

## NARRATIVES OF GENE PATENTING

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### ABSTRACT

*The debate over gene patenting in the United States has been ongoing for nearly three decades. It peaked in June 2013, with the Supreme Court's controversial decision in Assn. for Molecular Pathology v. Myriad Genetics. The Myriad case was remarkable for many reasons, not least because it fostered the emergence of six distinct narratives of the "facts" in dispute. I have termed these narratives Science, Pioneer, Administrative, Access, Dystopian and Anti-Commons. In this article, I trace the origins of each of the narrative types in Myriad from press accounts, published literature and the record in the case, including nearly one hundred separate amicus briefs filed at all stages of the litigation. Both the long time frame of the Myriad dispute, each representing the worldview of a particular stakeholder group, coupled with the large number of actors that it engaged, suggest that these six narratives represent the full complement of distinct narratives concerning the case. If the perspective is expanded beyond Myriad itself, these six narrative types may also be viewed a taxonomy of narratives within the broader realm of disputes involving new technology, scientific discovery and innovation.*

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## INTRODUCTION

The debate over gene patenting in the United States has been ongoing for nearly three decades. It peaked in June 2013, with the Supreme Court's controversial decision in *Assn. for Molecular Pathology v. Myriad Genetics*<sup>1</sup>. The *Myriad* case was remarkable for many reasons, not least because it fostered the emergence of six distinct narratives<sup>2</sup> of the "facts" in dispute. I have termed these narratives Science, Pioneer, Administrative, Access, Dystopian and Anti-Commons. In this article, I trace the origins of each of the narrative types in *Myriad* from press accounts, published literature and the record in the case, including nearly one hundred separate amicus briefs filed at all stages of the litigation. Both the long time frame of the *Myriad* dispute, each representing the worldview of a particular stakeholder group, coupled with the large number of actors that it engaged, suggest that these six narratives represent the full complement of distinct narratives concerning the case. If the perspective is expanded beyond *Myriad* itself, these six narrative types may also be viewed a taxonomy of narratives within the broader realm of disputes involving new technology, scientific discovery and innovation.

The use of narratives to explain philosophical and legal concepts has its roots in antiquity, with prominent examples cropping up throughout

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<sup>1</sup> 569 U.S. \_\_\_ (2013).

<sup>2</sup> The term "narrative" has entered the popular lexicon and, as such, is often used imprecisely. Numerous formal definitions exist. One such definition holds that a narrative must consist of at least: (a) two distinct events, (b) occurring in a temporal sequence, (c) that evidence a transformation or movement of some kind. See DENNIS R. KLINCK, THE WORD AND THE LAW 291-92 (1992) (citing Gülich & Quasthoff, *Narrative Analysis* in HANDBOOK OF DISCOURSE ANALYSIS, VOL. 2, DIMENSIONS OF DISCOURSE (T.A. van Dijk, ed. 1985). See also Lisa Kern Griffin, *Narrative, Truth and Trial*, 101 GEO. L.J. 281, 286-87 (2013) (summarizing definitions of 'narrative' offered by literary theorists Kenneth Burke and Roland Barthes); Jane B. Baron & Julia Epstein, *Is Law Narrative?* 45 BUFF. L. REV. 141, 146-48 (1997) (distinguishing among "rhetoric", "story" and "narrative" for purposes of legal analysis); Bernard S. Jackson, *Narrative Models in Legal Proof* 166, 175 in NARRATIVE AND THE LEGAL DISCOURSE: A READER IN STORYTELLING AND THE LAW (David Ray Papke, ed., 1991) (identifying temporality, action and intelligibility as the three elements of narrative). Another aspect of narrative (and the study of narratives, referred to occasionally as *narratology*) is the identifiability of a narrator (a speaker), the narrated (the entities to which things happen in the narration), and a narratee (the audience/listener). KLINCK, *supra*, at 291-92 (citing Prince, *Greimassian Narratology*, 58 SEMIOTICA 371, 371 (1986)). While some legal scholars use the term "narrative" informally to encompass a wide range of rhetorical devices such as statements of political position (e.g., the "pro-life narrative"), this usage diverges from the understanding of narrative among literary scholars, to which I attempt to hew in this paper.

classical<sup>3</sup> and Biblical texts.<sup>4</sup> Stories help their recipients (listeners and readers) to contextualize and temporalize complex sequences of events and to enhance their comprehension and recollection.<sup>5</sup> Cognitive scientists teach us that stories act as heuristics that enable us to place events within a recognizable framework and that, as such, they are essential to our processing and retention of information.<sup>6</sup>

The use of narrative to influence public policy has been well-documented, and others have observed how competing accounts of gene patenting have influenced both administrative agencies and legislative bodies considering patent law reform.<sup>7</sup> But perhaps the most pervasive and systematic use of narrative in lawmaking occurs in litigation. Every legal dispute arises from some combination of events coupled with the parties' actions and mental states. All of these taken together can broadly be termed "facts". At the outset of a dispute, the facts of a case consist of an undifferentiated and virtually infinite collection of information about the state of the world. In constructing a narrative, a party must distill the salient facts from the irrelevant ones.<sup>8</sup> This condensation process is essential, as excessively complex and convoluted stories are difficult for adjudicators (both judges and juries) to understand and internalize. In order to persuade, a narrative must be succinct and coherent.

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<sup>3</sup> See Stefan Iversen, *Narratives in Rhetorical Discourse* in *The Living Handbook of Narratology*, <http://www.lhn.uni-hamburg.de/article/narratives-rhetorical-discourse> (accessed March 30, 2014) (describing the classification and use of narrative in Aristotle's *Rhetoric*).

<sup>4</sup> GERARD LOUGHIN, *TELLING GOD'S STORY: BIBLE, CHURCH AND NARRATIVE THEOLOGY* (1996); GEORGE W. STROUP, *THE PROMISE OF NARRATIVE THEOLOGY* (1981).

<sup>5</sup> See, e.g., Nancy Levit, *Reshaping the Narrative Debate*, 34 SEATTLE U. L. REV. 751, 758-59 (2011) (summarizing neuroscience findings regarding narrative and recollection and comprehension).

<sup>6</sup> See Griffin, *supra* note 2, at 312-15 (describing use of heuristics by juries); John Martinez, *From Lark Rise to Storied City*, \_\_\_ BRIT. J. AM. LEGAL STUD. \_\_\_ (forthcoming 2014) (providing overview of cognitive science and law literature). Cf. Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 20-23 (2010) (observing that lay audiences require metaphors and simplifying heuristics to process complex information and applying this observation to the analysis of judicial interpretation of technology-based cases).

<sup>7</sup> Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECH. 1091, 1094 (2006) ("policy makers may be responding more to a high-profile anecdote or arguments with high face validity than they are to systematic data on the issues").

<sup>8</sup> As Livia Polanyi notes, "[e]very world is composed of innumerable states of affairs ... However, only a few of these are significant to the point of being made in a given telling". LIVIA POLANYI, *TELLING THE AMERICAN STORY: A STRUCTURAL AND CULTURAL ANALYSIS OF CONVERSATIONAL STORYTELLING* 13 (1985).

The facts that a party selects to recount, and the order in which they are recounted, reflect a particularized view of a dispute. It is inevitable that the narratives of opposing parties will differ, if not conflict, in at least some of their details. This is to be expected, as narrative construction is not an objective exercise, even when some events are uncontested.<sup>9</sup> Rather, each party, when constructing its narrative, runs the large and undifferentiated mass of facts through internal filters.<sup>10</sup>

The first such filter consists of a party's particular background, desires, recollections, legal positions and view of the world, or "worldview."<sup>11</sup> It is well-known that a narrator's worldview deeply influences the narratives that he or she tells. Consider, for example, the differing accounts of warfare offered by combatants on opposing sides of a conflict and by affected civilians. Or the different perspectives on street violence portrayed in Spike Lee's film *Do the Right Thing*.<sup>12</sup> Narrative is clearly subjective.

Narrative differences attributable to different worldviews often emerge subconsciously; they simply reflect the way that the narrator experiences the world. But narrative can also be shaped more deliberately, both by the inclusion and omission of facts perceived to be harmful or helpful to one's case. In classical rhetorical terms, a party's narrative necessarily amplifies some facts and diminishes others.<sup>13</sup>

At some level, every narrative relating to a dispute must have common elements which are either so indisputable or central that they must be included. For example, consider an automobile accident in which John

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<sup>9</sup> NEIL MACCORMICK, *LEGAL REASONING AND LEGAL THEORY* 92 (1978) ("When there is a conflict of evidence in a case, the effect may be the construction of two rival coherent versions of the past").

<sup>10</sup> See Hayden White, *The Value of Narrativity in the Representation of Reality* 10 in *ON NARRATIVE* (W.J.T. Mitchell, ed. 1981) ("every narrative, however seemingly 'full', is constructed on the basis of a set of events which might have been included but were left out"); DENNIS R. KLINCK, *THE WORD AND THE LAW* 293-94 (1992).

<sup>11</sup> The term "worldview" (*weltanschauung*) was introduced into the philosophical lexicon by Kant in his *Critique of Judgment* (1790). It means, broadly speaking, one's intuitive sense of the world. IMMANUEL KANT, *CRITIQUE OF JUDGMENT: INCLUDING THE FIRST INTRODUCTION* 111-12 (1790, trans. and intro. Werner S. Pluhar, with a foreword by Mary J. Gregor (1987)). The concept has frequently been applied to legal thought. See GUYORA BINDER & ROBERT WEISBERG, *LITERARY CRITICISMS OF LAW* 125 (2000) (describing use of the worldview and similar concepts in the hermeneutic tradition); Brooks, *supra* note x, at 11 (describing Roland Barthes's *doxa*, "that set of unexamined cultural beliefs that structure our understanding of everyday happenings").

<sup>12</sup> cite

<sup>13</sup> See ANTONIN SCALIA & BRIAN GARNER, *MAKING YOUR CASE* 94-95 (2008).

strikes Mary's car while driving through a 4-way intersection in Toledo, Ohio. Each party is likely to include in his or her narrative the time of day at which the accident occurred, whether it was raining, and the make and model of the other party's car. By the same token, there are some facts that, even if undisputed, are just so irrelevant that they need not be mentioned at all. The fact that it was sunny in Beijing at the time of the accident has no bearing on the case and each party will intuitively filter this fact from the narrative.

But beyond these obvious inclusions and omissions, each party has significant leeway to determine what facts to include. Thus, John's narrative may note that he is a physician of longstanding reputation in the community, and that Mary is a high school student who has been driving for only six months. Mary's narrative, on the other hand, might note that she is a straight-A student, and that John was returning from an office holiday party at which alcohol was served. Even assuming that each of these narratives recounts facts that are objectively true,<sup>14</sup> they portray very different pictures of the parties and the surrounding events. Thus, narrative is subjective, it is selective, and it is normative. As observed by Dennis Klinck, "in our stories, we re-create reality so as to make a point, implicitly or explicitly. Our stories are inevitably 'biased'".<sup>15</sup>

Unlike literary narratives, of course, stories in legal disputes are not told for their own sake. Rather, parties construct legal narratives as the foundations for *arguments* that they use while attempting to persuade courts to rule in their favor. After all, the point of litigation is not storytelling, but winning. Broadly speaking, the arguments advanced in litigation can be placed into two broad categories: "doctrinal": those arguments relating to what the law *is*, based on precedent, statutory authority, legislative intent, constitutional principles, and the like; and "policy", arguments that advocate what the law *ought to be*, based on notions of justice, fairness, efficiency, predictability, custom, administrability, social utility and similar considerations.<sup>16</sup>

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<sup>14</sup> The picture is further complicated by the fact that human memory is not only fallible, but consistently fallible. Individual recollections of events differ, and so long as every moment of our lives is not recorded on camera (a state of affairs that, alas, is rapidly changing), it cannot be assumed that even truthful recollections of facts can be assumed to be accurate. See, e.g., CHRISTOPHER CHABRIS & DANIEL SIMONS, *THE INVISIBLE GORILLA AND OTHER WAYS OUR INTUITIONS DECEIVE US* (2010) (recounting notorious examples of the failure of human memory, particularly in eyewitness legal testimony).

<sup>15</sup> KLINCK, *supra* note 10, at 294.

<sup>16</sup> The modalities of legal argument have been analyzed extensively in the literature. See, e.g., SCALIA & GARNER, *supra* note 13, at 26-30.

Neither doctrinal nor policy arguments are, themselves, narratives. That is, arguments are not stories and do not meet the general criteria of narrative (e.g., having a speaker, characters, events and some temporal arc).<sup>17</sup> A party's arguments are, however, supported by its narrative of the case and, if the narrative is sufficiently compelling, that party's arguments may remain entirely tacit, advanced simply by virtue of a strong narrative.

The *Myriad* case, like any other, gave rise to competing narratives. But *Myriad* is exceptional, in that its complex facts and long history generated not two, but *six*, distinct narratives. The competing narratives in *Myriad* were constructed by the litigants and *amici curiae* as well as external observers (scholars, commentators and the popular press), and adopted to a greater or lesser degree by the courts. These narratives supported a wide range of doctrinal, ethical, philosophical and economic arguments. Unlike the vast majority of literature dealing with *Myriad*, this article does not evaluate or advance any particular doctrinal or policy argument made by the parties or adopted by the courts. Rather, it focuses on the underlying narratives that provided the scaffolding on which the parties and the courts built their respective arguments.<sup>18</sup>

In Part I, I describe the factual and legal background of the *Myriad* case, as well as the background debate over gene patenting in the United States. In Part II, I distill and compare the six principal narrative strains that emerged from the *Myriad* case based on public sources and the record in the case. In Part III, I trace these narrative strains in the judicial decisions at the trial, appellate and Supreme Court levels, analyzing the influence of each narrative on the judicial opinion and decision. I conclude with observations regarding the generalizability of the six narrative types identified in *Myriad* to other cases involving innovation.

## I. MYRIAD AND THE GENE PATENTING DEBATE IN THE U.S.

At its heart, *Myriad* and the broader legal debate over gene patenting center on a narrow and fairly esoteric question of patent law: whether the so-called “product of nature” doctrine renders human DNA sequences ineligible for patent protection under Section 101 of the Patent Act.<sup>19</sup> This question is both nuanced and multifaceted, and much of the debate in the

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<sup>17</sup> See note 2, *supra*.

<sup>18</sup> See Table 1, *infra*, and accompanying text for an analysis of the correspondence between these narratives and various policy arguments.

<sup>19</sup> 35 U.S.C. Sec. 101.

literature and the courts has focused on answering it.<sup>20</sup> In this article, I largely avoid the product of nature debate and other doctrinal issues raised by *Myriad*, except to the extent that they are directly implicated by one or more of the narratives discussed.

### A. GENES AND DISEASE<sup>21</sup>

The nucleus of every human cell contains vast numbers of intertwined strands of DNA, each of which consists of approximately 3.2 billion paired molecules called nucleotides or bases.<sup>22</sup> There are four types of DNA nucleotide: adenine (A), thymine (T), cytosine (C), and guanine (G).

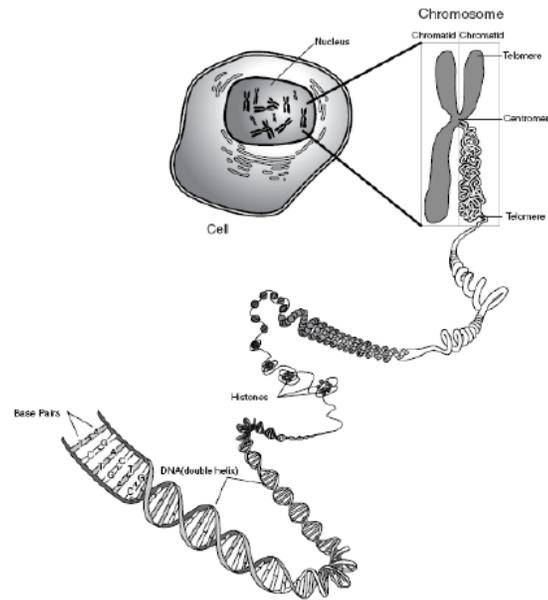
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<sup>20</sup> The literature discussing the “product of nature” doctrine in the context of gene patenting is too large to enumerate here. *See, e.g.*, [Burk 2013, Eisenberg 2012, others].

<sup>21</sup> This Part contains a basic explanation of the scientific terminology and concepts used throughout this article. Most of this information can be found in any modern biology textbook. In some cases, I have simplified the discussion of complex scientific concepts for the general reader. *See generally* STANLEY FIELDS & MARK JOHNSTON, GENETIC TWISTS OF FATE (2010); ARTHUR M. LESK, INTRODUCTION TO GENOMICS 22 (2007); WILLIAM S. KLUG & MICHAEL R. CUMMINGS, ESSENTIALS OF GENETICS (3rd ed. 1999).

<sup>22</sup> Scientists refer to DNA length in much the same way that we talk about computer memory. One million bases are referred to as a megabase (1 Mb), and one billion bases are referred to as a gigabase (1 Gb). Even though bases in a DNA molecule are always paired, A to T and C to G, and each “rung” of the double-helical DNA ladder consists of two paired bases, the convention is to count each rung as a single unit or base rather than two (so we say that the human genome is 3.2 Gb long, not 3.2 Gb pairs, or 6.4 Gb).

Figure 1  
DNA in a Human Cell<sup>23</sup>



Science still has only the vaguest idea of how DNA coordinates and regulates the millions of biological processes within our bodies, but it is at least known that some regions of DNA help to assemble more complex molecules called proteins, which in turn carry out various tasks that are essential to bodily functioning. The strands of DNA within an organism's cells are typically bound into discrete units called "chromosomes" (each human carries twenty-three pairs of chromosomes). The DNA that forms each chromosome is divided into smaller "genes", which range in length from a few hundred to millions of bases. It is currently estimated that humans have approximately 20,000 distinct genes, each of which performs multiple biological functions.<sup>24</sup>

The DNA *sequence*, the order in which the 3.2 billion pairs of A, T, G and C bases are arranged within our genes, is 99.9% identical in every human being. This is why we each have two arms, two legs, one nose, and so forth. The 0.1% variations in our DNA account for the differences in our

<sup>23</sup> Assn. for Molecular Pathology v. U.S. PTO and Myriad Genetics, \_\_\_ F.3d \_\_\_ (slip op. at 16 Fig. 4) (Fed. Cir. 2011).

<sup>24</sup> In the early 1990s, researchers commonly believed that humans had approximately 100,000 genes. Mary-Claire King, 'The Race' to Clone BRCA1, 343 SCIENCE 1462, 1463 (2014).

physical and physiological make-up, such as height, eye color and hair color. Sometimes variations in an individual's DNA can also lead to hereditary illnesses such as Huntington's disease, Down Syndrome and sickle cell anemia. Each of these conditions is caused by a single "error" in the DNA sequence.<sup>25</sup> These errors are called mutations. There are many factors that can give rise to mutations in human DNA: radiation, disease, aging, and simple bad luck. Some mutations, however, are hereditary. That is, the person carrying the mutation is born with it, and inherited it from one or both parents.

Since the mid-nineteenth century, researchers have hypothesized that certain forms of cancer might be hereditary. Breast cancer, in particular, attracted the attention of early medical professionals who observed an unusually high incidence of the disease among women in certain families.<sup>26</sup> Between the 1920s and 1940s, more researchers began to study cases in which families of breast cancer patients exhibited higher-than-average rates of cancer, lending greater credence to the theory that the disease was hereditary.<sup>27</sup> Throughout the 1960s and 1970s studies of breast cancer inheritance became increasingly sophisticated, with larger and larger sample populations and more advanced statistical analyses.<sup>28</sup>

Today we know that there are, indeed, some cancers that are passed down through families, and that specific mutations in an individual's DNA can greatly increase the risk of cancer. Several cancer-causing mutations occur in two genes that have been designated BRCA1 and BRCA2 ("BREast CAncer" susceptibility genes). Individuals who carry one of several known BRCA1 mutations have a lifetime risk of contracting breast

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<sup>25</sup> The genetic code is often analogized to an alphabet that forms 3-letter words. For example, a portion of a gene may read *cat dog rat ant gnu*. One type of mutation that can occur is called an "insertion", in which a single extra "letter" is inserted somewhere into the code, causing all of the other letters to shift by one space and transforming them into gibberish. Thus, if the letter "x" is randomly inserted into the word "cat" in the above sequence, the resulting code would be: *cxa tdo gra tan tgn*. In other words, the code no longer makes sense, nor can it correctly encode the proteins that would have been generated from the correct sequence.

