invention falls into a class of subject matter to which patent protection can be granted, it must comply with patentability requirements to be patented. An invention must be “new and useful,” which is referred to as the “utility” requirement.⁴¹ This utility requirement is satisfied if a

²⁰Leslie G. Restaino *et al.*, *Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?*, 2003 UCLA J.L. & TECH. 2, 2 (2003).

²¹See generally JAMES DARNELL, HARVEY LODISH, AND DAVID BALTIMORE, *MOLECULAR CELL BIOLOGY* 5, 11 (2d ed. 1990).

²²Restaino *et al.*, *supra* note 20, at 2.

²³KENNETH J. BURCHFIEL, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 18 (1995); see also MedicineNet.com for a basic definition of nucleic acid, <http://www.medterms.com/script/main/art.asp?articlekey=4594> (last visited Feb. 20, 2020).

²⁴*Id.*

²⁵*Id.*

²⁶BRUCE ALBERTS *ET AL.*, *MOLECULAR BIOLOGY OF THE CELL*, Part II 99 (3d ed. 1994).

²⁷RNA is involved in protein synthesis and sometimes in the transmission of genetic information. See RNA, MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/rna> (last visited May 14, 2019). Thus, DNA and RNA are both used by living organisms to carry hereditary information.

²⁸See International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE, 860–921 (2001).

²⁹Helen Pearson, *Genetics: What Is a Gene?*, 441 NATURE 398, 399 (2006) (“The idea of genes as beads on a DNA string is fast fading. Protein-coding sequences have no clear beginning or end and RNA is a key part of the information package.”).

³⁰Holman, *supra* note 8, at 307.

³¹U.S. CONST. art. I, § 8, cl. 8.

³²35 U.S.C. §§ 1–376 (2007).

³³35 U.S.C. §§ 1–13 (2007).

³⁴35 U.S.C. § 101. See *Gottschalk v. Benson*, 409 U.S. 63, 67–68 (1972).

³⁵35 U.S.C. § 101 (1952).

³⁶35 U.S.C. § 102 (2002).

³⁷35 U.S.C. § 103 (2004).

³⁸35 U.S.C. § 101 (1952).

³⁹*Diamond v. Chakrabarty*, 447 U.S. at 309.

⁴⁰See *Gottschalk v. Benson*, 409 U.S. 63, 67–68 (1972).

⁴¹See USPTO, *MANUAL OF PATENT EXAMINING PRACTICE* (MPEP), § 2107(I) (8th ed. Rev. 7, 2008). In Taiwan, art. 22 of Taiwan Patent Act also sets forth the utility requirement. It provides that in order to obtain a patent, an invention should be “industrially applicable.” The concept of industrial applicability is what referred as utility in the United States. See also Taiwan Patent Act, art. 22, para. 1 (2017).

patent application shows that the invention provides some practical benefit in its current form.⁴²

Section 102 of the patent law provides the novelty requirement.⁴³ Novelty is determined at the moment of the filing date.⁴⁴ For the novelty requirement, the invention must not have been known by someone other than the inventor before the inventor filed an application. The examiner reviews a patent application for compliance with the novelty requirement by comparing the claimed subject matter to what is known in the prior art.⁴⁵

Section 103 of the patent law describes the nonobviousness requirement, which requires that the subject matter of a patent application was not obvious at the time the invention was made.⁴⁶ An invention will not meet this requirement if the examiner finds that the differences in the subject matter and the prior art are such that the subject matter would have been obvious to a person having ordinary skill in the art. Since the obviousness requirement is measured at the time the invention is made, it is more difficult to assess than the utility and novelty requirements.⁴⁷

III. THE IMPLICATIONS OF THE MYRIAD DECISION ON GENE PATENT ELIGIBILITY

Since 1997, Myriad obtained patents on human genes BRCA1 and BRCA2 (hereinafter BRCA1/2)

that are linked to hereditary breast cancer and a process for the use of the gene for diagnostic and therapeutic purposes.⁴⁸ On May 12, 2009, Association Molecular Pathology together with the other plaintiffs (hereinafter AMP) filed a suit against the USPTO and Myriad in the United States District Court for the Southern District of New York.⁴⁹ AMP requested a declaratory judgment on the ground that Myriad's patents on genes BRCA1/2 are invalid under 35 U.S.C. § 101 because the patents granted to Myriad "are drawn to patent-ineligible subject matter."⁵⁰ Moreover, AMP also argued that Myriad's patents are unconstitutional because the granting of gene patents violated Article I, section 8, clause 8 and the First Amendment of the Constitution.⁵¹

The challenged patents-in-suit include composition claims and method claims.⁵² The composition claims cover two isolated human genes BRCA1/2, and certain mutations in these genes.⁵³ Representative composition claims include claims 1, 2, and 5 of U.S. Patent 5,747,282 (the '282 patent):

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1.

⁴²MPEP, *supra* note 41, § 2107.01(I)(c). The utility requirement contains three separate requirements. First, the invention must be operable or capable of use, which is referred to as general utility. Second, it must solve the problem it is designed to solve, which is referred to as specific utility. Third, the invention must have a minimal social benefit and not be merely harmful or deleterious, which is referred to as substantial utility. *See e.g., In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005); MPEP, § 2107.01(I)(B).

⁴³Patent Act, 35 U.S.C. § 102 (2002). The novelty requirement is set forth in art. 22, para. 1 of the Taiwan Patent Act (2017), which provides that in order to obtain a patent, an invention must not have been "published or used in public [or] has become known to the public" prior to the filing of the application.

