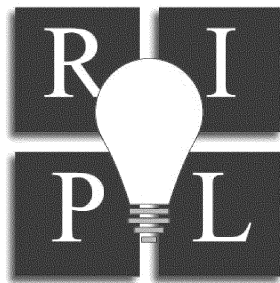


THE JOHN MARSHALL REVIEW OF INTELLECTUAL PROPERTY LAW



INTERPRETING *MYRIAD*: ACQUIRING PATENT LAW'S MEANING THROUGH CONTEMPORARY JURISPRUDENCE AND HUMANISTIC VIEWPOINT OF COMMON HERITAGE OF DNA

SABY GHOSHRAY

ABSTRACT

Until Judge Sweet's decision in *Association for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*, gene patentability in the United States has evaded prohibition for more than three decades since *Diamond v. Chakrabarty*. The *Myriad* decision has captured the imagination of the legal community—but not in isolation. This article examines *Myriad* through the lens of two contemporary European decisions related to gene patenting, *Eli Lilly & Co. v Human Genome Sciences, Inc* and *Monsanto Technology LLC v. Cefetra BV*, suggesting that *Myriad* is a narrative that evolves at the intersection of law's aspiration, humanity's common heritage, and corporate realities of the twenty-first century. The article examines the possibility of a future paradigm related to common heritage and distributive justice.

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INTRODUCTION

As we enter the second decade of the twenty-first century, the contentious issue of gene patenting seems to be acquiring a new legal meaning, driven in part by the series of court decisions invalidating isolated gene patents. Despite calls for courts to revisit the issue, gene patentability continued to evade the prohibition for more than three decades, until Judge Sweet's *Myriad*¹ district court opinion. *Myriad* captured the imagination of the legal community, not only due to its sudden shift in focus, but also for the sweeping implication it signals for the future of biotechnology in general and the human genome project in particular.² *Myriad*, however, did not come in ephemeral isolation, as I shall examine its implication through the lens of contemporary European decisions in gene patenting. Nor did *Myriad* evolve in a linear fashion, as can be seen through this article's trajectory, tracing a number of significant areas in the gene patent dispute. Therefore, in this article, I present *Myriad* as a narrative that evolves at the intersection of law's aspiration, humanity's common heritage and corporate realities of the twenty-first century. To understand the future of this narrative is to allow ourselves a retrospective inquest into its backdrop.

Beginning in the twentieth century, technological advancement in molecular genetics began colliding with increased corporatization, bringing to the surface issues over gene patents.³ As the socio-economic realities of gene patenting's exclusivity began to illuminate the collective consciousness of the masses, awareness for its economic deprivation came to surface.⁴ This deprivation resulted from an ever-

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¹ Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (*Myriad*), 702 F. Supp. 2d 181 (S.D.N.Y.), *appeal docketed*, 2010-1406 (Fed. Cir. July 6, 2010).

² See, e.g., Josh Schwartz & Andrew Pollack, *Judge Invalidates Human Gene Patent*, N.Y. TIMES, Mar. 29, 2010, at B1.

³ See Andrew W. Torrance, *Gene Concepts, Gene Talk, and Gene Patents*, 11 MINN. J.L. SCI. & TECH. 157, 181 (2010).

⁴ See GREENPEACE USA, STUDY: THE TRUE COST OF GENE PATENTS: THE ECONOMIC AND SOCIAL CONSEQUENCES OF PATENTING GENES AND LIVING ORGANISMS 4, 10-11 (2004) [hereinafter GREENPEACE STUDY], *available at* <http://www.greenpeace.org/usa/Global/usa/report/2007/7/the-true-cost-of-gene-patents.pdf>.

increasing array of patents trying to reach the finish lines of patent acceptability, most often sacrificing broader societal utility at the altar of economic incentive for the few.⁵ This explosion of patents began to challenge traditional conception of patentable subject matter, as the question of limits began straddling the intersection of ethics, morality, and legal policy.⁶

Since its very inception, the discussion of the patentability framework has acquired multiple hues, often unfolding as a quintessential dispute between maximalist-versus-minimalist positions,⁷ at times questions of a patent's exclusivity acquired meaning through the struggle between have and the have-nots.⁸ Patentability discussions promising to identify appropriate legal landscape, often times, gets shaped by our obligation to our common heritage of humanity, prompting us to consider a set of threshold questions protruding the ethical boundaries of patent law: such as, whose gene is it anyway?⁹ Can we take the seeds away from the farmers? How much bacterial toxin can we inject into the plant? In the continuing saga of exploration and invention, these types of existential questions have always shaped legal framework—from the disputes over the rights of minerals within the sea beds,¹⁰ to exploration of outer-space.¹¹ The battle on patentability of biological inventions premised on claiming the common heritage of humanity¹² is no exception.

⁵ See *id.* at 5.

⁶ See Annabelle Lever, *Ethics and the Patenting of Human Genes*, J. PHIL. SCI. & L. (Nov. 2001), http://www6.miami.edu/ethics/jpsl/archives/papers/ethics_lever.html; Theo Papaioannou, *Human Gene Patents and the Question of Liberal Morality*, 4 GENOMICS SOC'Y & POL'Y 64, 79–80 (2008), <http://www.hss.ed.ac.uk/genomics/V4N3/pdfs/Papaioannou.pdf> (arguing that issuance of gene patents leads to “information feudalism”).

⁷ The term “maximalist” is used to describe a position/theme and emphasis is placed on the inclusion of all factors possible associated with the position. Whereas, the term “minimalist” is used to describe a position/theme and emphasis is placed on eliminating any extra factors and reducing down to only the necessary elements.

⁸ See James Boyle, *Enclosing the Genome: What the Squabbles over Genetic Patents Could Teach Us*, in PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 97, 107–08 (F. Scott Kieff ed., 2003) (discussing maximalist and minimalist perspectives on gene patenting).

⁹ See Annabelle Lever, *Is it Ethical to Patent Human Genes?*, in INTELLECTUAL PROPERTY AND THEORIES OF JUSTICE 246, 252 (Axel Gosseries et al. eds., 2008).

¹⁰ See, e.g., Martin A. Harry, *The Deep Seabed: The Common Heritage of Mankind or Arena for Unilateral Exploitation?*, 40 NAVAL L. REV. 207, 207–08 (1992); Vienna Convention on the Law of Treaties art. 53, May 23, 1969, 1155 U.N.T.S. 331.

¹¹ See Linda Billings, *To the Moon, Mars, and Beyond: Culture, Law, and Ethics in Space-Faring Societies*, 26 BULL. SCI. TECH. & SOC'Y 430, 430–37; Lynn M. Fountain, *Creating the Momentum in Space: Ending the Paralysis Produced by the “Common Heritage of Man” Doctrine*, 35 CONN. L. REV. 1753, 1753–54 (2003).

¹² See Treaty on Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies art. I, Jan. 27, 1967, 18 U.S.T. 2410, 610 U.N.T.S. 205 (codifying the “Common Heritage of Mankind” principle for first time). The treaty states in Article I:

The exploration and use of outer space, including the moon and other celestial bodies, shall be carried out for the benefit and in the interests of all countries, irrespective of their degree of economic or scientific development, and shall be the province of all mankind. Outer space, including the moon and other celestial bodies, shall be free for exploration and use by all States without discrimination of any kind, on a basis of equality and in accordance with international law, and there shall be free access to all areas of celestial bodies. There shall be freedom of

Garnering traction in our legal discourse since the 1970s, riding the interpretative gloss of the United States Supreme Court's path-breaking decision in *Diamond vs. Chakrabarty*,¹³ gene patentability has assumed a paradoxical legal contour of late.¹⁴ Patent law's confusing conundrum stems partly from law's inability to catch up with the inventions, partly from policy's inadequacy to synchronize human welfare with corporate monopoly rent-seeking behavior.¹⁵ As a result, difficulties, discrepancies and inequalities in sharing the fruits of human ingenuity began to take center stage in policy discussions in two distinct areas: (i) biotechnological invention for agriculture¹⁶ and (ii) molecular biological discoveries related to human genes.¹⁷

The final quarter of the previous century saw the mad rush to patent inventions as biotechnology companies and research institutions brought tens of thousands of genes into the protective umbrella of exclusivity, primarily relying on the premise that an isolated gene or DNA sequence is different than its naturally occurring precursor.¹⁸ A general acquiescence into this premise within the patentability framework allowed a rapid surge of genetically modified ("GM") food crops in

scientific investigation in outer space, including the moon and other celestial bodies, and States shall facilitate and encourage international co-operation in such investigation.

Id. See also Agreement Governing Activities of States on the Moon and Other Celestial Bodies, G.A. Res. 34/68, Annex, U.N. Doc. A/RES/34/68 (Dec. 5, 1979); Antarctic Treaty art. VI, Dec. 1, 1959, 12 U.S.T. 794, 402 U.N.T.S. 71; Convention on International Liability for Damage Caused by Space Objects, Mar. 29, 1972, 24 U.S.T. 2389, 961 U.N.T.S. 187; Convention on Registration of Objects Launched into Outer Space, Jan. 14, 1975, 28 U.S.T. 695, 1023 U.N.T.S. 15.

¹³ *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980) (upholding the patentability of man-made bacteria that devours oil droplets in the ocean).

¹⁴ See discussion *infra* Part I.

¹⁵ By "corporate rent-seeking," I generally draw attention to the corporate practices where the corporate entity attempts to derive economic benefits by extracting economic rent via manipulating the existing socio-political landscape. In this context, rent-seeking occurs as the corporate entity extracts additional value by various means, such as imposing barriers to entry to other competitors or developing unilateral ability to fix a higher than normal market price. The term "monopoly" is included in the description to capture a unique dimension of such uncompensated value extraction in that the corporate entity enjoys monopoly privileges under the guidance of legal or regulatory framework. Originally introduced in 1967, the concept of "rent-seeking" was formalized in 1974 and identified as distinct from the basic profit-seeking behavior of economic agents. See generally Gordon Tullock, *The Welfare Costs of Tariffs, Monopolies, and Theft*, 5 W. ECON. J. 225 (1967) (introducing the idea of "rent-seeking"); Anne Krueger, *The Political Economy of the Rent-Seeking Society*, 64 AM. ECON. REV. 291 (1974) (formalizing the same concept). In the present context, I draw a distinction between profit-seeking and rent-seeking behaviors of bio-technology companies, where the former engages in mutually agreeable financial transactions within an efficient market environment, but where the later extracts abnormal profits in a skewed market environment by foreclosing other competitors' meaningful opportunities to compete due to patent exclusivity for a significant period of time.

¹⁶ See GREENPEACE STUDY, *supra* note 4, at 16.

¹⁷ See Thomas A. Hemphill, *Gene Patents, the Anticommons, and the Biotechnology Industry*, 53 RESEARCH TECH. MGMT. 11, 12 (2010).

