Baseball Bats and Chocolate Chip Cookies: The Judicial Treatment of DNA in the Myriad Genetics Litigation

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In June 2013, the U.S. Supreme Court rendered a controversial ruling that naturally occurring DNA segments are “products of nature” and therefore not patentable subject matter. At this intersection between science and law, in litigation of crucial importance to patients, science, and multibillion-dollar biotech enterprises, the appellate judges sidestepped genetics and engaged in a war of metaphors from diamonds to chocolate chip cookies. This case is not an outlier. Apprehensive judges and juries in both Canada and the United States find many convenient excuses to avoid coming to grips with the underlying science in patent cases. But this is simply not acceptable. Legal rulings must be, and must seem to be, well grounded, as a matter of both law and science. The legitimacy of court decisions in the eyes of the stakeholders and the broader public depends on it.

The face of the biotechnology industry changed dramatically with the U.S. Supreme Court’s decision in Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al. (133 S. Ct. 2107) (S. Ct. 2013) (Myriad USSC). As of June 2013, naturally occurring DNA segments are “products of nature” and therefore not patentable subject matter in the United States.

The Supreme Court’s brief opinion overturned more than 30 years of U.S. Patent and Trademark Office practice and outraged the thousands of patent holders and their attorneys who had relied for years on the validity of their issued gene patents. Instead, Justice Thomas for the unanimous court adopted what many scientists have argued all along: that DNA’s unique function and importance derives not from its status as a “composition of matter” but from its status as a carrier of information.

In the Myriad Genetics case, the utility of the claimed BRCA1 and BRCA2 genes and related mutations in identifying women with an increased risk of breast and ovarian cancers stemmed from the genetic information they contained. Myriad had merely discovered the genes’ precise location and sequences. And this, the Supreme Court held, was insufficient coin to purchase a 20-year patent monopoly.

At the same time, Myriad’s claims to BRCA1 complementary DNA (cDNA) were upheld on the basis that cDNA is not naturally occurring. Justice Thomas wrote that “the lab technician

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unquestionably creates something new when cDNA is made.”

Justice Scalia, obviously feeling adrift in these technically complex waters, concurred with the majority’s opinion, except with respect to the underlying science. His opinion was brief and to the point:

I join the judgment of the Court, and all of its opinion except Part I-A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief.

Our concern in this paper is not so much with the legal accuracy of the Myriad Genetics decision as it is with the questionable grip on the relevant science displayed at all appellate levels in getting to the result. Justice Scalia may have been the only judge willing to speak up and confess, but the hearing transcripts and reasons for decision reveal that both the Court of Appeals and the Supreme Court struggled with the scientific underpinnings of the case. At the hearing before the Supreme Court, the following exchange between Justice Breyer and Myriad’s counsel is illustrative:

JUSTICE BREYER: Now, have I misread what the scientists told us, or are you saying that the scientists are wrong?

MR. CASTANIAS: Well, I will tell you that—

JUSTICE BREYER: I probably misread it. There’s a better chance that I’ve misread it. [laughter]

Unfortunately, the judicial system’s disdain for science is not new. The ever perceptive Judge Learned Hand warned more than a century ago (Parke-Davis & Co. v. H.K. Mulford Co. (189 F. 95) (C.C.S.D.N.Y. 1911) at 50–51):

I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils, for only a trained chemist is really capable of passing upon such facts, e.g., in this case the chemical character of Von Furth’s so-called “zinc compound,” or the presence of inactive organic substances. . . . How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance.

Of course, similar problems are encountered in all courts of general jurisdiction, including the Canadian courts. There is a very real risk that the complexity of the underlying science will obfuscate and overwhelm the legal merits of patent cases.

OTHER HORROR STORIES

Before we review the American courts’ analyses in Myriad Genetics, it is worth mentioning a few other instances in which the “science” debated in the court seemed to bear little relation to what was generally accepted in the scientific community outside the court.

In one Canadian patent case involving a comparatively crude form of technology, a dryer-added fabric conditioner called Bounce (which is essentially a mixture of synthetic animal fat [tallow] and sugar extract [sorbitan]), the trial judge in his reasons threw up his hands in Scalia-type frustration (Unilever PLC v. Procter & Gamble Inc. (1993), 47 C.P.R. (3d) 479 Fed. T.D.):

A judge unschooled in the arcane subject is at difficulty to know which of the disparate, solemnly mouthed and hotly contended “scientific verities” is, or are, plausible. Is the eminent scientific expert with the shifty eyes and poor demeanour the one whose “scientific verities” are not credible? Cross-examination is said to be the great engine for getting at the truth, but when the unschooled judge cannot perceive the truth, if he

the most eminent scientific men flatly contradict each other’s assertions.”

