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Inhalt

InTeRnational Views

Since modern technologies and technology-related impacts do not know geographical boundaries (and neither do innovations), the editorial board of InTeR aims to establish a forum to assess how current topics or seminal questions of Law and Innovation and Technology are addressed, analyzed and solved under the scope of legal systems other than the German one. Starting with this issue we will, on a regular basis, publish papers written in English by authors representing different legal cultures who may provide us with valuable insight, who may offer new perspectives and who, at times, may lead us to call into question our own systems and solutions. "InTeRnational views" will alternate with another column dealing with InTeRdisciplinary challenges of Law and Innovation and Technology to be introduced with issue N° 1/2014. Our "InTeRnational views" will be launched with an analysis of the Myriad decision (issued by the U. S. Supreme Court on June 13, 2013) by Gary E. Marchant and Yvonne A. Stevens who demonstrate by reference to innovations in biotechnology how legal structures may co-evolve with changing scientific understanding.

Moderne Technologien sowie deren Folgen machen ebenso wenig an Staatsgrenzen Halt wie Innovationen und die damit verbundenen Wirkungen. Die Zeitschrift InTeR versteht sich deshalb auch als Forum dafür, wie aktuelle oder grundsätzliche Fragestellungen des Innovations- und Technikrechts in fremden Rechtsordnungen adressiert, behandelt und gelöst werden. Beginnend mit dieser Ausgabe werden wir in regelmäßiger Folge – im Wechsel mit einer Rubrik zu InTeRdisziplinären Herausforderungen des Innovations- und Technikrecht, die erstmals in Ausgabe 1/2014 erscheinen wird – englischsprachige Beiträge von Autorinnen und Autoren aufnehmen, die in fremden Rechtsordnungen beheimatet sind, damit diese uns neue, andere und womöglich ungewohnte Perspektiven und Einsichten vermitteln können. Den Auftakt für die „InTeRnational views" bildet eine Analyse einer aktuellen Grundlagenentscheidung des U. S. Supreme Court zum patentrechtlichen Schutz biotechnologischer Innovationen, der Myriad-Entscheidung vom 13.6.2013, durch Gary E. Marchant und Yvonne A. Stevens.

Gary E. Marchant and Yvonne A. Stevens*

The United States Supreme Court Resolves the Gene Patenting Controversy (Or Did It?)

In June 2013, the U.S. Supreme Court over-turned 30 years of established practice in the United States and held that patents on naturally occurring DNA sequences were invalid. The case involved Myriad Genetics' patents on the BRCA breast cancer predisposition genes. At the same time, the court upheld Myriad's patents based on complementary DNA (cDNA) sequences. This commentary summarizes the lead-up to, and the series of judicial decisions culminating in, the U.S. Supreme Court's opinion on the BRCA patents. The commentary traces how the legal status of gene patents in the United States has co-evolved with a shifting understanding of the importance of single genes to biomedical innovation. It concludes by identifying some of the uncertainties going forward with respect to some unaddressed internal conflicts in the U.S. Supreme Court's judgment and the impact on biotechnology innovation.

I. Introduction

Technology innovation is the most critical driver of long-term economic growth and prosperity in the industrialized countries of Europe, North America and Asia. Intellectual property is a core requirement for technology innovation. Patents are generally regarded as the most important form of intellectual property and the biomedical industry is the sector in which patents are most essential. Within the biomedical sector, no patenting issue has received more attention and controversy than the patenting of genes. Patents for the breast cancer predisposition genes BRCA1 and BRCA2 have been the primary focus of the debate over gene patents. The United States (U.S.) has been at the forefront of the controversy over the patenting of the BRCA genes, as it is a U.S. company that discovered and patented these important genes.

Given these predicates, it may not be surprising that the recent U.S. Supreme Court's decision on the validity of the BRCA gene patents was of considerable interest and significance on both sides of the Atlantic (and Pacific). On June 13, 2013, the U.S. Supreme Court invalidated gene patents for naturally occurring DNA, but upheld patents for complementary DNA (cDNA) gene segments, in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (hereinafter "Myriad Decision").[1] In this commentary, we trace the lead-up to this U.S. Supreme Court decision on

* Further information on the authors is provided on page III (at the end of this issue).

1 Association for Molecular Pathology, et. al., v. Myriad Genetics, Inc., 133 S.Ct. 2107 (2013).

the patenting of BRCA genes in the United States, summarize the Myriad Decision, and then briefly explore its implications and unresolved questions. As we shall demonstrate, the contested and evolving relationship between innovation and gene patents was a critical sub-text, sometimes explicit sometimes implicit, that drove much of the decision-making on gene patenting in the U.S. It will be interesting to see if other jurisdictions, such as the European Union (EU) and Australia, that have generally followed the same pattern as the United States up until the Myriad Decision in recognizing gene patents will now reconsider their position on patenting of isolated genetic sequences.

