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人體基因相關發明專利之研究

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中 文 摘 要 ： 美國聯邦最高法院2013年Association for Molecular Pathology v. Myriad Genetics, Inc.（簡稱 Myriad)判決，再次引起基因專利適格性討論。支持者認為專利權可作為鼓勵發明人持續研發之誘因；反對者則認為賦予基因相關發明專利，將使一般人因無法負擔權利金而無法享有基因檢測等醫療資源，同時可能使其他人無法就他人基因序列專利續為研究，阻礙醫學發展。

Myriad Genetics公司在1990年代純化與萃取出代表具有易罹患乳癌與卵巢癌之風險的BRCA1 and BRCA2基因序列，並向美國、歐洲與澳洲等數國申請專利，但結果互異。儘管美國法院對於專利保護客體向來持開放立場，但在2013年Myriad判決中，聯邦最高法院認定萃取分離出來的DNA序列，縱使前所未見，仍僅屬自然界已存在的產物之發現，不得申請獲准專利。

因此，本計畫將由Myriad案探討基因專利所涉及之法律與政策等議題。研究內容將先建立基因科技等背景知識，其後分析美國Myriad判決就基因專利適格性之判斷，並探討基因專利對公共利益、產業所生之影響。最後借鏡外國經驗，檢討我國對於基因序列專利適格性之判斷標準，並提出我國應如何兼顧發明人權益與社會公益的建議。

中 文 關 鍵 詞 ： 基因專利、基因檢測、Myriad、BRCA、專利適格性、自然產物、自然法則

英 文 摘 要 ： In 2013, the United State Supreme Court’s decision on Association for Molecular Pathology v. Myriad Genetics, Inc. (hereinafter Myriad) has drew the public’s discussion on the issue of patent eligibility of human genes. Gene patents, or patents attempting to claim a DNA or nucleotide sequence (hereinafter “Gene Patents”) have always been controversial. Proponents advocate that gene patents give inventors powerful incentives in genetic research. Opponents, however, argue that gene patents can restrict patient access to genetic diagnostic tests. Others object to gene patents because such patents potentially impede the progress of future research.

Myriad Genetics, a private biotechnology company, isolated the BRCA1 and BRCA2 genes associated with breast cancer and obtained patents in the U.S., Australia and Europe. The U.S. courts in the Myriad case have exemplified these concerns. The Supreme Court has interpreted the patentable subject matter broadly to include “anything under the sun that is made by man.” Therefore, a natural substance such as a gene in its natural form is barred from patent protection. However, the Supreme Court held in the Myriad case that a patent application claiming a purified and isolated form of a gene or the protein it creates, i.e.,

DNA, is a product of nature and therefore cannot be patented.

This project examines the legal and policy issues arising out of gene patens in light of the Myriad case. It begins with a brief overview of gene patents and outlines the basic patentability requirement under the U.S. Patent Law. It will also discuss the alleged problems created by gene patents in view of the Myriad decisions in the U.S. This project focuses on the policy concerns of gene patent debates as well as the issue of patent eligibility. Finally, it will look into the lessons from American and Australia experiences and figure out a feasible/possible approach to improving Taiwan's current patent law and proposes solutions to the competing interests.

英文關鍵詞：gene patent; genetic test; Myriad; BRCA; patent eligibility; product of nature; nature phenomena

人體基因相關發明專利之研究

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壹、 前言

「我的母親抗癌十餘年，但仍不敵病魔，在 56 歲過世。…我的小孩問我是否也會生一樣的病，我總是要他們別擔心。但事實上，我身上帶有一個讓我有極高風險罹患乳癌與卵巢癌的『BRCA1』基因……當我認清事實，我決定要主動出擊，降低罹癌風險--我決定接受乳房切除手術[1]。」

西元 2013 年 5 月，美國影星安潔莉娜裘莉（Angelina Jolie）投書美國時代雜誌，向世人宣告力戰病魔的決心。就在裘莉的告白震驚各界之餘，也向帶給世人一個啟發：對抗疾病除了治療以外，積極的事前預防也是一種可能的選擇。裘莉表示其接受乳癌基因檢測，醫師告知她將有 87%罹患乳癌的機率，以及 50%得到卵巢癌的可能[2]。裘莉的案例也讓吾人瞭解：基因檢測已為醫學開啟研究新頁。不僅親子鑑定、癌症基因篩檢及預防等，均可透過基因檢測技術實現[3]。甚至罕見疾病如小腦萎縮、帕金森氏症、亨丁頓舞蹈症等，亦能經由基因篩檢方式，即早檢測與治療[4]。

然而，基因序列是否具可專利性？迭有論爭。持肯定見解者認為專利權可作為鼓勵發明人持續投注研發之誘因，故認為基因醫學研究成果，亦應可獲准專利保護[5]；反對見解則認為賦予基因相關發明專利，將使一般人可能因無法負擔高額權利金而無法享有基因檢測、篩檢等醫療資源[6]，同時可能使其他發明人無法就他人已獲取專利之基因序列續為研究，阻礙醫學發展[7]。以前述乳癌基因為例，Myriad Genetics 公司在 1990 年代純化與萃取出 BRCA1 and BRCA2 基因序列，該等基因序列代表具有易罹患乳癌與卵巢癌之風險，Myriad 公司就前開基因分別向美國、歐洲與澳洲等數個國家申請專利，但其申請結果各國互有不同。比較前開基因序列發明在美、歐、澳洲等國申請專利之結果，亦可看出各國對於人類基因專利的不同看法。

在歐洲方面，歐洲專利局（the European Patent Office）於 2004 年 5 月 18 日撤銷 Myriad 公司的 BRCA1 專利[8]。歐洲專利局認定 Myriad 公司之 BRCA1 專利

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[1] *See* Angelina Jolie, *My Medical Choice "Now I Can Tell My Children They don't Need to fear that They will Lose Me"*, Times, at 38-39, 05/15/2013.

[2] *See* Angelina Jolie, *My Medical Choice "Now I Can Tell My Children They don't Need to fear that They will Lose Me"*, Times, at 38-39, 05/15/2013.

[3] 賴筱凡，「裘莉效應」掀起全球預防醫學熱潮—癌症基因解碼，今周刊，第 862 期，頁 102，2013 年 7 月 1 日。

[4] 同前註。

[5] *See* Wolrad Prinz zu Waldeck und Pyrmont, *Research Tool Patents After Integra v. Merck--Have They Reached a Safe Harbor?*, 14 Mich. Telecomm. & Tech. L. Rev. 367, 372 (2008); Brian Murphy & 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).

[6] Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, Dep't of Health & Human Servs., Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests, 3 (2010), http://oba.od.nih.gov/oba/sacghs/reports/sacghs_ Patents_report_2010.pdf

[7] *See* 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).