<sup>26</sup> French surgeon Pierre Broca is believed to have been the first to publish this hypothesis in the 1830s, though his work in this area went largely unnoticed. He is best known for his discovery of certain speech centers of the brain which are now known as "Broca's Area". See DAVIES & WHITE, *supra* note 38, at 80-81; King, *supra* note 24, at 1462.

<sup>27</sup> See V. ELVING ANDERSON, HAROLD O. GOODMAN & SHELDON C. REED, VARIABLES RELATED TO HUMAN BREAST CANCER 7 (1958); King, *supra* note 24, at 1462.

<sup>28</sup> See DAVIES & WHITE, *supra* note 38, at 84.

cancer that is six times greater than that of the general population.<sup>29</sup> Women who carry a known BRCA2 mutation have approximately four times greater risk of contracting breast cancer than women in the general population, and ten times greater risk of contracting ovarian cancer.<sup>30</sup> Recent studies estimate that 5-10% of breast and ovarian cancers (20,000 to 40,000 cases per year in the U.S.) are caused by mutations in the BRCA1/2 genes.<sup>31</sup>

Hereditary mutations are often noticed first in families within closely-knit ethnic groups. This is the case with the BRCA mutations, which occur at a high rate in the Ashkenazi Jewish population and also among Norwegian, Dutch and Icelandic populations.<sup>32</sup> Unfortunately, most of the disease-associated mutations in the BRCA1/2 genes are exceedingly small. In many cases, only one base pair out of more than 80,000<sup>33</sup> is out of place. This makes the mutations very hard to find.

By the 1970s, technology had evolved to a point at which researchers could slowly begin to identify the individual genes responsible for hereditary diseases like cystic fibrosis, Down syndrome and Huntington's disease. Even so, each of these discoveries took years of painstaking work and a measure of good luck to achieve.<sup>34</sup> It was not until 1986 that a revolutionary new process for copying DNA fragments called polymerase chain reaction (PCR) began to enable the large-scale, rapid determination of the nucleotide sequence of DNA molecules through a process called DNA sequencing.

Sequencing enabled researchers to derive the order of A, C, T and G

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<sup>29</sup> Natl. Cancer Inst., Fact Sheet: BRCA1 and BRCA2: Cancer Risk and Genetic Testing, <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA> (visited February 28, 2014) (approximately 12% of women in the general population will develop breast cancer during their lives, compared to 55-65% of women with a known BRCA1 mutation). Today, approximately 1800 distinct mutations have been identified in BRCA1. Fergus J. Couch, Katherine L. Nathanson & Kenneth Offit, *Two Decades After BRCA: Setting Paradigms in Personalized Cancer Care and Prevention*, 343 *SCIENCE* 1466, 1466 (2014).

<sup>30</sup> *Id.* (approximately 45% of women with a known BRCA2 mutation will contract breast cancer, and 11-17% will contract ovarian cancer (as opposed to 1.4% of the general population) during their lives). Today, approximately 2000 distinct mutations have been identified in BRCA2. Couch, Nathanson & Offit, *supra* note 29, at 1466.

<sup>31</sup> Am. Cancer Society, Breast cancer facts and figures, 2005–2006, <http://www.cancer.org/downloads/STT/CAFF2005BrF.pdf>.

<sup>32</sup> Natl. Cancer Inst., *supra* note 29.

<sup>33</sup> BRCA1 is 81,189 bases long; BRCA2 is 84,199 bases long. Gene Cards: The Human Gene Compendium (BRCA1, BRCA2), [www.genecards.org](http://www.genecards.org).

<sup>34</sup> [gene hunters]

bases along a strand of DNA. But the human genome was much too long to sequence in a single experiment. Thus, techniques were developed to sequence short fragments of DNA and to reassemble them into longer segments of interest. If enough segments were connected, the sequence of an entire gene could be determined.<sup>35</sup>

Sequencing was the key to finding disease-linked genetic mutations. If one could identify a particular mutation that occurred in disease sufferers but not in the general population, then it would be possible to develop a diagnostic test to determine who carried the mutation. If the test revealed that an individual carried a risk-elevating mutation, she could make educated healthcare choices including whether or not to undergo prophylactic chemotherapy or surgery before the onset of disease.<sup>36</sup> The life-altering decision faced by carriers of BRCA mutations received global attention last year, when actress Angelia Jolie announced her decision to undergo a prophylactic double mastectomy after being diagnosed as a BRCA mutation carrier.<sup>37</sup>

## B. FINDING BRCA

The dramatic story of the race to sequence the BRCA genes and its aftermath has been told many times. It has been the subject of books,<sup>38</sup> scholarly articles,<sup>39</sup> television documentaries,<sup>40</sup> at least one feature film,<sup>41</sup>

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<sup>35</sup> A decade later, similar techniques were used to sequence the 3.2 billion base pairs constituting the entire human genome in the Human Genome Project.

<sup>36</sup> Recommended prophylactic measures for individuals carrying risk-elevating BRCA1/2 mutations include enhanced screening, chemoprevention typically including the drug tamoxifen, and prophylactic bilateral mastectomy and oophorectomy. See Natl. Cancer Inst., *supra* note 29; Robert Cook-Deegan et al., *Impact of Gene Patents and Licensing Practices on Access to Genetic Testing for Inherited Susceptibility to Cancer: Comparing Breast and Ovarian Cancers with Colon Cancers*, 12 GENETICS IN MED. S15, S26 (2010).

<sup>37</sup> Angelina Jolie, *My Medical Choice*, N.Y. Times, May 14, 2013. See also JONATHAN HERMAN & TERI SMIEJA, LETTERS TO DOCTORS: PATIENTS EDUCATING MEDICAL PROFESSIONALS THROUGH PRACTICAL TRUE-LIFE EXPERIENCES (2013).

<sup>38</sup> SHOBITA PARTHASARATHY, BUILDING GENETIC MEDICINE: BREAST CANCER, TECHNOLOGY AND THE COMPARATIVE POLITICS OF HEALTH CARE (2007); KEVIN DAVIES & MICHAEL WHITE, BREAKTHROUGH – THE RACE TO FIND THE BREAST CANCER GENE (1995).

<sup>39</sup> See, e.g., E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 GENETICS IN MED. S39 (2010); Bryn Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 HEALTH L.J. 123 (2002).

<sup>40</sup> CBS 60 Minutes – Patented Genes, Apr. 4, 2010,

and numerous magazine and newspaper stories.<sup>42</sup> In this Part, I recount this story, particularly as it played out in the U.S.,<sup>43</sup> culled from public sources including scholarly articles and books, as well as the extensive trial record in the *Myriad* case.

Based on observations made during the first half of the twentieth century, by the 1970s many in the scientific community suspected that one or more mutations in a particular gene caused the elevated breast cancer risk seen in Ashkenazi Jewish women. Several important developments in the search for this gene occurred in the early 1970s. First, Mary-Claire King, a researcher at the University of California Berkeley, began a focused research program to search for the gene using data from families exhibiting an elevated incidence of breast cancer.<sup>44</sup> Second, in 1974 Eldon Gardner at the University of Utah, who had been studying cancer inheritance patterns in Mormon families since the 1940s, hired a new researcher named Mark Skolnick. Skolnick's initial assignment was to create a database of the vast collection of Mormon genealogical records maintained by the university<sup>45</sup> and link it to the existing Utah Cancer Registry.<sup>46</sup> Skolnick saw the great research potential of this cross-referenced database, which he later used to continue Gardner's earlier work on breast cancer inheritance.<sup>47</sup> Skolnick and his Utah database soon became a major force in genetics research, leading to collaborations with some of the most prominent researchers in

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<http://www.cbsnews.com/news/should-firms-be-able-to-own-your-genes/>.

<sup>41</sup> Decoding Annie Parker (Entertainment One Films 2013).

<sup>42</sup> See, e.g., Natalie Angier, *Scientists identify a mutant gene tied to hereditary breast cancer*. N.Y. TIMES, Sept. 15, 1994, A1, B7; M. Waldholz, *Finding breast cancer gene is battle, not war, won*. WALL ST. J. B1, B5, Sept. 15, 1994.

<sup>43</sup> The story of BRCA, gene patenting and Myriad Genetics is an international one, with significant developments occurring not only in the U.S, but also in the UK, France, Canada, Australia and Japan. This article focuses on the U.S. because it has been the site of the most heated disputes relating to Myriad's patents, and because the Myriad case rose all the way the U.S. Supreme Court, which issued a decision in June 2013. For a discussion of the landscape and debate outside the U.S., see PARTHASARATHY, *supra* note 38; Gold & Carbone, *supra* note 39. See also Robert Dalpé et al., *Watching the Race to Find the Breast Cancer Genes*, 28 SCI. TECH. HUMAN VALUES 187, 204 Table 3 (2003) (listing 13 countries involved in BRCA research).

<sup>44</sup> King, *supra* note 24, at 1462.

<sup>45</sup> The Church of Jesus Christ of Latter-day Saints, also known as the Mormon Church, based in Salt Lake City, Utah, has kept detailed genealogical records of its members since 1894. By the early 1970s, church records contained detailed genealogies of more than one million members. DAVIES & WHITE, *supra* note 38, at 184-85.

<sup>46</sup> In 1966, the state of Utah began to require that all cancer cases among Utah residents be reported to the state. Utah cancer records extend back to 1952. DAVIES & WHITE, *supra* note 38, at 185.

<sup>47</sup> DAVIES & WHITE, *supra* note 38, at 188.

the field, including King.

By the late 1980s, seven major research groups in the U.S., Europe and Japan had begun to search for the breast cancer gene (now commonly referred to as BRCA).<sup>48</sup> These groups included King's research team at Berkeley, a team at the University of Utah, now led by Skolnick, several researchers at the U.S. National Institutes of Environmental Health Sciences (NIEHS) and a group led by Michael Stratton at the Institute for Cancer Research in London. Despite their competition, in 1989 these different groups joined forces by forming the Breast Cancer Linkage Consortium, a collaborative effort to share research results and accelerate the location of the gene.<sup>49</sup>

A major breakthrough came in 1990, when the King team identified a strong cancer linkage with a particular region of chromosome 17.<sup>50</sup> This discovery enabled the competing research teams to narrow their search to this region, a mere 22 Mb segment of a chromosome approximately 80 Mb in length, or slightly more than one half of one percent of the entire human genome (3.2 Gb). It was as though the police, searching a large apartment building for a stolen jewel, received a tip revealing the particular apartment unit in which the jewel was hidden. Over the next several years, researchers continued to narrow the region in which BRCA1 might be hiding, so that by late 1992 the region of interest was down to 4.5 Mb, and by early 1994 it had been narrowed to only 1 Mb,<sup>51</sup> a single bureau within the suspect apartment unit.

In 1991 Skolnick left the University of Utah to form a private company with Nobel laureate Walter Gilbert and Salt Lake City venture capitalist Peter Meldrum.<sup>52</sup> The company, originally called Helix, was later renamed Myriad Genetics. Its purpose was to identify and sequence the BRCA1 gene and use the results as the basis for a genetic testing business. Myriad raised approximately \$22 million in private equity funding between 1992 and 1994.<sup>53</sup> It also received financial backing from pharmaceutical manufacturer

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<sup>48</sup> Gold & Carbone, *supra* note 39, at S40.

<sup>49</sup> See Breast Cancer Linkage Consor., The Breast Cancer Linkage Consortium – Past, Present and Future (Jun. 10, 1999), <http://www.humgen.nl/lab-devilee/BCLC/history.htm>.

<sup>50</sup> J.M. Hall, et al., *Linkage of early-onset familial breast cancer to chromosome 17q21*, 250 SCIENCE 1684 (1990).

<sup>51</sup> King, *supra* note 24, at 1463. See also DAVIES & WHITE, *supra* note 38, at 150-54.

<sup>52</sup> See DAVIES & WHITE, *supra* note 38, at 199-200 (Gilbert was one of the co-founders of biotech giant Biogen, and Meldrum founded Native Plants, Inc., a plant-based biotech company).

<sup>53</sup> *Myriad*, 702 F.Supp. 2d at 201.

Eli Lilly & Co., which paid approximately \$2.8 million for a combination of Myriad stock and the right to commercialize certain of Myriad's discoveries.<sup>54</sup>

In the summer of 1994 Myriad, together with collaborators from the University of Utah and NIEHS, succeeded in isolating and sequencing the BRCA1 gene.<sup>55</sup> Myriad filed a patent application covering the DNA sequence of the gene and several of its mutations in August, 1994,<sup>56</sup> and published these results in the journal *Science* that October.<sup>57</sup> Myriad's announcement was met with a flurry of media coverage, including a front page story in the *New York Times* announcing that Myriad had won "a genetic trophy so ferociously coveted and loudly heralded that it had taken on a near-mythic aura".<sup>58</sup> They had found the jewel.

Myriad's victory can be attributed to a number of factors. One was its access to rich genetic resources in Utah, including a single unfortunate family with twenty-five recorded cases of breast cancer spanning six generations.<sup>59</sup> Another key differentiating factor arose from the sequencing techniques used by the different teams. In order to sequence human DNA during the early 1990s, researchers were required to break DNA molecules into fragments and to create millions of copies of each fragment for analysis. The then-standard method for generating these copies was to insert the fragment of human DNA into a yeast cell (called a yeast artificial chromosome or YAC), which would reproduce the human DNA fragment each time it divided. The YAC techniques utilized by King and Collins allowed the reproduction of relatively long DNA fragments, but were bad at reproducing sections of DNA that themselves contained short repeating segments called "Alus".<sup>60</sup> Thus, while the King and Collins groups successfully employed YACs to narrow the location of BRCA1 along chromosome 17, they did not find BRCA1 because it lay along a 100 Kb stretch of DNA littered with Alus that was never revealed to them.<sup>61</sup> The

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<sup>54</sup> DAVIES & WHITE, *supra* note 38, at 199-200.

<sup>55</sup> DAVIES & WHITE, *supra* note 38, at 208.

<sup>56</sup> U.S. Patent No. 5,747,282A, DNA and cloning vectors for production of cloning vectors and gene expression for screening potential cancer therapy (Issued May 5, 1998).

<sup>57</sup> Yoshio Miki et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, 266 SCIENCE 66 (1994).

<sup>58</sup> Angier, *supra* note 42.

<sup>59</sup> DAVIES & WHITE, *supra* note 38, at 208 (if all of the members of such a family bore the same genetic mutation, then it is highly probable that the mutation played a role in their cancers).

<sup>60</sup> King, *supra* note 24, at 1463; DAVIES & WHITE, *supra* note 38, at 150-52.

<sup>61</sup> King, *supra* note 24, at 1464. The King team identified and sequenced fifteen other

Myriad group, on the other hand, used a newer technique involving bacterial cells (bacterial artificial chromosomes or BACs) to reproduce human DNA fragments.<sup>62</sup> Though BACs handled shorter fragments than YACs, they were more stable and avoided problems associated with Alu regions.<sup>63</sup> Thus, the Myriad group was the first to find BRCA1 and, after verifying its presence among cancer-prevalent families, confirmed its identity.

But the sequencing of BRCA1 did not fully solve the riddle of inherited breast and ovarian cancer, and researchers knew that another gene must be at work. In September 1994, Stratton in London, together with 30 other researchers, published a paper suggesting that the BRCA2 gene, as it became known, lay somewhere on chromosome 13.<sup>64</sup> Stratton, who had been collaborating with Myriad, ended his relationship with the company when he learned that Myriad intended to patent the BRCA2 sequence. With the rift between Stratton and Skolnick, a heated race to sequence BRCA2 began.<sup>65</sup> The competing groups in Utah and London, as well as others around the world, worked feverishly to complete the sequence for BRCA2 in much the same manner as they had BRCA1. The race ended in a dead heat, as the teams led by Stratton and Skolnick announced that they had completed the sequences within one day of each other. Stratton's group published its results in *Nature* on December 22, 1995<sup>66</sup> and filed a patent application in the UK.<sup>67</sup> But the Myriad group beat them and filed its U.S. patent application on December 21,<sup>68</sup> securing for Myriad the U.S. rights to the BRCA2 sequence.

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genes along the 1 Mb region of interest, five of which were previously unknown. It was only BRCA1 that eluded them. *Id.*

<sup>62</sup> The use of BACs was pioneered at Caltech, where several of the Myriad researchers had obtained their doctoral degrees. Personal communication with Sean Tavtigian, July 11, 2014.

<sup>63</sup> DAVIES & WHITE, *supra* note 38, at 218; Eric D. Green, *Strategies for the Systematic Sequencing of Complex Genomes*, 2 NATURE REV. GENETICS 573, 575 (2001); Cf. J. Craig Venter, Hamilton O. Smith & Leroy Hood, *A New Strategy for Genome Sequencing*, 381 NATURE 364 (1996) (confirming the superiority of BAC techniques over YAC techniques and recommending that the human genome project use BAC techniques).

<sup>64</sup> Richard Wooster et al., *Localization of a Breast Cancer Susceptibility Gene, BRCA2, to Chromosome 13q12-13*, 265 SCIENCE 2088 (1994).

<sup>65</sup> Myriad, 702 F. Supp. 2d at 202.

<sup>66</sup> Richard Wooster et al., *Identification of the Breast Cancer Susceptibility Gene BRCA2*, 378 NATURE 789 (1995).

<sup>67</sup> Cite patent

<sup>68</sup> cite patent

## C. PATENTING BRCA

1. *Gene Patents in the United States*

To understand the controversy surrounding Myriad's patents on the BRCA1/2 genes, it is useful to take a brief detour to review the history of gene patenting in the United States. The patentability of human genetic material in the U.S. has been the subject of heated public dispute since the 1960s. The debate began in earnest in the lead-up to the Supreme Court's landmark 1980 decision in *Diamond v. Chakrabarty*, which for the first time upheld the patentability of a living, genetically-modified organism.<sup>69</sup> After *Chakrabarty* the gene patenting debate intensified as the Patent and Trademark Office began to issue DNA patents in growing numbers.<sup>70</sup>

The controversy over gene patenting soon spilled into the then-nascent Human Genome Project (HGP), a government-sponsored effort to map the entire 3.2 billion base pairs constituting the human genome. In 1988, the National Research Council recommended that all data generated by the HGP "be provided in an accessible form to the general research community worldwide."<sup>71</sup> Other influential groups and leading scientists urged that all human DNA sequences be contributed to the public domain for the benefit of science.<sup>72</sup> But others in industry and NIH felt that patents on genes could

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<sup>69</sup> 447 U.S. 303 (1980). The organism in question was a bacterium that was genetically engineered to assist in the breakdown of crude oil. *Id.* at 305. Chakrabarty's patent application was initially filed in 1972 and was rejected by both the Patent and Trademark Office and the Patent Office Board of Appeals before being upheld by the Supreme Court. See Jack Wilson, *Patenting Organisms – Intellectual Property Meets Biology* in WHO OWNS LIFE? 25, 25 (David Magnus, Arthur Caplan & Glenn McGee, eds., 2002) (hereinafter WHO OWNS LIFE?). For a description of earlier unsuccessful attempts to obtain patents on living organisms see Lorance L. Greenlee, *Biotechnology Patent Law: Perspective of the First Seventeen Years, Prospective on the Next Seventeen Years*, 68 DENVER U.L. REV. 127, 128 n.6 (1991).

<sup>70</sup> See, e.g., Andrew W. Torrance, *Gene Concepts, Gene Talk and Gene Patents*, 11 MINN. J. L., SCI. & TECH. 158, 176-77 (2010) (describing the first patents on human genetic material issued during the late 1970s and early 1980s) and Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721, 721 n.4 (1990) (listing several such patents issuing during the 1980s).