We start in Part II by describing how U.S. patent policy is focused on promoting innovation, and how this innovation rationale explains the shifting positions on gene patents in the U.S. over the past three decades. In Part III, we trace the development of the U.S. policy on gene patents leading up to the Myriad Decision. Part IV summarizes the BRCA gene patents and the litigation challenging the validity of those patents, culminating in the June 2013 U.S. Supreme Court Myriad Decision. In Part V, we analyze the impact of the Myriad Decision on: BRCA testing, non-human DNA patents and biomedical innovation. We will also consider the *Prometheus* (defined below) U.S. Supreme Court decision and posit that *it* – not the Myriad Decision, is the real cause of the current confusion and uncertainty within the realm of gene-related patents. We conclude that while the Myriad Decision may create some injustice and puzzlement, it will not have a huge detrimental impact on future bio-innovation, given nowadays' movement away from past focus on single "blockbuster" genes.

II. Innovation: The Driver of U.S. Patent Policy

U.S. law and policy on gene patents, including the recent Myriad Decision, cannot be understood without attention to the underlying driver of U.S. patent policy, which is to promote innovation.[2] Until the recent Myriad Decision, the U.S. Patent and Trademark Office (USPTO) had pursued a thirty-year plus history of issuing patents on isolated, non-synthetic deoxyribonucleic acid (DNA) patents. This practice was influenced, in large part, by the long-standing pro-innovation American rationale for patenting, which dates back to the U.S. Constitution.[3] Article 1, section 8, of the U.S. Constitution provides Congress broad discretion to provide intellectual property exclusivity in order to "promote the progress of science and useful arts."[4]

As the White House recently reaffirmed, "[o]ur patent system – as enshrined in our Constitution – is meant to encourage innovation and invention."[5] The then-Director of the PTO recently expressed a similar sentiment about the central importance of intellectual property (IP) in encouraging innovation:

> So, our history has been driven by innovation. And our economic security continues to depend upon our ability to innovate – and to compete in an innovation economy. The key to economic success lies increasingly in innovative product and service development, and in intellectual property protection, which creates value for innovation. IP is – in effect – the global currency of innovation.[6]

Of course, the United States is not unique in its focus on the innovation rationale for intellectual property protection. For example, a recent EU document stated:

> Patents encourage companies to make the necessary investment for innovation. There would be little incentive otherwise for individuals and companies to devote the necessary resources to research and development.[7]

Other nations have not always steadfastly adhered to innovation as the raison d'être of patents, as has the U.S. For example, in the mid-to late-nineteenth century, Europe was swayed by a strong and successful patent abolitionist movement which viewed patents as injurious to the common welfare.[8] Instead, the abolitionists argued, alternative policies could be employed to reward inventors, such as government stipends, private industry awards or other means of recognition bestowed by participating organizations or associations. Although eventually defeated in the twentieth century, this movement focused more on rewarding inventors rather than promoting innovation.[9]

The steady, single-minded focus of the U.S. patent system on promoting innovation provides an analytical framework to understand the shifting status of gene patents in the U.S. There has been debate about whether patents on single isolated genes promote or block innovation from the outset of the era of modern molecular biology. Some stakeholders claim that gene patents are essential to stimulate the substantial economic investments needed to power biomedical innovations, whereas others claim that patents on genes are not only unethical, but actually block innovation by impeding access to genes by diagnostic test developers and health care providers. This debate about the innovation benefits of gene patents has occurred over a time period where the underlying scientific understanding of the utility and role of individual genes in disease processes has shifted markedly. As we will show in the subsequent sections of this commentary, the U.S. law on gene patents co-evolved, through both explicit findings and implicit nudges, with the changing scientific understanding of genes.

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2 *See, e.g.*, Council on Foreign Relations, Renewing America: U.S. Patents and Innovation (Dec. 19, 2012), available at http://www.cfr.org/innovation/us-patents-innovation/p29700 (visited Oct. 29, 2013) ("Sustainable economic growth relies on innovation, particularly for the United States… A well-designed patent system encourages both the creation and spread of innovations.").

3 U.S. Const. Art. 1, § 8.

4 Id.

5 Gene Sperling, Taking on Patent Trolls to Protect American Innovation, The White House Blog, June 4, 2013, available at http://www.whitehouse.gov/blog2013/06/04/taking-patent-trolls-protect-american-innovationm (visited Oct. 29, 2013).

6 David J. Kappos, The Innovation Economy: Unleashing Intellectual Property to Fuel Growth and Create Jobs (speech) (June 10, 2010), available at http://www.uspto.gov/news/speeches2010/Kappos_CAP_speech.jsp (visited Oct. 29, 2013).

7 EUBusiness, Single European Patent (Dec. 11, 2012), available at http://www.eubusiness.com/topics/research/single-patent (visited Oct. 29, 2013).

8 B. Zorina Khan, *An Economic History of Patent Institutions* (Feb. 5, 2010), available at http://eh.net/encyclopedia/article/khan.patents (visited Oct. 29, 2013).

9 *Id.*

III. Gene Patents in the United States

The paths and diversions by which U.S policy on gene patents has evolved can largely be understood by reference to the goal of promoting innovation. Patents have been granted on claims involving living organisms in the United States since the 1800's when Louis Pasteur was issued U.S. Patent 141,072 in 1873, claiming "[y]east, free from organic germs of disease, as an article of manufacture."[10] And while the U.S. Supreme Court had considered the patentability of live organisms many years earlier,[11] a crucial decision opening the door to biotechnology was the 1980 U.S. Supreme Court split 5-4 decision in *Diamond* v. *Chakrabarty* which held that the threshold issue for patenting was not whether the claimed invention was living or non-living, but rather whether it was naturally occurring or not.[12] Although numerous intervening and *amici* parties raised ethical and policy objections to patenting of living things, the U.S Supreme Court majority summarily dismissed such concerns and seemed more interested in clearing road-blocks to the emerging biotechnology industry. Although not expressly stated in the court's opinion, the intent and certainly the impact of the majority opinion was to encourage innovation in this new technology.