[8] Alison Abbott, "Clinician Win Fight to Overturn Patent for Breast-Cancer Gene", 429 Nature 329

不具進步性，於欠缺專利要件下，該基因序列因此不具可專利性。歐洲專利局雖然並非直接否定基因發明的可專利性，而係以系爭基因發明欠缺進步性而否准專利，但論者有謂 Myriad 公司就 BRCA1 專利於基因相關研究之影響與所居之近乎獨占性地位，應為歐洲專利局否決該專利時所斟酌考量因素之一[9]。本件揭示歐洲對於生物科技相關發明採取較為嚴格的解釋立場，其後歐洲聯盟於 1998 年通過生物科技指令（Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions）[10]，其前言明確表示由人類分離之基因序列或部分序列，不能賦予專利權[11]；但以自人體分離物質為基礎所完成之治療方法發明[12]或其他物的發明[13]等，則仍得於符合專利要件下，取得專利權。

有關基因序列是否得受專利保護之爭議，於澳洲亦起波瀾。2013 年 2 月 15 日澳洲聯邦法院於 *Cancer Voices Australia v. Myriad Genetics Inc.* [2013] FCA 65 判決中肯認基因序列之可專利性[14]。惟值得注意者，2015 年 10 月澳洲最高法院於另案 *D'Arcy v. Myriad*, [2015] HCA 35 則採相反見解，認定人類經分離後之基因序列不具專利適格性[15]。依澳洲法規定，發明是否具專利適格性，應判斷系爭發明是否合於「獨占法」（the Statute of Monopolies 1624）第 6 條所定"manner of manufacture"概念。因此，前開案件之爭點即在於經分離後的基因序列，是否符合"manufacture"之定義。就此，前述澳洲聯邦法院於 *Cancer Voices Australia v. Myriad Genetics Inc.*判決中認為，基於鼓勵發明的立場，"manner of manufacture"之範疇應採廣義解釋，以盡可能涵蓋各種技術發明成果。倘一個物質係經由人為因素介入所創造得出者（artificial state of affairs），該物質即應合於"manner of manufacture"之概念[16]。倘僅因系爭發明為基因序列，即將基因序列排除於得受專利保護範圍之外，不僅對發明人投注於研究心力成本有欠公允，亦與專利制度鼓勵發明之本旨有違[17]。惟澳洲最高法院於 *D'Arcy v. Myriad* 判決中則認為，經分離後的基因序列的本質（substance）與其存在於人類體內未經純化萃取係屬同一，詳言之，系爭發明為 BRCA1 及 BRCA2 基因序列，此基因序列係人為介入經由純化基因等技術所得之成果，與人體細胞內基因存在的形式雖不相同，但其內涵、

(2004).

[9] McCullough Robertson Lawyers, "Breast Cancer Gene Test Patent Revoked," Biotechnology Focus (Sep. 2, 2004) *available at* http://www.mccullough.com.au/defaulty.asp; EU Business, "European Patent for Breast, Ovarian Cancer Test Revoked (May 18, 2004).

[10] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions，全文請參見網址 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:NOT [hereinafter Directive]

[11] Directive, recital 16.

[12] *Id.* recital 17.

[13] *Id.* recital 20.

[14] Cancer Voices Australia v Myriad Genetics Inc [2013] FCA 65(2013)，判決全文請參見 http://www.judgments.fedcourt.gov.au/judgments/Judgments/fca/single/2013/2013fca0065

[15] D'Arcy v Myriad Genetics Inc (S28-2015) [2015] HCA 35，判決全文請參見

[16] *Id. paras.* 86-88. *http://www.hcourt.gov.au/cases/case_s28-2015*

[17] *Id. para*. 109.

本質仍屬相同，故並不符合法定可予保護之客體[18]。

相同爭議亦見諸美國 *Association for Molecular Pathology v. Myriad Genetics, Inc.*乙案。本案美國聯邦地院於 2010 年判決認定 Myriad 之 BRCA1 及 BRCA2 基因發明為自然產物(products of nature)，不具專利適格[19]。案經上訴，美國聯邦巡迴上訴法院推翻原審判決，認定系爭發明係由人為介入所得之成果（即解碼得出之序列），與自然產物有別，應具專利適格[20]。聯邦最高法院第一次受理本案上訴並將案件發回聯邦巡回上訴法院更審，聯邦巡迴上訴法院於更一審仍然維持與前審相同之見解，肯定基因序列之專利適格性[21]。其後，聯邦最高法院於 2012 年 11 月 30 日就「人類基因是否可予專利？」之爭議再次受理上訴[22]，並於 2013 年 6 月 13 日判決。

美國聯邦最高法院在本判決中，係援引該法院 1980 年之 *Diamond v. Chakrabarty* (447 U.S. 303, 1980)判決意旨，作為主要判斷標準。在 *Charkrabarty* 判決中，美國聯邦最高法院認定經由人為加工、改造而成的細菌，已非純粹的自然產物，即符合美國專利法第 101 條規定，可依法申請獲准專利。依該標準，凡屬自然界已存在的產物，縱使不為人所知，亦無從因「發現」該產物而取得專利。依此標準，美國聯邦最高法院認定在本案 Myriad 公司之系爭基因序列發明中，純粹將可能造成乳癌之基因序列自其他蛋白質包覆體萃取分離出來的「isolated DNA」（亦即，分離 DNA 序列），縱使前所未見，仍僅屬「自然界已存在的產物」之發現，而未曾由專利權人施以人為改造，不得申請獲准專利。然而，系爭發明中的「cDNA」（complementary DNA，一般稱互補 DNA），因係由專利權人進一步排除 DNA 中的「內含子」（intron；亦即，DNA 中不具作用之部分），而僅留下外顯子(exon)，已非「天然界已存在的產物」，而屬經「人為加工」之物，可依法申請獲准專利。

此外，美國聯邦最高法院在判決書末段，特別指明該判決並未審及「發明方法」、「如何運用乳癌致病基因序列」、「經人為變動後的 DNA 序列」等發明的可專利性。言下之意，美國聯邦最高法院雖否定以「isolated DNA」型態呈現的乳癌致病基因序列的可專利性，但專利權人仍可透過前開途徑（發明方法、運用手段、變動基因序列）等方式，確保其在乳癌致病基因序列的研究成果，不為他人使用。

貳、 研究目的

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[18] *Id.*

[19] 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).

[20] 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).

[21] Ass'n for Molecular Pathology v. U.S. Trade & Patent Office, 689 F.3d 1303, 1308-09 (Fed. Cir. 2012) [Myriad II], *cert. granted sub nom*. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012).

[22] 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.

Myriad 公司前開乳癌致病基因並未於我國申請專利。但一般而言，如發明人將基因序列以人為手段萃取、分離，並可顯現一定技術功效者，可依我國專利法獲准專利。按我國專利法第 24 條規定不予發明專利之客體包括：1. 動、植物及生產動、植物之主要生物學方法；2. 人類或動物之診斷、治療或外科手術方法；及 3. 妨害公共秩序或善良風俗者。依此規定，生物材料相關發明，例如生物資訊、生物晶片、生物相關發明之裝置等跨領域等[23]，倘非屬前揭範疇，於符合專利要件下，可獲得專利權保護。依經濟部智慧財產局專利審查基準彙編（下稱「專利審查基準」)，生物相關發明之申請標的包含基因、DNA 序列[24]。故而，我國專利主管機關並未將基因序列排除於可受專利保護範圍之外。惟依我國專利法第 21 條規定，發明係指利用自然法則之技術思想之創作。因此，生物相關發明倘僅為單純發現，不能授予專利。關於基因或 DNA 序列作為專利保護客體之問題，前開專利審查基準規定，發現未經分離或未經純化之微生物或蛋白質或 DNA 序列，因屬於自然界存在之物的發現，固屬不得准予發明專利之客體；然「對於自然界中存在之物，經人為操作而由自然界分離、製備並可顯現技術效果者，則為發明，例如經分離或純化之微生物、蛋白質或 DNA 序列」[25]。依前揭規定可知，我國智慧財產局就基因相關發明可專利性之立場，似與前述澳洲法院所持理由較為一致，均係以發明是否有人為因素介入為判斷重點。

關於基因相關發明之專利適格性爭議，不論採行肯定或否定立場，對於生物科技與醫學等產業發產，均有相當影響。我國與澳洲目前肯定基因與 DNA 序列等生物相關發明得為發明專利保護客體，惟美國及歐盟等國就此爭議則採相反立場，其理由與依據，尤其於訴訟過程中兩造所主張賦予基因專利對於病患就基因檢測等醫療方法之接觸可能性的阻礙、生醫領域下游研究之影響等議題，實有進一步探究之需要。又，自前述可知，美國聯邦最高法院在其 *Myriad* 案判決中，是援引三十餘年前作成的 *Chakrabarty* 判決，作為其判決的主要基礎。惟此三十餘年間生醫研究進展良多，美國法院以三十餘年前樹立的標準（用以評斷微生物的可專利性)，據以判斷基因發明的可專利性，妥適與否，亦待研求。