⁴⁴35 U.S.C. § 102(a) and (g).

⁴⁵*See* MPEP, *supra* note 41, § 2106. A patent application will be rejected based on the ground of lack of novelty when the examiner finds no differences between the claimed invention and the prior art. If the examiner finds differences between the claimed invention and the prior art, it must be noted that the assessment of those differences should be in light of the knowledge possessed by a person of ordinary skill in the art.

⁴⁶35 U.S.C. § 103. The non-obviousness requirement is set forth in art. 22, para. 4 of the Taiwan Patent Act. Under the law, an invention does not satisfy this requirement if it can be "easily accomplished by a person having ordinary knowledge in the art."

⁴⁷Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 731 (1990). In determining nonobviousness, a court considers: (a) the scope and content of the prior art, and (b) the differences between the prior art and the claims at issue; and (c) the level of ordinary skill in the pertinent art. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *In re O'Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988); *Custom Accessories Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 958 (Fed. Cir. 1986).

⁴⁸Myriad was granted six more patents relating to BRCA1 and BRCA2 genes in the United States between 1998 and 2000. *See Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1309–10 (Fed. Cir. 2012) [*Myriad II*], *cert. granted sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

⁴⁹*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 702 F. Supp. 2d 181, 94 U.S.P.Q.2d (BNA) 1683 (S.D.N.Y. 2010).

⁵⁰*Myriad II*, 689 F.3d 1309.

⁵¹Complaint at ¶ 103, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09CV04515, 2009 WL 1343027 (S.D.N.Y. May 12, 2009) [hereinafter AMP Complaint].

⁵²*Myriad II*, 689 F.3d at 1309.

⁵³*Id.*

5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.⁵⁴

Myriad's method claims relate to isolated gene sequences and diagnostic methods of identifying mutations in BRCA1/2.⁵⁵ These claims cover methods of analyzing or comparing a patient's BRCA sequence with the normal sequence to identify the presence of cancer-predisposing mutations, and screening potential cancer therapeutics.⁵⁶ Representative method claims include claim 1 of U.S. Patent 5,709,999 and U.S. Patent 5,710,001, and claim 20 of the '282 patent:

1. A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from the group consisting of the alterations set forth in Tables 12A, 14, 18 or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID NO:1.⁵⁷

1. A method for screening a tumor sample from a human subject for a somatic alteration in a BRCA1 gene in said tumor which comprises [] comparing a first sequence selected from the group consisting of a BRCA1 gene from said tumor sample, BRCA1 RNA from said tumor sample and BRCA1 cDNA made from mRNA from said tumor sample with a second sequence selected from the group consisting of BRCA1 gene from a nontumor sample of said subject, BRCA1 RNA from said nontumor sample and BRCA1 cDNA made from mRNA from said nontumor sample, wherein a difference in the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said tumor sample from the sequence of the BRCA1 gene, BRCA1 RNA or BRCA1 cDNA from said nontumor sample indicates a somatic alteration in the BRCA1 gene in said tumor sample.⁵⁸

20. A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said com-

pound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.⁵⁹

The district court granted the plaintiffs' motion for summary judgment and held that the composition claim to isolated DNA and the method claim to screening potential cancer therapeutics via changes in cell growth rates were patent-ineligible subject matter.⁶⁰ The Federal Circuit, however, reversed the district court's decision (*Myriad I*).⁶¹ The Supreme Court vacated the Federal Circuit's judgment and remanded the case for further consideration in light of its 2012 decision, *Mayo Collaborative Services v. Prometheus Laboratories*.⁶² On remand, the Federal Circuit reaffirmed its earlier ruling upholding the composition claims and one method claim (*Myriad II*).⁶³ On November 30, 2012, the Supreme Court granted *certiorari* as to Question 1 presented by the petitioners, "Are human genes patentable?"⁶⁴ In 2013, the Supreme Court invalidated Myriad's BRCA1 and BRCA2 patents.⁶⁵

In *Myriad*, AMP contended that Myriad's composition claims, BRCA1/2 sequences, embody naturally occurring genetic code and Myriad did nothing but discover the pre-existing gene sequence.⁶⁶ As such, the disputed claims covered

⁵⁴*Id.*

⁵⁵*Id.* at 1310.

⁵⁶*Id.* at 1309–10.

⁵⁷*Id.* at 1309.

⁵⁸*Id.* at 1310.

⁵⁹*Id.*

⁶⁰*Myriad*, 702 F. Supp. 2d at 232.

⁶¹*Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329, 1334 (Fed. Cir. 2011) [*Myriad I*], vacated *sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012).

⁶²*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794, 1794 (2012).

⁶³*Myriad II*, 689 F.3d at 1308–09.

⁶⁴*Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012); see also Petition for a Writ of Certiorari at 21, *Ass'n for Molecular Pathology*, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 U.S. S. Ct. Briefs LEXIS 4098, at 35.

⁶⁵*Myriad*, 133 S. Ct. at 2119–20.

⁶⁶Plaintiffs' Memorandum of Law in Support of Motion for Summary Judgment at 19–29, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 3269113 (S.D.N.Y. Aug. 26, 2009).

unpatentable products of nature and laws of nature.⁶⁷ Myriad responded that isolated DNA molecules encoding BRCA1/2 are structurally and functionally different from BRCA1/2 DNA as they exist in the human body.⁶⁸ Accordingly, the issue is whether Myriad's composition of matter claims are patent-eligible under 35 U.S.C. § 101.