Two years after *Chakrabarty*, the first gene patent was issued in the U.S. in 1982. That patent claimed a "recombinant DNA transfer vector containing the Chorionic Somatomammotropin gene."[13] In the early 1990's, the case of *Amgen v. Chugai* ("*Amgen*")[14] was decided by the U.S. Court of Appeals for the Federal Circuit, which has exclusive jurisdiction over all patent appeals at the court of appeals level in the United States. *Amgen* related to a patent for "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin."[15] In this case, the Federal Circuit observed that, in the context of a (now obsolete) interference proceeding, isolated and purified DNA is "invented" and thus eligible for patenting when a thorough and precise DNA sequence is presented:

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it.[16]

While the Federal Circuit did not squarely and expressly hold that DNA sequences are patentable, the clear implication of the *Amgen* opinion was that gene sequences are patentable. Surely, isolated DNA that was deemed eligible for interference proceedings presupposes that it was also patentable subject matter.

The USPTO made this common understanding that genes are patentable explicit in its 2001 utility guidelines where it rejected arguments that genes were not patentable subject matter because they existed in nature:

> An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.[17]

It is important to recognize the state of knowledge about genetics that existed at the time the USPTO was announcing this pro-gene patenting position. The USPTO's position was greatly influenced by what it and most experts thought would be a rapidly bourgeoning field of "blockbuster" genes that would easily translate into effective new treatments and a growing new industry. The view was that unitary genes as innovative single "disease solvers" would become big business in the U.S. Generous patent availability was therefore an important requirement for promoting innovation in this new field. Unfortunately, the science would ultimately not support this blockbuster gene paradigm. With few exceptions (including the BRCA genes discussed below), most of the subsequently discovered gene variants had individually only a small effect on health outcomes. Assessing genetic risk therefore usually required screening multiple genes that only when considered together would have a significant effect on outcomes. The focus of innovation thus shifted to multiplex diagnostics in which multiple genes were assessed with the assistance of diagnostic tools intended to quantify risk of hereditary disease and other predispositions across a broad spectrum of genetic variants. In this new model, where the innovative step is creating assays that combine multiple genes whose results are aggregated using a proprietary algorithm, patents on individual genes don't affirmatively promote innovation, and may even impede innovation if innovators developing multi-gene tests are required to obtain multiple licenses for the multitude of genes in their assays.

The shift from the presumption that more patents means more innovation was perhaps first indicated by a 2005 Federal Circuit case, *In Re Fisher.*[18] In that decision, the Federal Circuit held that expressed sequences tags (ESTs), which are short sequences of cDNA made from messenger RNA circulating in cells, are not patentable if they have no identifiable genetic function, as it was not possible to identify a public benefit meriting a patent. Interestingly, the court received a number of *amicus curiae* briefs from the U.S. government and industry entities arguing *against* patents for ESTs because such patents would impede innovation. Although the Federal Circuit stated that it was not permitted to consider those policy arguments, it nonetheless may have been somewhat swayed by those arguments in arriving at its decision consistent with those arguments.

10 *See* U.S. Patent and Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2011).
11 See *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127 (1948) (holding that a patent on the mixture of naturally occurring bacteria strains, even though the mixture was not naturally occurring, was invalid due to lack of sufficient innovative steps).
12 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
13 See Kathryn J. Kitzmiller, Genes, Law and the Race to Patent, available at http://www.cas.org/news/insights/science-connections/gene-patent (visited Oct. 27, 2013).
14 *Amgen* v. *Chugai*, 927 F.2d 1200 (Fed. Cir. 1991).
15 927 F.2d at 1204.
16 *Id.* at 1206.
17 USPTO, Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).
18 *In Re* Fisher, 421 F.3d 1365 (2005).

While ESTs without an identifiable function were held to be not patentable, genes with identified sequences and functions continued to be issued patents. The USPTO has issued over 4,000 human single-gene patents. However, in recent years, as the scientific and economic importance of single genes faded, so too did the interest in patenting individual genes. The number of new applications for human gene patents tapered off, and approximately half of the existing gene patents for human genes were abandoned.[19] Yet, a few individual human genes continued to be "blockbuster" genes of enormous medical and commercial significance, with the prototypical example being the two breast cancer predisposition genes, BRCA1 and BRCA2. It was these two BRCA genes that provided the context for the recent monumental legal battle over the patenting of genes in the United States.

IV. The BRCA Patents and Litigation

In this section, we first describe the BRCA genes and their patenting by Myriad Genetics, and then summarize each of the several stages in the *Myriad* litigation challenging the patentability of the BRCA genes.