¹⁸ See Utility Examination Guidelines, 60 Fed. Reg. 1092, 1092–93 (Jan. 5, 2001) (adopting new guidelines and responding to specific comments submitted in response to proposed guidelines affecting gene patentability).

agriculture,¹⁹ while the splicing and sequencing of genes continued unabated in molecular biology.²⁰ Driven by a misconception that current agricultural production is neither sustainable nor productive in the long run, patenting an agricultural seed's DNA sequence gained both legal legitimacy and social acceptance, allowing giant multinational corporations like Monsanto²¹ to become the Microsoft of the GM food business.²² On the other hand, as the idea of isolating genes acquired legal acceptance on a broader level, molecular genetics corporations began a monopolistic foray into gene-based diagnostic testing, much to the chagrin of the deprived masses.²³ Deprived, because they are now staring at a new form of preventive paradigm—prevention not from disease but from acquiring the fruits of genetic advancement.²⁴

The monopolistic uses of gene patents have a two-fold detrimental impact. First, due to exclusivity of rights granted to the patent owner, the broader scientific community and research institutions are unable to access new innovations or work on improvements.²⁵ Second, the cost-prohibitive nature of these inventions precludes their access to the expanded community of patients and caregivers. In an alarming array of recent instances, the genetic diagnostic testing companies have either withdrawn from providing patients with service or done so at exorbitant prices.²⁶ Their vantage position as the sole provider of such advanced diagnostics has conferred on them the ability to exhibit such monopoly rent-seeking behavior. Albeit, a faulty framework of patentability²⁷ has allowed biotechnology companies to unleash such existential chaos in human survivability²⁸ that opens up a Pandora's Box full of

¹⁹ See *Global Status of Commercialized Biotech/GM Crops: 2009 The First Fourteen Years, 1996 to 2009*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, <http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp>.

²⁰ Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES, July 1, 2007, § 3, at 3.

²¹ In 2005 and 2006, Monsanto brought an action against the Dutch importer, Cefetra for infringement of its European Patent, EP 0 546 090. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396. Monsanto's patent protects a soy plant it has called "Roundup Ready" and includes claims to both isolated DNA sequences and specific DNA sequences. *Id.*

²² See Roger Parloff, *Seeds of Discord, Monsanto's Gene Police Raise Alarm on Farmer's Rights, Rural Tradition*, WASH. POST, Feb. 3, 1999, at A1.

²³ See Lever, *supra* note 6, at 12.

²⁴ See George Bullwinkel, *Who Owns Your Genes?*, GEORGE BULLWINKEL (Apr. 4, 2010), http://www.bullwinkel.com/index.php?option=com_content&view=article&id=55&Itemid=70.

Corporations are erecting an insurmountable financial hurdle by virtue of making genetic inventions exclusive. Consider some of the costs: "Myriad charges \$3,000 per test, doesn't take Medicare, and by virtue of its heavily reinforced patent position has no U.S. Competitors. (Canada refuses to recognize Myriad's patents. There, a test costs only \$1,000.)" *Id.*

²⁵ See GREENPEACE STUDY, *supra* note 4, at 6.

²⁶ See Bullwinkel, *supra* note 24.

²⁷ See Kenneth G. Chahine, *Anchoring Gene Patent Eligibility to its Constitutional Mooring*, 28 NATURE BIOTECH. 1251, 1252 (2010) (noting that patentability decisions are "best rationalized based on how judges perceive the invention rather than any available legal theory").

²⁸ This existential chaos draws its meaning from the interaction between human productivity and environmental sustainability. For example, in agricultural biotechnology, injecting human intelligence to modify genetic codes of food grains has opened up a lot of existential threats for humanity. First, given the uncertainty where the newly introduced gene might land in the broader genomic array, it is not entirely possible to predict the final outcome, both of the formulated new

complex questions—questions surrounding human genes’ relationships with the function of its DNA and the basic tenants of patentability—in an area that is beginning to acquire new meaning.

So, is there a single flashpoint—a path-breaking doctrinal development in law that energized this patent race? Indeed, *Chakrabarty*’s patentability framework, one that “include[s] anything under the sun” that had “markedly different characteristics” from prior art is capable of being patented, broadened the scope of gene patentability in 1980.²⁹ This corporate race for DNA patenting, both in agricultural food processing and in human genome based genetic diagnostic testing industries, has been continuing on ever since, punctuated only periodically by isolated instances of judicial inquiry.³⁰ Not until later did we begin to see policy developments attempting to align legal requirements with biotechnology’s meteoric evolution, with initiatives both in the European Union (“EU”) and in the United States.³¹ Implementation of these initiatives resulted in significant doctrinal development in law over the last three years, unfolding through three constitutional cases in three different countries.³²

Indeed, these judicial decisions send us an unmistakable signal that, the courts are beginning to break away from the minimalist protectionist paradigm. As I shall establish in this article, this shift away from the minimalist framework is a growing recognition by the courts of the need for a stricter patentability framework.³³ This framework would justifiably put a brake on patent explosion by aligning a claimed invention of a gene or DNA sequence with functional specificity and inherent distinguishability.³⁴ This is revealed in *Myriad*; it is in Judge Sweet’s Southern District of New York ruling that we find invalidation of gene patents on the basis of a revised framework of patentability.³⁵

In eerily similar veins, two different court systems across the Atlantic also embarked on revising their patentability requirements. In the case of *Eli Lilly & Co. v. Human Genome Sciences*,³⁶ Justice Kitchin of the Chancery Division Patents Court in the United Kingdom restricted the scope of gene patentability in the U.K. by observing that the existing patent disclosure is academically broad.³⁷ In invalidating

gene sequence and also of the long-term impact of bacterial toxin, routinely being introduced in the name of pesticides. Second, the issue of gene flow via pooling—that is, the unwarranted consequences of either unwanted genes ending up in related plant, or the movement of genes freely across species—issues that have largely been kept out of current discourses. Humanity’s existential danger lurking beneath the avalanche of biological pollution, therefore, must be looked through a new prism. This prism exists not in the far-fetched outer limit of corporatization of agriculture but persisted too long in the absence of legal sensibility and logical prudence.

²⁹ See *Diamond v. Chakrabarty*, 441 U.S. 303, 309–10 (1980).

³⁰ See, e.g., *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) (upholding broad scope of a human genome-related patent).

³¹ See *infra* Part I.

³² See *Myriad*, 702 F. Supp. 2d 181; *Eli Lilly & Co. v. Human Genome Sciences*, [2008] EWHC (Pat) 1903, [2008] R.P.C. 29, *aff’d*, [2010] EWCA Civ 33, [2010] R.P.C. 29 (Eng.); *Case C-428/08, Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396 (EU).

³³ See *infra* Part I.

³⁴ See *infra* Part II.

³⁵ *Myriad*, 702 F. Supp. 2d at 232.

³⁶ *Eli Lilly*, [2008] EWHC (Pat) 1903.

³⁷ *Id.*

the patent application based on discord between the patentable DNA molecule's disclosed function and its prescribed industrial application,³⁸ the Justice also signaled the emergence of newer patentability requirements.³⁹ On the other hand, the European Court of Justice of the European Union ("ECJ") imposed new limitations on DNA patentability by focusing on connectivity between invention and its expected functionality.⁴⁰ In the case of *Monsanto v. Cefetra*,⁴¹ the Justice Advocate General M. Palo-Mengozzi denied protection for the claimed nuclei sequence type in enzyme gene, holding that such protection is limited to situations where genetic information currently performs the function described in the patent.⁴² Needless to say, courts' recognition of the ill-effects of gene patents' "abundance" in all of these cases is indeed driven by the social need to put a leash on the unbridled explosion of corporate monopoly through patenting.

Given the trend described thus far, do these decisions signal an apocalyptic end of gene patents for agricultural and biotechnology companies? Could these judicial decisions invite sweeping changes in the way these companies have engaged in rent-seeking for their part in promoting innovation? The biotechnology companies have already patented a large fraction of more than 25,000 genes identified under the Human Genome Project ("HGP")⁴³—a staggering one-fourth have already been patented and about another one-fourth are at various stages in the patenting process.⁴⁴ The stated functions of these genes range from developing new drugs, to designing more efficient diagnostics, to researching for genetic predisposition to disease, and to developing a prevention mechanism.⁴⁵ These include, among others, a diagnostic test for risk assessment, gene therapy, an optimizing treatment protocol, and cancer prevention.⁴⁶ Will the fall out of these decisions restrict the patentability of life-saving drugs by reducing incentives for biotechnology companies? Or, will the revised legal framework create a level playing field for research companies, while providing patients with better access to life-saving drugs by enabling increased participation? This article will examine in detail the broader impact of these three decisions, while connecting a continuous trajectory of their origin in *Diamond v. Chakrabarty*.

³⁸ *Id.* ¶ 327.

³⁹ *Id.* ¶ 226.

⁴⁰ Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396, ¶ 50 (EU).

⁴¹ *Id.*

⁴² *Id.* ¶¶ 62–63.

⁴³ The Human Genome Project is a world-wide effort to sequence and map the genes of the human body, which are made up of a staggering 100,000 genes, and the project is characterized as one of the largest mapping efforts in the biological realm. See Elizabeth J. Thomson, *Ethical, Legal and Social Implications of the Human Genome Project*, 3 DICK. J. ENVTL. L. & POL'Y 55, 55 (1994); G. Kenneth Smith & Denise M. Kettelberger, *Patents and the Human Genome Project*, 22 AIPLA Q.J. 27, 30 (1994); George J. Annas, *Mapping the Human Genome and the Meaning of Monster Mythology*, 39 EMORY L.J. 629, 636 (1990).

⁴⁴ Alex Osterlind, *Staking a Claim on the Building Blocks of Life: Human Genetic Material Within the United States Patent System*, 75 MO. L. REV. 617, 632 (2010).

⁴⁵ *Id.* at 617–18.

⁴⁶ *Id.*

Thus, Part I of the article discusses how these three decisions contradict the prior doctrinal trajectories of patent law while establishing connected threads of commonalities among them. Part II analyzes the broader impact of *Myriad*, especially outlining how *Myriad*'s expansive meaning is acquired through the lens of *Eli Lilly* and *Cefetra*. Part III will engage in a discussion of the future paradigm while diverging into several distinct threads, which will lead to the conclusion by examining questions related to common heritage and distributive justice.

I. *MYRIAD, CEFETRA AND HUMAN GENOME SCIENCES*—BOUND BY A COMMON THREAD

In this Section, I seek to explore the evolving contour of gene patentability by drawing the common lineage among the three opinions mentioned earlier. Instead of analyzing them in isolation, I intend to examine the common roots that illuminate the gene patentability paradigm embraced in these most recent decisions. An individual foray will allow me to tease out their structural similarities, which I shall use to examine their commonalities—through which the idea of an evolving legal framework of gene patentability might acquire its meaning. Taken individually, parts of each case may contradict isolated holdings in others. But taken as a whole, these cases indeed complement the gene patent puzzle and contribute to a much-needed, robust trajectory by informing us of the revised patentability framework.