To answer the question of patentability, a court will have to consider whether the claims-in-suit are within the boundary of the subject matter under the patent law. The claimed inventions must satisfy the meaning of the four categories of subject matter and must not fall into three accepted exceptions to patent-eligible subject matter: the law of nature, the physical phenomena, and abstract idea exceptions.⁶⁹ The district court and Federal Circuit relied on *American Fruit Growers, Inc. v. Brogdex Co.*,⁷⁰ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,⁷¹ and *Diamond v. Chakrabarty*,⁷² and asserted that an invention is patent-eligible subject matter if, compared with what exists in nature, the invention has been changed to such an extent as to have "markedly different, or distinctive characteristics."⁷³ However, their conclusions are different.

The district court held that Myriad's composition claims were ineligible for a patent because the claimed BRCA1/2 sequences are not markedly different from the natural DNA.⁷⁴ Focusing on the importance of the information-storing capacities of DNA, the court suggested that the fact that information encoded in the claimed BRCA1/2 remains unchanged between the claimed DNA and the natural DNA represents that the claimed DNA is not markedly different from the natural DNA.⁷⁵ Even the claims for cDNA are not markedly different from products of nature, because "[t]he splice variants represented by these cDNAs are the result of the naturally-occurring splicing of pre-mRNA into mature mRNA. Therefore ... the particular arrangement of those coding sequences is the result of the natural phenomena of RNA splicing."⁷⁶

Unlike the district court, the Federal Circuit held that Myriad's isolated DNA sequences are eligible for patent "because the claims cover molecules [] are markedly different—have a distinctive chemical structure—from those found in nature."⁷⁷ The court reasoned that isolated DNAs are "result[ed] from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA,"⁷⁸ and, "when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity" as compared to native DNA.⁷⁹ Further, the court rejected the plaintiff's argument that isolated DNA retains the same nucleotide sequence as native DNA and thus do not have any "markedly different"

characteristics.⁸⁰ The court focused on the structure and identity of isolated DNA in upholding its patent eligibility conclusion. The court reasoned that "the patent eligibility of an isolated DNA is not negated because it has similar informational properties to a different, more complex natural material."⁸¹

The U.S. Supreme Court drew a line between isolated DNA and cDNA as to the issue of patent eligibility. The Court held that "[a] naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring."⁸² The Court took an information view of DNA as opposed to a chemical-structural approach. It reasoned that "Myriad's DNA claim falls within the law of nature exception" because "[it] did not create or alter either the genetic information encoded in the BRCA1 and BRCA2 genes or genetic structure of the DNA."⁸³ Furthermore, the claims are concerned with the genetic information encoded in the BRCA1 and BRCA2 genes, "not with the specific chemical composition of a particular molecule." However, the Court reached a different result for cDNA by holding that cDNA is patent eligible under § 101. The Court reasoned that the creation of cDNA results in an exon-only molecule, which relies on human intervening to remove introns

⁶⁷*Id.*

⁶⁸Myriad Defendants' Memorandum of Law (1) in Support of Their Motion for Summary Judgment and (2) in Opposition to Plaintiffs' Motion for Summary Judgment at 20–34, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 09 Civ. 4515, 2009 WL 5785008 (S.D.N.Y. Dec. 23, 2009).

⁶⁹*Myriad II*, 689 F.3d at 1324 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

⁷⁰*American Fruit Growers v. Brogdex Co.*, 283 U.S. 1 (1931).

⁷¹*Funk Bros. Seed Co. v. Kalo Inoculant Co. (Funk Bros.)*, 333 U.S. 127 (1948).

⁷²*Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁷³*See Myriad*, 702 F. Supp. 2d at 223; *Myriad II*, 689 F.3d at 1327–28 (stating that "[o]ne distinction ... between products of nature and human-made invention for purpose of § 101 turns on a change in the claimed composition's identity compared with what exists in nature.").

⁷⁴*Myriad*, 702 F. Supp. 2d at 220.

⁷⁵*Id.* at 228–29.

⁷⁶*Id.* at 230.

⁷⁷*Myriad II*, 689 F.3d at 1328.

⁷⁸*Id.*

⁷⁹*Id.* at 1329.

⁸⁰*Id.* at 1330.

⁸¹*Id.*

⁸²*Myriad*, 133 S. Ct. at 2107.

⁸³*Id.* at 2109.

from a DNA sequence.⁸⁴ Therefore, “cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments.”⁸⁵ As such, “cDNA is not a product of nature, [] except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.”⁸⁶

With regard to Myriad’s method claims, the district court held that the method claims-in-suit are invalid because they do not satisfy the “machine or transformation” test articulated by the Federal Circuit in *In re Bilski*.⁸⁷ The court observed that the method claims-in-suit are “directed to the abstract process of ‘comparing’ or ‘analyzing’ gene sequences.”⁸⁸ The court further noted that “even if the method claims-in-suit were construed to include the physical transformations associated with isolating and sequencing DNA,” these claims represent “nothing more than data-gathering steps to obtain the DNA sequence information on which to perform the claimed comparison or analysis” and would still fail the “machine or transformation” test under § 101 for subject matter patentability.⁸⁹

The Federal Circuit in *Myriad I* and *II* both held Myriad’s method claims directed to “comparing” or “analyzing” DNA sequences fall into the “abstract, mental step” exception to patent eligible subject matter.⁹⁰ Additionally, courts in *Myriad I* and *II* also held Myriad’s claim to “method for screening potential cancer therapeutics” to be patent eligible because it is more than an abstract mental step of comparing data.⁹¹ The screening method includes “steps of growing transformed cells in the presence or absence of a potential cancer therapeutic” and “determining the cells’ growth rates,” which are an “inherently transformative step involving the manipulation of the cells and their growth medium.”⁹² Because the underlying subject matter in the screen method claims is patent eligible, the court held that “applying various known types of procedures to it is not merely applying conventional steps to a law of nature” and therefore is eligible as patentable subject matter.⁹³