A. The BRCA Genes and Gene Patents

Myriad Genetics, Inc. (Myriad), based in Salt Lake City, Utah, is a molecular diagnostics company involved in the discovery and commercialization of tests to help explain the genetic basis of disease and health risks. Myriad is at the center of the gene patenting controversy in the U.S. because of its role in discovering and patenting the BRCA genes. In 1990, a discovery was made by a group of scientists from the University of California, Berkley, of a region on chromosome 17 that significantly affected a woman's risk of breast and ovarian cancer. The specific gene affecting this risk, known as BReast CAncer 1 or "BRCA1," was identified, isolated and sequenced four years later by Myriad, researchers at the University of Utah, the U.S. National Institutes of Health and Montreal's McGill University. BRCA2, located on chromosome 13 and sequenced by Myriad shortly thereafter, is also implicated in hereditary breast and ovarian cancer. Mutations of BRCA1 and BRCA2 substantially elevate a woman's risk of developing hereditary breast cancer and/or ovarian cancer.

The University of Utah and Myriad quickly moved to patent their discoveries, and the first BRCA1 patent was issued in 1997 followed by the first BRCA2 patent in 1998. Myriad eventually held several broad patents on both BRCA1 and BRCA2 and on corresponding diagnostic testing methods. The company declined to license its patent rights to other laboratories, and issued cease and desist orders to other institutions that conducted BRCA testing. Myriad required all full sequencing of BRCA mutations to be conducted at its own facility and thereby built-up a large, proprietary database of BRCA mutations and their health outcomes. The company is developing a new business model to exploit this database protected as a trade secret in the post-BRCA patent era.

In 2009, the American Civil Liberties Union (ACLU) put together a coalition of parties that included scientific and medical organizations such as the Association for Molecular Pathology (designated as lead plaintiff), health researchers and practitioners, and individual plaintiffs with heritable risks of breast cancer. This group of plaintiffs filed a lawsuit challenging Myriad's BRCA1 and BRCA2 patents as eligible composition of matter as well as its related diagnostic method patents, covering a process for analyzing or comparing isolated DNA sequences to detect mutations in the BRCA1 and BRCA2 genes. The lawsuit listed Myriad and the University of Utah, as owners of the patents, and the USPTO, as the issuer of the patents, as the defendants in the lawsuit. The lawsuit also impugned the constitutionality of the patent claims as being abstract ideas or basic human knowledge and/or thought protected by the First and Fourteenth Amendments to the U.S. Constitution. The four-year saga of this case as it wound its way through the court system is summarized below.

B. U.S. District Court

The ACLU's lawsuit was filed in the U.S. Federal District Court for the Southern District of New York, which issued its decision on March 29, 2010.[20] The court's ruling invalidated both Myriad's composition of matter claims and its method claims. According to presiding Judge Robert Sweet, the claimed isolated DNA sequences are not markedly different from DNA as it occurs in nature and, therefore, do not constitute patentable subject matter. The identification of the gene sequences, while deserving of recognition and a worthy scientific achievement, was not something that entitled Myriad to a patent(s). The court also struck Myriad's method claims pursuant to a U.S. Supreme Court decision[21] that had very recently limited the patentability of methods and processes. Given its decision regarding the patent claims, the district court was not obliged to consider the plaintiffs' constitutional arguments, and those claims were never litigated further. Myriad appealed the decision to the U.S. Court of Appeals for the Federal Circuit, which has exclusive jurisdiction over all patent appeals in the United States.

C. Federal Circuit – Initial Appeal

On July 29, 2011, the three-judge Federal Circuit panel that heard the case issued a split decision.[22] Regarding the composition of matter claims, the majority of the court, although for different reasons, found in favor of Myriad. One judge forming the majority held that because the genes in question are isolated via chemical cleaving they are different from how they exist in nature and are, thus, patentable subject matter. The other judge in the plurality did not exclusively rely on chemical severance as being dispositive of the issue, but also relied on patent-holder interests and USPTO practice of granting such patents. The Federal Circuit further cited human intervention, markedly different characteristics and distinct chemical identity in support of its finding that human DNA is patentable. With respect to the method claims, only one claim passed the eligibility threshold. All others were determined to be patent ineligible abstract mental processes and did not

19 Aaron S. Kesselheim et al., *Gene Patenting – The Supreme Court Finally Speaks*, 369 N. Eng. J. Med. 869,873 (2013).

20 *Ass'n for Molecular Pathology v. USPTO*, 702 F.Supp.2d 181 (S.D.N.Y. 2010).

21 *Bilski* v. *Kappos*, 130 S. Ct. 3218 (2010).

22 *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

pass the established "machine or transformation test" (MOT). Although Myriad argued that because it had to extract and sequence the genes prior to conducting an analysis, the MOT was satisfied, the court rejected this argument given that neither the process of extraction nor sequencing was stated in Myriad's claims and could not be inferred. The Federal Circuit ultimately held that the process of comparing and analyzing the BRCA sequences is not sufficient to pass the MOT test.[23]

Significantly, the U.S. Department of Justice (DOJ), which had represented the USPTO as a defendant in the district court, changed its position on appeal to argue that isolated DNA sequences are not patentable, effectively arguing against its own "client" the USPTO (whose position regarding the patentability of isolated DNA had not changed). The U.S. government therefore was split on the case, with the DOJ arguing that isolated genes were not patentable and the USPTO maintaining its original position that such genes were patentable. Both the DOJ and USPTO agreed that cDNA gene sequences were patentable subject matter, however.