<sup>71</sup> NATIONAL RESEARCH COUNCIL, MAPPING AND SEQUENCING THE HUMAN GENOME 8 (1988) (hereinafter NRC – HUMAN GENOME).

<sup>72</sup> See NATIONAL RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH 27 (2006) (hereinafter NRC – GENOMIC AND PROTEOMIC RESEARCH) (citing a 1988 NIH advisory council report stating that "the data must be in the public domain, and the redistribution of the data should remain free of royalties"); James D. Watson, *The Human Genome Project: Past, Present and Future*, 248 SCI. 44, 48 (1990), FRANCIS COLLINS, THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALIZED

foster new businesses and fuel the discovery of drugs and diagnostic tests.

One of these supporters was Craig Venter, then a researcher at NIH, who in 1991 began to file patent applications covering short human DNA segments known as “expressed sequence tags” (ESTs).<sup>73</sup> The EST patents sparked what Robert Cook-Deegan has called “an international firestorm”.<sup>74</sup> NIH’s decision to pursue these patents was widely criticized, including by its own advisory committees who were “unanimous in deploring the decision to seek such patents,”<sup>75</sup> as well as influential groups such as the American Society of Human Genetics.<sup>76</sup>

Given the weight of opposition, in 1994 NIH decided not to appeal the Patent and Trademark Office’s (PTO) initial rejections of its EST patent applications.<sup>77</sup> Since then, NIH has adopted a consistently lukewarm, if not outright averse, attitude toward the patenting of genetic information.<sup>78</sup> NIH’s reversal of position did not, however, put an end to gene patenting in the U.S., and as DNA sequencing technology improved and became increasingly available to academic and industrial laboratories through the 1990s, the number of gene patents continued to grow. By late 1996, one source reports that more than 350 new gene patent applications claiming more than 500,000 DNA sequences had been filed.<sup>79</sup> And by the time the first EST patent issued to Incyte Pharmaceuticals in 1998, that company alone had filed patent applications claiming more than 1.2 million human DNA fragments.<sup>80</sup> Thus, by the late 1990s gene patenting had become big

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MEDICINE 301 (2010).

<sup>73</sup> Venter believed that ESTs could help to locate genes more quickly and efficiently than sequencing the entire genome. See JAMES SHREEVE, *THE GENOME WAR* 82-83 (2004). Venter, of course, went on to found Celera Genomics, the company that raced the public HGP to complete the human genome sequence. See *id.*

<sup>74</sup> See ROBERT COOK-DEEGAN, *THE GENE WARS – SCIENCE, POLITICS, AND THE HUMAN GENOME* 330-31 (1994). See also Christopher Anderson, *US Patent Application Stirs Up Gene Hunters*, 353 *NATURE* 485, 485 (1991); Leslie Roberts, *Genome Patent Fight Erupts*, 254 *SCIENCE* 184, 184 (1991).

<sup>75</sup> *Id.* at 317.

<sup>76</sup> Am. Soc’y of Hum. Genetics, *Position Paper on Patenting of Expressed Sequence Tags* (Nov. 1991) (available at <http://www.faseb.org/genetics/ashg/policy/pol-08.htm>).

<sup>77</sup> Christopher Anderson, *NIH Drops Bid for Gene Patents*, 263 *SCIENCE* 909, 909 (1994).

<sup>78</sup> See NRC - GENOMIC AND PROTEOMIC RESEARCH, *supra* note 72, at 52-53.

<sup>79</sup> Claire O’Brien, *US Decision 'Will Not Limit Gene Patents'*, 385 *NATURE* 755, 755 (1997).

<sup>80</sup> John Murray, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 *Chicago-Kent L. Rev.* 231, 231 (1999) (citing Incyte Pharmaceuticals, Inc., Press Release: Incyte Issued First EST Gene Patent).

business.

## 2. Myriad's Patents

Myriad's patents covering BRCA1 and BRCA2 began to issue in 1997 and 1998, respectively. The company obtained a total of nine patents covering different aspects of the two cancer susceptibility genes. These patents claimed the genes' basic chemical composition (the DNA nucleotide sequence itself), the composition of smaller DNA segments contained within the genes, the known mutations giving rise to elevated cancer risk, methods of detecting the genes, the use of the genes to diagnose different cancers, and their use as potential screens for cancer therapeutics.<sup>81</sup>

As noted above, the search for the BRCA1/2 genes was a massive undertaking, and even Myriad did not work in isolation. Researchers from the University of Utah, the NIEHS, McGill University and the Cancer Institute of Japan were all listed as co-inventors on one or more Myriad patents.<sup>82</sup> However, all of these institutions eventually assigned full control over the patents to Myriad.<sup>83</sup>

Moreover, Myriad was not the only entity to obtain patents relating to BRCA1/2. In addition to the UK group led by Stratton, another U.S.-based company, OncorMed, Inc., obtained licenses to some of the early BRCA markers discovered by the King group at Berkeley, and succeeded in patenting a slightly different set of BRCA sequences than Myriad.<sup>84</sup> OncorMed also obtained a license from the UK Cancer Research Campaign, which owned the rights to the discoveries made by the Stratton group. Like Myriad, OncorMed's principal U.S. patent on BRCA1 issued in 1997, and the two companies promptly sued each other for patent infringement. The litigation was eventually settled with Myriad's acquisition of OncorMed's BRCA patents in 1998,<sup>85</sup> thus consolidating in Myriad's hands substantially

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<sup>81</sup> Cite patents.

<sup>82</sup> The two NIH researchers were initially omitted from the Myriad patent application, and were only added as inventors after NIH filed a competing patent application at the U.S. Patent and Trademark Office. The dispute was settled with agreement to add the NIH inventors to Myriad's patent. See Andrew A. Skolnick, *Cancer Gene Patent Dispute Settled*, 273 J. AM. MED. ASSN. 833 (1995).

<sup>83</sup> See Gold & Carbone, *supra* note 39, at S41.

<sup>84</sup> See PARTHASARATHY, *supra* note 38, at 74, Gold & Carbone, *supra* note 39, at S41.

<sup>85</sup> OncorMed, Inc., Quarterly Report on Form 10-Q, June 30, 1998, <http://www.sec.gov/Archives/edgar/data/922821/0000950133-98-003049.txt> (reporting that OncorMed reported gain of \$525,000 on the sale of its breast cancer testing service,

all U.S. patent rights relating to the BRCA1/2 genes.<sup>86</sup>

#### D. BRCA TESTING

##### 1. *Competition in the BRCA Testing Market (1996-2000)*

From the beginning, it was known that once the BRCA genes were sequenced, it would be relatively straightforward to develop a laboratory test to detect cancer-associated mutations in individual DNA samples. If one or more mutations were found, then the individual carrying those mutations would be known to have an elevated risk of contracting the disease.

Soon after the BRCA sequences were published, a number of laboratories in the U.S. began to offer tests for the most common BRCA mutations. By the late 1990s, four commercial BRCA testing providers were operating in the U.S.: Myriad, OncorMed, the Genetic Diagnostic Laboratory at the University of Pennsylvania and the Genetics and IVF Institute (GIVF), a private clinic. Each of these organizations adopted a slightly different approach to BRCA testing, both from technological and patient interaction standpoints.<sup>87</sup> In addition to the commercial testing services, during this period a number of non-commercial laboratories also offered BRCA testing using less expensive screening techniques.<sup>88</sup>

As noted above, Myriad acquired OncorMed's patents in May 1998.<sup>89</sup> This acquisition effectively ended OncorMed's separate testing program. In early 1998, Myriad sent "cease and desist" letters to the University of Pennsylvania and GIVF, notifying them that their BRCA testing programs infringed Myriad's U.S. patents.<sup>90</sup> GIVF quickly discontinued its BRCA testing services. The University of Pennsylvania initially resisted, claiming that its testing services were protected under the patent law's so-called "research exemption".<sup>91</sup> Myriad sued the University of Pennsylvania for

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including customer lists, databases and other intangible assets).

<sup>86</sup> See Cook-Deegan, et al, *supra* note 36, at S20-S21 and Table 2 (showing ownership and licensing status of all issued U.S. patents covering BRCA1/2 genes).

<sup>87</sup> See PARTHASARATHY, *supra* note 38, at 68-92.

<sup>88</sup> See Williams-Jones, *supra* note 39, at 135.

<sup>89</sup> See PARTHASARATHY, *supra* note 38, at x.

<sup>90</sup> See PARTHASARATHY, *supra* note 38, at 117-18.

<sup>91</sup> See Cook-Deegan et al., *supra* note 36, at S28. For a discussion of the current status of the "research exemption" under U.S. law, see Jennifer Carter-Johnson, Jeffrey S. Carter-Johnson and Jorge L. Contreras *University Research and Licensing* in *BIOINFORMATICS LAW: LEGAL ISSUES FOR COMPUTATIONAL BIOLOGY IN THE POST-GENOME ERA* (Jorge L.

patent infringement in November 1998,<sup>92</sup> and the university discontinued its BRCA testing program some time in 1999.<sup>93</sup>

In addition, between 1998 and 2000 Myriad notified other academic laboratories that were offering or considering BRCA testing services of its patents. These laboratories included the Cancer Genetics Network Project sponsored by the National Cancer Institute (NCI), New York University, Georgetown University, and the Yale DNA Diagnostics Lab.<sup>94</sup> Following receipt of these notices, each of these laboratories discontinued offering BRCA testing services to the public, leaving Myriad as the sole provider of comprehensive BRCA1/2 testing services in the U.S.<sup>95</sup> According to one 2001 survey, nine different U.S.-based laboratories stopped performing BRCA testing as a result of Myriad's patent assertion and enforcement activities.<sup>96</sup>

## 2. Myriad's BRCA Testing Program (1996-2013)

### a. Types of Tests

Beginning in 1996, Myriad began to offer three forms of BRCA testing to the public (marketed under the brand "BRCAAnalysis"): (a) Single Site (testing for one of the three most common Ashkenazi mutations), (b) Multisite 3 (testing for all three of the most common Ashkenazi mutations), and (c) Comprehensive (full sequencing of the BRCA1/2 genes).<sup>97</sup>

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Contreras & A. James Cuticchia, eds., 2013) (the research exemption in the U.S. is, for all practical purposes, dead).

<sup>92</sup> Myriad Genetics, Inc. v. Univ. of Pennsylvania, 2:98-cv-00829 (D. Utah 1998).

<sup>93</sup> Assn. for Molecular Path. v. Myriad Genetics, Inc., Decl. of Haig H. Kazazian, Jr., 3-4 (Aug. 17, 2009).

<sup>94</sup> Ganguly and Matloff Declarations, Myriad.

<sup>95</sup> Although Myriad's U.S. patents covered the structure and use of the BRCA1/2 genes, the patents did not cover the detection of individual mutations by means other than replication of the entire genes. Thus, Myriad is not the only organization that offers testing services in the U.S. for single or small sets of BRCA1/2 mutations. One 2005 study found nine academic laboratories that offered testing for the three principal Ashkenazi Jewish BRCA mutations. Heidi D. Nelson, et al., *Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Evidence Synthesis No. 37 Prepared for Agency for Healthcare Research and Quality* at 2 and 56 Table 1 (2005). These limited tests have been recommended for individuals who have a close family member with a known Ashkenazi BRCA mutation.

<sup>96</sup> Mildred K. Cho, et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAG. 3, 5-6 (2003).

<sup>97</sup> Williams-Jones, *supra* note 39, at 133-34.

The selection of tests is best illustrated by an example. Suppose that Anne, a woman of Ashkenazi heritage, has been identified as carrying the BRCA1 mutation known as 185delAG (the A and G nucleotides are deleted at position 185 along the BRCA1 gene). Anne's daughter Barbara has at least at 50% chance of carrying the 185delAG mutation herself,<sup>98</sup> and testing for the presence of that mutation would likely be recommended. If the mutation were found, then Barbara's elevated risk of breast cancer would be confirmed and she would be advised to consider appropriate prophylactic measures.<sup>99</sup>

If the 185delAG mutation were *not* found, however, Barbara would not be in the clear, as there are nearly 2,000 known BRCA mutations that are less common, but which may also lead to an elevated cancer risk. These mutations are not well-known in the literature, and many are contained in Myriad's proprietary databases. Thus, for a member of a high-risk group who tests negative for one of the well-known BRCA mutations, it is likely that a more comprehensive test would be recommended. Individuals from high risk populations who do *not* know whether their immediate family members carry a known BRCA mutation<sup>100</sup> might also require more extensive testing.

*b. Pricing of Diagnostic Tests*

As the sole provider of comprehensive BRCA screening in the U.S., Myriad's pricing for this service has come under substantial scrutiny. In the early 2000s, Myriad charged \$295 for Single Site, \$450 for Multisite 3 and \$2,600 for Comprehensive BRCA analysis.<sup>101</sup> In comparison, the University of Pennsylvania charged approximately \$1,900 for its comprehensive testing prior to discontinuation.<sup>102</sup> By 2008, the cost of Myriad's Comprehensive BRCA test had risen to approximately \$3,120.<sup>103</sup> A 2008 Duke University study commissioned by the Secretary's Advisory

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<sup>98</sup> Each human inherits half of her genes from her mother and half from her father. If her father also carried the 185delAG mutation, then it would be almost certain that she carried the mutation.

<sup>99</sup> See note 36, *supra*.

<sup>100</sup> This situation is common, as there is little medical cause to test patients who have already contracted breast or ovarian cancer for the presence of risk-enhancing genes. Genetic testing of cancer patients is useful only to gain information that may help to understand the cancer risk of members of the family who are still healthy. As such, testing of cancer patients is not covered by some insurance plans.

<sup>101</sup> Williams-Jones, *supra* note 39, at 133-34.

<sup>102</sup> *Id.*

<sup>103</sup> Cook-Deegan et al., *supra* note 36, at S17.

Committee on Genetics, Health, and Society found that Myriad charged more for Comprehensive BRCA testing (\$3,120) than for other genetic tests, such as those relating to colorectal cancer, in which it did not have a controlling patent position.<sup>104</sup>

*c. Access and Reimbursement*

In the U.S., patient access to medical tests is highly dependent on coverage by private medical insurers and health management organizations (HMOs), as well as governmental reimbursement programs such as Medicare and Medicaid. Coverage for genetic testing is both uncertain and controversial, primarily because such tests are administered to *healthy* individuals (i.e., those who have not yet contracted a disease). For this reason, healthcare payors must develop criteria to determine which individuals, if any, they will pay to test and to what degree.<sup>105</sup>

Myriad began to approach U.S. healthcare payors regarding its BRCA testing services soon after they became available. By 1999, more than 390 private insurers, including Kaiser Permanente, Aetna U.S. Health Care, Blue Cross and Blue Shield, covered Myriad's BRCA analysis services.<sup>106</sup> By 2008, Myriad reported that it had been reimbursed for testing by more than 2,500 health plans.<sup>107</sup> In 2009, Myriad reported that 90% of the tests that it performed were covered by insurance at over 90% of their cost.<sup>108</sup>

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<sup>104</sup> *Id.* (at the time of the study, Myriad charged \$1,795 for familial adenomatous polyposis (FAP), a field with four competing labs charging between \$1,200 and \$1,675, and \$2,950 for hereditary non-polyposis colorectal cancer (HNPCC), a field with six competing labs charging between \$1,800 and \$4,646). Nevertheless, the study could demonstrate no correlation between Myriad's patent position and the pricing of its BRCA analysis service when compared to the prices of colorectal cancer tests due to a large number of potentially confounding variables. Cook-Deegan et al., *supra* note 36, at S30 ("Any price effect attributable to patents is buried in noise and confounding variables").

<sup>105</sup> From a payor's standpoint, this determination is largely actuarial. At one end of the coverage spectrum, a payor could cover BRCA testing for every individual, which would detect the largest number of at-risk individuals, but would likely be cost prohibitive. At the other end of the spectrum, a payor could cover no BRCA testing, meaning that even high-risk individuals would lack key information in deciding whether to undergo cost-saving prophylactic procedures before contracting cancer, thus increasing the payor's cost. From a cost-effectiveness standpoint, the payor would ideally cover testing for enough individuals who are likely to contract the disease that the cost savings from avoiding disease treatment would outweigh the total cost of testing plus prophylactic procedures for those who tested positive.

<sup>106</sup> Williams-Jones, *supra* note 39, at 136.

<sup>107</sup> Cook-Deegan et al., *supra* note 36, at S30-S31.

<sup>108</sup> Critchfield Decl. ¶¶ 32, 33, 52, 53. These statistics, of course, do not take into account individuals who were not tested because testing was not covered by their insurance.

Nevertheless, Myriad's testing is not covered by all U.S. healthcare payors, and as of 2010 BRACAnalysis was still not approved for Medicaid reimbursement in twenty-five states.<sup>109</sup> Moreover, even payors that cover BRCA testing may do so only for "high risk" individuals, e.g., women<sup>110</sup> having a family history of breast or ovarian cancer or of known Ashkenazi descent. And even when payors do cover testing, they may only allow limited testing for the primary BRCA mutations, rather than Myriad's comprehensive BRACAnalysis.<sup>111</sup>

In order to address some of these concerns, Myriad offers financial assistance to low-income and uninsured individuals.<sup>112</sup> While these programs have enabled many additional individuals to be tested, there are still individuals for whom testing is recommended by physicians and genetic counselors who are unable to obtain testing at all, or at the levels recommended.<sup>113</sup> This situation led to substantial public opposition to Myriad's practices and gene patents, in general.<sup>114</sup>

#### E. THE *MYRIAD* LITIGATION

In May 2009, two public interest law firms, the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PPF), filed a declaratory judgment action in the U.S. District Court for the Southern District of New York seeking to invalidate fifteen claims of seven different patents controlled by Myriad. The challenged claims each related to the composition or use of BRCA1/2. The plaintiffs in the case included: (1) medical and scientific societies who alleged that Myriad's patents impaired their members' ability to perform BRCA testing, (2) individual researchers

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providers or because they were uninsured.

<sup>109</sup> Rusconi Decl. ¶¶ 4-6; Critchfield Decl. ¶33; Ogaard Decl. ¶¶ 4-6.

<sup>110</sup> Though little-publicized, men are also susceptible to breast cancer and the elevated breast cancer risk associated with BRCA1/2 mutations.

<sup>111</sup> Plaintiff's Brief.

<sup>112</sup> Rusconi Decl. ¶¶ 4-6; Critchfield Decl. ¶33; Ogaard Decl. ¶¶ 4-6.

<sup>113</sup> 702 F. Supp. 2d at 204. *See also* Gale Scott, *Test that Saved Angelina not Widely Covered*, Crain's New York Business, May 15, 2013 ("The problem is that unless patients already have cancer, or have a family history where breast or ovarian cancer struck many relatives, particularly at a young age, insurance will not cover the more than \$3,000 test" (quoting Dr. Kathie Ann Joseph of NYU Langone Medical Center)).

<sup>114</sup> *See* A. Lane Baldwin & Robert Cook-Deegan, *Constructing narratives of heroism and villainy: case study of Myriad's BRACAnalysis® compared to Genentech's Herceptin®*, 5 GENOME MED. (2013) (observing the "villianization" of Myriad on account of its restrictive licensing practices and high pricing).

and physicians who had received cease and desist letters from Myriad, (3) individuals who were unable to obtain some or all BRCA testing recommended to them as a result of Myriad's pricing, and (4) advocacy groups seeking to advance women's health and cancer treatment and prevention. The defendants in the case were Myriad, which owned or licensed each of the challenged patents, the University of Utah Research Foundation, which owned or co-owned patents licensed to Myriad, and the U.S. Patent and Trademark Office (PTO), which issued the patents.<sup>115</sup> Numerous *amici curiae* submitted briefs in support of one or the other of the parties.