After the Supreme Court delivered its *Myriad* decision, the USPTO soon published a memorandum providing its preliminary guidance to the Patent Examining Corps relating to gene-related inventions.⁹⁴ Under the guidance, “[e]xaminers should now reject product claims drawn solely to naturally occurring nucleic acids or fragments thereof, whether isolated or not, as being an ineligible subject matter under 35 U.S.C. § 101.”⁹⁵ However, “[c]laims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has

been altered (*e.g.*, a man-made variant sequence), remain eligible.”⁹⁶ “Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and should be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility.”⁹⁷

IV. CONCERNS ARISING FROM GENE PATENTS

Advocates for gene patents contend that genes are not products of nature and should be eligible for granting patents.⁹⁸ Gene patents can stimulate investment and increase incentives for advancement by rewarding the inventors with exclusive rights in a limited term.⁹⁹ Opponents, however, argue that gene patents impede access to patient testing, decrease the quality of genetic testing, and impede the progress of further research.¹⁰⁰

A. Ineligibility of patent subject matter

Many groups, including civil rights advocates and medical professionals, have raised legal and public policy concerns in granting gene patents.¹⁰¹

⁸⁴*Id.*

⁸⁵*Id.*

⁸⁶*Id.*

⁸⁷*Myriad*, 702 F. Supp. 2d at 232–37.

⁸⁸*Id.* at 234.

⁸⁹*Id.* at 236–37.

⁹⁰*See Myriad I*, 653 F.3d at 1334; *Myriad II*, 689 F.3d at 1334–35.

⁹¹*Myriad I*, 653 F.3d at 1357.

⁹²*See id.* at 1357; *Myriad II*, 689 F.3d at 1336.

⁹³*Myriad II*, 689 F.3d. at 1336.

⁹⁴USPTO, *Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.*, (June 13, 2013), available at http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf (last visited Feb. 20, 2020).

⁹⁵*Id.*

⁹⁶*Id.*

⁹⁷*Id.*

⁹⁸Paul Cole, *Patentability of Genes: A European Union Perspective*, Cold Spring Harb Perspect Med, 2015;5(5):a020891 (2015); see generally DAVID KOEPESELL, WHO OWNS YOU?: THE CORPORATE GOLD RUSH TO PATENT YOUR GENES (Chichester, UK, 2nd ed. 2015).

⁹⁹SACGHS Report, *supra* note 5, at 28–29; Lisa M. Gehrke, *Is Gene Editing Patentable*, AMA J Ethics. 2019;21(12):E1049–1055 (2019); KOEPESELL, *supra* note 98, at 155.

¹⁰⁰SACGHS Report, *id.*, at 38–45.

¹⁰¹Zachary Kling, *A Myriad of Reasons: Incentives for Innovation in Genetic Research and Diagnostics Post-Myriad*, 9 BIOTECHNOLOGY & PHARMACEUTICAL L. REV. 1, 11 (2016).

As illustrated in the *Myriad* decision, they argue that isolated-gene sequence was a product of nature and, therefore, should be ineligible patent subject matter under 35 U.S.C. § 101.¹⁰²

In supporting the petitioners, the American Association of Retired Persons (AARP) argued in its *amicus* brief that “DNA molecules and human genes are natural phenomena that when discovered are not the kind of ‘discovery’ that Section 101 was designed to protect.”¹⁰³ Citing *American Wood-Paper Co. v. Fiber Disintegrating Co.*,¹⁰⁴ AARP states that “[t]he Court found that merely removing pulp from straw, wood, or other natural sources did not make it a patentable new composition of matter: ‘A process to obtain it [an extract] from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.’”¹⁰⁵ The AARP argues that “[s]imilarly, isolating a gene from the human body does not then make the gene itself, patentable.” Therefore, “human genes and DNA molecules, regardless of whether they are isolated or not, are natural phenomena and therefore are not patent-eligible under 35 U.S.C. § 101.”¹⁰⁶

There are counterarguments to the criticism of genetic patents. *Myriad* and other proponents argued that genes were not products of nature and are eligible patent subject matter because they were isolated and purified from their source.¹⁰⁷ The purification and isolation as invention doctrine was adopted in the dicta from *Parke-Davis & Co. v. H.K. Mulford Co.*¹⁰⁸ The patent in that case was “an extract from the suprarenal glands of living animals,” and the claim “concern[ed] only the product as extracted by the patentee.”¹⁰⁹ The court found the patent valid because the claimed invention was different from the existing chemical compound. The court reasoned that the claimed substance was separated from the suprarenal glands, and there was a distinction between the extracted product and the original chemical substance “not in degree, but in kind.”¹¹⁰ The court, therefore, held that “Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent.”¹¹¹

The Federal Circuit’s *Amgen, Inc. v. Chugai Pharmaceutical Co.* decision is an important biotechnology case following the *Parke-Davis* isolation and purification doctrine. The court held that “[a] purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human

erythropoietin” is patent-eligible subject matter.¹¹² Proponents of gene patents thus read the *Parke-Davis* case to mean that “synthesizing something found in nature made something ‘man-made’ and no longer natural.”¹¹³ The case law implies that “‘purified and isolated’ were sufficient to distinguish a claimed gene from its naturally occurring counterpart.”¹¹⁴ They argued that genes are not only isolated from their context but also need to be purified by removing unnecessary DNA.¹¹⁵ As such, isolated and purified genes are not natural products and should be eligible patentable subject matter.¹¹⁶

Also, shifting the position from granting gene patents for over 30 years to rejecting those inventions might cause economic chaos for the industry.¹¹⁷ A study conducted by Professor Guerrini and a group of team members from Baylor College of Medicine Center for Medical Ethics and Health Policy (BCM Ethics and Policy Center) in Houston, Texas, pointed out that “[i]nterviewees also expressed substantial concern about the new patent eligibility test” because “every invention is in some way an application of the natural world.”¹¹⁸ The patentable subject matter test represents “a radical

¹⁰²*Id.* See also generally *Myriad*, 133 S. Ct. 2107.