本於此等問題意識，本研究擬自美國聯邦最高法院 2013 年 *Myriad* 案以及澳洲 2013 年 *Myriad* 案等判決出發，除分析各該案件爭議事實與歷審法院見解外，並將探討人類基因相關發明所涉及專利爭議議題，包含專利適格性之比較分析，以及賦予基因相關發明專利後，對於基因檢測等預防醫學所可能產生之影響暨相關因應之道，以作為我國生物科技專利法制暨相關規範之適用參考。

參、 文獻探討

現有國內文獻以基因相關發明之專利適格性暨賦予基因專利可能衍生之爭議為主題者如下：

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[23] 經濟部智慧財產局，專利審查基準彙編，第 14 章生物相關發明，頁 2-14-1，2013 年[下稱專利審查基準]。

[24] 專利審查基準，頁 2-14-2。

[25] 專利審查基準，頁 2-14-3。

一、國內文獻

（一）學位論文共17篇，依發表時間順序分別簡要評述如下：

1. 沈宜禛,基因資訊權利性質之研究　人格權與財產權一元雙面結構,國立中正大學，財經法律學研究所，2013年。

   評述：本文從人性尊嚴、人格權及專利權的發展脈絡出發，分析基因資訊的法律上屬性,探討基因資訊於個人權利保護及公共利益需求的權衡。其中第七章特別針對基因資訊得否作為財產權為探討。作者以美國法及歐洲法討論生物科技乃至於基因資訊究為「發明」或單純之「發現」,並進而分析基因資訊之專利適格性。作者並深入比較美國專利法第101條及歐洲專利法上公序良俗條款，作為專利權保護在生物科技發展上的保護界限。最後，本文並以美國*The Association for Medical Pathology vs. USPTO and Myriad Genetics*案探討賦予人類基因專利,是否符合專利法之本旨及全人類福祉。

2. 辛王燕丹，論藥物基因體學對我國醫藥責任法制之影響，國立成功大學，法律學研究所，2012年。

   評述：本文肯認我國憲法具有國家對人民健康權的積極保障義務，也肯定衛生署因應藥物基因體學研究的成果,快述作出對應的醫療政策和命令。惟考慮日後藥物基因體學的研究發展下，國家應為符合經社文權利公約第14號一般意見的保障人民「享有能達到之最高的身體和心理健康的標準。」的健康權實踐，以及力行憲法的國家積極保護國人健康權義務的前提,應制定藥物基因體學誘發藥物不良反應的發病率上限數據,即是制定高危險病人藥害的發病率標準，以作為國家健保給付的初次服用藥物基因體之藥物者的基因檢測準據

3. 林珮慈,論消費者基因檢測之法律爭議及應有規範,國立交通大學，管理學院科技法律學程碩士班，2012年。

   評述：本文探討非經由醫療管道直接取得之基因檢測服務（又稱為消費者基因檢測）(direct-to-consumer genetic testing,DTC基因檢測）之法律爭議，借鏡美國等外國立法例之規範，分析我國對於DTC基因檢測應採取之行政管制措施，以於商業利益與公眾權益保護間取得平衡。

4. 何欣倫，論我國專利法對生物科技保護之新趨勢，銘傳大學法律學系碩士班，2011年。

   評述：本文廣泛討論各種生物科技相關發明於我國專利法之保護，其中關於醫療、藥品與基因技術等方面之發明，作者特別予以探討

專利適格性，並以美國、日本等國立法例與學說討論，分析生物科技相關技術所涉及之倫理性問題。作者認為我國應順應國際立法潮流，全面檢討現行專利法關於生物科技之保護部分，以利與國際接軌，造福全體國民之健康以及提昇國家競爭力。

5. 曾宇軒，論基因資訊-以基因專利為中心，嶺東科技大學，財經法律學研究所，2012年。
   評述：本文探討賦予基因相關發明專利後，於實施該專利時對於基因資訊之利用所衍生之法律與道德爭議。

6. 葉馨雯，基因檢測研發及商業化近用基因專利之探討，私立輔仁大學，財經法律學研究所，2011。
   評述：本文肯認基因為可受專利權保護之客體，作者於此前提下，分析說明基因檢測商業化對基因專利在上游基礎研究、下游研發，以及使用者近用基因檢測等三個階段可能造成之影響與解決之道。

7. 林芬瑜，基因專利對藥物基因體學發展之影響與因應—以生技製藥產業為例，私立輔仁大學，財經法律學研究所，2011年。
   評述：本文由探討基因相關發明可專利性爭議出發，進而分析賦予基因發明專利對產業與人類福祉所造成之衝擊影響。作者最後並提出試驗免責、專利授權及專利聯盟等作為調和發明人權益與公共利益之手段。

8. 張弘祥，論藥物基因體學應用到藥物研發與臨床試驗之專利法上影響，東吳大學，法律學研究所，2011
   評述：本文係以藥物基因體學為對象，討論其在智慧財產權、公共衛生法規上所衍生之議題。

9. 陳永震，基因治療法制化之研究，嶺東科技大學，財經法律學研究所，2011年。
   評述：本文分析基因、胚胎幹細胞等科技發展與研究所衍生之病患權益、合法性、專利保護客體等爭議。

10. 趙李英記，細胞基因檢測衍生資訊隱私權與專利權保護之研究，中國文化大學法律學系，2011。
    評述：本文探討基因檢測法所可能引發不確定科技風險之爭議，以及主管機關應如何建立法律風險管控手段之議題。

11. 何叔孋，癌症基因治療相關發明專利之研究，台灣大學，法律學研究所，2009年。

評述：本文探討癌症基因診療方法之可專利性，以及賦予基因治療相關發明專利後，應否就專利權人之權利範圍予以限制之不同見解。作者最後並闡述我國在癌症基因治療方面可能在國際上占有之優勢，對我國未來制定或修正基因治療相關規範持肯定立場。

12. 陳彥碩，論商業應用下基因檢測所涉法律議題，國立清華大學科技法律研究所，2007年。

評述：本文主要以基因檢測所涉及之倫理、法律與社會等議題為中心，作者認為基因檢測服務應在符合人格權益之維護、誠信原則以及消費者保護的概念下進行之。同時作者亦提出對於基因檢測管制之建議。

13. 孫玉苓，人類胚胎幹細胞研究之法律管制及發明之專利保護，國立交通大學，科技法律研究所，2005年。

評述：本文旨在分析人類胚胎幹細胞研究之合法性與相關法律管制規範。作者以外國立法例與我國相關法規範圍比較研究，分析利用胚胎進行研究及提供胚胎法律保護之正當性與適法性爭議。最後作者提出對人類胚胎幹細胞研究是否予以法律管制及如何管制之法制建議。

14. 余信達，基因序列技術之可專利性及其申請範圍之研究，中國文化大學，法律學研究所，2003年。

評述：本文採比較法之研究方法，以美國專利法、歐洲專利公約以及日本特許法出發，探討基因技術領域相關發明之適格性，作者並兼論及「美日歐三邊會議」（Trilateral Meeting）與「歐盟生物技術發明法律保護指令98/44/EC」等規範，以資與我國不予專利客體相互比較。本文並就我國、美國及日本等國有關基因相關發明申請案與獲准件數等資料予以分析，作者並實際提出撰寫基因技術相關發明時，專利說明書之撰寫應注意事項的具體建議。