Ibid. at 2120.

5 Transcript of the hearing before the U.S. Supreme Court on April 15, 2013, at p. 38 [USSC Hearing].

6 Reference may also be made to the comment of the English jurist James Fitzjames Stephens, almost 150 years earlier, in an address to the Juridical Society on November 7, 1859, titled, “On Trial by Jury, and the Evidence of Experts”: “Few spectacles, it might be said, can be more absurd and incongruous than that of a jury composed of twelve persons who, without any previous scientific knowledge or training, are suddenly called upon to adjudicate in controversies in which

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or she ever hears it, among all the chemical or other scientific baffle-gab, is it not a solemn exercise in silliness?

Similarly, in a case in the United States (Wells v. Ortho Pharmaceutical Corp. (788 F.2d 741) (11th Cir. 1986)), a federal court judge was befuddled by the “science” vigorously debated in his courtroom but, as it turns out, no longer considered debatable in the scientific community. The plaintiff claimed that serious birth defects had been caused by a spermicide used to prevent conception. There was a general consensus in the scientific community that because of its chemical properties, the spermicide could not produce the effects alleged. Nevertheless, the trial judge, sitting without a jury, accepted the causal relationship and awarded $5.1 million in damages. The figure was reduced on appeal to $4.7 million.

According to a study of the case by Samuel Gross (Gross 1991), the outcome was entirely at odds with a broad scientific consensus. An editorial in the New York Times described the unfortunate judge’s reasons as “an intellectual embarrassment” (New York Times 1986).

Jurors feel less of a vested interest in the legal system than do judges, and occasionally speak the unspeakable.

Take the Vioxx litigation. At one time there were about 7000 Vioxx lawsuits pending against Merck. In the first of those lawsuits to go to trial, Merck was found liable by a jury to pay $253 million to a single claimant. Merck adduced a mass of expert evidence to establish that the unfortunate deceased did not fit the Vioxx risk profile, having only taken Vioxx for a few weeks before his fatal heart attack. Merck’s scientific evidence suggested a danger threshold of about a minimum of 18 months (Woolner 2005) and denied there was any reputable scientific basis to the plaintiff’s claim. Not only was Merck’s evidence not accepted, but a posttrial press conference revealed:

Whenever Merck was up there it was like “wah wah wah,” juror John Ostrom told reporters, “we didn’t know what the heck they were talking about.”

Whether or not Merck’s case was valid, a “wah wah wah” verdict is not a satisfying or legitimate disposition of a case with such massive commercial and health-care implications.

High Stakes for the Biotech Industries

Patent law is intended to encourage the development of new, useful, and nonobvious inventions for the benefit of society. A bargain is struck between the inventor and the public: In exchange for disclosing the invention and teaching how it may be practiced upon expiry of the patent, the inventor gets the exclusive right to make, construct, use, and sell the invention for 20 years. A 20-year monopoly is a significant price for the public to pay, so consideration is always given to a fundamental concern: What is the public getting in return for the exclusion of competition?

The critics of gene patenting fear that patents on these fundamental tools of scientific research will inevitably inhibit downstream innovation and restrict patients’ access to affordable and effective healthcare. John Sulston, head of the British effort in the Human Genome Project and joint winner of the 2002 Nobel Prize in Medicine, publicly cautioned that “many human genes have patent rights on them and this is going to get in the way of treatment [and research] unless you have a lot of money” (Jha 2010).

Much of the scientific opposition to gene patents is based, as mentioned, on DNA’s capacity to encode information. James Watson and Francis Crick never attempted to patent the helical structure of DNA they identified because, although DNA is a chemical entity, Watson insists that “its importance flows from its ability to encode and transmit the instructions for creating humans. Life’s instructions ought not to be controlled by legal monopolies created at the whim of Congress or the courts.”

6See Woolner (2005).

In the public policy debate, Myriad has become the poster child for the evils of subjecting genetics to commercial monopolies. Just before Myriad Genetics, Justice Stephen Breyer cautioned in Mayo Collaborative Services et al. v. Prometheus Laboratories, Inc. (132 S. Ct. 1289) (2012) (at 1293):

"Phenomena of nature, though just discovered . . . are not patentable, as they are the basic tools of scientific and technological work. And monopolization of these tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."