The case was decided on motions for summary judgment by District Judge Robert W. Sweet, who rendered his decision on April 2, 2010. In it, he declared all fifteen challenged patent claims to be invalid as directed to ineligible subject matter under Section 101 of the Patent Act. With respect to Myriad's "composition of matter" claims covering the sequence of the BRCA genes and their mutations, he held that "[i]n 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 'markedly different' than naturally-occurring DNA."<sup>116</sup> With respect to Myriad's claims covering diagnostic methods "for diagnosing a predisposition for breast cancer in a human subject" using the identified BRCA mutations, he held that such claims were "mental processes and abstract intellectual concepts" that were also ineligible for patent protection.<sup>117</sup> Finally, with respect to one remaining claim covering "a method for screening potential cancer therapeutics" by comparing the effect of a drug candidate on the rate of cancer growth in cells containing mutated BRCA genes, Judge Sweet held that the claimed process was nothing more than "the scientific method itself", and likewise ineligible for patent protection.<sup>118</sup>

The defendants appealed to the Court of Appeals for the Federal Circuit, which rendered its decision on July 29, 2011. The defendants first challenged the standing of the various plaintiffs to bring a claim under the Declaratory Judgment Act. The Federal Circuit held that only one of the plaintiffs, Dr. Harry Ostrer of NYU Medical Center, had sufficiently

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<sup>115</sup> The plaintiffs alleged that the PTO violated Article I Section 8 of the U.S. Constitution by granting the patents at issue. The court dismissed these claims summarily. 702 F. Supp. 2d at 238.

<sup>116</sup> 702 F. Supp. 2d at 232.

<sup>117</sup> *Id.* at 236.

<sup>118</sup> *Id.* at 237.

immediate and concrete apprehension of suit to maintain an action under the Declaratory Judgment Act.<sup>119</sup> With respect to the patent eligibility of the challenged claims, the Federal Circuit affirmed the District Court's holding as to Myriad's diagnostic method claims, finding them to be directed to "abstract mental processes" and thereby ineligible for patent protection.<sup>120</sup> The Federal Circuit reversed the lower court's ruling, however, as to Myriad's composition of matter and therapeutic method claims. With respect to the composition of matter claims, the Federal Circuit held that the BRCA genes isolated and extracted from the cellular nucleus were chemically and structurally distinct from DNA found in the human body. As such, they are man-made products of "human ingenuity" and eligible for patent protection.<sup>121</sup> Finally, as to Myriad's claim to a method of screening a therapeutic using the BRCA genes, the Federal Circuit held that this method was "not so 'manifestly abstract' as to claim only a scientific principle", and that due to its "functional and palpable applications in the field of biotechnology", the claim was patent eligible.<sup>122</sup>

The plaintiffs filed a petition for *certiorari* to the Supreme Court, arguing both that the plaintiffs other than Dr. Ostrer should have standing to sue under the Declaratory Judgment Act, and seeking the invalidation of Myriad's composition of matter claims.<sup>123</sup> However, in March 2012 the Supreme Court decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>124</sup> a case calling into question the patentability of diagnostic methods. The Supreme Court granted *certiorari* in *Myriad*, vacated the Federal Circuit's 2011 decision, and remanded the case to the Federal Circuit for reconsideration in view of *Mayo*.<sup>125</sup> The Federal Circuit reheard argument and issued a new opinion on August 16, 2012, largely reinstating its 2011 decision.<sup>126</sup>

Following this decision, the plaintiffs again filed a petition for *certiorari*, which was granted, but only as to the single question: "Are human genes patentable?"<sup>127</sup> Oral argument was heard on April 15, 2013 and a decision handed down in June. In a unanimous decision delivered by

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<sup>119</sup> 653 F.3d 1329, 1345-48 (Fed. Cir. 2011).

<sup>120</sup> *Id.* at 1356-57.

<sup>121</sup> *Id.* at 1351-52.

<sup>122</sup> *Id.* at 1357-58.

<sup>123</sup> *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, Petition for a Writ of *Certiorari* (Dec. 6, 2011).

<sup>124</sup> 132 S.Ct. 1289 (2012).

<sup>125</sup> 132 S.Ct. 1794 (2012).

<sup>126</sup> 689 F.3d 1303 (Fed. Cir. 2012).

<sup>127</sup> The Court declined to grant *certiorari* on the question of standing.

Justice Thomas,<sup>128</sup> the Court held that Myriad's discovery of the location and sequence of the BRCA1/2 genes, even if it involved substantial time, expense and skill, was not "an act of invention."<sup>129</sup> Thus, Myriad's composition of matter claims sought to cover "products of nature" and did not meet the statutory requirements for patent eligibility.

The *Myriad* case attracted global media attention. Members of the public camped outside the Court for days in the hope of getting a seat at the oral argument. Demonstrators bearing colorful banners paraded in front of the Court on the day of the argument.<sup>130</sup> Clearly, the public interest in the case, and the gene patenting debate in general, arose from something more than concern over the product of nature doctrine under patent law.

## II. SIX NARRATIVES OF GENE PATENTING

In this Part, I identify six separate narratives used to explain the *Myriad* case and gene patenting more broadly. I have labeled these narratives, somewhat arbitrarily: Science, Pioneer, Administrative, Access, Dystopian and Anti-Commons. Each of these narratives is told from the perspective of a different stakeholder group: academic scientist, biotechnology company, patent attorney, at-risk individual, and ethicist, though there is inevitably crossover and overlap among these groups. The narratives are intended to represent viewpoints as of April 2013, when the *Myriad* case was argued before the Supreme Court.<sup>131</sup>

After identifying each narrative, I discuss the characteristics and historical positions of the stakeholder group that advanced it, as well as the policy arguments supported by each. A comparison of the six narratives is contained in Part II.B.

These six narratives of gene patenting were derived from multiple

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<sup>128</sup> Justice Scalia concurred in the Court's judgment, but wrote separately to note that he expressed no opinion regarding the "fine details of molecular biology" discussed in the Court's opinion. *Myriad*, \_\_ S.Ct. \_\_ (Scalia, J., concurring in part and concurring in the judgment).

<sup>129</sup> 133 S.Ct. 2107, 2117 (2013). However, the Court notes that synthesized cDNA sequences (which were not at issue in the case) were not "products of nature" and would be eligible for patent protection. 133 S.Ct. at 2119.

<sup>130</sup> Cite

<sup>131</sup> The time at which the narrative is told is important, as the situation regarding Myriad's patents, and the BRCA testing industry, has evolved substantially since the Court's decision.

sources, including the *Myriad* trial record and briefs, as well as public statements and other publications. Of particular note, in addition to the party briefs, we reviewed 96 briefs of *amici curiae* submitted in the *Myriad* litigation at the trial, appellate and Supreme Court stages by 60 different individuals or groups.<sup>132</sup> Each brief was coded to identify the principal narrative(s) contained within it. *Appendix 1* lists each brief and declaration filed in the *Myriad* case, together with the principal narrative(s) that it relates.

## A. THE NARRATIVES AND ASSOCIATED ARGUMENTS

### 1. *The Science Narrative*

*The discoveries that led to the sequencing of the BRCA1/2 genes were the work of hundreds of scientists around the world who collaborated with each other, and with Myriad. The fact that Myriad won the “race” to sequence the genes is largely irrelevant, as this final step merely built upon the work of many others and was itself a trivial scientific accomplishment. For these reasons, it is neither fair nor reasonable that patents on the BRCA genes should be awarded to Myriad.*

#### a. *Reductio ad absurdum*

Among academic research scientists, there is a historical aversion to the patenting of human genes. This attitude is exemplified by Dr. James Watson, the outspoken co-discoverer of the chemical structure of DNA, who claims that “[m]ost, although not all, eminent scientists recognize[] that human genes should not be monopolized by patents.”<sup>133</sup> At other times, he has referred to the patenting of DNA as “preposterous” and “lunacy.”<sup>134</sup> Dr. Watson’s view that patenting genes is absurd is reminiscent of Dr. Jonas Salk’s wry response when asked in 1955 who owned the patent on his newly-discovered polio vaccine. “There is no patent,” Salk replied. “Could you patent the sun?”<sup>135</sup> To scientists like Salk and Watson, the very notion

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<sup>132</sup> *Amici curiae* ranged from individuals to groups of like-minded individuals (e.g., law professors), trade associations, non-profit organizations and corporations. See Appendix 1, *infra*. The author was a signatory to an amicus brief submitted by fifteen law professors.

<sup>133</sup> Watson, Amicus Brief at 14.

<sup>134</sup> *Id.* at 14-15.

<sup>135</sup> Jonas Salk, CBS Television interview with Edward R. Murrow, on *See it Now* (12 April 1955) (quoted in JON COHEN, SHOTS IN THE DARK: THE WAYWARD SEARCH FOR AN AIDS VACCINE x (2001)).

of patenting a basic scientific discovery can be dismissed by this simple *reductio ad absurdum*.<sup>136</sup> What gives rise to such a visceral reaction by individuals who are arguably among the world's most advanced thinkers?

In the 1940s, sociologist Robert K. Merton postulated that a series of “norms” characterize both the practice and culture of science.<sup>137</sup> Among these is the custom of scientists to share their theories, findings and data broadly through publication, without restrictions on subsequent use.<sup>138</sup> While the validity of Merton's norms has been debated and various competing models of scientific practice offered up,<sup>139</sup> the Mertonian ideal of the “Republic of Science” retains its currency, at least in theory if not always in practice.<sup>140</sup>

*b. What Scientists?*

Scientific investigation today is practiced by a wide range of individuals, from high school students to laboratory technicians to industrial and government researchers. The worldview described above, however, is characteristic of only a particular subcategory of practicing scientist:

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<sup>136</sup> Dr. Salk has recently been taken to task for an allegedly inaccurate portrayal of the scope of patent law. See Raymond van Dyke, *Don't Use 'Could you Patent the Sun' Against Myriad*, Law360, Jun. 3, 2013.

<sup>137</sup> Robert K. Merton, *The Normative Structure of Science (1942)* in THE SOCIOLOGY OF SCIENCE 267-78 (Norman W. Storer, ed., 1973). Merton famously identifies four “norms” of science: universalism (scientific claims should be evaluated using objective criteria consistent with observation), communism (now generally referred to as “communalism”) (scientific findings should belong to the scientific community as a whole), disinterestedness (scientists should have no emotional or financial attachment to their work), and organized skepticism (scientists should act dispassionately, without regard to personal beliefs). Later commentators added a fifth norm (“originality”) to Merton's four, the group of which are now commonly referred to by the acronym CUDOS (communalism, universalism, disinterestedness, originality and skepticism). See JOHN M. ZIMAN, PROMETHEUS BOUND: SCIENCE IN A DYNAMIC STEADY STATE 177 (1994).

<sup>138</sup> Merton, *Normative Structure*, *supra* note 137, at 274.

<sup>139</sup> See, e.g., BRUNO LATOUR & STEVE WOOLGAR, LABORATORY LIFE: THE CONSTRUCTION OF SCIENTIFIC FACTS (1986).

<sup>140</sup> Of course, the ethos of scientific cooperation has never prevented scientists from seeking to claim credit as the first to make an important discovery. Scientific rivalries, furious races to publish and bitter disputes over priority have existed since at least the days of Newton and Leibnitz. Merton, *Normative Structure*, *supra* note 137, at 287, and Robert K. Merton, *Behavior Patterns of Scientists (1968)* in THE SOCIOLOGY OF SCIENCE, *supra*, 325, 336-37. One of the greatest such rivalries unfolded in the 1950s in the field of molecular biology, as competing teams in the U.S. and UK raced, with little concern for greater social goals, to discover the structure of DNA. See, generally, James Watson's entertaining autobiographical account, THE DOUBLE HELIX (1968). It would thus be inaccurate to portray science as motivated by selfless toil for a common good.

doctoral-level tenured or tenure-track researchers working at universities, teaching hospitals and other non-profit research institutions. These “academic scientists” today represent only a minority of the total number of individuals conducting scientific research in the U.S.<sup>141</sup>

Why, then, focus on this group? There are several reasons. First, most studies of scientific culture have typically focused on academic scientists, from C.P. Snow’s famous discourse on the “two cultures”,<sup>142</sup> to Merton’s sociological analysis of scientific norms,<sup>143</sup> to Kuhn’s work on the nature of scientific practice and revolution,<sup>144</sup> to much of the contemporary field of science and technology studies (STS). Academic science has been the object of substantial study, and as such can be said to constitute a community with a discernable voice and worldview. The community voice is often expressed through prominent and respected representatives (often Nobel laureates) and scientific societies, which do not hesitate to opine on matters of public policy ranging from animal welfare<sup>145</sup> to nuclear proliferation<sup>146</sup> to online publishing.<sup>147</sup> The worldview of academic scientists is thus discoverable through minimal investigation.

What’s more, the worldview of *this* group, as opposed to that of lobstermen or lumberjacks, is highly germane to the question of gene patenting. Scientists themselves are responsible for disentangling the DNA sequences of genes that they or others may seek to patent. They thus have a vital connection to the gene patenting enterprise, and often care deeply about the manner in which their work is used. Moreover, academic scientists are often recruited to influential government positions on the strength of their academic credentials.<sup>148</sup> As high-ranking officials within agencies such as NIH, EPA, DOE and NASA, academic scientists influence U.S. policy in a variety of fundamental ways, all shaped by their pre-existing attitudes and worldview. It is thus worth peeling back the layers of this worldview in some detail and gaining a deeper understanding of the attraction of the Science Narrative to academic researchers.

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<sup>141</sup> In 2009, approximately 18% of U.S. scientists and engineers, and 41% of U.S. scientists and engineers holding a doctoral degree, worked at institutions of higher education. Natl. Sci. Fndn., Science and Engineering Indicators 2012, 3-18. Other major employers of science and engineering professional are corporations and government.

<sup>142</sup> C. P. Snow, *The Two Cultures*, NEW STATESMAN, Oct. 6, 1956.

<sup>143</sup> Merton, *supra* note 140.

<sup>144</sup> THOMAS S. KUHN, *THE STRUCTURE OF SCIENTIFIC REVOLUTIONS* (1962).

<sup>145</sup> AAAS

<sup>146</sup> Union of concerned scientists.

<sup>147</sup> PLoS

<sup>148</sup> E.g., Varmus (NCI), Collins (NIH), Chu (DOE), Holdren (OSTP),

c. *Collective Effort*

The modern practice of science is a collective enterprise far removed from the antiquated image of the lone inventor toiling in his laboratory. Large-scale scientific endeavors such as the human genome project have involved thousands of researchers worldwide, and even the earlier search for the BRCA genes benefitted from the contributions of hundreds of scientists in multiple countries. The initial 1990 paper by King's group isolating BRCA1 to chromosome 17 included seven co-authors,<sup>149</sup> but the Myriad paper announcing the sequence in 1994 included forty-five researchers from five different institutions,<sup>150</sup> and the competing BRCA2 sequence papers from the Stratton<sup>151</sup> and Myriad<sup>152</sup> groups included thirty-eight and fifty-one researchers, respectively, with very little overlap.

Moreover, contributing to Myriad's discovery of the sequence for BRCA1 were not only the forty-five individual authors of Myriad's publication, but the members of the King, Collins and other teams that helped to narrow the gene to smaller and smaller sub-regions of the chromosome, not to mention King's foundational work placing the gene on chromosome 17 in 1990. According to one study, in 1993-1994, there were no fewer than sixteen leading institutions conducting BRCA research.<sup>153</sup> While most of the individuals at these institutions did not participate directly in Myriad's discovery, the discovery would have been impossible without them. It is for this reason that science is viewed by many academic scientists as a collective activity, one that engages large communities of researchers across the globe, the fruits of which should not be reserved for just a few.

Patents, on the other hand, reward relatively few individuals. For example, the initial Myriad patent claiming BRCA1<sup>154</sup> lists only ten co-inventors.<sup>155</sup> Many individuals on Myriad's team, not to mention the other teams researching BRCA1, were necessarily excluded from the benefits of inventorship. As such, it is not difficult to understand why patenting objects

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<sup>149</sup> Hall, *supra* note 50.

<sup>150</sup> Miki, *supra* note 57.

<sup>151</sup> Wooster, *supra* note 66.

<sup>152</sup> Sean Tavtigian et al, *The Complete BRCA2 Gene and Mutations in Chromosome 13q-linked Kindreds*, 12 *Nature Genetics* 333 (1996).

<sup>153</sup> Dalpé, *supra* note 43, at 205 Table 4.

<sup>154</sup> U.S. Patent No. 5,747,282A, *supra* note 56.

<sup>155</sup> As noted in note 82, *supra*, two NIH researchers were included in the list of inventors only after the settlement of a dispute between Myriad and NIH.

of scientific study such as human genes seems contrary to the notion of science as a collective enterprise.

*d. Significance of Findings*

Science is full of opportunities for the recognition of significant intellectual achievements, from the Nobel prize to national, institutional and departmental awards. This culture of recognition seeks to reward individual accomplishments based not so much on their economic significance, as on the intellectual rigor and insight involved in achieving them. It is for this reason that an auditorium full of scientists will rise to its feet and break into applause when one of their number proceeds to solve a formerly unsolved mathematical puzzle or confirm the existence of a new subatomic particle.<sup>156</sup> Yet academic scientists have generally reserved their kudos for discoveries that represent a significant leap in understanding, rather than the culmination of workaday technical procedures.<sup>157</sup>

For these reasons, academic scientists would likely view King's 1990 location of the BRCA1 gene on chromosome 17 as a more significant discovery than the Myriad group's eventual isolation and sequencing of the gene in 1994. While King's discovery was viewed as a breakthrough, the first time that hereditary cancer had been associated with a particular region of the human genome, Myriad's sequencing of the gene was viewed by many simply as the logical conclusion of a process that was undertaken by many and that would inevitably be completed by *somebody*. According to sociologist Shobita Parthasarathy, the methods employed by Myriad to identify BRCA1 were "well-understood, widely used, and fairly uniform" and "any scientist engaged in the process of looking for any gene would have followed a process similar to Myriad's."<sup>158</sup>

For this reason, academic scientists are often puzzled by the conferral of substantial financial benefits that flow from a patent not to the researcher making the the most significant discovery, but to the one completing the final step.

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<sup>156</sup> News stores re. Fermat's Last Theorem and Higgs Boson.

<sup>157</sup> See KUHN, *supra* note 144 (famously distinguishing between "normal science" and scientific "revolutions").

<sup>158</sup> AMP v. USPTO, Declaration of Shobita Parthasarathy, Ph.D (Aug. 26, 2009), at ¶19 (also citing similar statement by British Society of Human Genetics).

*e. Public Funding*

Many academic scientists point to the public funding of scientific research to support the position that the fruits of such research should inure to the public benefit, not to the benefit of individual researchers. In the U.S., the National Institutes of Health, with an annual budget in excess of \$30 billion, fund a large percentage of all biomedical research. By various accounts, the U.S. government contributed millions of dollars to the sequencing of BRCA1 through research grants to the University of Utah,<sup>159</sup> the dedication of scientists at NIEHS to the BRCA project, and funding of groups at Berkeley and other institutions that served as necessary prerequisites to Myriad's eventual discovery.<sup>160</sup> As such, they view the sequencing of the BRCA genes as properly belonging in the public sphere, not in the hands of a private company.

*f. Disdain for Financial Gain*

A closely related aspect of the traditional academic scientific worldview is a general suspicion of monetary incentives. Its adherents contend that the race to patent university research, and the revenue generated by university-owned patents, has caused academic institutions to shift their focus from basic research to commercial development.<sup>161</sup> This shift, they argue, has led to a reduction in non-remunerative basic research, a stifling of the free flow of ideas, and an inappropriate linkage, if not an outright conflict, between academic scientists and private industry.<sup>162</sup> These sentiments underlie the Science Narrative, which portrays researchers who seek and patents as "lesser" intellects who are driven by money rather than the traditional search for knowledge.

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<sup>159</sup> Rachel Nowak, *NIH in danger of losing out on BRCA1 patent*, 266 SCI. 209 (1994) (reporting \$2 million of direct NIH grant funding to University of Utah).

<sup>160</sup> See Parasarathy Declaration, *supra* note 158, at ¶18.