A. *European Court of Justice's Foray into Scope Reduction in Agricultural DNA Patent*

Unveiled in 1998, in its directive on the legal protection of biotechnological inventions (“Bio Directive”), the European Parliament presented a framework to review patents for DNA sequencing in plants and animals.⁴⁷ Although intended to provide common grounds in areas of protection for plant varieties,⁴⁸ these allowable guidelines lost their meaning in the uncertain cacophony arising out of diverging strands of patent mechanisms across Europe. A much needed flash point came in 2006, when a biotechnology dispute erupted between two companies.⁴⁹ The dispute surfaced from the shipment of soy milk from Argentina to the EU.⁵⁰ The soy milk in question was obtained from GM soy and it was rendered tolerant to the glyphosate herbicide.⁵¹ This Roundup Ready (“RR”) soy owed its existence to the presence of a specific gene-encoding enzyme, 5-enol-pyruvylshikimate-3-phosphate synthase (“EPSPS”).⁵² Although there is no dispute that Monsanto had patented this RR soy, other food crop manufacturing companies began to take advantage of the loose patent

⁴⁷ Council Directive 98/44/E, 1998 O.J. (L 213) 13 [hereinafter Bio Directive] (governing the legal protection of biotechnological inventions and outlining a wide set of rules which limits any legislation from going beyond the rules outlined therein, including those related to patents).

⁴⁸ *Id.* at 13–14.

⁴⁹ Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396, ¶¶15–32.

⁵⁰ *Id.* ¶ 19.

⁵¹ *Id.* ¶ 17.

⁵² *Id.*

protection mechanism in Argentina, where this particular gene was not protected.⁵³ Armed with their ability to legally plant these seeds in Argentina without Monsanto's permission, these companies began cultivating and exporting GM soy meal to several European Union ("EU") countries for profit.⁵⁴

Monsanto's exclusive rights to European Patent EP 0 546 090 (issued June 1996) were based on claim by its researchers that have isolated two DNA molecules that encode the EPSPS enzyme during 2005–2006.⁵⁵ However, based on the lack of patent protection in the cultivator country, several companies including the Cefetra Group began importing consignments from Argentina.⁵⁶ Thus began Monsanto's lawsuit against the importing countries for patent infringement in the Dutch District Court of the Hague in 2006. The lawsuit trickled its way through a delayed process of various stayed proceedings and cross-filings, eventually arriving at the ECJ, where a set of questions were presented before the Court.⁵⁷ These questions were intended to explore the limits of protection for DNA sequences currently available under Article 8 and 9 of the Bio Directive.⁵⁸ The ECJ's goal is to help in eventually arriving at a decision that would provide a much-needed interpretive gloss over the Bio Directive's applicability to patent protection for DNA sequencing. The following questions form part of the questionnaire that was posed to the ECJ:

1. Should Article 9 of the Bio Directive be understood such that the protection meant in this Article can also be relied upon in a situation such as in these proceedings whereby the product (the DNA) is present in a materials and does not express its function at the time of the stated breach but has indeed expressed its function or possibly, following the isolation from the material and its incorporation in the cell of an organism, could once again express its function?
2. Does proceeding from the presence of the DNA sequence as described in claim 6 of the patent in soy meal imported into the European Community by Cefetra and ACTI and assuming that DNA is incorporated in the soy meal as meant in Article 9 of the Bio Directive and that it therein no longer expresses its function?
3. Does the provided protection of a patent for biological material in the Bio Directive, specifically in Article 9, stand in the way for the national patent legislation¹ to (additionally) allow absolute protection for the product (the DNA) as such, whether or not the DNA expresses its function and must the protection provided by Article 9 therefore be considered exhaustive?⁵⁹

⁵³ *Id.* ¶ 18.

⁵⁴ *Id.* ¶¶ 20–21.

⁵⁵ *Id.* ¶¶ 15–17.

⁵⁶ *Id.* ¶ 19.

⁵⁷ *Id.* ¶¶ 33–77.

⁵⁸ *See id.*; Bio Directive, *supra* note 47, at 19.

⁵⁹ *See Monsanto*, 2010 ECJ EUR-Lex LEXIS 396, ¶¶ 33–77.

While delivering his opinion on behalf of the ECJ on March 9, 2010, the Justice Advocate General M. Palo-Mengozzi provided the court's rationale for the denial of Monsanto's patent protection for the claimed DNA sequence.⁶⁰ The court reasoned that the protection is limited to isolated genetic material that performs the function described in the patent.⁶¹ Therefore, for patent protection to be recognized, the genetic material must perform the said function at the time of alleged infringement.⁶² The court viewed the function of Monsanto's invention as the ability of the genetic information to protect the biological material by conferring upon it herbicide tolerance, without which the intended target could die.⁶³ However, the isolated genes in the soy meal did not necessarily perform the designated function of protecting the soy meal from the use of herbicide, as the genetic material could only be found in residual state as "dead material" in the soy meal.⁶⁴ Thus, in the ECJ's analysis of the protection provided for in Article 9 of the Bio Directive, the fundamental issue revolved around whether isolated genes enjoy the same protection as the laboratory-manufactured, specialized genes.⁶⁵ The court found that the processed soy meal did not contain functional genetic material and therefore, the protection was not available to the GM seeds in the soy meal, as the genetic information had ceased to perform the function in the processed material.⁶⁶

The patentability question here is based on arriving at the semantic distinction between "biological materials" and "product." The court in *Cefetra* observed that the DNA sequence can actively perform its function *only* in biological "living material" but *not* in dead matter.⁶⁷ Drawing support in the legislative history of the Bio Directive, the court discussed the difference between living material and the dead matter, clarifying that dead matter does not replicate in the same way as living matter.⁶⁸ Thus, the patentability determination relies on the necessary condition of whether the DNA sequence is capable of performing the claimed function at the time of infringement. The ability for the DNA sequence to perform such function in turn depends on the threshold condition of whether the identified genetic material retains its claimed functionality in the chemical compound, even where it only exists as a residue in processed product.

In its opinion, the ECJ developed other strands of reasoning, relying in part on the Bio Directive's superseding claim over domestic laws.⁶⁹ For the purpose of this article, I shall refrain from examining that area of the decision, as I intend to restrict this discussion on relevance to my main thesis of finding commonality of recent patent decisions. This relevance reveals itself through the threshold questions surrounding the patentability based on functionality, which draws attention to the function-specific aspect of this new development in European patent law. The

⁶⁰ *Id.*

⁶¹ *Id.* ¶ 50.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.* ¶ 6.

⁶⁸ *Id.* ¶¶ 48–50.

⁶⁹ *Id.* ¶ 78.

patentability under this function-specific, *de minimis* framework⁷⁰ unfolds in two threads: (i) if or when the DNA is performing a function, must the DNA be actively expressed at the time of infringement and (ii) is performing its function fundamentally indistinguishable in instances where the protection from the DNA sequence is absolute or omnipotent? Thus, we must answer the threshold question of whether the claimed DNA sequence is so narrowly tailored or function-specific that it is restricted to a specific function provided in the patent.

Indeed, the *Cefetra* decision by the ECJ will acquire expansive meaning over time, especially when seen through the lens of other contemporary opinions in patent protection cases. Taken in isolation, the ECJ decision restricts the scope and admissibility of patent application on fundamental difference between biologically active and biologically inert material.⁷¹ This binding opinion virtually forecloses EU-based, large biotechnology companies like Monsanto from isolating specific DNA sequences, altering their information content, and claiming exclusive rights. Mere isolation of DNA for the purpose of injecting them with human intelligence, therefore, would no longer grant companies absolute protection, as this newly devised threshold condition appears to be a difficult legal hurdle to overcome.

The ECJ promulgated framework, therefore, holds that if a DNA sequence cannot be proven to have performed the exact function as described in the patent application at the time of alleged infringement, the claimed patent loses its protection. This minimalistic approach in patentability will allow other companies to be part of the broader food chain by being able to compete meaningfully without specter of lawsuits. As a result, a newer economic reality will ensue—which, in the absence of a monopolistic paradigm, would evolve to be a more prudent doctrinal development in patent law in the long run.

B. The U.K. Court's Foray into Probing the Academic Confines of Patent Disclosure

In a case that had begun to unfold two years prior to the ground-breaking ruling in the *Monsanto* case, *Eli Lilly v. Human Genome Sciences*⁷² brought forward a legal dispute challenging the validity of Human Genome Sciences' ("HGS") European Patent EP0939804, where HGS patented a newly discovered protein called Neutrokine-alpha.⁷³ HGS appealed Justice Kitchin's decision invalidating the HGS patent, and the Court of Appeal affirmed in February 2010⁷⁴—around the same time as when the ECJ affirmed the *Monsanto* case. In *Eli Lilly*, the threshold question of

⁷⁰ *Id.* ¶¶ 39–40 (describing the “extremely small quantities” that may be present in the alleged infringing material).

⁷¹ *Id.* ¶ 48 (“As follows from paragraph 37 of this judgment, a DNA sequence such as that at issue in the main proceedings is not able to perform its function when it is incorporated in a dead material such as soy meal.”).

⁷² *Eli Lilly & Co. v. Human Genome Sciences*, [2008] EWHC (Pat) 1903, [2008] R.P.C. 29, *aff'd*, [2010] EWCA Civ 33, [2010] R.P.C. 14 (Eng.).

⁷³ *Id.*

⁷⁴ *See Eli Lilly & Co. v. Human Genome Sciences*, [2010] EWCA Civ 33, [2010] R.P.C. 14 (Eng.).

patent validity was whether the patent claim described an invention that follows the patentability requirement of “susceptible of industrial application.”⁷⁵ Under U.K. law, an invention is considered to be susceptible of industrial application *if and only if* it can be made or used in some kind of industry.⁷⁶ The Court determined the question of gene-patent validity by devising a two part test. Thus, a gene sequence is patentable if: (i) the applicant discloses the industrial application of the protein for which it encodes; and (ii) the applicant discovers the gene sequence.⁷⁷

Under this framework, therefore, an invention is not patentable if the applicant does not disclose how the invention is to be used. The background leading to the *Eli Lilly* case evolved in the following way: HGS had discovered the protein in question using bioinformatics and had duly filed a patent application well before the biotechnology researchers were able to perform traditional laboratory studies on the constituent gene that encodes the protein.⁷⁸ Although subsequent laboratory analysis were able to synchronize the functionality of the claimed protein with functionalities similar to *tumor necrosis factor* and related Cytokines,⁷⁹ this functionality had not been identified *a priori* at the time of the patent application. The argument against patentability, therefore, is primarily based on factual observation that, although identified functionality could be tied to the isolated protein, such functionality became identifiable after the DNA sequence was invented and patented.⁸⁰ The court observed that claimed functionality could not be tied to the claimed DNA without actually identifying the intended functionality of the claimed DNA, and therefore, the claimed DNA’s intended use must be declared beforehand. Although the patent application provided sufficient information to envision the plausibility that Neutrokin-alpha⁸¹ could be a member of TNF ligand super family,⁸² such information, provided without a deterministic framework, could not be sufficient to theorize the usage for the identified protein. Therefore, a fuzzy postulation of a plausible theoretical usage is not enough to confer exclusive patent protection to an invention of a biologic material. During the proceedings, the plaintiff observed that in the world of biotechnological inventions, the biological effects and activities of chemical compounds—especially the broader conglomeration of super family—were so poorly understood that attaching any usage for a recently invented protein was merely a speculative journey, rather than a definite trajectory from invention to usage.⁸³ The Appellate Court concurred with this observation by Justice Kitchin:

Neither the patent nor the common general knowledge identified any disease or condition which Neutrokin- α could be used to diagnose or treat.