A few months after the Federal Circuit's judgment, the ACLU filed a certiorari petition with the U.S. Supreme Court to challenge the decision. The U.S. Supreme Court granted the ACLU's petition, but then immediately remanded the case back to the Federal Circuit for reconsideration in light of its decision in a related case, discussed further below, *Mayo* v. *Prometheus* ("*Prometheus*").[24]

D. Federal Circuit on Reconsideration

On remand from the U.S. Supreme Court to reconsider its previous decision in light of *Prometheus*, the Federal Circuit once again ruled 2-1 on August 16, 2012 that isolated genes are patentable, "even if they correspond to naturally occurring sequences."[25] The Federal Circuit also held, unanimously, that patents on cDNA are valid while method patents for comparing sequences are not patentable.[26] Again, the U.S. Supreme Court was asked to weigh in on the matter relating to isolated DNA and the U.S. Supreme Court granted certiorari to hear the case. Myriad did not appeal the denial of the method patents, so the Federal Circuit's ruling on these remain the law at this time.

E. U.S. Supreme Court

In a much anticipated decision, the U.S. Supreme Court held unanimously on June 13, 2013 that Myriad did not invent the naturally occurring DNA under scrutiny, rather, it simply discovered their location and that effort alone is not patent worthy.[27] The severance of the chemical bonds during cleaving was also not sufficient to take the DNA out of its natural realm. Myriad's claims being based on informative content rather than chemical composition was detrimental to its position that the DNA is question is distinct from how it exists in the human body. The genetic information between the isolated and non-isolated DNA remains the same and indistinct and is, thus, not patentable.

However, with regard to synthetic cDNA, the court found it to be patent eligible and noted that,

> [t]he lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under § 101, *except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA* (emphasis added).[28]

In reaching its decision, the court made clear it was motivated in large part by the effect of DNA patents on innovation. The court explained that attempts to patent naturally occurring materials that "'are the basic tools of scientific and technological work'" had to be prohibited because of "the considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation based on them.'"[29] The court continued that "[t]his would be at odds with the very point of patents, which exist to promote creation."[30] Further, said the court, "patent protection strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'"[31] Contrary to this language emphasizing the importance of patent law for providing incentives for innovation, the court dismissed arguments based on other theories of patents, such as just reward: "extensive effort alone is insufficient to satisfy the demands of § 101."[32]

As we will discuss next, the Myriad Decision left unanswered questions, such as how the prohibition of patents on naturally occurring DNA sequences will be reconciled with the recognition of patents for cDNA that often contain much of the same DNA sequence.[33] As discussed further below, the court's failure to consider this inherent tension in its decision leaves scientists, researchers, physicians and other affected parties scratching their heads as to the future of genetic diagnostics and related applications.

V. Analysis and Lingering Uncertainties

A. Impact on BRCA Testing

Although it appears straightforward, the Myriad Decision has resulted in confusion as to its implications for the real

23 The one successful method claim directed to screening potential cancer therapeutics via changes in cell-growth rates, passed the MOT test as being inherently transformative as the method included the steps of growing transformed cells and determining related growth rates.

24 *Mayo Collaborative* Services v. *Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). The *Prometheus* decision and its implications are discussed further below at *infra* notes 54-59 and accompanying text.

25 *Ass'n for Molecular Pathology v. USPTO*, 693 F.3d 1303 (Fed. Cir. 2012).

26 The Federal Circuit also held that processes that involve testing transformed host cells are patentable.

27 *Myriad Decision*, 133 S.Ct. at 2117-18.

28 *Myriad*, 133 S.Ct. at 2119.

29 *Id.* at 2116 (citing *Prometheus*).

30 *Id.*

31 *Id.* (quoting *Prometheus*).

32 *Id.* at 2118.

33 Arti K. Rai, *Biomedical Patents at the Supreme Court: A Path Forward*, 66 Stan. L. Rev. Online 111, 114 (2013) ("the Court failed to enunciate *why* claims to information in the form of cDNA are less problematic than claims to information in the form of gDNA.").

world. To recap, the Myriad Decision "clarified" that naturally occurring DNA (sometimes referred to as genetic DNA or "gDNA") is not patentable whereas complementary DNA (cDNA) is patentable.[34] This means that while a gene cannot be patented, the laboratory version of that same gene, which includes all the important segments of the naturally occurring gene, can be patented. In essence that is like saying the contents of a novel that has had all blank space eliminated may be patented but the novel itself cannot be patented.[35] The U.S. Supreme Court never tried to reconcile, or perhaps did not even recognize, the internal conflict between the two parts of its decision.