<sup>161</sup> See DANIEL S. GREENBERG, *SCIENCE FOR SALE: THE PERILS, REWARDS, AND DELUSIONS OF CAMPUS CAPITALISM* 61 (2007); JENNIFER WASHBURN, *UNIVERSITY INC. – THE CORPORATE CORRUPTION OF HIGHER EDUCATION* (2005); DAVID B. RESNIK, *OWNING THE GENOME: A MORAL ANALYSIS OF DNA PATENTING* 168-70 (2004); John V. Frangioni, *The Impact of Greed on Academic Medicine and Patient Care*, 26 NATURE BIOTECHNOLOGY 503 (2008).

<sup>162</sup> See, Greenberg, *supra* note 161; Washburn, *supra* note 161; Rai, A. K. and R. S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289 (2003); Robert Lee Holz, *Falling from Grace – Science and the Pursuit of Profit in WHO OWNS LIFE?* 175, 176 (David Magnus, Arthur Caplan & Glenn McGee, eds. 2002).

*g. Impeding Research*

Finally, many academic scientists feel that patents claiming basic scientific discoveries impede their own ability to conduct research. If a human gene is claimed by a patent, the patent owner can, in theory, prevent researchers from replicating and studying the gene, thus halting research on it or imposing substantial royalties on those who wish to continue. As expressed by Francis Collins, the U.S. head of the Human Genome Project and current Director of NIH, patenting genes “is like putting up a whole lot of unnecessary toll booths on the road to discovery.”<sup>163</sup>

The prospect of having to pay royalties to conduct research on particular molecules, or of being blocked altogether from performing that research, runs contrary to another popularly held norm of science, that of communalism.<sup>164</sup> This norm is best summed-up by the well-known observation attributed to Sir Issac Newton, “If I have seen farther it is by standing on the shoulders of giants.”<sup>165</sup> It relies on the fact that later scientists almost always build upon the work of their predecessors, thereby growing the field in an accretive fashion. As explained by the U.S. National Academies of Sciences, “[S]cientific, engineering and medical research is a cumulative process. New ideas build on earlier knowledge, so that the frontiers of human understanding continually move outward. Researchers use each other’s data and conclusions to extend their own ideas, making the total effort much greater than the sum of the individual efforts.”<sup>166</sup> Allowing the patenting of genes thus raises the specter that affected scientists’ work will become more difficult or expensive, thereby rendering the Science Narrative, in which patents are not prevalent, attractive to such individuals.<sup>167</sup>

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<sup>163</sup> COLLINS, *supra* note 72.

<sup>164</sup> See also Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 90-91 (1999) (discussing in detail the norms of scientific research, including the Mertonian norm of communalism).

<sup>165</sup> Merton, *Normative Structure*, *supra* note 137, at 274-75.

<sup>166</sup> NATL. ACAD. SCI., ENSURING THE INTEGRITY, ACCESSIBILITY, AND STEWARDSHIP OF RESEARCH DATA IN THE DIGITAL AGE 55 (2009).

<sup>167</sup> The “impeding research” branch of the Science Narrative remains strong, despite the fact that Myriad has not historically enforced its patents against BRCA researchers, and has publicly pledged that it will not do so in the future. Myriad Genetics, Myriad’s Pledge to Our Patients and the Research Community, <https://www.myriad.com/responsibility/myriads-pledge/> (accessed July 12, 2014) (“we will not impede non-commercial, academic research that uses patented technology licensed or owned by us”).

## 2. *The Pioneer Narrative*

*Myriad's scientists developed innovative new techniques and applied substantial analytical skill to identify and isolate the genetic sequence of the BRCA1/2 genes. To fund this effort, Myriad and its investors made significant financial investments and took a substantial financial risk. As a result of these technological breakthroughs, it now offers life-saving diagnostic tests to the public. Myriad is an exemplar of the biotechnology industry, a strong contributor to American economic development and future employment opportunities.*

The Pioneer Narrative, which was advanced by Myriad throughout the litigation, emphasizes Myriad's contributions to science and economic growth. It begins later in time than the Science Narrative, starting with Myriad's entry into the "race" to sequence BRCA1/2, reaches a climax with Myriad's "discovery" of the genes, and ends with Myriad's testing programs and its contribution to public health and economic growth.

It is natural that Myriad's narrative portrays the company in a favorable light: as an innovator, a scientific pioneer and the purveyor of a lifesaving test. By the same token, Myriad's narrative omits facts that might detract from this favorable impression, such as the contributions made by other scientists around the world to the sequencing of the BRCA genes. As discussed in the Introduction, this selective approach to narrative construction is expected from a litigant in an adversarial proceeding.

The Pioneer Narrative has also been adopted by a range of organizations having perspectives and interests aligned with those of Myriad. For example, in an *amicus* brief submitted by four biotechnology companies, the *amici* refer to the "careful, intensive and creative efforts by Myriad researchers over a decade", "Myriad's transformative synthetic activity," its "laborious effort to identify the BRCA1 gene coding sequence" and its "human ingenuity".<sup>168</sup> Other groups, particularly associations of patent attorneys, submitted similarly glowing accounts of Myriad's ingenuity and technical contributions.<sup>169</sup>

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<sup>168</sup> Assn. Molecular Pathology v. Myriad Genetics, Inc., Brief for Amici Curiae Gilead Sciences, Inc., Elan Pharmaceuticals, Inc., Confluence Life Sciences, Inc., Euclides Pharmaceuticals, Inc. & Biogenerator, in Support of Respondents at 12.

<sup>169</sup> See, e.g., Assn. Molecular Pathology v. Myriad Genetics, Inc., Brief of Amicus Curiae Federal Circuit Bar Association in Support of Respondents at 8.

*a. Ingenuity*

The Pioneer Narrative plays a significant role in advancing Myriad's arguments in court, both doctrinal and policy-based. The doctrinal argument relates to the patent eligibility of human DNA. If DNA sequences, such as those discovered by Myriad, are merely "products of nature" that Myriad happened to be the first to unveil, then they are not patent eligible, whereas if they are the product of human ingenuity and invention, they are patent eligible. The first prong of the Pioneer Narrative thus focuses on Myriad's skill and ingenuity in discovering the sequences of the BRCA genes. Myriad describes this skill, while at the same time downplaying the contributions of other researchers, in the following passage:

Myriad succeeded where others failed by applying its genetic-mapping technology to define and locate the precise genetic regions associated with mutations predisposing a patient to breast and ovarian cancers (a collaborating scientist described this technique as "the closest thing to magic") ... Building on this foundation, Myriad then studied the BRCA genes to identify their particular structures, attributes, and characteristics. Once it deciphered this information, it sought to improve existing techniques for diagnosing an individual's hereditary cancer risk by designing isolated DNA molecules and producing them in the laboratory ...<sup>170</sup>

This emphasis on Myriad's technical prowess directly contradicts the thrust of the Science Narrative, which portrays Myriad as having stumbled upon the final piece of a vast puzzle that had largely been assembled by others. In the worldview of adherents to the Science Narrative, Myriad's contribution should not merit patent protection. But seen from Myriad's perspective, its scientists were trailblazers who fully deserve the protection afforded by the patent law for their innovative new invention.

As with most litigation narratives, there is an element of truth to each of these characterizations. The Science Narrative is correct in crediting the teams led by King, Collins, Stratton and others with much of the work that led to the identification and sequencing of BRCA1/2.<sup>171</sup> However, all scientific progress is cumulative, and the Pioneer Narrative accurately depicts Myriad as innovating both in its use of the Utah familial resources at

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<sup>170</sup> Myriad SCOTUS Brief, at 6.

<sup>171</sup> See notes 48-51, *supra*, and accompanying text.

hand and its decision to employ newer BAC sequencing techniques over the established YAC techniques utilized by others.<sup>172</sup>

*b. Incentives*

The second policy argument embodied by the Pioneer Narrative relates to the incentive effect of patents on innovation and, consequently, economic growth. This argument posits that patents offer crucial financial incentives that induce companies to perform socially-valuable but expensive research and development.<sup>173</sup> Without patents, it would be difficult for companies to recoup the high costs of drug discovery, development and clinical testing.<sup>174</sup> As a result, less research in this area would be conducted. One potential result of such a reduction in R&D is framed in terms of public health: less research will result in fewer drugs, which will result in more sickness and death from disease.<sup>175</sup> This argument is articulated by the Pharmaceutical Research and Manufacturers of America (PhRMA), which reasons that “[t]he discovery and development of new drug therapies and diagnostic tools is crucial to public health. The protections afforded by the federal patent laws are central to providing appropriate incentives to overcome the staggering costs and risks of developing new products and therapies.”<sup>176</sup>

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<sup>172</sup> See notes 59-63, *supra*, and accompanying text.

<sup>173</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) estimates that in 2011 its members spent approximately \$50 billion on R&D for new medications and vaccines. Pharm. Indus. Profile, at [http://www.phrma.org/sites/default/files/159/phrma\\_industry\\_profile.pdf](http://www.phrma.org/sites/default/files/159/phrma_industry_profile.pdf).

<sup>174</sup> See PhRMA Amicus Brief at 23 (“In the absence of adequate patent protection, investments in innovation are subject to the “free-rider” problem in which copyists can take advantage of the pioneering work of others, stifling competition”).

<sup>175</sup> See BIO Amicus Brief at 25 (“Private investment will be critical to ... identifying, isolating, and developing the innovative polynucleotides that will change the way we grow our food, fuel our cars, care for our environment, and even treat illness. A rule limiting patent eligibility ... could cut off that research in its infancy”).

<sup>176</sup> Assn. Molecular Pathology v. Myriad Genetics, Inc., Brief For the Pharmaceutical Research and Manufacturers of America as Amicus Curiae Supporting Respondents at 3 [hereinafter PhRMA Amicus Brief].

Interestingly, Amicus Curiae InHouse Patent Counsel LLC offers a narrative of a different company, Human Genome Sciences, Inc. (HGS), to make this point:

From its founding in 1992 until its acquisition in 2012, HGS was a biopharmaceutical company dedicated to the discovery, development, manufacture and marketing of innovative drug products for patients with unmet medical needs. HGS researchers explored the human genome to identify and isolate novel DNA and protein targets to develop useful

A related result is framed in economic terms: less research and development will result in fewer marketable products for U.S. biotechnology companies, negatively impacting domestic jobs and revenue and reducing U.S. competitiveness. The theme of patents as critical to the domestic biotechnology industry emerged early in the debate over gene patenting. One NIH representative writing in 1992 observed that:

The biotechnology industry in the United States is predicted to have as great an impact on jobs, productivity, and the nation's economy as the computer and electronics industries have had. The emergence of the biotechnology industry depends in large part on a system of patents and protection of intellectual property in the world markets.<sup>177</sup>

This theme was raised again during Congressional hearings in 2000: “The availability of patents to support the massive investment in genomic research is essential to capital formation. Investors in genomics companies require assurance that these companies will be able to profit for their research and development investments.”<sup>178</sup> This argument remained at the forefront in *Myriad*, and was advanced both by *Myriad* and several *amicus curiae*.<sup>179</sup> As such, it relies heavily on the Pioneer Narrative.

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treatments for human disease. Like many start-up biotechnology companies, much of the funding that made HGS' research and development possible was obtained on the basis that patents would protect its human gene-based discoveries. Those investments led to important new therapies for patients, such as Benlysta®, the first new drug approved for the treatment of lupus in more than 50 years. Without the protections offered by gene patents, the life-changing products developed by HGS would not currently exist, and it is likely that many fewer such products will be developed by others in the future.

Assn. Molecular Pathology v. Myriad Genetics, Inc., Brief For InHouse Patent Counsel, LLC as Amicus Curiae in Support of Respondents at 1 [hereinafter InHouse Amicus Brief].

<sup>177</sup> Bernadine Healy, Special Report on Gene Patenting, 327 NEW ENGLAND J. MED. 664, 666 (1992).

<sup>178</sup> Gene Patents and Other Genomic Inventions: Hearing Before the House Subcomm. on Courts and Intellectual Prop. of the Comm. on the Judiciary, 106th Cong. 51-71(2000) (statement of Dr. Randal W. Scott, President and Chief Scientific Officer, Incyte Genomics), [http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043\\_of.htm](http://commdocs.house.gov/committees/judiciary/hju66043.000/hju66043_of.htm).

<sup>179</sup> See, e.g., Myriad Brief, PhRMA Amicus Brief, IPO Amicus Brief, BIO Amicus Brief, AIPLA Amicus Brief at 23-24 (“The U.S. biotechnology industry has led the field in the global economy in large part due to strong patent protection of DNA-based

### 3. *The Administrative Narrative*

*Myriad and its attorneys followed standard practices for patenting DNA-based inventions, practices that have been used for more than three decades with other biomedical inventions. Patenting human DNA was pioneered by none other than the U.S. National Institutes of Health. Myriad complied with all rules and procedures of the Patent and Trademark Office, which thoroughly examined its patent applications and allowed them to issue only after Myriad satisfied all applicable criteria for patenting. Given that Myriad was the first to isolate the BRCA1/2 genes, the fact that the patents issued should be neither surprising nor controversial.*

The Administrative Narrative adopts the perspective of many patent attorneys, patent agents and others who view human DNA as “nothing special” and who argue that it should be treated no differently than any other chemical compound derived from natural sources.<sup>180</sup> They point out that DNA patents have been allowed by the U.S. PTO for nearly three decades, and that both the patent bar and industry have developed “settled expectations” regarding the patentability of human DNA.<sup>181</sup> As a result, tens of thousands of patents claiming DNA sequences already exist, and casting doubt on their validity would jeopardize existing businesses and investments.<sup>182</sup> Making such a radical change to the law, after so many years, they argue, should be left to Congress rather than the courts.<sup>183</sup>

In temporal terms, the Administrative Narrative focuses primarily on Myriad’s discovery of the BRCA genetic sequences and the subsequent prosecution of its patents. In this respect, Myriad did nothing unusual, and abided by long-established administrative procedures in obtaining its patents.

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inventions”).

<sup>180</sup> See ABA Amicus Brief at 3 (supporting “a patent-eligibility assessment of Isolated DNA Compounds that is no different than the assessment of other materials that are derived from or otherwise relate to natural materials or sources”).

<sup>181</sup> See *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 US 722 (2002) (“courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community”).

<sup>182</sup> See ABA Amicus Brief at 9 (noting that as of 2006, there were approximately 33,000 U.S. patents claiming nucleic acids).

<sup>183</sup> *Assn. Molecular Pathology v. Myriad Genetics, Inc.*, Brief For the Boston Patent Law Association as Amicus Curiae in Support of Respondents, at 2 [hereinafter BPLA Amicus Brief].

Just as the Science Narrative does not necessarily reflect the views of all scientists, the Administrative Narrative does not reflect the views of all, or even most, lawyers. Rather, this narrative reflects a particular “worldview” that is most commonly associated with patent attorneys, practitioners who devote their careers to obtaining patents on behalf of their clients. It is thus not surprising that eight different patent-related bar associations submitted *amicus* briefs in the Myriad case, all of which strongly supported the validity of Myriad’s patents.<sup>184</sup> These *amici* were joined by a chorus of private patent attorneys who produced numerous articles and blog postings bearing titles like “Swine Soar Higher in *Myriad* thanks to US Government’s *Amicus* Brief”, in which they criticized the courts and the U.S. Department of Justice for presuming to overturn “the longstanding practice of the Patent and Trademark Office” in granting such patents.<sup>185</sup> And while these authors often restated the incentive and ingenuity arguments associated with the Pioneer Narrative, their commentary was typically infused with a greater sense of indignation that their *own* longstanding practices, which always seemed eminently reasonable to them, were now being challenged and potentially upended.

#### 4. *The Access Narrative*

*Charlotte*<sup>186</sup>, a single mother with two young daughters, is of Ashkenazi Jewish heritage. Charlotte’s mother, her maternal grandmother and her older sister were all diagnosed with breast cancer in their thirties. Charlotte’s mother and grandmother were killed by the disease, and her sister is currently undergoing treatment. None of Charlotte’s relatives has been tested for the BRCA mutation. Charlotte’s physician has recommended that she be tested and that she consider testing for her daughters. The only provider of BRCA testing in the United States is Myriad Genetics, which charges more than \$3,000 for the test. Charlotte works as a substitute teacher for a parochial school and does not have health insurance. Though she qualifies for Medicaid, it does not cover BRCA testing in her state, and

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<sup>184</sup> Amicus briefs were submitted by the American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), Boston Patent Law Association, Federation des Conselies, Federal Circuit Bar Association, Institute of Professional Representatives before the EU Patent Office, Intellectual Property Owners (IPO), New York Intellectual Property Law Association and Philadelphia Intellectual Property Law Association.

<sup>185</sup> Dan Vorhaus & John Conley, *Swine Soar Higher in Myriad thanks to US Government’s Amicus Brief*, GENOMICS L. REP., Nov. 1, 2010.

<sup>186</sup> Charlotte is a fictitious character.

*Charlotte cannot afford to pay for testing out of pocket. As a result, Charlotte and her family must live with the uncertainty of this dread disease and cannot make an informed decision regarding potentially life-saving prophylactic procedures.*

There are many variations of the Access Narrative, but they all focus on individuals confronting the risk of breast and ovarian cancer without the benefit of BRCA diagnostic testing. In each of these stories, an individual at risk of carrying a cancer-related BRCA mutation cannot obtain recommended testing. There are two primary scenarios in which this inability plays out. The first, illustrated in the sample narrative above, occurs when Myriad's BRCA testing is not covered by her insurance or she does not have insurance, and she cannot afford to pay the cost out of pocket. In the second scenario, the individual has received some preliminary BRCA testing, but requires follow-up tests, either because a positive result was of uncertain significance or because she tested negative for the most common BRCA mutations. In all of these situations, Myriad's patent-based control over BRCA testing is identified as problematic: either because Myriad's pricing is too high or because Myriad prevents other laboratories from validating Myriad's test results.<sup>187</sup>

The narrators of these stories are typically at-risk individuals, family members, survivors and physicians.<sup>188</sup> The original plaintiffs in the Myriad case included five women who all related stories generally conforming with the narrative outlined above.<sup>189</sup> Breast Cancer Action, a non-profit organization dedicated to "representing the voices of people affected by breast cancer" and the Boston Women's Health Book Collective also joined the suit as plaintiffs.<sup>190</sup>

The focus of the Access Narrative is typically two-pronged, first addressing the individual's (or her family's) personal experience with cancer, and the second addressing the individual's experience with Myriad's BRCA testing services. In this narrative, the scientific research

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<sup>187</sup> While the focus of this article is on the Myriad case and BRCA testing, there are other cases in which gene patents have been alleged to have caused increased pricing for diagnostic tests. See, e.g., Debra L. Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material*, 15 ANNALS HEALTH L. 213, 242 (describing hospital's pricing of patented genetic test for Canavan's Disease).

<sup>188</sup> See HERMAN & SMIEJA, *supra* note 37 (collecting stories about hereditary breast/ovarian cancer from dozens of individual patients, physicians and family members).

<sup>189</sup> Declarations of Runi Limary, Genae Girard, Patrice Fortune, Vicky Thomason and Kathleen Raker.

<sup>190</sup> Myriad, 702 F. Supp. 2d at 188.

that led to the sequencing of the BRCA genes, and the level of innovation necessary to bring the test to market, are largely irrelevant. The point of the narrative, and the policy outcomes that its narrators typically support, relate to increasing affordable access to BRCA testing for at-risk individuals. The lack of access to testing is alleged to have serious health consequences for at-risk individuals and their families, as described by plaintiff Lisbeth Cerani:

I have undergone extensive treatment for my breast cancer, including a bilateral mastectomy, chemotherapy, radiation, and physical therapy, but I still have not been able to obtain BRCA genetic testing ... My doctors suspect that I have a BRCA mutation and will strongly recommend a prophylactic oophorectomy to remove my ovaries if I do. However, I would not risk putting myself through such a serious surgery and accompanying side effects without validation of increased risk of ovarian cancer such as a confirmed BRCA genetic mutation ... I am in this situation because the patents over the BRCA genes allow one company to control all genetic testing, and that company has chosen not to accept my insurance.<sup>191</sup>

Because its gene patents are perceived to enable Myriad to sustain high prices for its BRCAanalysis testing program, and to exclude competing BRCA testing providers from the market, the narrators typically oppose Myriad's patents and gene patenting in general.<sup>192</sup> This opposition takes several forms. First, proponents of the Access Narrative adopt doctrinal arguments in favor of excluding DNA patents from patentable subject matter. Second, they frequently adopt the "impeding research" policy arguments put forward by proponents of the Science Narrative.