⁷⁵ *Id.* ¶ 51.

⁷⁶ Convention on the Grant of European Patents art. 52, Oct. 5, 1973, 1065 U.N.T.S. 255. To explain from a U.S. perspective, this patentability requirement is akin to the utility requirement under U.S. patent law. See 35 U.S.C. § 101 (2006) (requiring “new and useful” for patentability).

⁷⁷ *Eli Lilly*, [2010] R.P.C. 14, ¶¶ 55, 64.

⁷⁸ *Id.* ¶ 5 (discussing *Eli Lilly*, [2008] R.P.C. 29, ¶¶ 1, 7–9).

⁷⁹ *Id.* ¶¶ 133–35.

⁸⁰ *Id.*

⁸¹ *Id.* ¶¶ 145–47, 149, 153–54.

⁸² *Id.*

⁸³ *Id.* ¶ 120.

Its functions were, at best, a matter of expectation and then at far too high a level of generality to constitute a sound or concrete basis for anything except a research project.⁸⁴

While agreeing with the Chancery Court's findings of patent invalidation on lack of sufficiency of information at the patent disclosure stage, the Appellate Court further observed that the application disclosure fell short of providing the necessary description of an "immediate and concrete benefit."⁸⁵

Clearly, this requirement of a more definitive connection between patentable material and its prescribed usage signals a narrowing of the prospective field of patents by the U.K. courts in the upcoming days. Patentable invention of DNA sequence must, therefore, clearly delineate and identify possible use, the absence of which would invite more denials than ever before. This would preclude inventors from rushing to claim protection for every DNA sequence they are able to isolate.

Therefore, the U.K. court's decision has structural coherence with the *Cefetra* decision, as resonates within its finding is the ECJ's invalidation of Monsanto's claim on absence of linkage between the invention with its intended functionality. We, therefore acquire a deeper appreciation for the patentability framework in recognizing the rationale of the European courts' restricting foray into gene patenting. This will allow eventual pruning of the field from an explosive abundance of patent claims, which in turn, will allow other companies to share the results of their research in molecular genetics. Therefore, the court straddles a minimalistic approach in crafting a restrictive approach in connecting definitive trajectory from invention to specific usage, a framework I compare next as I examine Judge Sweet's decision in *Myriad*.

C. *Myriad*—A Preview

On March 29, 2010, three weeks after the ECJ decision, Judge Sweet of the U.S. District Court for the Southern District of New York granted a summary judgment to *Myriad*, by holding that fifteen claims of seven different patents (claims-in-suit) were invalid due to non-patentable subject matter under 35 U.S.C. § 101.⁸⁶ In invalidating the patent claim of *Myriad*, the exclusive licensor of the patent-in-suit, the district court identified two different classes.⁸⁷ The first class consisted of composition claims directed towards isolated DNA coding for the BRCA1, BRCA2 genes.⁸⁸ The second class comprised of method claims, directed towards identifying specific mutations in the BRCA genes, by analyzing and comparing the sequencing obtained from human samples.⁸⁹ Judge Sweet held the classes of claims invalid as belonging to non-patentable subject matter, while devising two different tests of patentability under

⁸⁴ *Id.* ¶ 118 (discussing *Eli Lilly*, [2008] R.P.C. 29, ¶ 234).

⁸⁵ *Id.* ¶ 146 (discussing *Eli Lilly*, [2008] R.P.C. 29, ¶ 234).

⁸⁶ *Myriad*, 702 F. Supp. 2d at 232–33, 236–38.

⁸⁷ *Id.* at 185.

⁸⁸ *Id.* at 217.

⁸⁹ *Id.* at 233.

section U.S.C. § 101.⁹⁰ These include the analysis of the “machine or transformation” test devised earlier, which was subsequently upheld by the Supreme Court in *Bilski v. Kappos*.⁹¹ The threshold questions proposed by Judge Sweet are as follows:

- i. Did the composition claim cover subject matter that had *markedly different* properties from composition found in nature?
- ii. Did the method claims satisfy the “machine or transformation test” in that, the claim process is tied to a particular machine or apparatus, or it transforms a particular article into a different state or thing?⁹²

In invalidating these claims, Judge Sweet broke new ground in various ways. First, he asserted that long-standing practice of giving judicial deference to USPTO policy in determining patentability is no longer viable.⁹³ The Judge did not bring in arguments of constitutionality in the contextual analysis of his decision-making process, although noting in passing that the unconstitutionality of the *takings argument* is unsupported by legal precedent.⁹⁴ Indeed, we cannot escape noticing the dichotomous threads in this decision, as the Judge treads in some uncertainty. This is revealed in the Judge’s rejection of judicial deference to USPTO policies, while relying on precedents in invalidating constitutional claims. However, the significance of this decision comes not from any individual statutory strand adopted by the Judge, but from the trajectory of his entire enquiry that will illuminate the revised framework of patentability in unveiling as a newer patentability paradigm.

⁹⁰ *Id.* at 232–33, 236–38.

⁹¹ *Bilski v. Kappos*, 130 S. Ct. 3218, 3225–27, 3229–31 (2010). *Bilski* was billed to be the definitive case to test the limit of the machine or transformation framework of determining whether certain methods are patentable subject matter. Unfortunately, however, *Bilski* failed to live up to that reputation. The Supreme Court decided *Bilski* on very narrow grounds. *Id.* The Court unanimously rejected *Bilski*’s business method claim as unpatentably abstract, addressing the patentability of process patent claim under 35 U.S.C. § 101. *Id.* at 3230. While *Bilski*’s core holding will have little impact on patent holders, the Court left open the possibility to reshape the patent statute by forbidding patenting of certain classes of business methods. *Id.* at 3231. Straddling the same development lines of the last several decades, the Court’s guidance remained both shallow and somewhat unambiguous while considerable uncertainty will continue to influence the patentability of business methods as the Court rejected the Federal Circuit’s sole reliance on machine or transformation tests. *Id.* Thus, rather than providing new guidance on testing the patentability on process claims, the Court, invoking earlier precedents held claims directed toward laws of nature, physical phenomena, or abstract ideas are unpatentable. *Id.* at 3230.

⁹² *Myriad*, 702 F. Supp. 2d at 227–28, 233.

⁹³ *Id.* at 221.

⁹⁴ *Id.* at 221–22.

*D. Anatomy of the Myriad Ruling—
Its Connectivity with the European Opinions*

In invalidating Myriad's claim, the court based its decision on patentability of the isolated DNA by noting that these DNA did not have markedly different properties from its native counterpart DNA.⁹⁵ The court arrived at the conclusion by adopting a fundamental-based approach to highlight inherent features of DNA, in that the isolated DNA sequence does not alter the fundamental property of DNA from the version that resides in the body.⁹⁶ This is an unexpected departure from the course long held by U.S. courts.⁹⁷ By not focusing on the chemical composition of DNA, the Judge shifted his attention to an information content paradigm. In asserting that isolated and purified DNA's chemical differences from their natural precursors are not sufficient enough, in and of itself, to grant an isolated DNA patent protection, the Judge explained how *Myriad* differs in applicability from the bedrock constitutional case of *Chakrabarty*.⁹⁸ Although *Chakrabarty* revolutionized the patent doctrine—where a genetically engineered bacteria, with the ability to break down components of crude oil was determined to have “markedly different characteristics” than anything found in nature—Judge Sweet maintained that the *Myriad* case did not involve such “markedly different characteristics” based on chemical differences between isolated and naturally occurring DNA.⁹⁹

While bringing a more fundamental function-driven analysis of DNA sequencing by focusing on DNA's unique qualities as the physical embodiment of information, the Judge concluded that, difference in chemical composition renders no significant distinguishability between the native BRCA and the isolated BRCA, in that they do not possess both a structural and functional difference.¹⁰⁰ In prior practices, the court granted a patent if the DNA is isolated, whereas district courts premised its findings on the observation that isolated DNA should be treated no different than naturally occurring DNA. Therefore, the decision came down to embracing and relying on a significantly different framework than the previous one.

In addressing Myriad's purification argument, the court determined the question of whether the purification of naturally occurring compound provides them the protection of patentability. The court did this by observing that purification, in and of itself, without having a more fundamental transformation, does not render a compound patentable.¹⁰¹ By going through the doctrinal development in patent law, the court cited a panoply of past Supreme Court and lower court opinions,¹⁰² while carefully dissecting and addressing Myriad's arguments based on precedents. On the grounds of novelty under § 102, the court held ground on the patentable subject

⁹⁵ *Id.* at 232.

⁹⁶ *Id.* at 185.

⁹⁷ See David J. Kappos, *Building Bridges and Making Connections Across the IP System*, 20 FED. CIR. B.J. 273, 278 (2010) (discussing the unexpected and potential far-reaching impact of the *Myriad* decision).

⁹⁸ See *Myriad* at 223–24.

⁹⁹ *Id.* at 223, 232.

¹⁰⁰ *Id.* at 229.

¹⁰¹ *Id.* at 223.

¹⁰² *Id.* at 221–28.

matter framework of § 101.¹⁰³ It observed that products of nature constitute patentable subject matter only by introducing changes in that product which invariably result in a fundamentally new product.¹⁰⁴ Therefore, merely by being isolated and purified and by being different in a DNA sequence of a chromosome, this does not guarantee characteristics of “markedly different” in a compound. Without this guarantee, the compound is not patentable.

Although the *Myriad* case has been appealed to the Court of Appeals for the Federal Circuit and might eventually end up in the Supreme Court, the striking similarities between the three cases described above—all decided within a span of thirty days in three markedly different jurisdictions—perhaps points to a more fundamental thread emerging in patent law. U.K. law restricts patentability of protein sequences on the disclosure doctrine.¹⁰⁵ Under this principle, the disclosure must be both plausible and precise as it relates to how the gene sequence should be used and what immediate and concrete benefits can be expected from its function.¹⁰⁶ Recall that the ECJ restricted the patentability of biotechnological DNA used in agriculture on grounds that at the time of alleged infringement, the DNA must function in the same way as when it was invented.¹⁰⁷ Resonating within Judge Sweet’s *Myriad* decision, I see the contour of a similar function-specificity requirement and a similar disclosure focus. A focus on function as information carrier is the common thread that resonates in all three cases, the impact and broader consequences of which, I shall discuss next.

II. ANALYTICAL FRAMEWORK OF *MYRIAD* AND WHAT IT MEANS FOR PATENTABILITY

In *Myriad*, the district court reduced the scope of patentability by stepping back from the existing legal framework. The district court achieved this revision by following a two-step process. In the first, the district court applied the “markedly different characteristic” test from *Chakrabarty* to observe that isolated and purified genes do not differ significantly from the native DNA.¹⁰⁸ In so doing, the district court reduced the strength of “therapeutic and commercial value” argument of earlier framework.¹⁰⁹ In the second, the district court categorized DNA as information and not as a chemical compound, while concluding that isolated and purified DNA is indistinguishable from the native DNA and thus, does not become patentable subject matter.¹¹⁰ Despite becoming a subject of criticism for venturing into uncharted

¹⁰³ *Id.* at 226.