15. 陳明群，基因治療之發明專利保護，國立政治大學，法律學系碩士班學士後法學組，2003年。

評述：本文由基因檢測、基因藥物乃至於基因移轉等醫療方法，探討目前相關專利法制之規定及其爭議，作者認為我國未來不妨參酌美國立法例，適度開放治療方法之專利。

16. 陳志興，基因發明專利之保護-以人體基因組序列相關發明可專利性為核心，國立台北大學，法律學研究所，2002年。

評述：本文以基因發明為主軸，探討其作為保護客體與專利要件等爭議，作者同時論及美日歐三邊會議及美國2001年通過之實用性審查基準。

17. 李文琦，基因可專利性之研究：以美國專利制度為中心，東吳大學，法律學系研究所，2001年。

評述：本文以美國專利法為主要研究對象，探討基因專利之可專利性及專利要件等問題，內容並輔以相關法院判決等見解，作者並於相關章節中兼論及歐洲及日本專利局對於基因專利所持見解。

（二）專書論文計有3篇，依發表時間順序分別簡要評述如下：

1. 馮震宇，從重要專利案例看專利法發展，收錄於智慧財產權發展趨勢與重要問題研究，頁95-151，2011年01月。

評述：本文第四子單元係由美國聯邦最高法院Charkarbarty判決出發，探　討美國生物科技專利保護之問題，並論及基因相關發明之專利爭議。

2. 李震山，基因資訊利用與資訊隱私權之保障，法治與現代行政法學—法治斌教授紀念論文集，頁83-110，2004年05月。

評述：本文雖非探討基因相關發明之專利適格性爭議，但對於基因資訊之利用與個人隱私權之衝擊有深入之分析，可供為本研究衍伸思考相關議題之參考。

3. 林子儀，基因資訊與基因隱私權－從保障隱私權的觀點論基因資訊的利用與法的規制，當代公法新論(中)－翁岳生教授七秩誕辰祝壽論文集，頁693-726，2002年07月。

評述：本文由隱私權保障角度出發，探討基因資訊之利用與相關法律觀制規範。與前述文獻相同，本文可供為本研究衍伸思考相關議題之參考。

（二）期刊論文計有14篇，依發表時間順序分別簡要評述如下：

1. 陳文吟，由Myriad案探討因應基因專利之合理措施，專利師，第13期，頁25-43，2013年04月。

評述：本文認為賦予基因專利已行之有年，不宜驟然因政策考量而

全面否准之。實則應考量賦予基因專利後如何兼顧專利權人權益與公共利益之維持。作者提出以強制授權、實驗免責等手段，應足以因應Myriad案所衍生之爭議。本文為目前國內探討Myriad判決之最新文獻，對本研究有相當重要參考價值。

2. 李素華，基因研究成果之專利保護及權力範圍—從美歐新近個案談基因專利權對公共衛生之影響，2011科技發展與法律規範雙年刊，第15期，頁57-129，2012年12月。
評述：本文分析美國及歐洲關於基因專利之判決，並由醫學與專利涉及之法律、科學及倫理等面向，探討專利權對於公共衛生之影響。作者建議未來應從專利法與公共衛生政策，思考如何建立適度限制專利權之機制。

3. 曾勝珍，以美國經驗探討基因專利之法制研究，法令月刊，第62卷第12期，頁168-201，2011年12月。
評述：本文從基因專利的歷史緣由、國際規範到美國法制與美國實務，並述及Myriad案在美國及歐盟、加拿大之後續發展，兼論基因專利在研究與診療方法上與道德、公共利益間的焦點，最後提出對立法改革上的建議。

4. 陳昭華、鍾鏡湖、張乃文、林芬瑜、鄭耀誠，基因有關研究工具授予專利之探討：以基因專利之審查為中心，國立臺灣大學法學論叢，第39卷第1期，頁403-447，2010年03月。
評述：本文探討賦予基因有關研究工具專利後，對該技術之後續研發的影響。作者認為可由基因專利之審查基準及基因專利之利用等方面討論如何避免後續研發受到影響。另外，本文就「延展性申請專利範圍」之專利審查基準議題，亦有論述。

5. 沈宗原，基因的可專利性適格-從案Myraid談起，萬國法律，第181期，頁51-60，2010年2月。
評述：本文認為基因之可專利性判斷應從專利制度的本質出發，考量進步性及產業利用性的角度加以審視，以合理限制專利權的範圍，避免不成熟的知識過度切割基礎知識，造成反共有財的障礙。

6. 李森堙，基因專利與原民權益爭議：機制性與正本清源的解決之道，科技法律透析，第22卷第5期，頁8-12，2010年05月。
評述：本文認為要解決基因專利與原住民權益之爭議或衝突，應思考富與基因發明專利之必要性，進而應考慮賦與基因專利後，授權

是否為該成果擴散應用之唯一方式，或是有不同的研究成果應用模式可供應用。

7. 朱淑尹，DNA 與基因發明之可專利性，理律法律雜誌雙月刊，99 年 5 月號，頁6，2010年05月。
   評述：本文分析基因序列發明之專利適格性爭議。

8. 李素華，從BRCA1省思專利制度對基因檢測發明之專利保護，生物醫學，第2卷第2期，頁149-159，2009年05月04日。
   評述：本文以歐洲BRCA1基因專利之個案探討基因檢測相關發明之專利保護爭議，以及所衍生之公共衛生議題。

9. 李素華，基因及基因醫藥之專利法制發展趨勢，法學新論，第4期，頁53-80，2008年11月。
   評述：本文以基因專利應用於醫藥領域為核心，討論專利制度保護基因發明之餘，對公共衛生可能產生的不利影響爭議，最後並分析國外新近修法及實務發展中值得我國借鏡與參考之處。

10. 李素華、謝銘洋，生技醫療產業所面對新興專利課題—基因檢測、細胞治療與基因治療之專利保護與權利限制，台灣科技法律與政策論叢，第4卷第2期，頁49-100，2007年06月。
    評述：本文檢討基因檢測、細胞治療與基因治療之專利保護及其對醫療活動之影響與專利制度所應扮演之角色，作者認為我國專利法第24條第3款醫療方法不予專利及第58條專利權效力不及於藥品調製行為之規定，容有修正之必要，以落實公共衛生政策；對於新興生醫技術之研發與應用，亦應於專利法予以適度其專利權範圍。

11. 余信達，從人性尊嚴與倫理道德之定位探索基因相關技術之可專利性，月旦法學雜誌，第113期，頁175-195，2004年10月。
    評述：本文認為應將基因序列定性為具有「人格法益」性質之主體，進而肯定其「人性尊嚴」之價值所在。作者認為藉由解釋論與立法論，或可將專利法第24條第1、2款視為同條第3款「妨害公共秩序、善良風俗或衛生者」之例示規定。從而可將「侵害人性尊嚴、違反倫理道德及公序良俗」之發明，直接引為「判斷『不予專利之客體』之消極要件」。

12. 何建志，基因專利違反道德？，應用倫理研究通訊，第27期，頁55-63，2003年07月。

評述：本文分析基因專利所涉及之倫理爭議，作者分別就基因專利與人類生存權、生命本質之衝突，以及專利制度本旨與將基因私有化等議題逐一分析討論。

13. 張文貞、牛惠之，淺談人類基因專利：科技發展、倫理與法律的三角習題，應用倫理研究通訊，第27期，頁42-47，2003年07月。
評述：本文分析基因科技對產業所帶來之影響，並就賦予基因專利所產生之利益分配、族群正義與倫理法律等議題分別探討。

14. 李森墉，談日本基因發明之專利制度 — 以ETSs、SNPs、全長cDNA為例，科技法律透析，第14卷第2期，頁38-54，2002年02月。
評述：本文首先比較說明賦予基因專利之利弊，其後作者以日本「生理活性物質測定法」事件判例出發，探討檢測方法專利之範圍。

二、國外重要參考文獻及評述：

茲就國外探討關於*Myriad*判決以及基因專利相關議題之重要文獻臚列如下：

(一) Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341 (2013).
評述：本文為美國專利法學術界夙負盛名之學者Eisenberg教授最新舊基因等生技相關發明之文獻，作者對於Myriad判決理由涉及的爭議問題逐一提出個人看法。有助於本研究更精確掌握Myriad案之爭點。

(二) Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109 (2013).
評述：本文由專利制度旨在鼓勵發明的角度，探討基因序列已為自然產物、先前技術所先佔而不具可專利性。作者從DNA與cDNA的技術分析，認為基因序列乃人為因素介入之成果，考量發明人投注之心力與專利制度本質，仍應肯定基因專利。

(三) Elle Marino, *A Look at the Technical, Social, and Economic Considerations Behind Gene Patents*, 22 KAN. J.L. & PUB. POL'Y 299 (2013).
評述：本文認為賦予基因專利將阻礙生技產業，尤其是基因領域之後續發明，且對於病患接近基因檢測之權益亦有衝擊。作者由社會、公共衛生等面向分析基因專利之爭議，最後認為基因應不具專利適格性。本文在專利適格性分析上提出許多政策面的考量因素，可供

本研究對於我國賦予基因專利應如何因應同樣問題之參考。

(四) Douglas L. Rogers, *After Prometheus, are Human Genes Patentable Subject Matter?* 11 DUKE L. & TECH. REV. 434 (2013).