Finally, they introduce a new policy argument directed primarily at Myriad's pricing for its BRCAanalysis test. This argument is exemplified by popular author Michael Crichton, who wrote in a 2007 *New York Times* op-

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<sup>191</sup> Myriad, Declaration of Lisbeth Ceriani, Aug. 13, 2009, at 3.

<sup>192</sup> Interestingly, patient advocacy groups, more broadly defined, are not unanimous in condemning gene patents. For example, in the District Court, *amici curiae* March of Dimes Foundation, Canavan Foundation, Claire Altman Heine Foundation, Breast Cancer Coalition, Massachusetts Breast Cancer Coalition, National Organization for Rare Disorders, and National Tay-Sachs & Allied Diseases Association opposed Myriad's patents, while Genetic Alliance, a non-profit dedicated to patient-focused genetic research, adopted the "incentives" argument, urging that "the abolition of patents on isolated DNA ... would diminish the promise of genetic research for patients". Myriad, 702 F. Supp. 2d at 190-91.

ed:

You, or someone you love, may die because of a gene patent that should never have been granted in the first place. Sound far-fetched? Unfortunately, it's only too real. Gene patents ... raise costs exorbitantly: a test for breast cancer that could be done for \$1,000 now costs \$3,000. Why? Because the holder of the gene patent can charge whatever he wants, and does.<sup>193</sup>

This objection to gene patenting is based on the monopoly pricing that a patent holder is able to extract from the market. This policy argument is uniquely tied to the Access Narrative, the focus of which is the availability and pricing of Myriad's BRCA testing. The argument is reminiscent of similar arguments made in the years-old debate over "access to medicines", the effort to make certain pharmaceutical products widely available in developing countries in which the majority of the affected population is unable to afford them.<sup>194</sup> This argument is, at its core, economic, and seeks to prompt governmental intervention to reduce the prices at which such products are offered. In the context of gene patents, no one has credibly argued for price controls or governmental subsidy, but advocates have sought to achieve the same price relaxation through the invalidation of patents giving monopoly leverage to Myriad.

### 5. *The Dystopian Narrative*

*If genes are patented, corporate interests will embark on a program of immoral and destructive research that could lead to a range of depredations including the rise of Frankenfoods, the introduction of dangerous new species, farming of human fetusus, genetic doping, designer babies, human cloning, human-animal hybridization, drug-resistant diseases, and irreversible environmental degradation.*<sup>195</sup> *These scientific*

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<sup>193</sup> Michael Crichton, *Patenting Life*, New York Times, Feb. 13, 2007.

<sup>194</sup> See, e.g., Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. MED. & ETHICS 184, 185 (2009). Ironically, the pharmaceutical industry has developed a counter-narrative in which profits from patented drugs enable it to develop and distribute drugs targeting neglected diseases such as malaria and tuberculosis to patients in the developing world. See Paul Herling, *Patent Sense*, 449 NATURE 174 (2007) (telling the story of Coartem, a patented malaria therapy delivered by Novartis to 30 low-income countries at cost). Cf. notes 230-229, *infra*, and accompanying text (counter-narrative to Anti-Commons Narrative).

<sup>195</sup> The short passage offered here is hardly a narrative at all, but is intended to evoke

*“advances” are both immoral and degrading to the human race, if not inimical to its very survival.*

The Dystopian Narrative is admonitory and forward-looking. It focuses neither on the events leading to Myriad’s sequencing of the BRCA genes, nor on Myriad’s BRCA testing program. Rather, the plot of this narrative begins in a hypothetical future *after* gene patenting is allowed and paints a disquieting portrait of the world that might result. This world is grotesque and frightening, largely due to the perversion of recognizable human, plant and animal forms through genetic manipulation. As such, the focus of the narrative is not on Myriad or any other identifiable company, but the whole of the biotechnology and scientific research establishment. This narrative is most often adopted by those who oppose gene patenting on moral, philosophical, ethical or religious grounds.<sup>196</sup>

In broad terms, there have been four principal ethical arguments raised in opposition to gene patenting.<sup>197</sup> These arguments hold that patents on human DNA: (1) subvert basic notions of human dignity,<sup>198</sup> (2) inappropriately commodify the human body,<sup>199</sup> (3) grant private ownership

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the countless stories, novels and films that depict a dystopian future in which genetic manipulation has run amok. *See, e.g.*, MICHAEL CRICHTON, *NEXT* (2006); MARGARET ATWOOD, *ORYX AND CRAKE* (2003); MICHAEL CRICHTON, *JURASSIC PARK* (1990); Peter Weingart, *Of Power Maniacs and Unethical Geniuses: Science and Scientists in Fiction Film*, 12 *PUB. UNDERSTANDING OF SCI.* 279 (2003).

<sup>196</sup> For convenience, I refer collectively to moral, philosophical, ethical and religious arguments as “ethical” policy arguments.

<sup>197</sup> There have been numerous attempts to categorize these arguments. *See, e.g.*, RESNIK, *supra* note 161, at x; Jonathan Kahn, *What’s the Use? Law and Authority in Patenting Human Genetic Material*, 14 *STAN. L. & POL’Y REV.* 417 (2003), James Boyle, *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us*, 50 *ADVANCES IN GENETICS* 97 (2003).

<sup>198</sup> *See, e.g.*, RESNIK, *supra* note 161, at 93-129 (concluding that DNA patents, while potentially threatening human dignity, do not themselves violate dignitary notions); Aurora Plomer, *Human Dignity and Patents* in *RESEARCH HANDBOOK OF HUMAN RIGHTS AND IP RIGHTS* (C. Geiger, ed., 2014); Sirpa Soini et al., *Patenting and Licensing in Genetic Testing: Ethical, Legal and Social Issues*, 16 *EURO. J. HUMAN GENETICS* S10, S16-S17 (2008) (European perspective); Kahn, *supra* note 197, at 441-42 (“Those who invoke the dignity of the human subject are trying to resist the incursion of property and commerce, as carried by patent law, into any area directly involving human genetic material. They are more concerned with what a gene *is* as a singular embodiment of human identity, than with what it *does* as a disembodied chemical entity ... They view patents variously as the intrusion of the profane world of the market into the sacred world of the human essence, a property regime tantamount to slavery insofar as it confers ownership over constituent aspects of human identity”).

<sup>199</sup> *See, e.g.*, SHUBHA GHOSH, *IDENTITY, INVENTION, AND THE CULTURE OF*

over the commonly-held heritage of humanity,<sup>200</sup> and (4) grant private ownership over that which is the province of a spiritual Creator.<sup>201</sup>

The ethical debate over gene patenting has been going on for decades, and to some degree reflects a much older philosophical debate over the propriety of genetic research more generally.<sup>202</sup> Without a doubt, images of designer babies, eugenics and human cloning do not arise exclusively in the context of patenting. Patents are implicated because they create a financial incentive to conduct the genetic research to which opponents object, and might thus encourage more of this research to occur.<sup>203</sup>

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PERSONALIZED MEDICINE PATENTING 12-15 (2012) (“The challenging question is whether attributes of a person can be owned and treated as property in the legal sense”); Mark J. Hanson, *Patenting Genes and Life – Improper Commodification?* in WHO OWNS LIFE?, *supra* note x, at 161, 166-70; Boyle, *supra* note 197, at 101-02; Kahn, *supra* note 197, at x (“commodification through patents is presented as profoundly degrading both to the individual and to society”)

<sup>200</sup> See, e.g., RESNIK, *supra* note 161, at, at 77-82 (comparing the human genome to other elements of the common heritage of humanity, including the oceans, the moon, Antarctica and the atmosphere); Patricia Lacy, *Gene Patenting: Universal Heritage vs Reward for Human Effort*, 77 OREGON L. REV. 783, 798, (1998) (citing Hubert Curien, *The Human Genome Project and Patents*, 254 SCIENCE 1710, 1710 (1991)); Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application of the Common Heritage of Humankind*, 13 AM. U. INT’L L. REV. 219 (1997); Watson, *supra* note 72, at 48, COLLINS, *supra* note 72, at 301; Boyle, *supra* note 197, at 102-03; and Margaret Graham Tebo, *The Big Gene Profit Machine*, ABA J., Apr. 2001, 46, 52 (describing efforts to develop a treaty treating the human genome as “‘common property’ to be shared by all countries for the good of humanity”).

<sup>201</sup> See, e.g., ARTHUR GERSHMAN, OTHER PEOPLES BODIES – HOW THE BIOTECH INDUSTRY-GOVERNMENT-PATENT COMPLEX IS TRYING AND SUCCEEDING TO MONOPOLIZE YOUR GENES (2011) (Judaic perspective); RESNIK, *supra* note 161, at, at 75-77 (“by claiming exclusionary property rights in a genetically-altered composition of matter, the human manipulator is assuming a place which belongs alone to God” (quoting C. Mitchell)); Foundation for Economic Trends and General Board of Church and Society of the United Methodist Church, statement issued at press conference, 18 May 1995, Washington, D.C. (“We, the undersigned religious leaders, oppose the patenting of human and animal life forms ... We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions”).

<sup>202</sup> See, e.g., GORDON GRAHAM, GENES: A PHILOSOPHICAL INQUIRY 113-42 (2002); FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 148-50 (2002).

<sup>203</sup> See *Parker v. Chakrabarty*, Brief on Behalf of the Peoples Business Commission, Amicus Curiae, 1979 WL 200005 at 4 (1979) [hereinafter PBC Amicus Brief] (permitting patenting of living organisms “would significantly contribute to the profit potential of the genetic industry, thus generating a greater momentum in research and development of genetic engineering technologies”). See also Baruch A. Brody, *Protecting Human Dignity and the Patenting of Human Genes* 111, 122 in PERSPECTIVES ON GENETIC PATENTING (Audrey R. Chapman, ed., 1999) (noting objections to the patenting of human genes rooted

The Dystopian Narrative in the gene patenting legal debate was first invoked more than thirty years ago in *Diamond v. Chakrabarty*,<sup>204</sup> the 1980 case in which the Supreme Court first upheld the patentability of living organisms. In *Chakrabarty, amicus curiae* Peoples Business Commission (PBC)<sup>205</sup> invoked dignitary and religious arguments in opposition to the patenting of a living bacterium.<sup>206</sup> PBC painted a grim picture of the potential consequences of rewarding genetic research with patents:

Scenarios which once appeared far-fetched – the manufacturing of mammals, including human beings, to specification; the creation of super-intelligent beings; the asexual reproduction of organisms through cloning; the advent of genetic surgery designed to alter the heredity of complex organisms - will become science fact, if not tomorrow, then certainly within the lifetimes of the majority of Americans.<sup>207</sup>

While the Court upheld the patentability of living organisms in *Chakrabarty*, it took note of the “gruesome parade of horrors” envisioned by PBC and their potential “to depreciate the value of human life”.<sup>208</sup>

The objections to patenting genes and living organisms raised by PBC in *Chakrabarty* continued to be voiced by religious groups throughout the 1980s and 1990s, culminating in the 1995 *Joint Appeal Against Human and Animal Patenting* issued by a coalition of more than 185 leaders from eighty different religious organizations.<sup>209</sup>

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in a desire to avert the development of a future eugenics movement).

<sup>204</sup> 447 U.S. 303 (1980).

<sup>205</sup> PBC was co-directed by Jeremy Rifkin, an outspoken opponent of genetic engineering and the author of the book *Who Should Play God?* (1977). PBC Amicus Brief, *supra* note 203, at 4. See also Neil Gross & John Carey, *Who Owns the Tree of Life?*, BUS. WK., Nov. 4, 1996 (discussing Rifkin’s campaign against gene patents and a coalition he assembled of “Southern Baptists, mainline Protestants, Catholic bishops, Muslims, Hindus, and Buddhists – all opposed to patenting genes”).

<sup>206</sup> PBC Amicus Brief, *supra* note 203, at 15 (“we are already witnessing the erosion of our idea of man as something splendid or divine, as a creature with freedom and dignity. And clearly, if we come to see ourselves as meat, then meat we shall become” (quoting Leon Kass, *Making Babies - The New Biology and the ‘Old’ Morality*, THE PUBLIC INTEREST, Winter, 1972)).

<sup>207</sup> PBC Amicus Brief, *supra* note 203, at 12.

<sup>208</sup> *Chakrabarty*, 447 U.S. at 316.

<sup>209</sup> See Audrey R. Chapman, *Background and Overview* 7, 17-20 in PERSPECTIVES ON GENETIC PATENTING (Audrey R. Chapman, ed., 1999); C. Ben Mitchell, *A Southern Baptist Looks at Patenting Life* 167, 167-74 in PERSPECTIVES ON GENETIC PATENTING

In the *Myriad* case two decades later, there were fewer overt evocations of the Dystopian Narrative. Nevertheless, the Dystopian Narrative was evident in the popular press and literature opposing gene patenting. One of the most outspoken voices against gene patenting was the late science fiction writer Michael Crichton, who portrayed the transgressions of an unethical biotechnology company in his novel *NEXT*<sup>210</sup> and became an active figure in the policy debate in Washington.<sup>211</sup> In his novel, Crichton concocts a wide range of genetically modified organisms including talking orangutans, super-intelligent chimps, and bioluminescent fish genetically altered to display corporate advertising. Patents play a substantial role in motivating the unethical corporations and researchers that populate the novel.<sup>212</sup>

These popular evocations of the Dystopian Narrative also found their way into Congressional debate. For example, when European medical researchers reported in 2003 that they had successfully transplanted cells from a male to a female human embryo, one member of Congress decried both the creation of these “she-male embryos” and the prospect of patents issuing on such “ghoulish research”.<sup>213</sup>

But ethical arguments against gene patenting are not exclusively consequentialist. That is, they do not simply aver that gene patenting is wrong *because* it could lead to one or more undesirable outcomes. In fact, most ethical arguments relating to gene patenting today do *not* explicitly invoke the Dystopian Narrative as I have constructed it, or any narrative at all. Rather, these arguments are frequently rooted in moral philosophy, untethered to tangible examples and stories, and those who object to gene patenting on ethical grounds often do so because they view the practice of patenting genes itself as objectionable, irrespective of its potential

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(Audrey R. Chapman, ed., 1999).

<sup>210</sup> MICHAEL CRICHTON, *NEXT* (2006). For a critical review of the novel’s cavalier treatment of legal and policy issues, see Jorge L. Contreras, *Book Review: NEXT and Michael Crichton’s Five-Step Program for Biotechnology Law Reform*, 48 *JURIMETRICS* 337 (2008).

<sup>211</sup> See, e.g., Michael Crichton, *What’s Wrong with Patenting Genes* (Speech to Congressional Aides, Sept. 2006) (<http://www.whoownsyourbody.org/crichton-congress.html>).

<sup>212</sup> CRICHTON, *NEXT*, *supra* note 210, at 322.

<sup>213</sup> 157 Cong. Rec. E1177, E1178 (2011) (statement of Rep. Dave Weldon on Jul. 22, 2003) (cited and discussed in Yaniv Heled, *On Patenting Human Organisms or How the Abortion Wars Feed into the Ownership Fallacy*, 36 *CARDOZO L. REV.* \_\_ (forthcoming 2014)).

consequences. Ethicist David Resnik, for example, carefully assesses dignitary and commodification objections to gene patenting in terms of Kantian and Christian moral philosophy.<sup>214</sup> While he acknowledges the Dystopian Narrative that others have advanced, he does not engage with it.<sup>215</sup>

Nevertheless, not even the most dispassionate philosophical reasoning can divorce itself entirely from the narratives that can be, and have been, spun from its threads. Thus, James Boyle observes proponents of the commodification argument evoking a “dystopian future in which transgenic, subhuman creatures are traded as chattel”.<sup>216</sup> In order to persuade, some arguments must, at least implicitly, be grounded in narrative.

### 6. *The Anti-Commons Narrative*

*More than twenty percent of the human genome is already patented, and more gene patents are being issued every year. The large number of patents on this limited biological resource will grind biomedical research to a halt, as researchers will be unable to obtain licenses from the dispersed holders of rights necessary to advance scientific progress, or to pay the tolls that will be necessary to clear all of these rights. This hindrance on research will result in fewer medical advances and life-saving treatments.*

Like the Dystopian Narrative, the Anti-Commons Narrative is forward-looking and admonitory. Like the “impeding research” branch of the Science Narrative, it envisions a reduction in scientific research if patents on human genetic material are allowed to proliferate.

The Anti-Commons Narrative originated with Michael Heller’s and Rebecca Eisenberg’s 1998 *Science* article positing the risk of a patent-fueled “anti-commons” in biomedical research.<sup>217</sup> In the article which, as of this writing, has been cited nearly 2000 times in the scholarly and academic

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<sup>214</sup> RESNIK, *supra* note 161, at 95-105.

<sup>215</sup> *Id.* at 93-94.

<sup>216</sup> Boyle, *supra* note 197, at 101-02. *See also* Heled, *supra* note 213, at x (“the notion of “patenting humans” tends to evoke images that offend our sensibilities. Indeed, one can hardly remain unmoved by the imagined plight of helpless fellow humans “tagged” with patent numbers (perhaps on their forearms) who are the property of someone, perhaps an ominous, heartless regime or corporate entity.”)

<sup>217</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *Science* 698 (1998).

literature,<sup>218</sup> the authors envision a scenario in which a proliferation of patent claims on biological resources make it increasingly difficult for any single institution to conduct research. Heller and Eisenberg famously describe this effect as the “tragedy of the anticommons”.<sup>219</sup> As explained by Dan Burk and Mark Lemley, “[t]he anticommons is characterized by fragmented property rights that must be aggregated to make effective use of the property.”<sup>220</sup>

Another key trope of the Anti-Commons Narrative derives from a 2005 article by Kyle Jensen and Fiona Murray, which made the claim that “20% of human gene DNA sequences are patented”.<sup>221</sup> The Jensen and Murray article, for the first time, *quantified* the gene patenting phenomenon in a way giving rise to widespread concern. The findings and methodology of that paper, as well as its frequent invocation, have been criticized.<sup>222</sup> Nevertheless, the 20% figure continues to be cited both in the scholarly literature and, even more frequently, in the popular press, legal briefs and public debate.<sup>223</sup> Recently, even bolder claims have been made, asserting that the *entire* human genome is effectively covered by patent claims.<sup>224</sup>

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<sup>218</sup> Based on citation results produced by Google Scholar (accessed by author on May 19, 2013).

<sup>219</sup> This phrase is a variation on Garrett Hardin’s classic narrative of natural resource depletion which he termed the “tragedy of the commons”. Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968).

<sup>220</sup> DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 76 (2011).

<sup>221</sup> Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239 (2005).

<sup>222</sup> Christopher M. Holman, *Debunking the Myth that Whole-Genome Sequencing Infringes Thousands of Gene Patents*, 30 NATURE BIOTECH. 240 (2012).