¹⁰⁴ *Id.* at 223.

¹⁰⁵ Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255; see *Eli Lilly & Co. v. Human Genome Sciences*, [2010] EWCA Civ 33, [2010] R.P.C. 14 (Eng.), ¶¶ 149–54.

¹⁰⁶ *Eli Lilly*, [2010] R.P.C. 14, ¶¶ 149–54.

¹⁰⁷ Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396, ¶¶ 48–49; see discussion *supra* Part I.A.

¹⁰⁸ *Myriad*, 702 F. Supp. 2d at 226–27, 232 (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

¹⁰⁹ *Id.* at 226.

¹¹⁰ *Id.* at 228.

territory of revising the formula for patentability under 35 U.S.C. § 101 patentable subject matter, the decision is to be appreciated for informing us of its structural similarity with ECJ's opinion in *Monsanto* and the U.K. Chancery Court's opinion in *Eli Lilly*. As I have shown in Section I, *Myriad* acquires an expansive meaning when placed alongside these European cases. Having examined the connectivity among the three cases, I seek to analyze Judge Sweet's reduction in the scope of DNA patentability through the twin lens of, (i) distinction from *Chakrabarty's* "markedly different characteristic" test, and (ii) primacy of information content argument over chemical composition characteristics.

A. *Stepping Away from the Novelty Argument*

In *Myriad*, the district court narrowed the scope of the novelty and non-obviousness argument by citing several precedential cases to establish that novelty and non-obviousness considerations are not necessary in determining patentable subject matter.¹¹¹ Observing that novelty and non-obvious considerations are separate requirements, the court felt these requirements are ancillary to the threshold determination of whether the invention contains "markedly different characteristics" over products existing in nature.¹¹² Because these characteristics neither hold primary force nor stand alone in their deterministic objective, their patentability requirement value attenuated in this revised framework.¹¹³ By reducing the force of commercial and therapeutic properties of the invention in determining patentability, the court further established that the novelty argument can no longer stand alone.¹¹⁴

To achieve its intended goal of scope reduction, the district court reminded us of the factual surroundings in the Supreme Court's rejection of patents on claims of commercially useful natural products in *American Fruit Growers*,¹¹⁵ *Funk Brothers*,¹¹⁶ *American Wood-Paper*,¹¹⁷ and *O'Reilly*.¹¹⁸ In each of these cases, the Supreme Court has shown that the novelty and non-obviousness characteristics have lesser value in defining patentable subject matter than the utility requirement framed in § 101 and thus, the cases provide illustrations of non-patentable subject matter. Embracing these precedential cases, in a clever construction of patentability, the district court also managed to deconstruct *Myriad's* framework premised upon *Park-Davis & Co. v. H.K. Mulford Co.*,¹¹⁹ which found isolated and purified DNA patent-eligible on being separate in characteristics from those naturally occurring. Here the district court takes great care in crafting its reasoning around the "prior

¹¹¹ *Id.* at 225–27.

¹¹² *Id.* at 226.

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931).

¹¹⁶ *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

¹¹⁷ *Am. Wood-Paper Co. v. Fiber Disintegrating Co.*, 90 U.S. 566 (1874).

¹¹⁸ *O'Reilly v. Morse*, 56 U.S. 62 (1853).

¹¹⁹ *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911).

art” argument.¹²⁰ The “prior art” argument relies on a combination of “commercial and therapeutic properties of the invention” test, which eliminates the requirement of “markedly different characteristic” requirement in establishing patentability.¹²¹

Before *Myriad*, the courts and the USPTO could consider the validity of a patent if the invention contained some of the desired therapeutic properties, even if lacking markedly different distinguishable characteristics.¹²² In the pre-*Myriad* framework, therefore, in a competition between the “markedly different characteristics” and the therapeutic properties, the latter could win if the former is conspicuous by its absence in the invention. Indeed, the *Myriad* court narrowed the older paradigm’s expansive limits as it observed the framework to be unnecessarily encompassing, while being vaguely amenable to all kinds of claims.¹²³ *Myriad* thus prompts us to follow a two-step process in its § 101 requirement analysis. In the first, we must determine if the claimed invention satisfies the utility requirement. In the second, we must determine if the claimed invention contains statutory subject matter in identifying whether it is a “process, machine, manufacture, or composition of matter,” or any new or useful improvement thereof. Here, the utility determination resides on analyzing utility of invention, not for a commercial and therapeutic value, but for invention containing distinguishable characteristic as outlined in *Chakrabarty*’s “markedly different characteristic from any found in nature, and one having the potential for significant utility.”¹²⁴

The threshold question, therefore, is whether isolation or purification of the gene is a necessary step in order to utilize the diagnostic utility of the gene mutation and whether this diagnostic aspect in of itself constitutes a markedly different characteristic.¹²⁵ The court distinguished *Chakrabarty*’s patentable subject matter characteristic test under § 101 in observing that simply extracting a product of nature for improved therapeutic use does not assign the characteristics of “markedly different” upon the invention.¹²⁶ This revised application of the “markedly different characteristics” standard seems to have the potential to invalidate patentability of all purified products, which may have more commercial and therapeutic value than the utility that is sought under the new paradigm. In *Chakrabarty*, the Supreme Court qualified the “markedly different characteristics” standard:

In choosing such expansive terms as “manufacture” and “composition of matter,” modified by the comprehensive “any,” Congress plainly contemplated that the patent laws would be given wide scope. . . .¹²⁷

¹²⁰ *Myriad*, 702 F. Supp. 2d at 225–26.

¹²¹ *Id.*

¹²² See *Parke-Davis*, 189 F. at 103 (considering therapeutic properties in determining a patent’s validity).

¹²³ *Myriad*, 702 F. Supp. 2d at 226 (stating the old standard is no longer good law because it does not require patent to have markedly different characteristics over products existing in nature).

¹²⁴ See *id.* at 228.

¹²⁵ See *id.* at 227.

¹²⁶ See *id.* at 229.

¹²⁷ See *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

In declining to apply *Chakrabarty*, the district court rejected this expansive argument by narrowing the subject matter requirement into a more restrictive subset of characteristics that must satisfy the requirements of § 101.¹²⁸

*B. Information Carrier versus Chemical Compounds—
Isolated versus Natural DNA*

In categorizing DNA as information and not as a chemical compound, the district court stripped the isolated and purified DNA's special patentability status and emphasized that the isolated and purified version is not distinct from the native version. Judge Sweet's focus on DNA's unique status as the "the physical embodiment of information"¹²⁹ is based on an understanding that information stored and transmitted in DNA remains unchanged whether for naturally occurring DNA or for isolated and purified DNA. In this carrier of physical information argument, DNA, while both serving the purpose of defining human body and acting as the physical expression of laws of nature, remains indistinguishable in both forms being contested here.¹³⁰ Therefore, an isolated and purified DNA functions as the encoder for proteins to define physical traits, functioning as that of naturally occurring DNA—which leads to the observation that simply isolating and purifying DNA does not render the invention (patented gene) a "markedly different characteristic."

Indeed, while chemicals perform some biological functions within the body, such as conveying information content from a source to a destination, they do so as part of revealing their molecular structure and for the biological expression of their own chemical identity. In this sense, DNA separates itself fundamentally from the chemical compound in that it directs the synthesis of other molecules while encoding the characteristics of other chemical compounds, biological processes, and physical properties within the biologic framework.¹³¹ Therefore, even if an isolated and purified DNA has a structure where the DNA contains only the coding sequence, in which the accompanying intron sequence is spliced out, the resulting purification cannot be considered a structural metamorphosis, but is a change emerged as a result of RNA splicing—a natural phenomenon.¹³² In addition, the court reasoned that the physical coding sequences of cDNA are the same as those of spliced mature mRNA, such that a cDNA is the carrier of DNA, where as mRNA, the messenger RNA is derived from the DNA by splitting out the intron sequence.¹³³ This biological basis of distinction between isolated, purified DNA and naturally occurring DNA acquires meaning from its functional property, which validates the court's conclusion of not having "markedly different characteristics."¹³⁴

¹²⁸ *Myriad*, 702 F. Supp. 2d at 229.

¹²⁹ *Id.* at 229.

¹³⁰ *See id.* at 185, 194 (recognizing that DNA represents the physical embodiment of biological information and is traditionally seen as an embodiment of laws of nature—like heredity).

¹³¹ *Id.* at 228 (explaining that "it would be erroneous to view DNA as 'no different[]' than other chemicals previously the subject of patents").

¹³² *Id.* at 230.

¹³³ *See id.*

¹³⁴ *See id.*

Clearly the court embarked on a new journey—a journey that focused on the functionality of the compound itself, restricting the class of purified products that can be made patentable. This also calls into question the validity of some of the older cases, where purified adrenaline, vitamin B12, and other life saving drugs have been deemed patentable subject matter based not on their chemical functions but on their non-obviousness and therapeutic characteristics.¹³⁵ So, collapsing this distinction between pure and isolated form and naturally occurring form is a new framework—a framework based on the understanding that DNA contains the functional property of an information carrier, whether isolated or native. Could this patentability framework, so ordained, withstand appellate review? This is an area I explore next as I trace the shared contours of *Myriad* and its European cousins.

C. Dissecting the Framework of Shared Connectivity

Myriad presents a new patentability argument under § 101, where the “markedly different characteristics” argument gets primacy over the novelty and non-obviousness argument. This paradigm shift ordained by the district court acquires a superior interpretative gloss if further dissected through the threshold questions presented in *Cefetra* and *Eli Lilly*, as I have shown before.¹³⁶ The patentability of the gene sequence in *Cefetra* was determined based on finding direct connection between the invention and the function it was designed for.¹³⁷ In *Eli Lilly*, the threshold question was whether the patentable sequence should disclose its function and whether this function has concrete and immediate benefit.¹³⁸ Tracing the path taken by Judge Sweet in *Myriad*, the patentability was determined based on whether the claimed invention is fundamentally different while arguing that the subject matter of invention must be seen as an information carrier—performing a function, as opposed to being only a chemical composition—thus, not connecting it with functionality as such.¹³⁹ This function versus composition argument finds resonance in the European cases as well, where the patent eligibility is tied to prescribed functionality.¹⁴⁰ Their similarity signals a trend in judiciary towards restricting the scope of patentability for DNA sequences. These judicial invalidations should be seen as a broader indication of the emergence of a new, minimalistic patent paradigm. The scope restriction in these decisions must be seen as judiciary’s attempt to introduce functional efficiency in patentability doctrine. Therefore, let us step back and try to understand this emergent patentability argument from its structural suitability.

Policy initiatives on both sides of the Atlantic, reveal policymakers’ recognition that the law must synchronize with technology’s advancement. This is especially true, given the explosion of patents in the last three decades under an overtly

¹³⁵ *E.g.*, *Merck & Co. v. Olin Mathieson Chem. Corp.*, 253 F.2d 156, 164 (4th Cir. 1958); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911).

¹³⁶ See discussion *supra* Part I.D.

¹³⁷ See discussion *supra* Part I.A.

¹³⁸ See discussion *supra* Part I.B.