¹⁰³See Brief for AARP as *Amicus Curiae* in Support of Plaintiffs-Appellees and Arguing for Affirmance, at 2, available at <https://patentdocs.typepad.com/files/aarp-amicus-brief.pdf> (last visited Feb. 19, 2020) [hereinafter AARP *amicus* brief].

¹⁰⁴90 U.S. 566 (1874).

¹⁰⁵See AARP *amicus* brief, *supra* note 103, at 3.

¹⁰⁶*Id.*

¹⁰⁷Kevin E. Noonan, *Forward, in WHO OWNS YOU?: THE CORPORATE GOLD RUSH TO PATENT YOUR GENES*, *supra* note 98, at xv; Kling, *supra* note 101, at 16–17.

¹⁰⁸See *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).

¹⁰⁹*Id.* at 96.

¹¹⁰*Id.* at 103.

¹¹¹*Id.*

¹¹²*Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1204 (Fed. Cir. 1991).

¹¹³KOEPSSELL, *supra* note 98, at 96.

¹¹⁴John M. Conley, *Gene Patents and the Product of Nature Doctrine*, 84 CHI.-KENT L. REV. 109, 116 (2009).

¹¹⁵Kling, *supra* note 101, at 16–17.

¹¹⁶KOEPSSELL, *supra* note 98, at 155.

¹¹⁷Noonan, *supra* note 107, at xxii–xxiii.

¹¹⁸Christi J. Guerrini *et al.*, *Constraints on Gene Patent Protection Fuel Secrecy Concerns: A Qualitative Study*, 4(3) J. L. & BIOSCIENCES 542, 552 (2017), available at: <https://doi.org/10.1093/jlb/lxx034>.

new experiment in restricting the scope of the patent system that's not at all consistent with the way things have worked for the past 150 years."¹¹⁹ As such, a general ban on patenting naturally occurring products would result in negative practical outcomes. New drugs derived from natural products and biologic drugs would be ineligible for patent protection.¹²⁰

B. Patient access concerns

Some fear that granting exclusive rights to gene-related inventions may impede patient access to gene-based diagnostic tests.¹²¹ When an entity is the sole holder of a genetic test patent, the lack of competition creates the problems of availability and affordability of products or medical treatments falling within the scope of the patents.¹²²

First, gene patent holders have the right to exclude other laboratories from offering testing relating to gene-based inventions. In order to avoid infringement, clinical laboratories have to stop offering or developing those tests.¹²³ As such, the number of providers of genetic diagnostic tests will be limited, and sometimes the patent holders may become the sole provider of the test.¹²⁴ Although clinical laboratories may negotiate a license with the patent holder, it can "also limit clinical access if laboratories cannot afford or are unwilling to pay the royalty fees associated with the license."¹²⁵ Scholars worried that issuing gene patents might create "patent anticommons" and make it inefficient to negotiate all the licenses necessary to do research.¹²⁶

Second, patients are not able to access genetic tests if the provider of the test does not accept patients' insurance.¹²⁷ Under these circumstances, patients cannot afford the increased cost of testing and have no choice but to forgo it.¹²⁸ As AARP argued in its brief, "[gene] [p]atents such as those present in this case prohibit diagnosis and treatment based on second medical opinions and discourage full medical testing," and patents "also significantly elevate the cost of genetic testing."¹²⁹ Additionally, when there is a sole test provider in the market, patients lack the ability to obtain a second genetic test opinion.¹³⁰ However, a second opinion is significant in helping patients making major medical decisions. As the SACGHS Report noted, "[c]onfirmatory testing by another laboratory is the laboratory equivalent to the time-honored practice of obtaining a second opinion from a clinician," and "the ability to obtain a confirmatory test from a second laboratory is important because genetic test results can have implications for major medical decisions."¹³¹

However, under the current U.S. health system, patients always "face unequal access to medical care, including diagnostic tests."¹³² Patient access is not a problem unique to genetic testing. Also, the essence of the affordability problem is the refusal by the insurer to cover genetic testing rather than whether the test is patented or not.¹³³ Insurance companies are free to refuse coverage even if a test is widely provided across the country.

C. Incentive concerns

The lack of competition in the genetic test market may also decrease the quality of genetic testing. The most commonly used method for assuring the performance of genetic diagnostic tests is through the comparison of results obtained from different test providers.¹³⁴ The incentive to improve genetic tests will increase if there are multiple competing peers engaged in providing tests. The overall genetic testing quality would be improved through the development of new and efficient techniques of testing.¹³⁵ However, since gene patent holders have the exclusive right to prevent others from practicing their patents, laboratories may stop performing patented genetic testing to avoid infringing patents. When the number of competing peers is reduced, there is less availability of different testing results to compare with the genetic testing results performed by the patent holder. As such, gene patents impact genetic testing quality.