<sup>223</sup> A Google Scholar search conducted by the author found 143 scholarly citations for the paper. See, e.g., Inst. of Medicine, *The Economics of Genomic Medicine – Workshop Summary* at 10 (2013) (20% figure mentioned by a prominent professor of genetics and medicine without citation). [add popular press citations]

<sup>224</sup> See Jeffrey Rosenfeld & Christopher E. Mason, *Pervasive Sequence Patents Cover the Entire Human Genome*, 5 GENOME MEDICINE (Mar. 25, 2013) (finding that “current gene patents cover almost half of all known genes” and “100% of known genes have at least one 15mer claimed in a known patent”). The findings and methodology of this paper have been criticized by several legal experts (including the author). See Chris Holman, *A Critique of a Recent Article Which Found that Sequence Patents Cover the Entire Human Genome*, Holman’s Biotech IP Blog (Apr. 5, 2013) (<http://holmansbiotechblog.blogspot.com/2013/04/a-critique-of-recent-article-which.html>); Donald Zuhn, *Revisiting Genome Medicine Article on “Pervasive Sequence Patents” That “Cover the Entire Human Genome”*, Patent Docs (Apr. 8, 2013) (<http://www.patentdocs.org/2013/04/revisiting-genome-medicine-article-on-pervasive-sequence-patents-that-cover-the-entire-human-genome.html>); and Shine Tu et al, *Letter to the Editor: Response to ‘Pervasive Sequence Patents Cover the Entire Human Genome’*, 6

The Anti-Commons Narrative, like the Dystopian Narrative, is cautionary in that it warns what *could* happen if gene patenting is allowed to continue. Yet the world that it portrays, while far from ideal, is less fantastical than that portrayed by the Dystopian Narrative. It is inspired, in fact, by actual market failures observed by Heller in post-Soviet retail space arrangements (the origin of the “anti-commons” label).<sup>225</sup> It is not surprising, therefore, that the Anti-Commons Narrative has been invoked more frequently in the recent debate over gene patenting than the Dystopian Narrative, which has not, in the thirty years since *Chakrabarty*, materialized in a meaningful way.<sup>226</sup>

The Anti-Commons Narrative also differs from the Dystopian Narrative in that it is grounded in economics rather than morality. That is, gene patents are viewed as undesirable because of the effect they are likely to have on the conduct of biomedical research, rather than any inherent evil associated with the practice. As such, proponents of the Anti-Commons Narrative include legal and social science scholars who generally favor open science configurations, rather than religious and ethics-based groups.

The Anti-Commons Narrative portrays a world in which the proliferation of patents substantially hinders biomedical research, the progress of science and the improvement of human health.<sup>227</sup> Not surprisingly, its predictions have been disputed by those who favor gene patenting. Thus, like the Access Narrative,<sup>228</sup> the Anti-Commons Narrative

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GENOME MED., Feb. 27, 2014.

<sup>225</sup> Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621 (1998).

<sup>226</sup> See Caulfield et al, *supra* note x (describing prevalence of anti-commons narrative in policy debates over gene patenting).

<sup>227</sup> See, e.g., Lori Andrews, et al., *When Patents Threaten Science*, 314 SCIENCE 1395 (2005), Gertrui Van Overwalle, *Turning Patent Swords into Shares*, 330 SCIENCE 1630 (2010); Coll. Am. Pathologists, *Genes Patents* (Aug. 31, 2004) (reproduced in LORI B. ANDREWS, MAXWELL J. MEHLMAN & MARK A. ROTHSTEIN, GENETICS: ETHICS, LAW AND POLICY 247 (1st ed. 2002); Rai, *supra* note x, at 90-91 (the increased availability of patents on biomedical inventions has hindered the advancement of science); Stephen Hilgartner, *Potential Effects of a Diminishing Public Domain in Biomedical Research Data*, in NRC PUBLIC DOMAIN, *supra* note x, at 137 (“[e]xcessive concern with the protection of intellectual property can erect barriers to establishing new public domains”); Waston Amicus Brief at 19 (“A human genome cluttered with no trespassing signs granted by the Patent Office inhibits scientific progress”); Genformatic LLC, Amicus Brief 1 (“whether and to what extent third parties hold intellectual property rights to portions of those nucleotide sequences affects or impairs the ability of scientists, clinicians, and innovators to practice genome analysis and improve the technology of DNA sequencing”).

<sup>228</sup> See note 194, *supra*.

has spawned the growth of a powerful counter-narrative<sup>229</sup> holding that a research-inhibiting anti-commons has *not* developed,<sup>230</sup> and that it is the financial incentives offered by patenting, not the absence of patenting, that is more likely to advance medical discovery and improve human health.<sup>231</sup>

Thus, like the classical two-sided litigation narrative, the Anti-Commons Narrative and the Counter-Anti-Commons Narrative exist in an uneasy balance, neither definitively established by the empirical evidence, each presenting itself to the adjudicator in the hope of being adopted.<sup>232</sup>

## B. DIVERGENT NARRATIVES

For purposes of comparison, *Table 1* contains a summary of the six gene patenting narratives described in Part II.A, showing in abbreviated format the narrator and the policy arguments that are typically associated with each.

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<sup>229</sup> In this article I do not treat the Counter-Anti-Commons Narrative as a separate, seventh, narrative of gene patenting because it is largely reactive to the Anti-Commons Narrative and not an independent story that is integral to any particular worldview.

<sup>230</sup> See, e.g., Ann E. Mills & Patti M. Tereskerz, *Changing Patent Strategies: What Will They Mean for the Industry*, 25 NATURE BIOTECH. 867, 867 (2007) (citing “diminished concern in the biotech industry over the possible occurrence of an anticommons”); Caulfield et al, *supra* note x, at 1092 (“the effects predicted by the anticommons problem are not borne out in the available data”); Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 171–94 (2005) (finding previous studies inconclusive).

<sup>231</sup> See, e.g., RESNIK, *supra* note 161, at 131-35 and 155-56 (outlining scientific and medical progress arguments in favor of gene patenting), and F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science – A Response to Rai and Eisenberg*, 95 Nw. U. L. REV. 691 (2001) (rebutting the “open science” arguments posited by Rai and Eisenberg).

<sup>232</sup> The Anti-Commons Narrative, including the 1998 Heller-Eisenberg article and the 2005 Murray 20% statistic, makes a significant appearance in the District Court’s opinion in *Myriad*. 702 F.Supp 2d at 208.

Table 1  
*Summary of Gene Patenting Narratives and Policy Arguments*

<b>Narrative</b>	<b>Narrator(s)</b>	<b>Associated Policy Arguments</b>	<b>Should Isolated DNA be Patentable?</b>
<b>Science</b>	Academic researchers	<p><i>Merit:</i> trivial scientific accomplishments do not merit patent protection</p> <p>-- scientific discovery is a collective effort and rewards should not be claimed by the performer of the final step</p> <p><i>Impeding Research:</i> gene patents will impede scientific research</p>	No
<b>Pioneer</b>	Myriad Bio/pharma industry Patent attorneys	<p><i>Incentives:</i> gene patents provide needed incentives for R&amp;D</p> <p><i>Economic Growth:</i> eliminating gene patents will harm the biotech industry and thereby impair U.S. economic growth and jobs</p>	Yes
<b>Administrative</b>	Patent attorneys	<p><i>Innovation:</i> isolating genes is non-trivial and deserving of protection</p> <p><i>Settled Expectations:</i> don't upset long settled expectations of the bar and industry</p>	Yes
<b>Access</b>	At-risk individuals Medical professionals	<i>Public Health:</i> allowing a company to charge monopoly rents for a critical diagnostic test endangers lives	No
<b>Dystopian</b>	Religious organizations Bioethicists Other individuals	<p><i>Dignity:</i> patenting genes violates fundamental notions of human dignity</p> <p><i>Commodification:</i> patenting genes is a dangerous step toward commodification of the human body</p> <p><i>Common Heritage:</i> human DNA is part of the common heritage of humanity and cannot be privately owned</p> <p><i>Religion:</i> patenting DNA violates fundamental religious tenets</p>	No
<b>Anti-Commons</b>	Academic researchers, open society advocates	<i>Impeding Research:</i> gene patents will impede scientific research	No

Clearly, there are significant differences among these narratives. To some degree (perhaps to every degree) these narratives are self-serving. That is, they are constructed to persuade either a court or a policy maker that gene patenting should or should not be permitted.

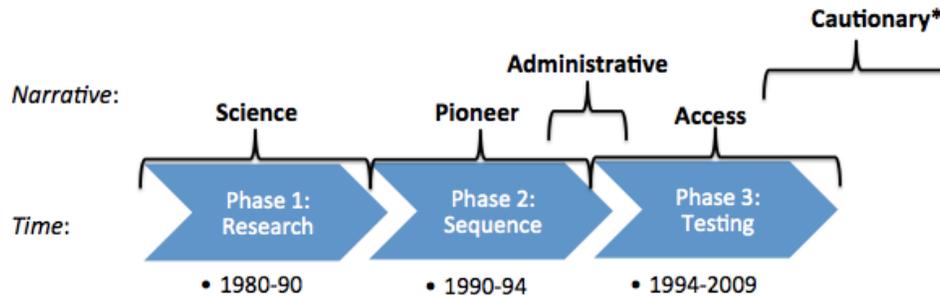
However, even the most self-serving narratives must be confined to certain boundaries of facticity. That is, Myriad could not claim that it located the BRCA1 gene on chromosome 17 in 1952, because there is ample extrinsic evidence showing that this milestone was not achieved until 1990. Likewise, opponents of gene patenting could not embellish the Dystopian Narrative with claims that the dinosaurs of Michael Crichton's *Jurassic Park* do, in fact, exist on an island in the Pacific, as this claim is patently false. The play among narratives is more subtle: a matter of selectivity, tone and emphasis.

One significant feature that distinguishes the different narratives of gene patenting is the time period covered by each. The comprehensive narrative offered in Part II starts with early twentieth century observations associating certain cancers with family history and ends with the current state of Myriad's BRCA testing program. This lengthy and complex story is distilled in each of the individual narratives to include only the time period most relevant to the narrator's policy arguments. For example, the Science Narrative focuses on the "race" to sequence the BRCA genes, but does not devote much attention to Myriad's testing practices and pricing. The Access Narrative, on the other hand, focuses almost entirely on Myriad's current BRCA testing program and pricing, while paying scant attention to the work leading up to the discovery of the BRCA genes.<sup>233</sup> *Figure 1* illustrates the time periods emphasized by each of the six principal narratives of gene patenting.

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<sup>233</sup> These time periods align with previously observed phases of the BRCA debate. See Dalpé, *supra* note 43, at 203.

Figure 1  
Temporal Focus of Gene Patenting Narratives



\*Includes Dystopian and Anti-Commons

The selection of a temporal framework for a narrative is fundamental to narrative construction. As illustrated above, the narrator has considerable latitude to choose a time period on which to focus. The choice of time period, if executed prudently, will enable the narrator to include within his narrative those events that are most supportive of his policy arguments and to exclude less favorable events.<sup>234</sup>

In fact, simply observing the temporal scope of a particular narrative offers a significant clue as to what policy arguments and outcome the narrator is likely to support. For example, a recent article in the *New England Journal of Medicine* offers a timeline purporting to illustrate “Important Events in DNA Patenting and the Discovery and Use of Genes Conferring susceptibility to Breast and Ovarian Cancer”.<sup>235</sup> The timeline begins in 1953 with Watson’s and Crick’s discovery of the structure of DNA and includes both the 1989 formation of the International Breast Cancer Linkage Consortium and Mary-Claire King’s location of BRCA1 on chromosome 17.<sup>236</sup> Myriad is not mentioned by name under any of the entries for “BRCA1 sequence reported,” “BRCA2 sequence reported,” or “BRCA analysis test launched”. However, an event in 2004 is listed as:

<sup>234</sup> See, e.g., Griffin, *supra* note 2, at 284 (describing conflicting narratives of a murder/suicide case in which the accused begins his description of the victim early in her life so as to include examples of her emotional disturbance, as well as symptomatic behavior in members of her family, whereas the victim’s narrative, revealed through a letter that she wrote prior to her death, focuses on the troubled period of her marriage to the accused); Kim Lane Scheppelle, *Foreword: Telling Stories*, 87 MICH. L. REV. 2073, 2094 (1989) (“in legal stories, ‘where one begins’ has a substantial effect because it influences just how the story pulls in the direction of a legal outcome.”).

<sup>235</sup> Aaron S. Kesselheim & Michelle M. Mello, *Gene Patenting – Is the Pendulum Swinging Back?*, 360 NEW ENGLAND J. MED. 1855, 1856 (2010).

<sup>236</sup> *Id.*

“Myriad’s patent rights severely limited by court in European Union”.<sup>237</sup> Taken together, the events displayed on this timeline convey the ideas that (a) many research groups other than Myriad were involved in the research leading to the sequencing of BRCA1/2, (b) Myriad was not a significant player in the global research effort, and (c) Myriad’s patents are in some way suspect. Simply by looking at this chart, one could conclude that the authors of the article, a physician and a health policy specialist from Harvard, generally oppose the patenting of human DNA. The time periods covered by their graphical narrative offer a telling clue that this is their position.

### III. MAPPING NARRATIVE TO LAW

#### A. NARRATIVE AND ADJUDICATION

All common law legal systems rely, to a large degree, on competing narratives to construct the factual scaffolding on which a decision favoring one party over the other is based.<sup>238</sup> Much of the theoretical literature addressing the use of narrative in law making has focused on the jury as decision maker.<sup>239</sup> Yet judges also develop their understanding of a case from the factual narratives presented to them. Unlike juries, however, which are simple “finders of fact”, judges must decide questions of law. They must thus process not only the factual narratives presented to them, but also a range of legal and policy arguments. Moreover, unlike juries, judges approach cases with pre-existing knowledge of, and views regarding, the legal doctrines in dispute. And, finally, unlike juries, judges (at least in some trials and most appellate cases) must support their decisions with written opinions that offer at least some rendition of the facts of the case.

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<sup>237</sup> *Id.*

<sup>238</sup> The dynamics of civil law jurisdictions have been observed to be quite different. See, e.g., Kent Greenawalt, *Legal Reasoning and Personal Convictions*, in *PRESCRIPTIVE FORMALITY AND NORMATIVE RATIONALITY IN MODERN LEGAL SYSTEMS* 125 (Werner Krawietz, Neil MacCormick & Georg Henrik von Wright, eds. 1994).

<sup>239</sup> See, e.g., ROBERT P. BURNS, *A THEORY OF THE TRIAL* (1999); Griffin, *supra* note 2 (critiquing “story model” of jury decision making); Peter Brooks, *Narrative Transactions – Does the Law Need a Narratology?*, 18 *YALE J.L. & HUMANITIES* 1, 2 (2006) (“it is assumed that juries often decide verdicts on the basis of the more persuasive story presented at trial.”); Binny Miller, *Give Them Back Their Lives: Recognizing Client Narrative in Case Theory*, 93 *MICH. L. REV.* 485 (1994) (analyzing use of narrative in case theory); Nancy Pennington & Reid Hastie, *A Cognitive Theory of Juror Decision Making: The Story Model*, 13 *CARDOZO L. REV.* 519 (1991).

A judge deciding a case is invariably presented with two or more narratives, the consistency of which will vary, sometimes dramatically, depending upon the case. It is a commonplace of legal reasoning that the judge must decide between these two competing renditions of facts when making a decision.<sup>240</sup> But, in actuality, the judge's function is more than one of mere selection. The judge must actively *construct* a coherent narrative of events, a third narrative independent of, but derived from, what has been presented to him or her.<sup>241</sup> The narrative constructed by a judge is critical to explain and justify the court's holding, both on doctrinal and policy grounds.<sup>242</sup> Dworkin thus begins *Law's Empire* with the observation that "legal reasoning ... consists in the narrative story that makes [legal] practices the best they can be."<sup>243</sup>

## B. ADJUDICATION OF THE *MYRIAD* CASE

In this Part, I assess the extent to which the six narratives of gene patenting are reflected in the judicial opinions in the *Myriad* case and the degree to which these narratives influenced the reasoning and decisions of the courts.<sup>244</sup>

### 1. *District Court*

The District Court in *Myriad* offers a lengthy narrative account of the case which can be divided into roughly two parts. In the first, Judge Sweet describes the events leading to the sequencing of the BRCA1/2 genes. In the second, he describes Myriad's BRCA testing programs and pricing.

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<sup>240</sup> See, e.g., MACCORMICK, *supra* note 9, at 119 ("Our system of administering justice in civil affairs proceeds on the footing that each side, working at arm's length, selects its own evidence. Each side's selection of its own evidence may, for various reasons, be partial in every sense of the term ... It is on the basis of two carefully selected versions that the judge is called upon to adjudicate" (quoting *Thompson v. Glasgow Corp.*, 1962 S.C. (H.L.) 36, per Lord J.-C. Thomson at p. 52).

<sup>241</sup> In this respect I part ways with Professor MacCormick, who maintains that "the answer to question how the judges come upon the generalization of the fact situation essential to the evaluative justification of decisions is indeed the simple one that they are presented to them by counsel." MACCORMICK, *supra* note 9, at 122.

<sup>242</sup> Judges generally wish to be well-regarded by their peers, not to be overruled on appeal, and to appear thoughtful and considered for potential promotion.

<sup>243</sup> RONALD DWORCKIN, *LAW'S EMPIRE* at vii (1986). See also Jackson, *supra* note 2, at x (noting the essentiality of narrative to Dworkin's view of judicial lawmaking).

<sup>244</sup> Each court's discussion of the case begins with a fairly elementary description of DNA, medical genetics and the impact of BRCA1/2 mutations on cancer risk. I will not address these portions of the opinions, as they are relatively consistent and non-controversial.

a. *First among Many*

The first part of Judge Sweet’s narrative is derived largely from the Science Narrative.<sup>245</sup> As discussed above, this narrative, told from the perspective of academic scientists, tends to emphasize the collective contributions of the scientific community to identifying the BRCA genes, with significant credit given to Mary-Claire King for locating the gene on chromosome 17, as well as the substantial public funding that supported this research. By the same token, the Science Narrative portrays Myriad’s contribution to the sequencing of the BRCA genes as relatively minor.

Consistent with this worldview, Judge Sweet begins his narrative in the 1980s, when “scientists from the United States, England, France, Germany, Japan, and other countries sought to be the first to identify DNA nucleotide sequences associated with breast cancer.”<sup>246</sup> He mentions the creation of the International Breast Cancer Linkage Consortium in 1989, as well as King’s “landmark” 1990 paper placing the BRCA gene on chromosome 17. In the wake of King’s announcement, Judge Sweet describes the intensification of research efforts by “teams around the world” to pinpoint the location of the BRCA1 gene, and mentions Mark Skolnick, the founder of Myriad, as one of *several* researchers who joined this search.<sup>247</sup> The aggregate effect of this description is to portray Myriad not as a leader or an innovator in the field, but as one fairly minor participant in a much larger research community. Even the sequencing of BRCA1 itself is portrayed as a group effort: “In September 1994, the group at Myriad, along with researchers from [NIEHS], the University of Utah, McGill University, and Eli Lilly and Company announced that they had sequenced the *BRCA1* gene.”<sup>248</sup>

b. *Standard Procedures*

Further compounding the impression that Myriad’s technical contribution was not particularly important or novel, the court notes that “*BRCA1/2* sequencing by Myriad follows the *typical* process for sequencing extracted genomic DNA.”<sup>249</sup> And in nearly the same breath that the court

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<sup>245</sup> The principal source of the Science Narrative at the District Court was the Declaration of Shobita Parthasarathy (Aug. 24, 2009), *supra* note 158, a social scientist who had studied genetic diagnostic testing for her PhD dissertation and developed it into a monograph on the subject. *See* PARTHASARATHY, *supra* note 38.

<sup>246</sup> 702 F.Supp. 2d at 201.

<sup>247</sup> *Id.* at 201.

<sup>248</sup> *Id.* at 202-02.

<sup>249</sup> *Id.* at 200 (emphasis added).

recognizes that “[t]he isolation of the *BRCA1/2* genes required considerable effort on the part of Myriad and its collaborators as well as ingenuity in overcoming technical obstacles”, it also observes that “the process and techniques used were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.”<sup>250</sup> These statements again devalue Myriad’s contribution to the sequencing of the BRCA genes.

*c. Not One of Us*

The minimization of Myriad’s scientific contribution is also achieved through subtly belittling the qualifications and experience of Myriad’s founder, Mark Skolnick. Judge Sweet introduces Skolnick as “a 1968 *economics* graduate” who became interested in genetics through a chance encounter in Italy with “three Mormons who were microfilming parish records”.<sup>251</sup> This portrayal makes Skolnick appear to be an outsider to the genetics community (an economist) who stumbled upon the field through happenstance (meeting a group of religious non-scientists). Both the selection of facts (largely irrelevant to the case) and the manner in which they are related tend to characterize Skolnick as an interloper or a talented amateur, rather than a respected academic researcher in the field of genetics.