評述：本文作者以美國法院於*Mayo*案所用以判斷個人化醫療方法發明專利適格性之基準，逐一檢驗基因發明之專利適格性。經分析後，本文得出基因發明並無法合於美國專利法第101條之規定，故不具專利適格。

(五) Nicholas D. Walrath, *Expanding Standing in Patent Declaratory Judgment Actions to Better Air Public Policy Considerations*, 88 N.Y.U. L. REV. 476 (2013).

評述：本文係以肯定基因專利為前提，作者提出維持基因專利品質的其他可採行措施。作者認為現行美國專利法中的專利審查及舉發等機制，均未將公共利益等政策性因素納入考量，在基因專利容易產生公共衛生等議題的情況下，作者建議美國國會應增訂得以此等公共政策因素為理由，對有爭議的基因專利提起確認專利無效之訴。

(六) Samantak Ghosh, Note, *Gene Patents: Balancing the Myriad Issues Concerning the Patenting of Natural Products*, 27 BERKELEY TECH. L.J. 241 (2012).

評述：本文作者評析Myriad聯邦巡迴上訴法院原審判決中關於判斷基因專利適格性之基準，作者並認為基因專利（物的發明）不應賦與專利，惟有關基因的方法發明，則應仍具專利適格。對於本研究關於基因專利適格性部分的討論，值得參考。

(七) Shannon K. Murphy, Comment, *Who is Swimming in Your Gene Pool? Harmonizing the International Pattern of Gene Patentability to Benefit Patient Care and the Biotechnology Industry*, 89 U. DET. MERCY L. REV. 397 (2012).

評述：本文詳細分析Myriad案地院及聯邦巡迴上訴法院等判決，作者並由歐洲及日本等外國法角度，比較分析如何兼顧發明人權益保障與維護公共利益。

(八) W. Nicholson Price II, *Unblocked Future: Why Gene Patents Won't Hinder Whole Genome Sequencing and Personalized Medicine*, 33 CARDOZO L. REV. 1601 (2012).

評述：本文對於基因純化、萃取技術有詳細說明，作者認為由基因技術的複雜性，並不容易認定構成侵權，從而作者認為賦予基因專利並不致對生技產業造成過度影響。本文對於本研究關於基因技術部分的分析有很高的參考價值。

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

評述：本文由專利制度鼓勵發明之本旨出發，探討賦予基因發明專利之鄭、反意見。作者最後認為基因發明應具專利適格而得受專利保護。

(十) Stephen H. Schilling, *DNA as Patentable Subject Matter and a Narrow Framework for Addressing the Perceived Problems Caused by Gene Patents*, 61 DUKE L.J. 731 (2011).

評述：本文就基因專利之支持與反對見解有詳細分析，基於鼓勵發明，作者採取肯定基因專利之立場，並就反對見解所持基因專利可能造成的產業影響等爭議，提出因應之道與建議。

(十一) Peter Edwards, *AMP v. Myriad: The Future of Medicine and Patent Law,* 12 MINN. J.L. SCI. & TECH. 811 (2011).

評述：本文著重於賦予基因專利可能帶來的公共利益衝擊影響，作者由*Myriad*案出發，同時也就基因發明之可專利性予以分析，並採取肯定立場。本文對美國法基因專利之政策方面議題著墨甚多，值得本研究參考。

(十二) Maureen E. Boyle, *Leaving Room for Research: The Historical Treatment of the Common Law Research Exemption in Congress and the Courts, and its Relationship to Biotech Law and Policy*, 12 YALE J. L. & TECH. 269 (2009-2010).

評述：本文主要在探討美國髮上研究免責之發展沿革與適用要件，對本研究在美國法的試驗、研究免責分析上有相當參考價值。

(十三) Miri Yoon, *Gene Patenting Debate: The Meaning of Myriad*, 9 J. MARSHALL REV. INTELL. PROP. L. 953 (2010).

評述：本文提出以強制授權與研究免責的方式，作為賦予基因專利後對產業與公共利益造成的衝擊調和手段。

(十四) Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001).

評述：本文逐一比較美國與歐盟關於基因專利之各要件判斷，基此討論基因之可專利性。作者最後並提出以強制授權及研究免責等配套措施，作為基因專利所可能帶來的影響。本文與本計畫研究主題契合，有相當參考價值。

肆、 研究方法

一、本計畫採用之研究方法

本研究係從2013年美國聯邦最高法院Myriad案判決探討有關基因專利的專利適格性問題，以及賦予基因專利所衍生之公共利益維護議題暨其因應之道。因此，本研究之計畫內容可分為四大部分：

第一部分：對於生物科技，尤其是基因、DNA等技術概念與予以分析，以建立本計畫之基本背景知識。

第二部分：分析Myriad案於美國法院之判決及相關評論，本部分主要在於釐清美國法院對於基因專利適格性之判斷基準與澳洲法院所持見解之異同。於論述過程中，同時亦將探究美國專利司法實務對於自然法則之判斷基準與歷來法院見解之沿革，並以此作為第四部分我國法之借鏡的依據；

第三部分：探討賦予基因專利可能對生物科技產業產生之爭議以及衍生之公共政策相關議題，並進一步比較支持與反對基因專利者之看法。就反對基因專利所持理由部分，深入思考是否有其他可資解決之方法；

第四部分：我國法的檢討與借鏡。

基於以上研究架構，本研究將綜採文獻分析及比較研究等研究方法。本研究擬自美國專利法制與實務有關基因發明之規範與判決出發，詳為探究美國對基因專利過去至現在的立場轉變，故就美國專利法制、美國法院判決之分析探討，採取文獻分析研究法。就我國現行專利制度對基因發明之規範與專利適格性之判斷，則採比較研究法，分析比較我國專利法規定與美國立法與實務運作之異同，以俾評估我國現行專利法制是否有需進一步改革之處，並借鏡美國法，思考我國對於基因專利所造成之影響所應採取的因應之道。

二、本計畫進行步驟及執行進度

本於前開研究方法，本研究將依以下各階段實施：

1. 第一階段：蒐集美國有關基因相關發明專利適格性之相關判決與文獻。

2. 第二階段：了解並分析美國法院就基因相關發明專利適格性之判斷基準，並比較各界對於賦予基因相關發明專利之支持與反對意見，此部分並將一併與專利制度本旨探討。

3. 第三階段:分析研究美國關於基因發明專利適格性判斷之法院見解，此部分將以Myriad案為主軸，同時，本階段亦將討論賦與基因發明專利可能產生之影響。

4. 第四階段：比較我國專利法對基因發明專利適格性之立法模式，並探討國內對於基因專利之正、反意見。

5. 第五階段：由美國各界對於Myriad案的討論，探討我國專利法是否對於基因發明專利適格性之判斷（尤其是關於自然產物、自然現象之認定）應予修正。此外，並將探究分析我國倘維持肯定基因專利之立場，對於美國反對基因專利之疑慮是否已有足夠的解決之道？倘無，未來應如何因應修法？

伍、 結果與討論

Table of Content

I. Introduction

The United States (hereinafter the U.S.) Supreme Court's 2013 *Association for Molecular Pathology v. Myriad Genetics, Inc.* decision[26] (hereinafter *Myriad*) has drew the debate over patent eligibility of human genes.[27] Gene patents, or patents attempting to claim a DNA or nucleotide sequence (hereinafter "Gene Patents")[28] have always been controversial. Proponents advocate that gene patents give inventors powerful incentives in genetic research.[29] Opponents, however, argue that gene patents can restrict patient access to genetic diagnostic tests and many other essential health services.[30] Others object to gene patents because such patents potentially impede the progress of future research.[31]

The Supreme Court has interpreted the patentable subject matter broadly to include "anything under the sun that is made by man."[32] Therefore, a natural substance such as a gene in its natural form is barred from patent protection because it is a product of nature.[33] However, a patent application claiming a purified and isolated form of a gene or the protein it creates is patentable[34]. Although there are

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[26] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).