¹³⁹ See discussion *supra* Part I.C.

¹⁴⁰ See discussion *supra* Part I.D.

inclusive DNA patent paradigm.¹⁴¹ The USPTO introduced a new set of guidelines in 2001 for assessing the utility of patents, as a partial response to the concerns over granting excessive biotechnology patents.¹⁴² One of the USPTO's announced objectives is to develop a, "specific, substantive, and credible utility test" to prevent granting patents that protect a specific DNA sequence in cases where the function of the sequence or the associated protein is unknown.¹⁴³ The European Biotech Directive in 1998 was designed with a similar objective in view, which required the identification of an industrial application of a sequence claimed in a patent application.¹⁴⁴

Therefore, the judiciary's scope reduction is not isolated legal maneuvering. Rather, it is a continuation of the regulatory development that started near the end of last century in an effort to shrink the available universe of patentable genes. Technology's advancement has allowed biotechnology companies to engage in excessive experimentation of random isolation and purification of human DNA and protein sequence, either by data mining or by using computer algorithms, to generate random fragments of sequences. Using superior technology to eventually match these sequences, in some instances by displaying homological similarities to previously characterized genes, and in some instances simply by speculating on functions, the companies also began claiming patent protection at an excessive frequency. This prompted regulatory bodies on both sides of the Atlantic to reign in the process of patenting—albeit, via scope reduction of patentable DNA sequences.

Comprehending the process, which the biotechnology companies use to generate excessive amount of patentable DNA, can illuminate us in recognizing the urgency for scope reduction. The identification of genes with specific functionality is mostly done by high-speed computer algorithms using highly sophisticated statistical analysis in a remarkably different approach to the traditional "wet lab" approach.¹⁴⁵ Their dissimilarity lies in the fact that activity of the genes, connecting a specific

¹⁴¹ See Chester S. Chuang & Denys T. Lau, *Case Prohibiting Patents on Human Genes Ignites Debate*, RECORDER (S.F.), Dec. 20, 2010, at 9 ("It is estimated that about 20 percent of human genes are associated with at least one U.S. patent and that the number of DNA-related patents exceeds 40,000.").

¹⁴² See Utility Examination Guidelines, 60 Fed. Reg. 1092, 1092–93 (Jan. 5, 2001) (adopting new guidelines and responding to specific comments submitted in response to proposed guidelines affecting gene patentability).

¹⁴³ *Id.*

¹⁴⁴ See Bio Directive, *supra* note 47, ¶ 22 (requiring disclosure of the industrial application in the patent application).

¹⁴⁵ A bioinformatics approach differs from traditional "wet lab" approach in that material is not analyzed through a classical means of analysis using chemical solvents, specialized apparatus, and in a process that involves various intermediate steps, such as distillation, ventilation, etc. See *Eli Lilly & Co. v. Human Genome Sciences*, [2010] EWCA Civ 33, [2010] R.P.C. 29 (Eng.), ¶¶ 42–43 (explaining the complicated techniques of "wet lab" experiments were what litigation was focused on before bioinformatics existed). The results of wet lab experiments are not based on random events, rather results are obtained via chemical analysis of compounds. *Id.* On the other hand, in bioinformatics, experiments are performed based on computer algorithms, in which identification and prediction of compounds are done via statistical matching of large number of compounds in a computationally intensive process. *Id.* ¶ 44. Thus, the activity of a gene identified using bioinformatics could be statistically predicted based on the activities of the members of the family of genes—not based on an actual chemical composition-driven analysis. *Id.* ¶ 48.

DNA sequence to functionality, is predicted not based on fundamental based scientific methods.¹⁴⁶ Rather, this identification with the activities of the members of a broader family of genes is done via bioinformatics approach.¹⁴⁷ In this scenario, an actual identification of the DNA's function does not become apparent until the DNA has been cloned outside its natural environment and its protein encoded.¹⁴⁸ Therefore, when this particular DNA sequencing mechanism is claimed for the patent application, oftentimes it is done based on random speculation with the aspiration that computer-based procedure will ultimately obtain the required connectivity. Thus, the assignment of claimed invention to its intended use sometimes is done not in *a priori* basis, but rather on an *ex post facto* basis. In the current context of *Myriad*, the patentability of the transformation that is brought before the judicial determination, falls within this category of bioinformatics-driven, random matching algorithm, which is more of a data manipulation and transformation than a "markedly differently transformation."

In a similar vein, the *Eli Lilly* court at Chancery rejected HGS's argument that the patent was not novel, was obvious, and was not useful. Basing its determination on the Article 57 of the European Patent Convention ("EPC"),¹⁴⁹ the U.K. court noted that on the basis of its structural properties, the claim may have been correctly identified as belonging to a member with known functionalities.¹⁵⁰ The connection between invention and its intended usage, however, suffers from fatal flaws and thus, not patentable. Because, the court argued, those members of one protein class may share well-characterized and clearly-understood functions, but the members of other protein class may display different effects, where no single effect can be assigned to the new member without relying on some experimental data.¹⁵¹ Similarly, the ECJ rejected Monsanto's contention that its patented DNA loses exclusivity to the claimed invention if it cannot be conclusively proven that the claimed function is performed in instances of alleged infringement.¹⁵² Because, the court observed, the alleged invention at the time in question may have lost its functionality, it can no longer be cloaked under the exclusive protection of a claimed patent.

¹⁴⁶ See *id.* ¶ 49 (explaining that using bioinformatics is akin to a very well-educated and planned guess).

¹⁴⁷ *Id.* ¶ 48.

¹⁴⁸ *Id.*

¹⁴⁹ Convention on the Grant of European Patents, Oct. 5, 1973, 1065 U.N.T.S. 255. The European Patent Convention is a multilateral treaty, which provides a legal framework in which European patents are awarded. *Id.*

¹⁵⁰ *Eli Lilly & Co. v. Human Genome Sciences*, [2010] EWCA Civ 33, [2010] R.P.C. 29 (Eng.) ¶¶ 51, 139 (emphasizing the inquiry of whether correctly identifying the gene's connection to the member family of genes is enough to satisfy the functionality requirement).

¹⁵¹ *Id.* ¶¶ 145–46 (explaining that "plausible" functionality is not sufficient for patentability).

¹⁵² Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 ECJ EUR-Lex LEXIS 396, ¶ 40.

III. GOING BEYOND *MYRIAD*—EXAMINATION OF BROADER TRENDS

So, what is next in this evolving saga of dispute over patentability of human gene or isolated DNA sequences? Discussion thus far informs us that the judiciary may have finally caught up with the law's inability to catch up with biotechnology's leap. First, it was the European courts' restricting the scope of DNA patents by articulating a new paradigm that connects patentability with functionality.¹⁵³ Then, it was the U.S. district court revising the patentability requirement by adopting better semantics and restricted focus.¹⁵⁴ Based on the history of gene patents' long-standing dispute over doctrinal difficulties, several questions come naturally before us. Can we elicit a deeper meaning from the new direction being charted for the patentability of human biological framework? What do these decisions teach us vis-à-vis the profound issues of human heritage and its relationship with its genome? Where does this newer legal framework fall in relation to perennial conflict between the maximalist and minimalist positions? I intend to address these important questions in the following discussion.

*A. Shaping Patentability Under the Common
Heritage of Mankind Principle*

Patentability doctrines have evolved through the quintessential tension between the two frameworks: one predicated on the idea of state supervision and the other premised on corporate ownership of natural resources based on monopoly rent. Patent discussions have largely ignored the viability of the patrimony of the heritage of all citizens in making judicial decision with respect to the ownership of human genes.¹⁵⁵ The arguments have been conceived, described, and determined along a vacillating thread that begins with the idea of not challenging the ownership,¹⁵⁶ and then moves to the concept of granting of rights under a source doctrine.¹⁵⁷ Given the narratives of individual human suffering prompted by delayed medical care, which is now unfolding in the background of the *Myriad* case,¹⁵⁸ it is high time to take retrospective inquest at searching for patent law's legal lineage under mankind's common heritage. More than 150 years ago, the U.S. Supreme Court recognized the abstract fundamentals of human invention by tracing its roots shared by all humanity.¹⁵⁹ One court characterized it by noting:

¹⁵³ See discussion *supra* Part I.A–B.

¹⁵⁴ See discussion *supra* Part C.

¹⁵⁵ See *Myriad*, 702 F. Supp. 2d at 190 (describing several amici curiae's contentions that human genes should be part of the public trust doctrine and patenting human genes runs contrary to that doctrine).

¹⁵⁶ See *id.* at 193.

¹⁵⁷ See *id.* at 190.

¹⁵⁸ See *id.* (summarizing the view of several amici who argued that *Myriad*'s gene patent deprives women access to needed medical testing).

¹⁵⁹ *Leroy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

The Supreme Court has recognized that scientific principles of laws of nature, even when for the first time discovered have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the subject of exclusive rights to any one person.¹⁶⁰

This declaration informs us of humanity's inherent desire in sharing the fruits of human invention sourced from their common biological structure, thus revealing that every human has a shared interest in whom and by what means it is manipulated. Premised behind this observation is the fundamental dogma of human civilization—that every human is connected with his or her forefathers, descendants, and siblings. Therefore, a gene sequence extracted at any given time from any individual human for the purpose of genetic testing, directly or indirectly, connects all humanity. When a DNA sequence from a specific individual, either belonging to a particular ethnic group or from a specific geographical region, is extracted for the purpose of biologic testing, parts of that extracted DNA are shared by humans across ethnic frontiers and across geographical boundaries. Thus, the results of a manipulation performed on an isolated biological extract impact both in future evolution and in welfare of all humans—a sublime recognition that resonates with the broader meaning of *Myriad*, that there is no fundamental difference in DNA, in whatever state it is brought for testing. *Myriad*'s fundamental holding—espousing a scope reduction for DNA testing—acquires further illumination in understanding the connectivity of DNA among all humans¹⁶¹ in the sense that sequencing DNA is akin to an extract of the broader and more expansive human genome.

The above sentiments get additional primacy as seen in the echo of the United Nations Declaration on the Human Genome and Human Rights, observing that human genomes are part of a common heritage.¹⁶² Similarly, both the Council of Europe and the International Human Genome Organisation (“HUGO”) have observed that data manipulation, experimentation, and scientific discovery of any part of human genome extract must be understood in the broader light of commonality of human heritage.¹⁶³ Rights and legal framework must reflect these commonalities. The U.S. Supreme Court, almost a century after its proclamation in *Leroy v. Tatham*¹⁶⁴ has observed in *Funk Brothers*, “They are manifestation of law of nature is

¹⁶⁰ *In re Meyer*, 688 F.2d 789, 795 (C.C.P.A. 1982) (citing *Leroy v. Tatham*, 55 U.S. at 175).

¹⁶¹ *Myriad*, 703 F. Supp. 2d at 228–29 (explaining that DNA is the physical embodiment of information and because its nucleotide sequence is important to both the natural biological function and the utility of DNA in its isolated form, it is an unpatentable product of nature).