On the other hand, there is no doubt that in terms of "bargain theory," Myriad provided the public with a massive benefit through its work on the BRCA genes and their role in breast cancer and ovarian cancer. Myriad's discoveries have helped hundreds of thousands of cancer patients, medical professionals, researchers, and public health authorities in the United States alone. The biotech industry claims to rely on patents to amass the considerable investment needed to develop its products. Certainly the money has to come from somewhere. The U.S. Patent and Trademark Office has historically been particularly aggressive in patenting genes and gene fragments; between 1971 and 2006, approximately 33,000 nucleic acid patents were issued in the United States alone (Merrill and Mazza 2006).

With so much at stake, Myriad's shareholders no doubt expected that if the intellectual foundation of their multimillion-dollar business was about to be devastated, the judges responsible for guiding the wrecking ball would have at least considered the accuracy of the scientific arguments for and against the validity of the patent.

**PRODUCTS OF NATURE**

One important check on the patent bargain is the distinction between discoveries and inventions, a distinction that is maintained in patent regimes throughout the world. Only inventions are patentable.

The theory is that if a scientist discovers what is actually a "product of nature"—some aspect of the natural world that preexists its identification by human beings, like "the heat of the sun, electricity or the quality of metals"—any beneficial utility arising from the discovery is the result of nature's handiwork and not the patentee's. The public would have paid the patentee a 20-year monopoly in return for something that was already part of the "commons."

In 1902 the English judge Buckley provided the following rationale:

"Discovery adds to the amount of human knowledge, but it does so only by lifting the veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result."

A century later, in Apotex Inc. v. Wellcome Foundation Ltd., a unanimous Supreme Court of Canada agreed:

A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act. Monopolies are associated in the public mind with higher prices. The public should not be expected to pay an elevated price in exchange for speculation, or for the statement of "any mere scientific principle or abstract theorem" (s. 27(3)), or for the "discovery" of things that

BRCA1/2 DNA and the isolated BRCA1/2 DNA claimed—render the claimed DNA markedly different."

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9*Funk Brothers Seed Co. v. Kalo Inoculant Co.* (333 U.S. 127) (S. Ct. 1948) at 130.


11*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77 at 37.
already exist, or are obvious. The patent monopoly should be purchased with the hard coinage of new, ingenious, useful and unobvious disclosures.

Thus, regardless of the extraordinary exercise of skill and imagination required to unlock nature’s unknown secret, it will remain “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”

In the United States, the so-called “product of nature doctrine” purports to distinguish between “a hitherto unknown natural phenomenon” and “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character and use.’”

This test is of uncertain scope, and its application is sometimes difficult to predict. Thus, courts have rejected patents on such products as diverse as a combination of naturally occurring bacterial strains, purified vanadium (In re Marden (47 F.2d 958) (C.C.P.A. 1931)), and fruit skin treated with mold-resistant borax (American Fruit Growers v. Brogdex Co. (283 U.S. 1) (S. Ct. 1931)). In contrast, patents have been upheld on purified adrenaline capable of therapeutic application, isolated prostaglandins (In re Bergstrom (427 F.2d 1394) (C.C.P.A. 1970)), and a purified and isolated DNA sequence encoding human erythropoietin (Amgen, Inc. v. Chugai Pharmaceutical Co. (927 F.2d 1200) (Fed. Cir. 1991)).

IS NOT EVERYTHING A “PRODUCT OF NATURE”?

In one of the classic biotech patent cases, Justice Felix Frankfurter observed that ultimately more or less everything is a “product of nature.” We note the disconnect between this statement and the U.S. Commissioner of Patents’ contention to Congress that “anything under the sun” could be patented, cited by the U.S. Supreme Court in Diamond v. Chakrabarty. In that case, consistent with a broad view of patent law (but without adopting an “anything under the sun approach”), the court upheld as patent-eligible subject matter a species of genetically engineered bacteria that could break down crude oil. The invention was (and still is) used to clean up oil spills.

The patenting of modified genes and their progeny is now a well-established and relatively uncontroversial practice in courts throughout the world. But the patents at issue in Myriad Genetics, which claimed genes that have not been modified but only “isolated and purified,” were a new and more scientifically complex challenge for courts to address.