¹¹⁹*Id.*

¹²⁰Noonan, *supra* note 107, at xx–xxi.

¹²¹SACGHS Report, *supra* note 5, at 38–45.

¹²²*Id.* at 38–39.

¹²³*Id.* at 42.

¹²⁴*Id.*

¹²⁵*Id.*

¹²⁶*See e.g.*, Conley, *supra* note 114, at 130; Michael A. Heller and Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (May 1, 1998); Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 295 (2003).

¹²⁷SACGHS Report, *supra* note 5, at 42.

¹²⁸*Id.* at 44.

¹²⁹*See* AARP *amicus* brief, *supra* note 103, at 2.

¹³⁰SACGHS Report, *supra* note 5, at 43–44.

¹³¹*Id.* at 43.

¹³²Mara Aspinall *et al.*, "Statement of Dissent from Ms. Aspinall, Dr. Billings, and Ms. Walcoff," in SACGHS Report, *supra* note 5.

¹³³*Id.*

¹³⁴SACGHS Report, *supra* note 5, at 4.

¹³⁵*Id.* at 46.

Moreover, opponents also argue that granting gene patents may impede research and innovation.¹³⁶ They worry that gene patent holders will create a “patent thicket” that may impede further research and innovation.¹³⁷ A large number of patent holders may force other laboratories to negotiate licenses. If the cost of licensing and the license royalty is too expensive to be affordable by the licensees, they will stop advancing further innovations.¹³⁸ Instead of promoting the progress of science and technology, too much patent protection can hinder further research and invention.¹³⁹

However, a recent report by the National Research Council (NRC) reveals that human gene patents are unlikely to hinder biomedical research.¹⁴⁰ According to scientific publication databases, there are more than 11,000 research papers published after the issuance of BRCA1 and BRCA2 patents.¹⁴¹ Patent protection provides the biotechnology industry with incentives to promote innovation of new drugs and diagnosis treatments.¹⁴² Without patent protection on genetic inventions, inventors would consider protecting their inventions through trade secrecy.¹⁴³ Unlike patent protection, trade secrets are undisclosed and researchers thus have no access to the result of those inventions.¹⁴⁴ It could impede the innovation of medical research.¹⁴⁵ Therefore, prohibiting gene patents does not necessarily encourage innovation.¹⁴⁶

V. RECOMMENDATIONS: EXPERIENCES FROM TAIWAN

Although gene patents are not available under the *Myriad* decision in the United States, other countries, for instance, the European Union, Japan, and Taiwan, still provide patent protection for genetic inventions.¹⁴⁷ Under the European Patent Convention, “biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature,” is patentable.¹⁴⁸ The clause was incorporated in Article 3 of the European Union Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions.¹⁴⁹ Thus, the European Patent Office (EPO) allows an isolated gene for patent protection even if it previously occurred in nature.¹⁵⁰ The Japanese Patent Office (JPO) and the Taiwan Intellectual Property Office take a similar approach to that of the EPO, recognizing the eligibility of gene sequence inventions.¹⁵¹ The JPO clarified in its Examination Guidelines in Life Sciences that, in order to be patented, the appli-

cation must provide a gene sequence and demonstrate its utility, such as in diagnosis or treatment.¹⁵²

Under the Taiwan Patent Act, genes are qualified as patentable subject matter.¹⁵³ Like the U.S., a gene patent will be granted if it satisfies the patentability requirements such as utility, novelty, and nonobviousness.¹⁵⁴ The standards are similar to those of the U.S. This part proposes possible solutions in response to the competing interests between a gene patent holder and public interests. By referring to the U.S. patent law and the Taiwan Patent Act, we can see that a beneficial compromise supporting genetic research and patient access to

¹³⁶See, e.g., *Myriad I*, 653 F.3d at 1379–80 (Bryson, J., concurring in part and dissenting in part).

¹³⁷*Id.* at 1380.

¹³⁸*Id.*

¹³⁹*Myriad I*, 653 F.3d at 1380; John P. Walsh, Ashish Arora, and Wesley M. Cohen, *Science and the Law: Working Through the Patent Problem*, 299 SCIENCE 1020 (Feb. 14, 2005).

¹⁴⁰See NAT'L RESEARCH COUNCIL OF THE NAT'L ACADEMIES, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 2 (Stephen A. Merrill and Anne-Marie Mazza, eds., National Academies Press 2006) [hereinafter NAT'L RESEARCH COUNCIL'S REPORT].

¹⁴¹Noonan, *supra* note 107, at xvi.

¹⁴²*Id.* at xv.

¹⁴³Guerrini *et al.*, *supra* note 118, at 553–555, 560; Kling, *supra* note 101, at 30–32.

¹⁴⁴Guerrini *et al.*, *supra* note 118, at 556.

¹⁴⁵*Id.*

¹⁴⁶Noonan, *supra* note 107, at xxiii.

¹⁴⁷See generally Alice Yuen-Ting Wong and Aurélie Mahalatchimy, *Human Stem Cells Patents—Emerging Issues and Challenges in Europe, United States, China, and Japan*, J. WORLD INTEL. PROP. 1–30 (2018).

¹⁴⁸European Patent Convention, Rule 27(a).

¹⁴⁹European Union Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L. 213) 30.7 (1998).

¹⁵⁰Timo Minssen and Robert M. Schwartz, *Separating Sheep from Goats: A European View on the Patent Eligibility of Biomedical Diagnostic Methods*, 3(2) J. L. & BIOSCIENCES, 365, 369–70 (2016).

¹⁵¹Asako Saegusa, *Japanese Guidelines Specify the Terms of Gene Patents*, 401 NATURE 731 (1999).