Shortly after the U.S. Supreme Court's decision was announced, a number of diagnostic test companies declared that they would start offering BRCA testing at a significantly discounted price relative to Myriad's cost of $4000 per patient. For example, Quest, one of the largest diagnostic test companies in the U.S. announced that it would begin BRCA testing with its "BRCAvantage" test that will be significantly less expensive than Myriad's test:

> Quest's position as a leader in lab testing gives it confidence it can win a share in the BRCA marketplace. The company operates 2,100 testing centers nationwide and has the clout necessary to provide services like counseling and help navigating insurers.[36]

But the Myriad Decision did not eliminate all of Myriad's patents, including Myriad's cDNA patents. Myriad claimed that only 11 of its 520 gene-related patent claims were invalidated as a result of the Federal Circuit and U.S. Supreme Court decisions,[37] and has indicated its intention to vigorously fight to protect its position in the field when it detects potential infringement by others. It still holds patents on cDNA, probes, primers and other screening/evaluation methods and has already engaged in new litigation against Ambry Genetics Corporation and Gene By Gene Ltd. suing both companies in federal district court in its home state of Utah for alleged patent infringement relating to those patents.[38] Also, two other companies, Counsyl and Quest filed preemptive suits in the state of California seeking declaratory judgment that their BRCA testing does not violate any patents held by Myriad. Myriad has responded by filing a cross-suit against Quest in Utah. Myriad's position in these cases is that as part of their testing, the other companies use a non-naturally occurring primer that is patented by Myriad, while the defendants counter that Myriad's patented primer contains a sequence of gDNA that is not patentable. It will be of great interest to see how these cases are resolved in light of the Myriad Decision which has left quite a bit of wiggle room for argument with regard to the patentability of "combo-matter."

Of additional interest will be the response of other nations. Jurisdictions such as the European Union and Australia have also decided legal challenges to BRCA patents, but in contrast to the U.S. Myriad Decision, have generally upheld those patents.[39] It will be interesting to see how other jurisdictions respond to the U.S. Supreme Court's decision, if at all, given that the United States has traditionally been seen as the nation most "bullish" on gene patenting up until recently.

B. Impact on Non-Human DNA Patents

The U.S. Supreme Court expressly granted certiorari to decide the validity of "human" DNA gene patents, but in its decision made no distinction between human and non-human gene patents. There is thus no reason to believe that the decision would let stand patents for naturally occurring plant or animal genes, any more than it would allow patents for naturally occurring human DNA patents, since the arguments applied by the court would apply equally to all naturally occurring DNA, regardless of source. Graff et al. have suggested that the Myriad Decision may not have the detrimental effect that some stakeholders fear in regard to human genetics, but could result in unanticipated impacts on non-human DNA patents.[40] Graff et al's empirical analysis of gene patenting had found that over the last few years, patent applicants appear to have avoided the kinds of risky claims that were the source of controversy in the Myriad case, and that "more than half" of the genes that would likely be affected by the Myriad Decision protected applications "in other fields of industry, such as veterinary medicine, crop agriculture, food and beverage manufacturing, industrial enzymes or bioenergy."[41] Specifically, their analysis estimated there were 8,073 U.S. patents in force that contained claims to naturally-occurring DNA sequences, "of these 8,073 patents with composition-of-matter claims to simple nucleic acid molecules with natural sequences, 3,535 (41%) involve human genetic sequences whereas the other 4,538 (59%) involve sequences from other taxa, including animals, plants and microbes."[42] Very little if any analysis was conducted by the court or the participants in the litigation on the impacts of invalidating patents on naturally occurring genes for these important and growing industries, so only time will tell what those effects will be.

However, the Myriad Decision will only affect patents on naturally occurring DNA, not modified DNA. The court made expressly clear that it was not addressing patents for modified DNA: "Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of such § 101 to such endeavors."[43]

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34 The Court did not recognize that cDNA is something that can sometime also exist naturally. For example, HIV can change its own RNA into cDNA to make copies of itself. Maggie Koerth-Baker, *Making Sense of the Confusing Supreme Court DNA Patent Ruling,* BoingBoing (June 17, 2013), available at http://boingboing.net2013/06/17/making-sense-of-the-confusing.html (visited Oct. 27, 2013).

35 Id.

36 Todd Campbell, *Quest Diagnostics Threatens Myriad's Grip on BRCA Tests,* The Motley Fool (Oct. 17, 2013), available at http://www.fool.com/investing/general2013/10/17/quest-diagnostics-threatens-myriads-grip-on-brca-t.aspx (visited Oct. 23, 2013).

37 John Conley, *Myriad Back in Court Again – This Time as a Defendant,* Genomics Law Rep., Oct. 8, 2013, available at http://www.genomicslawreport.com/index.php2013/10/08/myriad-back-in-court-again-this-time-as-a-defendant/ (visited Oct. 26, 2013).

38 *University of Utah Research Foundation et al.*, v. *Ambry Genetics Corporation,* Case No 2:13-cv-00640-RJS (2013); *University of Utah Research Foundation, et al.*, v. *Gene By Gene Ltd.*, Case No. 2:13-cv-00643-EJF (2013).

39 *See* Howard Wolinsky, *Gene Patents and Capital Investment,* 14 EMBO Rep. 871, 873 (2013).

40 Gregory D. Graff et. al., *Not Quite a Myriad of Gene Patents: Assessing the Potential Impact of the U.S. Supreme Court on the Changing Landscape of U.S. Patents That Claim Nucleic Acids,* 31Nature Biotech. 404 (2013).

41 Id. at 407.

42 Id.

43 *Myriad Decision,* 133 S.Ct. at 2120.