THE MYRIAD GENETICS CONTROVERSY

The Myriad Genetics litigation, as it is well known, focused on the “composition of matter”...

12 Funk Brothers, supra, at 130.
14 Funk Brothers, supra.
15 Parke-Davis, supra.
16 Funk Brothers, supra, at 134–145, per Frankfurter, J., concurring.
17 Chakrabarty, supra, at 309.
18 Note that in Canada, the Supreme Court has departed from most jurisdictions in the world and rejected as unpatentable the Harvard oncomouse, the genetically modified rodent with a heightened susceptibility to cancer: Harvard College v. Canada (Commissioner of Patents), [2002] 4 S.C.R. 45 (S.C.C.).
19 The impugned claims of Myriad’s patent directed at the BRCA1 gene (U.S. Patent No. 5,747,282) read:

1. An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2.
2. The isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1 [complementary DNA claim] . . .
5. An isolated DNA having at least 15 nucleotides of the DNA of claim 1.
6. An isolated DNA having at least 15 nucleotides of the DNA of claim 2.
7. An isolated DNA selected from the group consisting of:
   a. a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having T at nucleotide position 4056;
   b. a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having an extra C at nucleotide position 5385;
   c. a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having G at nucleotide position 5443; and,
   d. a DNA having the nucleotide sequence set forth in SEQ ID NO:1 having 11 base pairs at nucleotide positions 189-199 deleted.
claims for two isolated human gene sequences (BRCA1 and BRCA2) and certain mutations in these genes associated with a predisposition to breast and ovarian cancers.\textsuperscript{20} As compared to the average woman’s 12% or 13% risk of developing breast cancer in her lifetime, women with the BRCA mutations face a cumulative risk of between 40% and 85% (Gold and Carbone 2010). For ovarian cancer, the rates jump from 1.4% in the general population to 16%–40% in those possessing the BRCA mutations.

Myriad had developed a diagnostic test for identifying mutations in the BRCA1 and BRCA2 “isolated gene sequences,” as distinguished from the wild-type sequences. Myriad’s diagnostic tools help to determine whether to undertake preventative options, including prophylactic surgery, and help to structure an appropriate course of treatment, as certain forms of therapy are more effective in treating cancers related to BRCA mutations. A famous beneficiary of the diagnostic test is the actress Angelina Jolie.

The importance of locating and sequencing these BRCA genes is undoubted. In terms of ingenuity and innovation, Myriad has paid “hard coinage” for its monopoly. However, the question that went up to the Supreme Court was whether, regardless of the medical importance of Myriad’s findings, the isolated BRCA1 and BRCA2 genes are “products of nature” and therefore patent-ineligible subject matter.

\textbf{JUDGMENT AT THE DISTRICT COURT LEVEL}

At first instance, on a motion for summary judgment,\textsuperscript{21} District Judge Sweet of the District Court for the Southern District of New York concluded that isolated DNA is not patentable subject matter (\textit{Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al.} (702 F. Supp. 2d 181) (S.D.N.Y. 2010)).

District Judge Sweet began his decision by diving head-on into molecular biology, acknowledging the fundamental importance of the underlying science both to the patents at issue and to his conclusions.\textsuperscript{22} The relevant science remained front and center throughout the judgment. Although the learned judge reviewed each party’s policy arguments regarding the impact of gene patents and of Myriad’s patents specifically on scientific and medical innovation, he put aside those disputes as outside his immediate mandate.\textsuperscript{23} Similarly, he found that the long line of biotech patent cases preceding \textit{Myriad Genetics} provided limited guidance, given DNA’s unique role as an information carrier:

Any “information” that may be embodied by adrenaline and similar molecules serves no comparable function, and none of the declarations submitted by Myriad support such a conclusion. Consequently, the use of simple analogies comparing DNA with chemical compounds previously the subject of patents cannot replace consideration of the distinctive characteristics of DNA.\textsuperscript{24}

For District Judge Sweet, the essence of the claimed invention was its structure. And despite the significant value that Myriad had contributed to cancer research and treatment by disclosing this structure, Myriad had not created anything “markedly different” from natural DNA so as to earn a patent.\textsuperscript{25} He concluded:

The resolution of these motions is based upon long recognized principles of molecular biology and genetics: DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA’s existence in an “isolated” form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to “isolated DNA” containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter under 35 U.S.C. § 101.\textsuperscript{26}

\begin{itemize}
\item \textsuperscript{20}Myriad also laid claim to various associated methods to assist in the diagnosis and treatment of breast cancer and ovarian cancer, which were upheld by the Court of Appeals for the Federal Circuit and not appealed to the Supreme Court.
\item \textsuperscript{21}Compared to a full trial, summary judgment motions are a simplified form of procedure involving a limited evidentiary record.
\item \textsuperscript{22}Ibid. at 185.
\item \textsuperscript{23}Ibid. at 206–211.
\item \textsuperscript{24}Ibid. at 229.
\item \textsuperscript{25}Ibid. at 232.
\item \textsuperscript{26}Ibid. at 185.
\end{itemize}
A WAR OF METAPHORS AT THE COURT OF APPEALS

On remand from the Supreme Court following the Mayo case, a majority of the Court of Appeals for the Federal Circuit reversed District Judge Sweet’s judgment on the composition-of-matter claims and upheld the patentability of the isolated BRCA1 and BRCA2 genes and corresponding cDNA (Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al. (689 F.3d 1303) (Fed. Cir. 2012) (Myriad CAFC)).

All three justices agreed (without citing much scientific support) on the questionable assumption that isolated DNA fragments of the human genome do not occur in nature. The division of opinion turned on whether the claimed molecules were “markedly different” from products of nature.

In grappling with the scientific basis of the case, the Court of Appeals turned to more user-friendly, nonscientific analogies to describe how “different” would be different enough to make something patentable.

Each judge wrote a separate opinion. The majority concluded that the claimed isolated DNA molecules were patentable because they exist in a “distinctive chemical form” from DNA in the body, having undergone chemical separation from the surrounding structure. In contrast, the dissent argued that the claimed DNA molecules were unpatentable, as the functional portion of the composition, the DNA sequence itself, is necessarily identical to naturally occurring material.

The Magic Microscope

In its intervention, the U.S. government attempted to make the scientific analysis more accessible to the generalist judges with its somewhat patronizing “magic microscope test.” If the court had access to a microscope capable of visualizing molecular structures, would it be able to “see” within the woman’s body the BRCA1 and BRCA2 genes and their mutations? If so, on this theory, the “composition of matter” claims were simply the “products of nature” and ineligible for a patent.

Justice Lourie, for the majority, rejected this analogy:

The government’s microscope could focus in on a claimed portion of any complex molecule, rendering that claimed portion patent ineligible, even though that portion never exists as a separate molecule in the body or anywhere else in nature, and may have an entirely different utility. This would discourage innovation.

In Justice Lourie’s view, the BRCA molecules were inventions because they had been “cleaved” from the larger DNA sequence that exists in nature. Cleavage involved the severing of the covalent chemical bonds—an exercise he considered to require great skill and technical expertise. Justice Lourie wrote that patentability of the gene sequences was based entirely on principles of patent law and had nothing to do with “whether it is desirable for one company to hold a patent or licence covering a test that may save people’s lives or for other companies to be excluded from the market encompassed by such a patent.” In his view, the outcome was a relatively orthodox application of the patent law definition of invention as interpreted by the courts throughout the years.

Metaphors from Sports, Anatomy, and Travel

Each of the appellate justices took up and debated the “real world” analogies proposed by their colleagues. In defining the scope of patent-eligible subject matter, the minority and the dissent both compared isolated DNA to a baseball bat, with differing conclusions about whether a

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27The court also upheld various associated method claims designed to assist in the diagnosis and treatment of breast cancer and ovarian cancer.
28Ibid. per Lourie, J., at 52, per Moore, J., at 100–101, and per Bryson, J., at 127.
29Ibid. at 61.
30Ibid. at 136–137.
31Ibid. at 55–56.
32Ibid. at 70–71.
33Ibid. at 61.
34Ibid. at 50.
baseball bat could be considered patent-eligible subject matter (a rather different argument, it would seem, than one about gene sequences). As to baseball bats, Justice Moore for the minority wrote:

“[M]an has defined the parts [of the tree] that are to be retained and the parts that are to be discarded, and he has molded (sic) the retained portion into a product that bears little resemblance to that which occurs naturally.” The exact same thing is true with regard to primer and probe claims. Man has whittled the chromosomal DNA molecule down to a 15 nucleotide sequence—defining the parts to be retained and discarded. And the result is a product with a function (primer or probe) that is entirely different from the full gene from which it was obtained.