¹⁵²*Id.* See also Japanese Patent Office, *Examination Guidelines in Life Sciences*, available at https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/document/lifescience_kijun/lifescience_kijun_e.pdf (last visited Feb. 20, 2020).

¹⁵³See Taiwan Patent Act, art. 24; Taiwan Intellectual Property Office, *Substantive Examination Guidelines*, ch. 14, pp. 2-14-1–2-14-3 (2017).

¹⁵⁴See Taiwan Patent Act, art. 22.

genetic tests would be offering a research exemption framework and compulsory licensing of a gene patent.

A. Research exemption

The U.S. patent law provides statutory exemptions to patent infringement. For instance, § 271(e)(1) of the law provides an exemption to infringement of pharmaceutical compound patents.¹⁵⁵ The exemption applies only to the use of patented pharmaceutical compounds in order to submit new compounds to the Food and Drug Administration.¹⁵⁶ Moreover, § 287(c)(1) protects medical practitioners when performing patented medical or surgical procedures for patients.¹⁵⁷ However, this exemption does not apply to the use of a patented composition of matter.¹⁵⁸ Accordingly, neither of the exemptions provided in the patent law apply to the experimental use of a patent.

While there is no general statutory exemption for experimental or research use in the Patent Act of 1952, the court had established a defense to patent infringement for “experimental” use in *Madey v. Duke University*.¹⁵⁹ In *Madey*, the Federal Circuit adopted a restrictive approach and held that practice of patented inventions “in any way commercial in nature” or “conduct that ... keep[s] with the alleged infringer’s legitimate business, regardless of commercial implications” is not immune from infringement liability for such conduct.¹⁶⁰ Thus, the experimental use exemption applies only to activities undertaken for the purpose of amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.¹⁶¹ Critics have cautioned that the *Madey* decision “may undermine the informal exemption that [] is important for open science.”¹⁶² They also called on policymakers to “ensure an appropriate exemption for research intended for the public domain.”¹⁶³

In Taiwan, Article 59 of Taiwan Patent Act provides limitations on the patent right.¹⁶⁴ It exempts a person from being held liable for patent infringement under certain circumstances. Under the article, a patent right shall not extend to the following circumstances:

- (1) acts done privately and for noncommercial purpose(s);
- (2) necessary acts to exploit the invention for research or experimental purpose(s);
- (3) acts done by a person who has been exploiting the invention or making all the necessary preparations for doing such act in this country before the filing date of the invention. However, this provision shall not apply where

a person learning of the invention from the applicant for patent within six months and the applicant has made a statement reserving his right in the event of a patent being granted;

(4) a vehicle merely passing through the territory of this country, or any device of such vehicle;

(5) where a patent granted to a person not entitled to apply for a patent is revoked as a result of an invalidation filed by the patentee, acts done by a licensee who has, prior to patent invalidation, been exploiting the invention in good faith or making all the necessary preparations to do such an act;

(6) where, after the sale of a patented product made by the patentee or made under consent of the patentee, using or reselling such product. The making and selling as stated above are not limited to acts done domestically;

(7) where, after an invention patent is ceased pursuant to subparagraph 3, paragraph 1 of Article 70 and before it is reinstated and published under paragraph 2 of Article 70 of this Act, acts done by a person who has been exploiting the invention in good faith or making all the necessary preparations to do such an act.

Like the U.S., Article 59(1) of the Taiwan Patent Law applies to the use of a patent without any commercial purpose. This exemption can be used to protect researchers’ experimental use of a patent with no business objectives. Moreover, Article 59(2) covers activities for research or experimental purposes. If the use of a patent is for experimental and research purposes at the time it is conducted, the exemption affords immunity from infringement. Thus, even if school-funded research projects embody the purpose of furthering the university’s business objective, the researcher still can utilize this exemption as long as the activities are done for research or experimental purposes.

¹⁵⁵35 U.S.C. §§ 271(e)(1).

¹⁵⁶*Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 205 (2005).

¹⁵⁷35 U.S.C. §§ 287(c)(1)–(c)(2)(A).

¹⁵⁸35 U.S.C. § 287(c)(2)(A).

¹⁵⁹*Madey v. Duke Univ.*, 307 F.3d 1351, 1355 (Fed. Cir. 2002).

¹⁶⁰*Id.* at 1362.

¹⁶¹*Id.*

¹⁶²Walsh *et al.*, *supra* note 139.

¹⁶³*Id.*

¹⁶⁴Taiwan Patent Act, art. 59 (2017).

In comparison, the current U.S. experimental use exemption is very restricted. In order to encourage research, the U.S. courts must expand the exemption to include experimental uses for noncommercial and experimental purposes.¹⁶⁵ As such, the proposed exemptions adopt Article 59(2) of the Taiwan Patent Law to include activities for research or experimental purposes, regardless of future commercial implications. The exemption does not extend to the non-patent holders' further commercial use based on the activities. It applies only to the "moment" of the practice of gene patents. Accordingly, the patentee's legitimate business interests will not be affected. Further, providing researchers exemptions for research on patented genes can increase the incentives of advancing innovations and enhance the quality and efficiency of current gene-related inventions.¹⁶⁶