Thus, the decision should not affect new technologies such as gene therapy, genetically modified plants and animals, or synthetic biology.

C. Impact on Biomedical Innovation

As discussed above, promoting innovation is the raison d'être of patents in the United States. Just as stakeholders and experts argued about the impact of gene patents in biomedical innovation prior to the Myriad case, the decision invalidating some gene patenting has opened a new round of debate on the impact on innovation. Some commentators expressed concern that the Myriad case will cause disruption in the biotechnology industry and harm innovation.[44] Others contend that the decision will enhance innovation.[45] The analysis by Graff et al.[46] indicating that the Myriad Decision may "undo" over 8,000 U.S. patents currently in force (both human and non-human) will undoubtedly have some detrimental impacts on affected patent holders. Moreover, many in the biotechnology industry are concerned about the implications of the court's decision for patents on other arguably "naturally occurring" materials such as therapeutics.[47] To be sure, any time a court decision disrupts settled expectations and retroactively undoes long-standing business and legal practices and agreements, it will have some detrimental and even unfair consequences.

But it is our thesis here that the U.S. Supreme Court was comfortable to "upset the applecart" and reverse the thirty-year practice of patenting genes in the United States precisely because they concluded that the decision would not seriously harm innovation, and may indeed even promote innovation in the long run. The court was likely influenced by *amici curiae* briefs filed by the U.S. government and prominent scientists who argued that patenting on naturally occurring genes was impeding, not promoting, scientific advances.[48]

Indeed, after the decision, many other commentators have argued that the decision will not have much bearing on biomedical innovation given the limitations in the Myriad Decision (e.g., does not affect cDNA patents and patents for altered genes) and the fact that most biomedical innovation has moved beyond single gene discoveries.[49] As Myriad's own General Counsel has noted, "[t]he types of patents that we're now seeing in the molecular diagnostic space are no longer with respect to specific genes … What you're seeing today is a shift from molecular diagnostic testing focused on a single gene or a small set of genes rather to what we call panels of genes."[50] Moreover, the "next big thing" in molecular diagnostics and personalized medicine is whole genome sequencing, which potentially could run afoul of gene patents (although this is disputed), and thus the Myriad Decision helps clear the path for that important new technology.[51]

According to one author,

> The Myriad Genetics ruling is really, really narrow. Yes, it prevents companies from patenting a gene that they just happened to find in the human body (or anyplace else). But it leaves plenty of room to patent genetic information – and it leaves plenty of room for future court battles over what genetic information can and cannot be patented. This is a big court case that only reduced uncertainty a tiny bit.[52]

Another optimistic view of the future as it relates to the patentability of DNA in the wake of *Myriad* is shared by attorney Nicholas Landau who states that,

> [i]nventions such as genetically modified organisms, genetic probes, and recombinant DNA are not affected by the decision, and remain patentable. Going forward, biotechnology innovators simply must avoid attempting to claim DNA that only includes a naturally occurring sequence. The utility of such DNA is highly limited in the context of modern biotechnology, and its exclusion from patent eligibility should only complicate patenting in very few circumstances.[53]

D. The *Prometheus* Juggernaut

While much of the public and media attention in the United States has focused on the Myriad Decision, a far more sinister threat to biomedical innovation is posed by the *Prometheus* decision decided by the U.S. Supreme Court one year earlier.[54] Recall that the first time the *Myriad* case was before the U.S. Supreme Court, the court granted certiorari and immediately remanded the case back to the Federal Circuit for reconsideration in light of *Prometheus*. Although the Federal Circuit resisted any modification of its decision on the BRCA patents in response to *Prometheus*, the U.S Supreme Court did cite to and extend its approach to *Prometheus* in its Myriad Decision. In the *Prometheus* case, decided on March 20, 2012, the U.S. Supreme Court ruled that methods of evaluating correlations between blood test results and patient health are unpatentable. Prometheus is a diagnostics company that held patents on methods providing a means to measure the level of two metabolites in the blood (for patients taking thiopurine drugs), whereby higher levels indicated a toxicity warning, further indicating to a physician that the dosage might require adjustment. The Mayo Clinic initially licensed the Prometheus test, but subsequently developed its own test that it concluded worked better, and Prometheus sued for patent infringement. The Federal Circuit held that the method was patent eligible despite a prior ruling by the U.S. Supreme Court with regard to a related methods patent case.[55]

The U.S. Supreme Court unanimously reversed the Federal Circuit decision, adopting a "preemptive test" that was designed to "prohibit patentability of claims that broadly

44 *See* Turna Ray, *Innovation Boom or Bust? Industry Gauges Impact of SCOTUS Ruling on Gene Patents*, GenomeWeb Pharmacogenomics Reporter, June 19, 2013, available at http://www.genomeweb.com/clinical-genomics/innovation-boom-or-bust-industry-gauges-impact-scotus-ruling-gene-patents (visited Oct. 31, 2013).
45 Kesselheim et al., *supra* note 19, at 874.
46 Graff et al., *supra* note 40.
47 Rai, *supra* note 33, at 116.
48 *See* Rai, *supra* note 33, at 114.
49 Kesselheim et al. *supra* note 19, at 874.
50 Dan Packel, *Myriad GC Soft-Pedals Importance Of High Court IP Ruling*, Law360, Sept. 23, 2013, available at http://www.law360.com/articles/474393/myriad-gc-soft-pedals-importance-of-high-court-ip-ruling (visited Oct. 30, 2013).
51 Wolinsky, *supra* note 39, at 873.
52 Koerth-Baker, *supra* note 34.
53 Nicholas Landau, *The Real Impact For Healthcare And Biotechnology Of The Supreme Court's Decision In Myriad Genetics*, Mondaq, July 24, 2013.
54 *See supra* note 24.
55 *Bilski* v. *Kappos*, *supra* note 21.