In his dissent, Justice Bryson floated the idea that if the majority were correct that only isolation and purification were required, what about a kidney surgically removed from a patient’s body? Why wouldn’t the “isolated” and cleaned-up kidney be patentable? On the hunt for a more plausible metaphor, however, he went on to suggest that “extracting a gene is akin to snapping a leaf from a tree”:

Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention . . . That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf, unless those differences imparted “markedly different characteristics” to the plucked leaf. [citations omitted]

No, no, no, replied the majority, “[s]napping a leaf from a tree is a physical separation, easily done by anyone. Creating a new chemical entity is the work of human transformation, requiring skill, knowledge and effort.” On this reasoning, the ingenious “transformation” technology may well be patentable subject matter. But why should the patent monopoly be extended to the gene sequence itself?

Prior to the Supreme Court hearing, a significant piece of scientific information was advanced in the brief filed by Eric Lander, founding director of the Broad Institute of Massachusetts Institute of Technology and Harvard and a former leader of the Human Genome Project.

In contrast to the assumption shared by all members of the Court of Appeals panel, the Lander Brief reviewed 30 years of scientific literature demonstrating that isolated DNA fragments, including the ones claimed in Myriad’s patents, are routinely found in nature.

At the hearing, several of the Supreme Court justices pressed Myriad’s counsel to respond to the scientific literature suggesting that isolated BRCA genes were, in fact, naturally found in the body. Justice Breyer asked:

I want to know [if the Lander Brief is wrong], because I have to admit that I read it and I did assume that as a matter of science it was correct. So I would like to know whether you agree, as a matter of science, that it is correct, not of law, but of science

After some equivocating by Myriad’s counsel, Justice Breyer asked again:

If you are saying it is wrong, as a matter of science, since neither of us are scientists, I would like you to tell me what I should read that will, from a scientist, tell me that it’s wrong.

Myriad’s attorney finally mustered this response:

Justice Lourie was exactly correct to say that there is nothing in this record that says that isolated DNA fragments of BRCA1 exist in the body. Nei-
ther does Dr. Lander's brief, for that matter. And for that matter, those isolated fragments that are discussed in Dr. Lander's brief again are—are what are known not—not in any way as isolated DNA, but as pseudogenes.42

Critics quickly pounced on this answer as a mischaracterization of the Lander Brief, which does not mention pseudogenes and explicitly states that isolated BRCA1 and BRCA2 fragments are very common both inside and outside cells of the human body.43 In fact, a declaration filed by Mark Kay in the district court case had provided support for Justice Lourie’s position,44 but counsel to Myriad was apparently not prepared (or willing) to discuss the underlying science in the Supreme Court in any meaningful way.

The Descent into Cooking, Sports, and Travel

In spite of this scientific time bomb ticking in the middle of the case, the Supreme Court justices embarked on a series of nonscientific analogies, as had their colleagues on the Court of Appeals.

Chief Justice Roberts was drawn back to the baseball bat. He suggested that this was a true invention, because “[y]ou don’t look at a tree and say, well, I’ve cut the branch here and cut it here and all of a sudden I’ve got a baseball bat.”45 Conversely, the BRCA genes did not require invention, because “[y]ou snip off the top and you snip off the bottom and there you’ve got it.”

Counsel for Myriad later seized on this analogy to downplay the impact of the Lander Brief. He submitted that the brief only suggested that isolated DNA molecules could exist, just as a baseball bat could possibly exist in nature if a branch fell off a tree into the ocean, was eroded by the waves, and eventually washed up on shore.46

Justice Sotomayor preferred a sweeter metaphor: If the chromosome were a chocolate chip cookie, weren’t the claimed BRCA1 and BRCA2 genes no more patentable than the salt, flour, eggs, and butter used to make that cookie?47

Then there was the mythical trip to Amazonia. Comparison was made between the BRCA1 and BRCA2 genes in a human chromosome and a plant in the Amazon forest: If “Captain Ferno” ventures into the forest, uproots an indigenous plant, and carries it back to the United States, does he or she have something patentable?48

After all these literary allusions, the scientific observer might be left to wonder exactly what role the actual science played in the Supreme Court’s reasoning.