[27] Andrew Pollack, *Justices Consider Whether Patents on Genes Are Valid*, N.Y. Times, April 14, 2013, *available at*: http://www.nytimes.com/2013/04/15/business/as-court-considers-gene-patents-case-may-overlook-relevant-issues.html?pagewanted=all&action=click&module=Search&region=searchResults%230&version=&url=http%3A%2F%2Fquery.nytimes.com%2Fsearch%2Fsitesearch%2F%3Fvertical%3Dbusiness%2F%23%2Fmyriad%2Bpatent%2F365days%2F (last visited 2014/2/27); Adam Liptak, *Justices Seem Wary of Bold Action in Gene Patent Case*, N.Y. Times, April 15, 2013, *available at:* http://www.nytimes.com/2013/04/16/business/justices-tackle-the-patenting-of-human-genes.html?action=click&module=Search&region=searchResults%230&version=&url=http%3A%2F%2Fquery.nytimes.com%2Fsearch%2Fsitesearch%2F%3Fvertical%3Dbusiness%2F%23%2Fmyriad%2Bpatent%2F365days%2F (last visited 2014/2/27).

[28] *See* 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.").

[29] *See* Wolrad Prinz zu Waldeck und Pyrmont, *Research Tool Patents After Integra v. Merck--Have They Reached a Safe Harbor?*, 14 Mich. Telecomm. & Tech. L. Rev. 367, 372 (2008); Brian Murphy & 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)

[30] Sec'y's Advisory Comm. on Genetics, Health, & Soc'y, Dep't of Health & Human Servs., *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, 3 (2010), http://oba.od.nih.gov/oba/sacghs/reports/sacghs_ Patents_report_2010.pdf [hereinafter SACGHS Report]

[31] *See* 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).

[32] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[33] *See* 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).

[34] John 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

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 (hereinafter "USPTO") issued its "Utility Examination Guidelines (the 'Utility Guidelines')" in 2001.[35] Based on the Guidelines, a patent may contain claims directed to an isolated and subsequently purified genetic composition.[36] Therefore, gene patents typically cover the manifestation of genetic information in a physical form[37], and a 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.[38] 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.[39] The courts in the Myriad case have exemplified these concerns.[40] 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 patent because they lack of inventive step (nonobviousness criteria in the U.S.).[41]

This article will explore the legal and policy issues arising out of gene patens in light of the *Myriad* decision. Part II begins with a brief overview of gene patents and outlines the basic 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 Taiwan Patent Act. These solutions would ensure scientists and 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.[42] Before addressing the issues raised in the *Myriad* case, one should understand the concepts of genes and the

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of a vector.

[35] The USPTO, Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

[36] *Id.*

[37] *Id.*

[38] Aljalian, *supra* note 5, at 53.

[39] *Id.* at 53-54.

[40] *See* infra Part III.

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

[42] Sirpa Soini, Ségolène Aymé and Gret Matthijs, *Patenting and licensing in genetic testing: ethical,*

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)."[43] Biotechnology uses biological techniques to advance the development or manufacture, or both of a product for industry.[44] As such, the advancement in biotechnology has broad and significant impacts on industry.[45] For instance, the discovery of DNA structure in 1953 by James D. Watson and Francis H. C. Crick[46] brought 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 industry materials and drugs.[47]

DNA, which stands for deoxyribonucleic acid, consists of two long polymers of nucleotides.[48] These two strands, in the shape of a double helix, are formed by linking together four different nucleotides called bases.[49] There are four types of nucleotides in a DNA molecule: adenine (A), thymine (T), cytosine (C) and guanine (G).[50] The nucleotide bases A and T form a bond, and so do the bases C and G[51]. It is the sequence of these four bases along the backbone that encodes information which is read using the genetic code. With the exception of some RNA (ribonucleic acid) viruses, most organisms use DNA to carry hereditary information.[52] 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.[53] The term "gene" refers to "a locatable region of genomic sequence, corresponding to

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legal and social issues, 16 EUROPEAN J. OF HUMAN GENETICS S10, S10 (2008).

[43] *See* MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/biotechnology (last visited 2010/10/4).

[44] *See* ENCYCLOPEDIA BRITANNICA, biotechnology is defined as "the application to industry of advances made in the techniques and instruments of research in the biological sciences," http:// www.britannica.com/search?query=Biotechnology&ct=&fuzzy=N (last visited 2010/10/4)

[45] Leslie 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).

[46] *See* generally JAMES DARNELL *ET AL*., MOLECULAR CELL BIOLOGY 5, 11 (2d ed. 1990).

[47] Restaino, *supra* note 18, at 2.

[48] KENNETH 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 2010/10/4).

[49] *Id.*

[50] *Id.*

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

[52] RNA is involved in protein synthesis and sometimes in the transmission of genetic information. *See* MERRIAM-WEBSTER, http://www.merriam-webster.com/dictionary/rna (last visited 2010/10/4). Thus, DNA and RNA are both used by living organisms to carry hereditary information.

[53] *See* International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE, 860-921 (2001).

a unit of inheritance, which is associated with regulatory regions, transcribed regions and/or other functional sequence regions."[54] However, increasingly, except the concept of protein-encoding genetic sequences, the term "gene" is also broadly used to encompass other functional regions of the genome as well.[55]

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."[56] Based on this authority, Congress has enacted the U.S. Patent Law,[57] and the law authorizes the USPTO to examine patent applications and issue patents.[58] To be patentable, an invention must meet several requirements. The claimed invention must be patentable subject matter,[59] and satisfy the patentability requirements which include utility,[60] novelty[61] and nonobviousness.[62]

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…"[63] The Supreme Court has recognized that patentable subject matter should "include anything under the sun that is made by man."[64] 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.[65]

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.[66] This utility requirement is satisfied if a patent application shows that the invention provides some practical benefit in its current form.[67]

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[54] Helen 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.")
[55] Holman, *supra* note 5, at 307.
[56] U.S. Const. art. I, § 8, cl. 8.
[57] 35 U.S.C. §§ 1-376 (2007).
[58] 35 U.S.C. §§ 1 -13 (2007).
[59] 35 U.S.C. § 101. *See Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972).
[60] 35 U.S.C. § 101 (1952).
[61] 35 U.S.C. § 102 (2002).
[62] 35 U.S.C. § 103 (2004).
[63] 35 U.S.C. § 101 (1952).
[64] Diamond v. Chakrabarty, 447 U.S. at 309.
[65] *See* Gottschalk v. Benson, 409 U.S. 63, 67-68 (1972).
[66] *See* The USPTO, Manual of Patent Examining Practice (MPEP), § 2107(I) (8th ed. Rev. 7 2008). In Taiwan, art. 22 of Zhuanlifa [Patent Act] also set 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* Zhuanlifa [Patent Act], art. 22, para. 1 (Taiwan).
[67] *Id.* § 2107.01(I)(c). The utility requirement contains three separate requirements. First, the invention

Section 102 of the Patent Law provides the novelty requirement.[68] Novelty is determined at the moment of filing date.[69] To satisfy 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.[70]

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.[71] An invention would 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.[72]

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 use of the gene for diagnostic and therapeutic purposes.[73] On May 12, 2009, Association Molecular Pathology together with the other plaintiffs (hereinafter AMP) file a suit against the USPTO and Myriad in the United States District Court for the

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

[68] Patent Act, 35 U.S.C. § 102 (2002). The novelty requirement is set forth in art. 22, para. 1 of Taiwan's Zhuanlifa [Patent Act], 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. *See* Zhuanlifa [Patent Act], art. 22, para. 1 (Taiwan).