¹⁶² E.S.C. Res. 29/16 (Nov. 11, 1997), <http://unesdoc.unesco.org/images/0011/001102/110220e.pdf#page=47>; see generally Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425 (2007) (considering the common heritage of DNA under property principles).

¹⁶³ See Eur. Consult. Ass., *Protection of the Human Genome by the Council of Europe*, 107th Sess., Doc. No. 9002 (2001), <http://assembly.coe.int/main.asp?Link=/documents/workingdocs/doc01/edoc9002.htm>; Statement, Human Genome Org., Intellectual Prop. Comm., Statement on the Scope of Gene Patents Research Exemption, & Licensing of Patented Gene Sequences for Diagnostics (Dec. 2003), http://www.hugo-international.org/img/ip_gene_2003.pdf.

¹⁶⁴ 55 U.S. (14 How.) 156 (1872).

free to all men reserved exclusively to none.”¹⁶⁵ Patentability of human genes should, therefore, not be based on corporate interests, nor should it be based on governmental understanding of hierarchical rights. Because such deterministic principles of patentability creates exclusivity, a right that confers economic incentive on a limited few, these principles deprive the majority from the fruits of labor that must be shared by all.

Therefore, the common heritage of mankind principle is poised to acquire further meaning within our contemporary discussions on patentability, albeit not in splendid isolation of exclusion of other competing doctrines premised on either economic exclusivity or rights. The series of judicial opinions that have illuminated our most recent understanding of law’s applicability surrounding patentability of DNA sequences may have attempted to arrive at that understanding of the common heritage of mankind principle. Although courts have not explicitly articulated such an argument, perhaps there is an underpinning of that awareness.

B. Property Rights Discussions of Patentability

As we transition from the discussion of humanity’s shared interests, our collective construct begins to become illuminated by an awareness of a communal property mindset. However, to essentialize this concept of property under public domain will mean conferring presumptive liberty rights to appropriate information related to existing art. Corporations and industry trade associations have been immensely successful in pushing their super-maximalist agenda through the public domain while subverting public interest and sending important patent policy problems into oblivion.¹⁶⁶ Debates occurred over whether patent rights doctrine should be fundamentally based on the government’s eminent domain power under the Takings Clause of the U.S. Constitution.¹⁶⁷ Eminent domain empowers the government to alter, supervise, and influence patent policy issues to ensure that protectionist regimes are not depriving the common majority who are not in a position to ask “whose rights are they anyway?”¹⁶⁸

¹⁶⁵ Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

¹⁶⁶ See generally Yochai Benkler, *Free as the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U. L. REV. 354 (1999) (expressing apprehension that public domain is increasingly being used for subverting the public’s vital interest against in contradiction to Constitutional grants); LAWRENCE LESSIG, *CODE AND OTHER LAWS OF CYBERSPACE* 59 (2000) (arguing that a corporation’s broader power in developing technology for the public’s use is essentially privatizing public domain); Michael Heller, *The Tragedy of the Anticommons*, 111 HARV. L. REV. 621 (1998) (describing how socially optimal use of resources have been impeded by over-extension of property rights granted to private entities).

¹⁶⁷ See Adam Mossoff, *Patents as Constitutional Property: The Historical Protection of Patents Under the Takings Clause*, 87 B.U. L. REV. 689, 693–96 (2007) (discussing privatizing patents). The last clause of the Fifth Amendment is called the Takings Clause, U.S. CONST. amend. V, and refers to the government ability to recapture property through its power of eminent domain. This clause restricts the power of eminent domain by requiring that a fair or “just compensation” be paid if private property is taken for public use. U.S. CONST. amend. V.

¹⁶⁸ Mossoff, *supra* note 167, at 693–96.

The Takings Clause allows government to take over private property under situational exigencies where government intervention is warranted to ensure the greatest welfare for the majority of the people.¹⁶⁹ The problem is that embracing the concept would mean conceding the argument that patent is a property right that can be privatized.¹⁷⁰ Consider the following scenario: A corporation extracts biological physical material from a human individual, while recognizing that, any isolated human biological material is shared across the broader human genetic pool. Can the knowledge of that sequence be kept exclusive under the category of private property? On the other hand, empowering the government to take property under eminent domain virtually defines genetic material as personal property¹⁷¹—which can be owned, transferred, and confiscated.¹⁷² If we proceed along each of these distinct threads, we will eventually arrive at untenable legal positions, by encountering significant tensions among competing conceptions of rights—an area I shall refrain from further entering at this developmental stage of the new framework for patentability.

What is patentable then? An object, a substance, an art, an invention—any manifestation of real property is patentable under a set of guidelines and a developed framework that evolved over several centuries.¹⁷³ In this respect, each type of property can be seen as an object or manifestation of an object that contains a bundle of rights, such that a different type of property obtains a different bundle of rights.¹⁷⁴ Also, because each type of property differs both in its natural existence and in its temporal manifestations, the associated bundle of rights is not identical but slightly overlapping other bundles, such that some rights are shared amongst various non-identical types of property. Clearly, if we bring human genome or DNA extracts or any related derivatives or equivalent products, in the conversation surrounding property rights, we might go down the slippery slope of conferring rights on common heritage property. If an exclusive right is conferred on such property, it would deprive the majority from gaining access to the common heritage. So, we are back to square one.

Therefore, we must understand human genes as a fundamental substance, whose rights are not deterministically based on inventions, commoditization,¹⁷⁵ or corporate rights.¹⁷⁶ The awareness must develop that some substances are so inviolable and fiercely fundamental that they must remain outside the property

¹⁶⁹ U.S. CONST. amend. V.

¹⁷⁰ Mossoff, *supra* note 167, at 693–96.

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ 35 U.S.C. § 101 (2006). See also *Chakrabarty*, 447 U.S. at 308–10 (explaining that the Committee Reports that accompanied the 1952 Patent Act suggested that Congress intended “anything under the sun that is made by man” to be patentable subject matter, with exceptions for laws of nature, physical phenomena, and abstract ideas).

¹⁷⁴ See B. Bjorkman & S.O. Hansson, *Bodily Rights and Property Rights*, 32 J. MED. ETHICS 209, 210 (2006) (discussing how the rights that make up each bundle of rights may differ depending on the nature of the object at issue).

¹⁷⁵ See David B. Resnik, *The Commodification of Human Reproductive Materials*, 24 J. MED. ETHICS 388, 392 (1998) (discussing the commodification of genomes).

¹⁷⁶ See Leslie Roberts, *Who Owns the Human Genome?*, 237 SCIENCE 358, 358 (1987) (discussing corporate interests in genetic research).

system.¹⁷⁷ It is undisputed that DNA exists inside each cell of every human being and that each of these sequences has some similarity or shared properties. So, if we patent a particular DNA sequence, any human genome extract, or its allele, we immediately envelope that substance with exclusivity, while denying the rights or usage of benefits to the rest of humanity.¹⁷⁸ This is not only contrary to the fundamental precepts of life, but also violates the rights of source doctrine. Under the rights of source doctrine, if a bundle of rights are conferred upon any substance or real property, then those rights cannot be decoupled from the source where that property has originated.¹⁷⁹ If an individual instance of a human gene is extracted from a human source and the process of extraction and subsequent data manipulation and experimentation result in a product that during the judicial process is determined to be patentable, is it therefore, fundamentally acceptable that the source for that product of invention should be denied access to that product? This is where the fallacy of the rights of source and the maximalist paradigm of gene patent framework collide. Thus, my recommendation would be to decouple the rights-based property discussion from the patentability argument when it comes to determining patentability of human genome or any extract or subtract thereof.

C. Deconstructing Myriad's Product of Nature Claim

The product of nature argument in *Myriad* centered on a dispute between the parties concerning the interpretation and meaning of the terms “DNA” and “isolated DNA.”¹⁸⁰ The court examined the question of whether “isolated DNA” covered subject matter that was protectable by statute in the United States, in which governing law states: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”¹⁸¹ The court systematically deconstructed Myriad's product of nature argument along multiple threads.

First, the court provided a revised understanding of DNA in observing, “In light of DNA's unique qualities as a physical embodiment of information, none of the structural and functional differences cited by Myriad . . . render the claimed DNA

¹⁷⁷ See Gerald Dworkin, *Should There Be Property Rights in Genes?*, 352 PHIL. TRANS. R. SOC. B. 1077, 1077–78 (1999) (referring to fundamental arguments against patent property rights in living things).

¹⁷⁸ See *id.*

¹⁷⁹ Here, I draw attention to the fundamental tension between construing rights as alienable property and rights as inalienable inherent construct. If viewed as natural rights, we can perceive them as absolute and inalienable and therefore, cannot be decoupled from its source. On the contrary, if rights are seen as alienable, they are subject to regular economic trade-off related behavior, such as bargains and negotiations. See generally Edward Andrew, *Inalienable Right, Alienable Property and Freedom of Choice: Locke, Nozick, and Marx on the Alienability of Labour*, 18 CAN. J. OF POL. SCI. 529 (1985) (illuminating the contradiction at the center of natural rights debate, while illustrating the tension between the two apparently incompatible views).

¹⁸⁰ *Myriad*, 702 F. Supp. 2d at 216–17.

¹⁸¹ 35 U.S.C. § 101 (2006); *Myriad*, 702 F. Supp. 2d at 218–19.

‘markedly different.’¹⁸² In responding to Myriad’s claim of isolated DNA having different structural and chemical properties as opposed to native DNA, the court reasoned that DNA is not only a chemical compound capable of encoding protein, but it also has the ability to act as the physical information carrier.¹⁸³ The patent’s specification of isolated DNA is thus fundamentally misleading¹⁸⁴ in that it does not capture the functional aspect of the definition, as it focuses on chemical composition analysis between isolated DNA and native DNA. Myriad challenged DNA’s role as an information carrier and instead argued that DNA referred to “a real and tangible molecule, a chemical composition made up of *deoxyribonucleotides* linked by a *phosphodiester* backbone.”¹⁸⁵ While this definition explains isolated DNA, it does so by presenting an isolated DNA that has been extracted from the human genome at a given time from an individual source. While the chemical definition of isolated DNA is fundamentally correct, it suffers from incorporating the expansive meaning intended by the court. Although isolated DNA can be identified—and with technological advancement can be manipulated—it may not be designated as capable of functioning explicitly the way a patent application claims it does. This functionality argument goes to the very core of why an isolated DNA should not be seen as inseparable from the DNA existing in nature for the purpose of patent eligibility discussion.

Second, the court, in addressing patentability, observed that, mere “purification” of a naturally existing compound does not render patentability.¹⁸⁶ In a sharp departure from Judge Learned Hand’s 1911 observation in *Parke-Davis* that isolated and purified adrenaline is patentable, the court signaled a clear shift to keep products of nature outside the scope of patentability.¹⁸⁷ In disclosing that, to be patentable, a composition must have markedly different characteristics from any occurring in nature, Judge Sweet revised the patentability framework, based on significant difference of the claimed invention. Indeed, in this framework of markedly different characteristics, there exist no fundamental distinction between isolated and purified DNA and DNA existing in nature. The prior framework of patenting a DNA sequence based on mere “isolation” was invalidated in *Myriad* as the Judge clarified that isolation was “simply the application of techniques well-known to those skilled in the art.”¹⁸⁸

Third, the Judge may have foreclosed the patentability of all naturally occurring products, in a broad stroke of rule-making, by proclaiming that discovery is of the

¹⁸² *Myriad*, 702 F. Supp. 2d at 229.