A MIXED RECEPTION TO THE SUPREME COURT’S DECISION

Some scientists have embraced the Supreme Court’s decision. Geneticist Mary-Claire King, who led the team that originally localized the BRCA1 gene more than 20 years ago, called the decision “a fabulous result for patients, physicians, scientists, and common sense” (Reardon 2013). Eric Lander told the New York Times that “[t]he Supreme Court got it exactly right” (Pollack 2013). In his view, the decision was a victory for science, patients, and the biotech industry. It is not clear that the biotech industry shared his enthusiasm for the “victory.”

Other scientists have argued that whatever may be the merits of the Supreme Court’s decision in terms of public policy, the reasons of Justice Thomas do not withstand scientific scrutiny. For example, Justice Thomas’s decision refers to introns as “nucleotides that do not code for amino acids” and to cDNA as “composite DNA” (an error that appears to have been fixed in the online version of the decision).49 These, admittedly, are errors of marginal significance in the overall scheme of the judgment.

Still other critics have questioned the validity of the distinction drawn between “natural”

\[\text{\small 42Ibid. at p. 47–48.} \]
\[\text{\small 43Lander Brief, supra, at p. 14–15. See, e.g., Cohen (2013).} \]
\[\text{\small 44Declaration of Dr. Mark A. Kay, executed December 21, 2009, at 131–137, USSC Hearing at p. 40.} \]
\[\text{\small 45USSC Hearing, ibid., at p. 41.} \]
\[\text{\small 46Ibid. at p. 48.} \]

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DNA and cDNA in light of the fact that both serve as information carriers (Fisher 2013). One wonders whether the court’s carve-out for cDNA will be revisited once the magic of gene splicing wears off (if it hasn’t already). As one lawyer lamented, “It’s one of these situations where candidly, it just makes me sad there isn’t a higher level of basic biology knowledge in the world. . . . Unfortunately, this is the Supreme Court.”

A FEW CONCLUSIONS

Although there will always be differences of opinion on the outcome of a case, the legitimacy of court decisions ultimately depends on the public being satisfied that the judges understand what they are talking about.

Judges and lawyers are storytellers, generally without much scientific training, and storytellers naturally reach for analogies and metaphors. But analogies and metaphors are inherently imprecise and can be misleading.

Moreover, as was seen in the Myriad Genetics case, the argument can become in many ways a battle of metaphors rather than a coming to terms with the underlying science. For comprehensive judges and juries, metaphors may be a convenient excuse to ignore the need to understand the underlying science properly but such apologias are not much comfort to those whose investments and livelihoods are at stake.

There are extenuating circumstances. The courtroom, with all its formalities and cumbersome evidentiary rules, may be a poor schoolhouse for judges and “dueling experts” may make bad teachers. Courts are, however, the masters of their own procedure and have the flexibility to modify to their own advantage the framework within which experts testify. Why, for example, in a case like Myriad Genetics that required the judges to grapple with serious scientific evidence, could the parties not have arranged for a prior out-of-court seminar on the basic science specific to the dispute? Such modifications of the adversarial process have been used in other courts in patent cases, including the British House of Lords (hardly a revolutionary institution) in Kirin-Amgen Inc. v. Hoechst Marion Roussel Ltd. (No. 2). The court explained:

. . . the work which Professor Yudkin did by means of these carefully prepared seminars enabled all those involved to concentrate on the issues of law in the appeal without having to spend a good deal of extra time in the course of the hearing on learning about the technology.

Similarly, judges of the Federal Court of Canada have been greatly assisted when parties in complicated patent proceedings submit, sometimes jointly, a tutorial or video backgrounder on the basic science at play. Experts are now routinely ordered into “Australian hot tubs” to testify in the presence of one another. Codes of professional ethics for scientific witnesses and other experts are being strengthened.

A result reached in which the “science” debated in court bears little relation to the scientific consensus in the “real world” lacks legitimacy. Courts need to rethink their procedures. The adversarial system needs to become more scientifically literate. The science and the law must collaborate rather than live as two solitudes in mutual incomprehension. There is still time, as Justice Learned Hand said in 1911, for “all fair persons not conventionalized by provincial legal habits of mind . . . [to] unite to effect some such advance.”

REFERENCES


Ibid.

Kirin-Amgen, Inc. v. Hoechst Marion Roussel Ltd. (No. 2), [2004] UKHL 46 at ¶135.

Parke-Davis, supra, at 51.


Baseball Bats and Chocolate Chip Cookies: The Judicial Treatment of DNA in the *Myriad Genetics* Litigation

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