[69] 35 U.S.C. § 102(a) and (g).

[70] *See* MPEP, *supra* note 40, § 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.

[71] 35 U.S.C. § 103. The nonobviousness requirement is set forth in art. 22, para. 4 of 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."

[72] Rebecca 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).

[73] Myriad 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. Trade & Patent 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).

Southern District of New York.[74] 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 drown to patent-ineligible subject matter."[75] 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.[76]

The challenged patents-in-suit include composition claims and method claims.[77] The composition claims cover two isolated human genes BRCA1/2, and certain mutations in these genes.[78] Representative composition claims include claim 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.
>
> 5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.[79]

Myriad's method claims relate to isolated gene sequences and diagnostic methods of identifying mutations in BRCA1/2.[80] 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.[81] 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 ana-lyzing 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.[82]

> 1. A method for screening a tumor sample from a human subject for a

[74] 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).
[75] Myriad II, 689 F.3d 1309.
[76] Complaint 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].
[77] Myriad II, 689 F.3d at 1309.
[78] *Id*.
[79] *Id*.
[80] *Id*, at 1310.
[81] *Id*, at 1309-10.
[82] *Id*, at 1309.

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.[83]

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 compound 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.[84]

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.[85] The Federal Circuit, however, reversed the district court's decision (Myriad I).[86] 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*.[87] On remand, the Federal Circuit reaffirmed its earlier ruling upholding the composition claims and one method claim

[83] *Id*, at 1310.
[84] *Id*.
[85] Myriad, 702 F. Supp. 2d at 232.
[86] 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).
[87] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794, 1794 (2012).

(Myriad II).[88] On November 30, 2012, the Supreme Court granted certiorari as to Question 1 presented by the petitioners that "are human genes patentable?"[89] In 2013, the Supreme Court invalidated Myriad's BRCA1 and BRCA2 patents.[90]

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.[91] As such, the disputed claims covered unpatentable products of nature and laws of nature.[92] 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.[93] 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 subject matter under the patent law. The claimed inventions must satisfy the meaning of the four categories of subject matter and do not fall into three accepted exceptions to patent-eligible subject matter: the law of nature, the physical phenomena and abstract idea exceptions.[94] The District Court and Federal Circuit relied on *American Fruit Growers, Inc. v. Brogdex Co.,*[95] *Funk Bros. Seed Co. v. Kalo Inoculant Co.,*[96] and *Diamond v. Chakrabarty,*[97] 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 a "markedly different, or distinctive characteristics."[98] However, their conclusions are different.

The district court held that Myriad's composition claims were ineligible for patent because the claimed BRCA1/2 sequences are not markedly different than the natural DNA.[99] Focusing on the importance of the information-storing capacities of DNA, the court suggested that the fact that information encoded in the claimed

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[88] Myriad II, 689 F.3d at 1308-9.
[89] 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.
[90] Myriad, 133 S. Ct. at 2119-20.
[91] Plaintiffs' 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).
[92] *Id.*
[93] Myriad 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).
[94] Myriad II, 689 F.3d at 1324 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).
[95] American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931).
[96] Funk Bros. Seed Co. v. Kalo Inoculant Co. (Funk Bros.), 333 U.S. 127 (1948).
[97] Diamond v. Chakrabarty, 447 U.S. 303 (1980).
[98] *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.")
[99] Myriad, *id,* at 220.

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.[100] 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."[101]

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.[102] The court reasoned that isolated DNA are "result[ed] from human intervention to cleave or synthesize a discrete portion of a native chromosomal DNA,"[103]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.[104] 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.[105] 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."[106]

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."[107] The Court took an information view of DNA as opposed to a chemical-structural approach. It reasoned that "[M]yriad's DNA claim falls within the law of nature exception" because "[i]t did not create or alter either the genetic information encoded in the BRCA1 and BRCA2 genes or genetic structure of the DNA."[108] 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 section 101. The Court reasoned that the creation of cDNA results in an

[100] *Id.* at 228-9.
[101] *Id.* at 230.
[102] Myriad II, 689 F.3d at 1328.
[103] *Id*.
[104] *Id,* at 1329.
[105] *Id,* at 1330.
[106] *Id*.
[107] Myriad, 133 S. Ct. at 2107.
[108] *Id.* at 2119.

exon-only molecule, which relies on human intervening to remove introns from a DNA sequence.[109] Therefore, "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments."[110] 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."[111]

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*.[112] The court observed that the method claims-in-suit are "directed to the abstract process of 'comparing' or 'analyzing' gene sequences."[113] 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.[114]

The Federal Circuit in *Myriad I* and *II* both held Myriad's method claims directed to "comparing" or "analyzing" DNA sequences fall into "abstract, mental step" exception to patent-eligible subject matter.[115] Additionally, the court both 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.[116] The screen 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."[117] 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 for patentable subject matter.[118]

After the Supreme Court delivered its *Myriad* decision, the USPTO soon published a memorandum providing its preliminary guidance to the Patent Examining

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[109] *Id*.
[110] *Id.*
[111] *Id.*
[112] Myriad, 702 F. Supp. 2d at 232-37.
[113] *Id*, at 234.
[114] *Id*, at 236-37.
[115] *See* Myriad I, 653 F.3d at 1334; Myriad II, 689 F.3d at 1334-35.
[116] Myriad I, *id*, at 1357.
[117] *See Id*, at 1357; Myriad II, 689 F.3d at 1336.
[118] Myriad II, *id*, at 1336.

Corps relating to gene related inventions.[119] 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 ineligible subject matter under 35 U.S.C. § 101."[120] 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."[121] "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."[122]

IV. Concerns Arising From Gene Patents

Advocates for gene patents contend that patents can stimulate investment and increase incentives for advancement by rewarding the inventors with exclusive rights in a period of time.[123] Opponents, however, argue that gene patents impede access to patient testing, decrease the quality of genetic testing, and impede the progress of further research.[124]

Some fears that granting exclusive rights on gene related inventions may impede patient access to gene based diagnostic tests.[125] 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.[126]

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.[127] 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.[128] 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."[129]

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[119] United States patent and Trademark Office, *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 2014/2/27).
[120] *Id.*
[121] *Id.*
[122] *Id.*
[123] SACGHS Report, *supra* note 4, at 28-29.
[124] *Id*, at 38-45.
[125] *Id*.
[126] *Id*, at 38-39.
[127] *Id*, at 42.
[128] *Id*.
[129] *Id.*

Second, patients are not able to access genetic tests if the provider of the test does not accept patients' insurance.[130] Under the circumstance, patients cannot afford the increased cost of testing and have no choice but to forgo it.[131] Additionally, when there is a sole test provider in the market, patients' abilities to access a second genetic test opinion are unavailable.[132] Second opinion is significant in helping the 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." [133]

However, under the current U.S. health system, patients always "face unequal access to medical care, including diagnostic tests."[134] Patient access is not a problem unique to genetic testing. In addition, the essence of the affordability problem is the refusal by the insurer to cover genetic testing rather than the test is patented or not.[135] Insurance companies are free to refuse coverage even if a test is widely provided across the country.