B. Compulsory licensing

In the U.S., compulsory licensing may occur under: (1) the Bayh-Dole Act;¹⁶⁷ (2) 35 U.S.C. § 154(a)(1);¹⁶⁸ and (3) the Clean Air Act.¹⁶⁹ The Bayh-Dole Act provides "march-in" rights on federally funded research.¹⁷⁰ In order to promote the utilization of inventions and public availability of federally funded inventions,¹⁷¹ a federal agency, under certain circumstances, may exercise the "march-in" rights to require the recipient of federal funds to license the patented inventions to a third party.¹⁷² The statute provides that a federal agency may exercise its march-in rights when such action is "necessary to alleviate health and safety needs."¹⁷³ In addition, compulsory licensing may be ordered by a court under 35 U.S.C. § 154(a)(1) when a court refuses to issue injunctive relief.¹⁷⁴ Furthermore, a court may also order a compulsory license under the Clean Air Act if the patent is critical to control air pollution.¹⁷⁵ Factors that are taken into consideration when making the decision regarding compulsory licensing of a patent include the availability of the patented invention, the existence of reasonable alternatives, and the possibility of forming a monopoly if such rights are not available.¹⁷⁶

The necessity of exercising march-in rights was echoed by Senator Leahy's letter sent to the Director of the National Institutes of Health (NIH).¹⁷⁷ In encouraging NIH to "consider using march-in rights under the Bayh-Dole Act to ensure greater access to genetic testing for breast and ovarian cancer," Senator Leahy indicated that Myriad's patents, which were based on federally funded research, are essential for public health.¹⁷⁸ "Myriad is the

only provider of this test because it is covered by patent protection. Unfortunately, testimony before the United States Patent and Trademark (USPTO) revealed that Myriad does all of this testing in-house, and charges between \$3,000 and \$4,000."¹⁷⁹ Expressing his concern that "the health needs of the public are not reasonably satisfied by the patentee in this situation because testimony presented to the USPTO made clear that many women are not able to afford the testing provided by Myriad," Senator Leahy, therefore, encouraged the Director to consider using the government's march-in rights for the Myriad's BRCA test.

In Taiwan, Articles 87 to 91 of the Taiwan Patent Act provide statutory compulsory licensing. According to Article 87, the Taiwan Intellectual Property Office (TIPO) has the authority to issue a compulsory license. If a national emergency or other extreme urgency circumstances exist, TIPO should grant compulsory licensing of a patent in accordance with an emergency order passed by the central government authorities.¹⁸⁰ Moreover, anyone may request TIPO to grant compulsory licensing of a patent under any of the following circumstances for which it is deemed necessary:

¹⁶⁵Jennifer Vogel, *Patenting DNA: Balancing the Need to Incentivize Innovation in Biotechnology with the Need to Make High-Quality Genetic Testing Accessible to Patents*, 61 U. KAN. L. REV. 257, 288 (2012).

¹⁶⁶*Id.*

¹⁶⁷Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200–212).

¹⁶⁸35 U.S.C. § 154(a)(1).

¹⁶⁹Clean Air Act, Pub. L. No. 84-159, 69 Stat. 322 (1955) (amended by Clean Air Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (codified as amended at 42 U.S.C. §§ 7401–7626)).

¹⁷⁰35 U.S.C. § 203.

¹⁷¹35 U.S.C. § 200.

¹⁷²35 U.S.C. § 203(a).

¹⁷³35 U.S.C. § 203(a)(2).

¹⁷⁴*eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006); *Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F. Supp. 2d 951, 987 (N.D. Cal. 2009).

¹⁷⁵42 U.S.C. § 7608 (2006).

¹⁷⁶42 U.S.C. § 7608 (2006).

¹⁷⁷The letter from Senator Patrick Leahy, Committee on the Judiciary, to Francis S. Collins, Director of National Institutes of Health (July 12, 2013), is available at: <https://patentdocs.typepad.com/files/leahy-letter.pdf> (last visited Feb. 20, 2020).

¹⁷⁸*Id.*

¹⁷⁹*Id.*

¹⁸⁰Taiwan Patent Act, art. 87 (2017).

1. where a patented invention is to be exploited noncommercially for the enhancement of public interest;
2. where a later invention or utility model patent cannot be exploited without infringing upon a prior invention or utility model patent, and where the later invention or utility model patent involves an important technical advancement of considerable economic significance in relation to the prior invention or utility model patent; or
3. where a patentee has committed acts restricting competition or has committed unfair competition acts, for which a judgment has been made by a court of law or a decision has been rendered by the Fair Trade Commission of the Executive Yuan.¹⁸¹

The proposed compulsory licensing of human gene patents is very narrow. By referring to the Taiwan Patent Law and the U.S. Clean Air Act, a court may order compulsory licensing of a gene patent only for the public interest. Before requesting a court to order compulsory licensing of a gene patent, the non-patent holder is required to negotiate with the patent holder in advance. If the negotiation of the license fails, the non-patent holder may request compulsory licensing of the patent for the public interest. For instance, if gene patents create

a barrier to whole-genome sequencing, a court may order compulsory licensing of a gene patent to whole-genome-sequencing diagnostic tests. Likewise, a court may also require compulsory licensing of specific gene patents for patients' benefits.

VI. CONCLUSION

There are alternatives to an outright ban on all gene patents. In order to balance the competing interests of encouraging innovation while making gene-based medical treatment less inaccessible, the U.S. Congress should provide a framework of research exemptions from patent infringement and provide for the compulsory licensing of a gene patent. The research exemption enables researchers to research on patented genes without a risk of being held liable for infringement, thereby promoting further advancement in the related gene industry. The framework of a compulsory license ensures patient access to genetic treatment. These solutions, on the one hand, solve primary concerns surrounding gene patents, and on the other hand, maintain gene patent protection and the incentives needed to promote the progress of gene-related technologies.

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¹⁸¹*Id.*