¹⁸³ *Id.*

¹⁸⁴ *Id.* at 216. The patent specifications expressly defined “isolated DNA” as one that: “is substantially separated from other cellular components which naturally accompany a native human sequence [such as] human genome sequences and proteins and includes recombinant or cloned DNA, isolates and chemically synthesize analog or analogs biologically synthesized by heterologous systems.” *Id.* (quoting the patent specifications for U.S. Patent Nos. 5,693,473, 5,747,282, and 5,837,492).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at 227–28.

¹⁸⁷ *Id.* at 225–26 (acknowledging Judge Hand’s opinion in *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95 (S.D.N.Y. 1911) but dismissing it as non-precedential).

¹⁸⁸ *Id.* at 232.

“handiwork of nature” and not patentable.¹⁸⁹ Indeed, a flawed patentability requirement and a lack of appreciation for the technical complexities of DNA existed in the *Myriad* decision. In excluding products of nature as patentable subject matter under § 101, the district court did not arrive at this sweeping broad-brush generalization in isolation. It reflects the Supreme Court’s long-standing view that phenomena of nature (even if just discovered), mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.¹⁹⁰ Thus, the reason for this exclusion is based on the fundamental awareness of the interaction between man and its environment, in recognizing that, sometimes *too much* patent protection can stymie rather than advance the progress of science and useful arts, the constitutional objective of patentability.

D. Examining Myriad’s Deconstruction of Innovation Centric Argument

Biotechnology companies have long held that the exclusivity of patents is required as incentive for invention or innovation.¹⁹¹ Indeed, the DNA patent community seeks to protect their exclusive rights vested in human genome patents and advances this innovation argument on a faulty logic. Although premised on recovering the cost of drug manufacturing and new research, the actions of these companies have gone far beyond a basic cost benefit analysis, as has been highlighted before. *Myriad* confronted this myth. If its holding stands up to upcoming appellate reviews, no longer would biotechnology companies be allowed to extract monopoly rent for their effort in inventing diagnostic testing in the area of genetics. Whether *Myriad*’s rejection of “innovation and invention” argument for patentability would stand the test of time largely depends on three threshold questions: (i) Would restriction to gene patenting impede development? (ii) Is patent protection necessary to drive innovation? (iii) Will reduction in scope of patentable subject matter stymie the advancement of science?

Indeed, patent holders have an exclusive right to use that patented invention to derive economic benefits for a limited period, in exchange for providing full disclosure to the patented article or invention such that other researches may benefit from enhancing the patented product.¹⁹² In the context of DNA patenting, new sequencing techniques can create faster and less expensive sequences,¹⁹³ if fully disclosed to the

¹⁸⁹ *See id.*

¹⁹⁰ *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (“Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.”).

¹⁹¹ *E.g.*, David M. Gersten, *The Quest for Market Exclusivity in Biotechnology*, 2 *NEURORX* 572, 573 (2005) (discussing market exclusivity as vital to the biotechnology industry).

¹⁹² U.S. CONST. art. I, § 8, cl. 8; *see Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730–31 (2002).

¹⁹³ *See, e.g.*, Meni Wanunu et al., *Electrostatic Focusing of Unlabelled DNA into Nanoscale Pores Using a Salt Gradient*, 5 *NATURE NANOTECH.* 160 (2009); *Your Genome in Minutes: New Technology Could Slash Sequencing Time*, *SCIENCEDAILY* (Dec. 31, 2010), <http://www.sciencedaily.com/releases/2010/12/101220121111.htm>.

broader scientific community. This in turn can provide economies of scale to the consuming public. A focus away from anticommons,¹⁹⁴ by making knowledge accessible to more people, new vistas can be opened for the scientific community. On the contrary, reviewing the history of patent application and post-patent disputes perhaps gives the indication how patent holders can prevent scientific community from accessing the anatomy of new inventions.

Admittedly, a patenting entity routinely grants licenses to other competing organizations for use of its patent. It does so, however, on a selective basis and, quite frequently engages in sending cease and desist letters to preclude them from developing competing products. This is especially troublesome in the DNA patent area, as any specific DNA sequence can be interrelated to other potential inventions of DNA sequences, due in part to the shared interconnectivity of the human genome—an interconnected entity. If a patent for a specifically isolated gene is granted, the temporary exclusivity, therefore, prevents scientific organizations from including those sequences in tests for other disease predisposition¹⁹⁵ nor does it allow them to develop competing and cheaper diagnostic processes—thereby, stymieing the ultimate benefits or general welfare of the public.

Another drawback of gene patenting has been unraveling in recent years, as we witness an explosive array of extraction, sequencing, and testing of DNA being performed at various molecular genetics laboratories.¹⁹⁶ Testing, at times, evolves into laboratories resorting to predatory practices of exclusive testing for genetic susceptibility, while extracting excessive prices for these services and without ethical considerations for patient welfare and wellbeing.¹⁹⁷ Exclusivity enables patent owners to prevent other laboratories in devising their own test or reviewing the testing protocol of the patented entity.¹⁹⁸ At times, it seems no universal protocol or framework exists to supervise testing errors.¹⁹⁹ This monopolistic practice by patenting organizations is what actually can impede development, not the other way around.²⁰⁰

Therefore, hiding behind a protectionist paradigm will not provide driving force for continued innovation in science and technology. It is the spirit of co-operation and mutual learning that has advanced human construct incrementally towards acquiring more meaning from existing process and objects. In addition, most of today's scientists work in the academia under the paradigm of publish-or-perish.

¹⁹⁴ For information on the “anticommons” principle in biomedical research, see generally Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCIENCE* 698 (1998).

¹⁹⁵ *E.g.* *Myriad*, 702 F. Supp. 2d at 208–10 (describing the negative effects on public research due to patent holders); see also Robert Cook-Deegan et al., *The Dangers of Diagnostic Monopolies*, 458 *NATURE*, 405, 405 (2009).

¹⁹⁶ See Hunter et al., *Letting the Genome Out of the Bottle—Will We Get Our Wish*, 358 *NEW ENG. J. MED.* 105, 105 (2008) (describing the proliferation of genetic testing).

¹⁹⁷ See, *e.g.*, Cook-Deegan et al., *supra* note 195, at 405–06.

¹⁹⁸ *Id.*

¹⁹⁹ David Magus et al., *Direct-to-Consumer Genetic Tests: Beyond Medical Regulation?* 1 *GENOME MED.* (Feb. 2, 1009), <http://genomemedicine.com/content/pdf/gm17.pdf>; Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, *ISSUES IN SCI.& TECH.*, Spring 2006, at 59.

²⁰⁰ See Heller & Eisenberg, *supra* note 194.

Evidence suggests that federal grants account for a disproportionately large portion of the innovation in science and technology in the last several decades.²⁰¹ Therefore, the search for a new product for the benefit of mankind cannot stop if the number of patents gets reduced, or the scope of patenting becomes restrictive, rather too much power at the hands of a corporation, who develops a predatory practice and develops a practice in which primacy may be given to selective products based on economic realities, thereby excluding the invention of other utility based products.

CONCLUSION

Anchoring the trailblazer *Myriad* opinion penned by the district court Judge Sweet, this article examined DNA patentability through multiple threads. While *Myriad* is being hailed as the game-changer in twenty-first century patent law, this article provided a different viewpoint—that of seeing *Myriad*, not in its splendid isolation, but within a continuous contour with contemporary patent cases of Europe. This line of enquiry has been prompted, in part by the need for convergence in patent law across jurisdictions and in part by the recognition that, an isolated opinion can never rise beyond shallow dogmatic discourse—something not entirely desirable in our contemporary patent discourse.

Myriad, in the analytic framework of this article, acquired expansive meaning for various reasons. First, by placing the opinion as part of a trifecta, I attempted to impart a broader meaning on its holding—in observing that *Myriad's* adoption of “information-first argument” is in line with the European courts’ aligning of invention with function and prescribed usage. Further, *Myriad's* rejection of “DNA-in-isolation argument” traces the same judicial contours revealed in European courts’ invalidation of patentability of DNA outside of its natural environment. Second, I see these cases as a response to the law’s inability to synchronize technology’s advancement. Thus, following a restricted patentability framework, these cases signal judiciary’s intention to close that statutory gap in law, while reducing the patentability scope to restrict “everything under the sun” to come under the purview of law. Third, the *Myriad* case, in conjunction with these European cases, opens the door to develop patent framework based on convergence across jurisdictions—a crying need for many decades as claimed inventions and their stated functions can reveal themselves across geographical borders, albeit causing differing judicial interpretations.

Myriad, through its bold proclamation, opened new intellectual strands in patent law. In revising the patentability requirement for gene patents, *Myriad* adopted a new focus on the “markedly different characteristics” test and re-invigorated the “product of nature” doctrine—perhaps signaling the judiciary’s intention to examine patentability discussion premised at the intersection of law, ethics, and humanity. In this article, I have attempted to examine some of these less talked about patentability frameworks, especially given *Myriad's* broader examination, certainly calls for such discussions. Indeed, some remain unsaid, some

²⁰¹ See Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1667–69 (1996).

unexplored. But, *Myriad*'s sweeping observations impinge upon a number of doctrines that open the door for such inquiry for future work—some of which, I shall briefly highlight.

First, *Myriad* reminded us that whenever exclusive rights are conferred upon a selected few, the majority suffers. *Myriad*'s product of nature doctrine is a fervent reminder that a more positive outcome might result if patenting is forever foreclosed on human genes, thereby ensuring that majority is never deprived of a common heritage of mankind. Perhaps, the days may not be too far, when patenting of human genes is not legally possible.

Second, *Myriad* can acquire meaning in distributive justice, as it informs us of the perils of a legal process, in which exclusivity enjoyed by a selective few precludes the majority from the utility and beneficial use of the product in contention. In patenting a DNA sequence, sourced in human genome, we unleash a type of unequal distribution, where every person belonging to a common heritage does not receive his or her fair share. More specifically, in deprivation of the medical benefit that must be conferred upon all, even if a single strand of DNA is sequenced, as it is part of everyone's common heritage.

Third, *Myriad* points to a silent dichotomy in prior patentability frameworks. Let us, for argument's sake, decouple ourselves from the invocation of the common heritage of mankind and leave the patentability argument to rise and fall on corporate monopoly rent-seeking behavior. If corporations intend to commoditize gene patents, then under the minimalist framework, we should let the efficiency of market model dictate terms, and thus, no exclusivity would be required. Logic would dictate that this would be desirable from the market model, which would eliminate the need for excessive patent protection. Indeed, this is not the case in reality.

Finally, *Myriad* and its European counterparts provided a long sought-after clarity in gene patentability. Despite this, society's general reluctance, perhaps, in the not so distant future, the path to patentability will begin to straddle some of the humanistic contours identified here. In such a traversal, our ethical compass must be guided by the realm of sacred, a sacred borne out of our longing for the common heritage of mankind and fundamentals of distributive justice.