The lack of competition in 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.[136] 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.[137] Gene patent holders have the exclusive right to prevent others from practice their patents. Laboratories may stop perform patented genetic testing to avoid infringing patent. While the competing peers are 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 may have some impacts on genetic testing quality.

In addition, opponents also argue that granting gene patents may impede research and innovation.[138] They worry that gene patents holders will create a "patent

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[130] *Id*.
[131] *Id*, at 44.
[132] *Id*, at 43-44.
[133] *Id*, at 43.
[134] Mara Aspinall *et al, Statement of Dissent from Ms. Aspinall, Dr. Billings, and Ms. Walcoff* in SACGHS Report, supra note 4.
[135] *Id*.
[136] SACGHS Report, supra note 4, at 4.
[137] *Id*, at 46.
[138] *See, e.g.*, Myriad I, 653 F.3d at 1379-80 (Bryson, J., concurring in part and dissenting in part).

thicket" that may impede further research and innovation.[139] The 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.[140] Instead of promoting the progress of science and technology, too much patent protection can hinder further research and invention.[141] However, a recent report by the National Research Council ("NRC") reveals that human gene patents are unlikely to hinder biomedical research.[142]

V. Recommendations: Experiences from Taiwan

Under Taiwan Patent Act, genes are patentable subject matter.[143] Like the U.S., a gene patent will be issued if it satisfies the patentability requirements such as utility, novelty and nonobviousness.[144] 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 Taiwan Patent Act, the beneficial compromises for genetic research and patient access to genetic tests would be offering 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, section 271(e)(1) of the law provides an exemption to infringement of pharmaceutical compounds patents.[145] The exemption applies only to the use of patented pharmaceutical compounds in order to submit new compounds to the Food and Drug Administration.[146] Moreover, section 287(c)(1) protect medical practitioners when performing patented medical or surgical procedures on patients.[147] However, this exemption does not apply to the use of a patented composition of matter.[148] Accordingly, neither of the exemptions provided in the Patent Law apply to 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*.[149] In *Madey*, the Federal Circuit

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139 *Id*, at 1380.
140 *Id*.
141 Myriad I, 653 F.3d at 1380.
142 *See* 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 & Anne-Marie Mazza, eds., National Academies Press 2006) [hereinafter NAT'L RESEARCH COUNCIL'S REPORT].
143 *See* Taiwan Patent Act, art. 24; Substantive Examination Guidelines, ch. 14, pp. 2-14-1~2-14-3.
144 *See* Taiwan Patent Act, art. 22.
145 35 U.S.C. §§ 271(e)(1)
146 Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205 (2005).
147 35 U.S.C. §§ 287(c)(1)-(c)(2)(A).
148 *Id*. § 287(c)(2)(A).
149 Madey v. Duke Univ., 307 F.3d 1351, 1355 (Fed. Cir. 2002).

adopted a restrict 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" does not immune from infringement liability to such conduct.[150] Thus, the experimental use exemption applies only to activities undertaken for the purpose of amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.[151]

In Taiwan, article 59 of Taiwan Patent Act provides limitations of patent right.[152] It exempts a person from being held patent infringement under certain circumstances. Pursuant to the article, a patent shall not extend its right to the following circumstances:

> (1) acts done privately and for non-commercial 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.

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[150] *Id*, at 1362.
[151] *Id*.
[152] Taiwan Patent Act, art. 59 (2013).

Like the U.S., article 59 (1) of 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 conducted, the exemption affords immunity from infringement. Thus, even if school funded research projects embodied the purpose of furthering the university's business objective, the researcher still can utilize this exemption as long as the activities are done for the purpose of research or experiment.

Accordingly, 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 non-commercial and experimental purposes.[153] As such, the proposed exemptions adopt article 59 (2) of 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 to research on patented genes can increase the incentives of advancing innovations and enhance the quality and efficiency of current gene related inventions.[154]

B. Compulsory Licensing

In the U.S., compulsory licensing may occurs under: (1) the Bayh-Dole Act[155]; (2) 35 U.S.C. § 154(a)(1)[156]; and (3) the Clean Air Act.[157] The Bayh-Dole Act provides "march-in" rights on Federal funded research.[158] In order to promote the utilization of inventions and public availability of federally-funded inventions,[159] 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.[160] The statute provides a federal agency to exercise it march-in rights when such action is "necessary to alleviate health and safety needs," [161] In addition,

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153 Jennifer 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).
154 *Id.*
155 Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015 (codified at 35 U.S.C. §§ 200-212).
156 35 U.S.C. § 154(a)(1).
157 Clean 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)).
158 35 U.S.C. § 203.
159 35 U.S.C. § 200.
160 35 U.S.C. § 203(a).
161 35 U.S.C. § 203(a)(2).

compulsory licensing may be ordered by a court under 35 U.S.C. § 154(a)(1) when a court refuse to issue an injunctive relief.[162] Furthermore, a court may also order a compulsory license under the Clean Air Act if the patent is critical to control air pollution. [163] Factors that are taken into consideration when making the decision of compulsory licensing 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.[164]

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).[165] 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," Sen. Leahy indicates that Myriad's patents, which were based on federally-funded research, are important for public health.[166] "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."[167] 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," Sen. Leahy therefore encourages the Director to consider using the government's march-in rights with respect to the Myriad's BRCA test.

In Taiwan, articles 87 to 91 of Taiwan Patent Act provide statutory compulsory licensing. According to article 87, Taiwan Intellectual Property Office (TIPO) has the authority to issue a compulsory license. If 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.[168] Moreover, anyone may request TIPO to grant compulsory licensing of a patent under any of the following circumstances for which it is deemed necessary:

> 1. where a patented invention is to be exploited non-commercially 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

[162] 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).
[163] 42 U.S.C. § 7608 (2006).
[164] 42 U.S.C. § 7608 (2006).
[165] The letter is available at: http://www.leahy.senate.gov/download/07-12-13-pjl-to-nih-re_-myriad-march-in (last visited 2014/2/27).
[166] *Id.*
[167] *Id.*
[168] Taiwan Patent Act, art. 87 (2013).

> 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. [169]

The proposed compulsory licensing of human gene patents is very narrow. By referring to Taiwan Patent Law and the U.S. Clean Air Act, a court may order compulsory licensing of a gene patent only for 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 license fails, the non-patent holder may request for compulsory licensing of the patent for public interests purpose. 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 a 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 and making gene based medical treatment less inaccessible, the U.S. Congress should provide a framework of research exemption from patent infringement and compulsory licensing of a gene patent. The research exemption enable researchers to research on patented genes without a 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 incentives needed to promote the progress of gene related technologies.

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科技部補助計畫衍生研發成果推廣資料表

日期:2016/02/23

科技部補助計畫	計畫名稱: 人體基因相關發明專利之研究
	計畫主持人: 陳龍昇
	計畫編號: 103-2410-H-005-012- 學門領域: 商事財經法

無研發成果推廣資料

103年度專題研究計畫研究成果彙整表

計畫主持人：陳龍昇	**計畫編號：**103-2410-H-005-012-
計畫名稱：人體基因相關發明專利之研究	

成果項目			量化			單位	備註（質化說明：如數個計畫共同成果、成果列為該期刊之封面故事...等）
			實際已達成數（被接受或已發表）	預期總達成數（含實際已達成數）	本計畫實際貢獻百分比		
國內	論文著作	期刊論文	0	0	100%	篇	
		研究報告/技術報告	1	1	100%		
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	成果項目	量化	名稱或內容性質簡述
科教處計畫加填項目	測驗工具(含質性與量性)	0	
	課程/模組	0	
	電腦及網路系統或工具	0	
	教材	0	
	舉辦之活動/競賽	0	
	研討會/工作坊	0	
	電子報、網站	0	
	計畫成果推廣之參與（閱聽）人數	0	

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