cover the application of a law of nature or natural phenomena and preempt all uses and applications of the natural phenomena."[56] The court found that the claimed methods did not include any steps to transform unpatentable laws of nature into patentable applications of such natural laws. Steps consisting of administering and determining were insufficient to take the method in question out of the scope of abstract ideas and laws of nature.

The *Prometheus* decision has created great uncertainty for diagnostic method patents, particularly in the area of personalized medicine, as it failed to provide guidance in respect of how much more is necessary to take a diagnostic method involving a natural biomarker and correlation out of the realm of ineligible subject matter. As has been said,

> the Court appeared to be narrowing the boundaries of patentable subject matter in a field that has long taken for granted the availability of patent protection for its innovations. By broadly defining "laws of nature" to include human interpretation of biological responses to medical interventions, the Court seemed to call into question the validity of many previously allowed claims, [and] inviting more litigation contesting patentable subject matter ….[57]

It is this *Prometheus* U.S. Supreme Court decision, not the Myriad Decision, that is causing the most disruption and uncertainty in the market and on innovation in the biomedical industry.[58] It has already started to have adverse impacts on diagnostic patent claims in lower courts such as the Federal Circuit.[59] The only certainty amongst the uncertainty is that more litigation is very likely necessary in order to remove the confusion created by this particular U.S. Supreme Court decision.

VI. Conclusion

The U.S. Supreme Court's decision that naturally occurring DNA sequences are not eligible for patenting has overturned thirty years of established practice and settled expectations in the United States. While the decision will no doubt create some disruptions and unfairness, both for human and non-human genetic applications, it will not have the detrimental effect on biotechnology innovation that was once feared. The science and business of genetics has moved on from the paradigm in place when gene patents were first recognized by the courts and USPTO in which "blockbuster" single genes were to be the source of value for both patients and investors. The model today is very different, in which multiple genes affect most traits and risks, and it is the integration of dozens or even hundreds of genes that is the focus of innovation. In this new paradigm, patents on individual genes are less important, and may even be an impediment to innovation. The Myriad Decision implicitly if not explicitly tracks this change in the underlying science and shifted the law in a direction that will promote innovation consistent with the science,[60] and thus represents an example of the law co-evolving with changing scientific understanding.

56 Michael J. Cronin and Grady J. Frenchick, *Hold the Mayo…An Overview of Mayo v. Prometheus*, WHD Special Report (May 2012).

57 Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. 341 (2013).

58 *See* Rai, *supra* note 33, at 113. ("On its face, then, *Mayo*'s reasoning is in tension with an economically oriented approach.")

59 *See, e.g., PerkinElmer v. Intema*, 2012 WL 5861658, 105 U.S.P.Q.2d 1960 (C.A.Fed., Nov. 20, 2012).

60 Rai, *supra* note 33, at 111 ("Notably, however, the policy analysis in *Mayo* and in *Myriad* focuses on innovation. That focus is appropriate.").

Aufsätze

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Vertragsgestaltung im Supply Chain Management

Die Funktionsfähigkeit integrierter Lieferketten hängt nicht zuletzt von einem optimierten Vertragsdesign des Netzwerkes ab. Erfolgreiches Supply Chain Management bedarf deshalb der Reflektion von Rechtsstruktur und -funktion des Netzwerkes ebenso wie von dessen fundamentalen rechtlichen Stellgrößen, um so insbesondere Ablauforganisation, Qualitätssicherung und Risikomanagement rechtlich wirkungsvoll zu unterstützen.

I. Meinungsstand und Problemfeld

Seit Jahren ist der betriebswirtschaftlichen Literatur der Begriff des Supply Chain Managements (SCM) geläufig und ist SCM gleichermaßen gelebte Unternehmenspraxis. SCM lässt sich dabei etwa beschreiben als strategische Konzeption und Organisation einer ganzen Wertschöpfungskette, um die dort involvierten Güter-, Informations- und Geldflüsse möglichst effizient, d. h. vor allem ganzheitlich, unternehmensübergreifend, zu gestalten.[1] Es geht also um Design und Administration eines strukturierten Netzwerks „vertikal alliierter, rechtlich selbständiger Unternehmen,

* Auf Seite III erfahren Sie mehr über den Autor.

1 Vgl. für viele nur *Corsten/Gössinger*, Einführung in das Supply Chain Management, 2. Aufl. 2008, S. 94; *Pfohl/Gallus/Köhler*, Konzeption des Supply Chain Risikomanagements, in: Pfohl (Hrsg.), Sicherheit und Risikomanagement in der Supply Chain. Gestaltungsansätze und praktische Umsetzung, 2008, S. 19.

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