*d. Other Peoples’ Money*

Judge Sweet’s narrative further downplays Myriad’s technical contribution by focusing on the funding provided by the U.S. National Institutes of Health to the BRCA sequencing effort. “In addition to funding the six NIEHS researchers who participated in the identification of *BRCA1*, the NIH had also provided approximately \$2 million in funding to the University of Utah. According to one analysis, the NIH contributed one-third of the funding for the identification of *BRCA1*.”<sup>252</sup>

Even more damning is Judge Sweet’s account of the dispute that developed between Myriad and NIH over the inventors listed on several of the BRCA1 patents. The court states that “NIH maintained that its scientists had conducted some of the most important work leading up to the sequencing of the gene.”<sup>253</sup> This dispute resulted in Myriad’s agreement to add a number of NIH scientists as inventors on the relevant patents and to

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<sup>250</sup> *Id.* at 202-03.

<sup>251</sup> *Id.* at 201 (emphasis added).

<sup>252</sup> *Id.* at 202.

<sup>253</sup> *Id.*

pay them royalties.

Again, most of these facts are largely irrelevant to the doctrinal patent law question before the court,<sup>254</sup> but they undoubtedly shape the picture that is being painted of Myriad as a relatively minor player in the overall effort required to sequence BRCA1.

*e. Winning by a Nose*

Many of the themes drawn from the Science Narrative are repeated during the court's description of the race to sequence BRCA2. In the case of BRCA2, however, the court appears even more willing to question not only the magnitude, but even the existence, of Myriad's technical contribution. Thus, after describing the neck-and-neck race between Myriad and the Stratton group in England, ending with Myriad's filing of a patent application just one day prior to Stratton's publication of the BRCA2 sequence, the court questions Myriad's victory itself, citing Parthasarathy's view that "the consensus among the scientific community is that the Stratton group, rather than Myriad, was the first to sequence the *BRCA2* gene".<sup>255</sup> This consensus, seemingly based on the completeness of the BRCA2 sequence published in the scientific literature,<sup>256</sup> is irrelevant to the doctrinal question before the court: whether human DNA constitutes patentable subject matter.<sup>257</sup>

*f. Anti-Commons*

Judge Sweet also gives credence to the Anti-Commons Narrative,

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<sup>254</sup> The question whether NIH scientists contributed more to the BRCA1 sequencing effort than Myriad is wholly irrelevant to the case, as the NIH scientists were listed as inventors on the very Myriad patents being challenged. *Id.* at 202. Thus, any innovations made by the NIH scientists would strengthen Myriad's claim that the patents were valid, rather than diminish it.

<sup>255</sup> *Id.* at 202 (citing Parthasarathy Declaration, ¶13 (relying on Dalpé, *supra* note 43, at 198)).

<sup>256</sup> Dalpé, *supra* note 43, at 198-99.

<sup>257</sup> Moreover, the U.S. Patent and Trademark office deemed Myriad to be the first to sequence the BRCA2 gene. If, for some reason, this conclusion were incorrect and Myriad were actually not the first to determine the sequence, then its patent would be subject to challenge on a number of other, more conventional, grounds such as anticipation under Section 102 of the Patent Act. At this early stage in the proceedings, however, neither party had made a case for or against anticipation of the inventions claimed by the patents. The irrelevancy of the question who was first to sequence BRCA2 is explicitly recognized by Judge Bryson, dissenting in the Federal Circuit decision reversing Judge Sweet's decision. \_\_\_ F.3d. at \_\_\_ (Bryson, J., dissenting, slip op. at 3 n.1).

prominently citing Heller's and Eisenberg's foundational 1998 article, and going on to discuss Jensen's and Murray's claim that 20% of the human genome is patented.<sup>258</sup> He then recognizes numerous other studies proffered by the plaintiffs purporting to demonstrate "the chilling effect of gene patents on the advancement of both genetic research and clinical testing."<sup>259</sup> He fails, however, to cite the literature questioning the prevalence of an anti-commons effect in biomedical research.<sup>260</sup> Judge Sweet's adoption of the Anti-Commons Narrative is seemingly unquestioning.

*g. Access and Pricing*

Once the court completes the Science Narrative and Anti-Commons Narrative, it moves almost immediately to the Access Narrative. As described in Part II.A.4 above, the Access Narrative concerns itself with the ability of at-risk individuals to obtain and pay for Myriad's BRCA testing. The court here recounts sympathetically the allegations of the individual plaintiffs who "have been unable to obtain funding for all of Myriad's testing services".<sup>261</sup>

Judge Sweet attributes this lack of access to the high pricing of Myriad's BRCA tests: "The Myriad tests are available to clinicians and patients at a cost of over \$3000 per test. In 2008, the total cost to Myriad of providing these tests was \$32 million with resulting revenues of \$222 million."<sup>262</sup> The profit earned by a patent holder is hardly relevant to the patentability of its invention. Nevertheless, the court feels compelled to portray Myriad as a rent seeker, profiteering from the misfortune of vulnerable men and women. And if there were any doubt as to this characterization, Judge Sweet informs the reader that "In Ontario, where the regional public healthcare plan is ignoring Myriad's patent, the testing for breast cancer is performed for a third of Myriad's cost." Here, the court appears both to condone the Ontario health plan's disregard for Myriad's Canadian patent, and to demonstrate that the pricing of Myriad's test is excessive. Both of these techniques cast Myriad in a bad light, and call into question both its ethics and its compassion.

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<sup>258</sup> 702 F.Supp. 2d. at 208.

<sup>259</sup> *Id.*

<sup>260</sup> See note 230, *supra*.

<sup>261</sup> 702 F.Supp. 2d. at 204.

<sup>262</sup> *Id.* at 203.

#### *h. The District Court's Holding*

Given that the District Court relied almost entirely on the Science Narrative, the Access Narrative and the Anti-Commons Narrative in constructing its own account of the *Myriad* case, it is hardly surprising that the court ruled for the plaintiffs, and against Myriad, on all counts. The Court spent little to no time on Myriad's Pioneer Narrative, in which it claims considerable ingenuity and dedication in sequencing the BRCA genes and emphasizes the economic benefits of patents to the overall economy.

### *2. Federal Circuit*<sup>263</sup>

A three-judge panel of the Federal Circuit reversed the District Court's holding with respect to Myriad's composition of matter patents, finding that DNA sequences were valid subject matter for patent protection. Each of the judges on the panel wrote separately: Judge Lourie for the majority, Judge Moore concurring in part, and Judge Bryson dissenting in part.<sup>264</sup> The different narrative approaches used by the three Federal Circuit judges is telling. Judges Lourie and Moore, who upheld Myriad's claims, focused largely on the Administrative Narrative, while Judge Bryson, dissenting, focused on the Science Narrative. These narrative perspectives alone are highly predictive of the doctrinal position taken by each judge. The narratives and policy rationale adopted in each opinion are discussed in greater detail below.

#### *a. Majority Opinion – Myriad's Story*

The Federal Circuit majority opinion offers a very different narrative of the case than the District Court. Judge Lourie, writing for the Court, encapsulates the entirety of the action in the following paragraph:<sup>265</sup>

The inventors of the patents in suit identified the genetic basis

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<sup>263</sup> As discussed in Part I.E, the Federal Circuit issued two opinions in *Myriad*. The first was issued on appeal from the District Court on July 9, 2011, and the second, on remand from the Supreme Court following its decision in *Mayo v. Prometheus*, on August 16, 2012. The opinions are similar. For convenience, this article refers to the 2011 opinion.

<sup>264</sup> The panel was unanimous in upholding the District Court's finding that Myriad's method claims constituted "mental processes" that were not eligible patent subject matter.

<sup>265</sup> As noted above, I omit the court's lengthy explanation of the nature of DNA and hereditary illness from this discussion.

of *BRCA1* and *BRCA2*-related cancers using an analysis called positional cloning. Relying on a large set of DNA samples from families with inherited breast and ovarian cancers, the inventors correlated the occurrence of cancer in individual family members with the inheritance of certain marker DNA sequences. This allowed the inventors to identify, or “map,” the physical location of the *BRCA* genes within the human genome and to isolate the *BRCA* genes and determine their exact nucleotide sequences. This in turn allowed Myriad to provide *BRCA* diagnostic testing services to women.<sup>266</sup>

Unlike Judge Sweet, Judge Lourie devotes no attention to the scientific race to sequence the *BRCA* genes. His narrative is essentially an abbreviated version of the Pioneer Narrative, which credits Myriad with the discoveries covered by the patents. He spends no time discussing the competing research teams, never mentions Mary-Claire King, and offers no commentary on the formation of Myriad or its backers. Instead, he begins his account with “the inventors”, the individual researchers listed on the patents in suit, and refers to them repeatedly as “inventors” (as opposed to “researchers”, “scientists” or simply “Myriad”), a positively valenced term that presupposes their innovative activity. In the next two sentences he describes the technical process that they used to isolate the *BRCA* sequence, omitting any judgment about the novelty or banality of the approach. He ends with a terse sentence linking the discovery to Myriad’s *BRCA* testing, with no mention of access or pricing of the Myriad tests.

On one hand, one might commend Judge Lourie for disregarding a wealth of extraneous narrative facts that, while intrinsically interesting, are irrelevant to the narrow doctrinal questions before the court. Judge Lourie’s narrative seems to exemplify the objective approach that a positivist judge should use, dispassionately applying the law to a set of known facts.

But on further inspection, it becomes clear that Judge Lourie too has constructed a narrative to support his desired outcome of the case. Yet rather than the Pioneer Narrative, it is the Administrative Narrative that seems to capture his imagination. He explains:

In this case, the PTO has issued patents directed to DNA molecules for almost thirty years. In the early 1980s, the Office granted the first human gene patents ... It is estimated

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<sup>266</sup> CAFC, slip op. at 17-18.

that the PTO has issued 2,645 patents claiming “isolated DNA” over the past twenty-nine years, and that by 2005, had granted 40,000 DNA-related patents covering, in non-native form, twenty percent of the genes in the human genome. In 2001, the PTO issued Utility Examination Guidelines, which reaffirmed the agency’s position that isolated DNA molecules are patent eligible ...<sup>267</sup>

Judge Lourie is clearly concerned with the issues raised by the patent bar, among others. The fact that patents have been issued on DNA sequences for many years is, to him, a key consideration. While he does not elaborate on the potential consequences of upending the settled expectations of the bar and industry, he implies that they would be grave. His repeated use of numerical figures (29 years, 2,645 isolated DNA patents, 40,000 DNA-related patents, 20% of the human genome) is intended to persuade by appealing to mathematical precision and seemingly large numbers. Thus, Judge Lourie appears to be more concerned with the systemic effects of his decision (i.e., on the patent bar and overall patent system) than its impact on Myriad, which he discusses very little.

*b. Concurrence – Economic Impact*

Judge Moore concurs in the court’s judgment, but writes separately to explain her somewhat different doctrinal approach.<sup>268</sup> Like Judge Lourie, she adopts the Administrative Narrative to support her decision to uphold Myriad’s patents.

Judge Moore’s rendition of the Administrative Narrative is less quantitative than Judge Lourie’s and embodies three distinct elements. First, she appeals to history, noting that the PTO’s longstanding policy of granting patents on DNA-based inventions has roots that extend back more than a century, when a U.S. patent claiming “yeast, free from organic germs of disease” was issued in 1873 to none other than Louis Pasteur.<sup>269</sup> The citation of a famous historical scientist already puts Myriad in good company and shows it in a positive light.

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<sup>267</sup> Slip op at 48 (citations omitted).

<sup>268</sup> Whereas the majority found Myriad’s composition of matter claims to be patent-eligible on the basis that the BRCA1/2 genes, as patented, were isolated and thus different than naturally-occurring DNA, Judge Moore proposed that the appropriate analysis would determine whether the compositions in question “have markedly different characteristics with the potential for significant utility, e.g., an “enlargement of the range of . . . utility” as compared to nature.” Slip op. (Moore, J., concurring) at 7.

<sup>269</sup> *Id.* at 20 (citing U.S. Pat. 141, 072 (1873)).

Second, Judge Moore appeals to the intrinsic unfairness of reversing a long line of PTO and judicial decisions upholding DNA-based patents, reasoning that “[c]hanging course years after the fact will only serve to *punish* those companies who made the reasonable decision to invest large amounts of time and money into the identification, isolation, and characterization of genes”<sup>270</sup>.

Finally, Judge Moore suggests that a reversal of existing policy regarding DNA patenting could have dire economic consequences. As an example of the significant financial ramifications of DNA-based patents, she cites the case of erythropoietin (EPO), a DNA-based therapeutic patented by biotechnology company Amgen. When Amgen’s patent was challenged by Chugai Pharmaceutical Co. in the late 1980s, the Federal Circuit upheld the patent. Judge Moore approvingly notes that “EPO went on to become the biggest-selling biotechnology drug developed to that point, resulted in billions of dollars in sales ... Isolated DNA claims, at least in the case of Amgen, represent crucial and exceedingly valuable property rights.”<sup>271</sup> Like Amgen, she reasons, the rest of the biotechnology industry has invested substantial time and money in R&D, relying in part on the promise of patent protection for resulting discoveries.<sup>272</sup> Disrupting this *status quo* would jeopardize both the industry (an economic risk) and the “outpouring of scientific creativity” that has characterized the industry (a social risk).<sup>273</sup>

*c. Dissent - Science*

Judge Bryson, who dissented from the portion of the majority opinion upholding Myriad’s composition of matter patents, tells a markedly different story than his colleagues. Rather than the Administrative Narrative, Judge Bryson’s version of the facts is based on the Science Narrative. Like Judge Sweet in the District Court, Judge Bryson minimizes Myriad’s contribution to scientific knowledge and its technical accomplishments:

Myriad was *not the first* to map a BRCA gene to its

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<sup>270</sup> *Id.* at 28 (emphasis added).

<sup>271</sup> *Id.* at 20-21 (citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991) and *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 77 (D. Mass. 2001)).

<sup>272</sup> *Id.* at 21.

<sup>273</sup> Slip op. (Moore, J., concurring) at 21.

chromosomal location. That discovery was made by a team of researchers led by Dr. Mary-Claire King. And Myriad did not invent a new method of nucleotide sequencing. Instead, it applied *known sequencing techniques* to identify the nucleotide order of the BRCA genes.<sup>274</sup>

Thus, Judge Bryson argues that Myriad was merely one of many researchers working to solve the BRCA sequence, that it did not make the most significant breakthrough (Dr. King's location of the gene on Chromosome 17), and that it used known (i.e., non-innovative) techniques to sequence the BRCA genes. All of these facts taken together lead Judge Bryson to conclude that Myriad's "invention" of isolated BRCA DNA was not eligible for patent protection.

### 3. Supreme Court

At the Supreme Court, Justice Thomas, writing for a unanimous<sup>275</sup> Court, draws primarily from the Science Narrative in sketching the facts of the case. Like Judge Sweet at the District Court, Justice Thomas minimizes the importance of Myriad's technical contribution. He does so first by emphasizing the knowledge that existed in the scientific community before Myriad appeared on the scene: "Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer".<sup>276</sup>

More importantly, Justice Thomas repeatedly stresses that Myriad merely identified the "exact" or "precise" location and sequence of the BRCA1/2 genes.<sup>277</sup> This characterization trivializes Myriad's contribution, reducing it from a broad discovery with far-reaching implications to a mere refinement of existing knowledge, the addition of just another figure behind the decimal point. Justice Thomas's intention becomes unambiguous when he declares that "Myriad did not create anything".<sup>278</sup> With this narrative in place, the Court could not possibly rule in favor of Myriad or its patents.

An even more puzzling aspect of the Court's narrative relates to Myriad's enforcement of its patents against the University of Pennsylvania

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<sup>274</sup> Slip op. (Bryson, J., dissenting in part) at 3 (emphasis added, citations omitted).

<sup>275</sup> *But see* note 128, *supra*.

<sup>276</sup> Myriad, \_\_\_ S.Ct. at \_\_\_ (slip. op. at 1, 4, 12).

<sup>277</sup> *Id.* at 12, x, y.

<sup>278</sup> *Id.* at 12.

and other academic institutions and the eventual solidification of “its position as the only entity providing BRCA testing.”<sup>279</sup> This history, which postdates the issuance of Myriad’s patents, is largely irrelevant to the single question before the Court: whether human DNA is patentable. A discussion of the patentee’s exploitation of its patents could bear some relevance to potential antitrust claims or even claims of patent misuse, but certainly not to the initial patentability of a broad class of inventions. This additional narrative gloss can only have been included to further diminish Myriad in the eyes of the Court and the world.

### C. COMPARING ADJUDICATORY NARRATIVES

The *Myriad* case is perhaps the ideal lens through which to view the proliferation of multiple factual narratives and their adoption in judicial opinions. First, the narrow doctrinal question presented (whether human DNA is eligible for U.S. patent protection) could have been answered without recourse to any narrative facts whatsoever (other than, perhaps, the textbook biochemistry lesson offered by each court). Thus, the race to sequence the BRCA genes, Myriad’s pricing policies, and the economic growth of the biotechnology industry are all largely irrelevant to the question actually before the courts. A decision could have been reached without reference to any of these narrative elements, meaning that the construction of narratives by the courts was, to a large degree, rhetorical. Second, unlike the typical two-party dispute, the *Myriad* case presented six distinct narrative variants. This diverse narrative “menu” allowed each court to pick and choose among different narrative elements to its own taste.

As shown in Part III.B above, each of the U.S. courts hearing the *Myriad* case constructed a different narrative version of the facts, notwithstanding that they were all adjudicating the same case. Moreover, the narratives presented by the parties and *amici* did not change radically from district to appellate to Supreme Court. The significant narrative differences reflected in the competing judicial opinions all originated with the courts themselves and the authors of the individual opinions.

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<sup>279</sup> *Id.* at 7.

Table 2  
*Judicial Narratives and Holdings in Myriad*

Opinion	Narrative(s) Adopted	Patentability of Myriad's Isolated DNA Claims
SDNY (Sweet)	Science Access Anti-Commons	No
CAFC Majority (Lourie)	Pioneer Administrative	Yes
CAFC Concurrence (Moore)	Administrative	Yes
CAFC Dissent (Bryson)	Science	No
Supreme Court (Thomas)	Science	No

As shown in *Table 2*, the narratives adopted by each court and judge correlate with the doctrinal holding of that court or judge. Thus, referring to Appendix 1, proponents of the Science Narrative were largely opposed to the patenting of human DNA. The courts and judges that adopted the Science Narrative ruled against Myriad's DNA patents. Proponents of the Administrative Narrative were largely supportive of DNA patents, and the courts and judges adopting the Administrative Narrative ruled in favor of Myriad's patents.<sup>280</sup>

It is important to note that the judicial selectivity evidenced by this analysis includes acts of omission as well as commission. That is, judges ruling against gene patenting did not merely adopt the Science Narrative and Access Narrative to support their reasoning, they also *omitted* to include in their judicially constructed narratives the principal elements of the Pioneer Narrative and the Administrative Narrative. By the same token, those judges supporting gene patenting generally avoided the facts embodied in the Science Narrative and the Access Narrative.

#### D. TOWARD A NARRATIVE TYPOLOGY FOR INNOVATION?

The *Myriad* case is remarkable in several respects, not least for the

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<sup>280</sup> Interestingly, the Dystopian Narrative plays little role in the opinions of the courts considering the *Myriad* case. There are several possible explanations for this omission. First, the Dystopian Narrative, while advanced by some *amici curiae* and members of the public, was never forcefully advanced by the parties to the litigation. Second, the old "parade of horrors" first raised in the 1970s and asserted in the *Chakrabarty* case (see notes x, *supra*, and accompanying text) may have lost their potency in the intervening decades. To wit, thirty years after *Chakrabarty*, none of the science fiction scenarios posited by the Dystopian Narrative came to pass.

number of distinct narrative accounts that have been constructed regarding its underlying facts. Whereas most legal cases generate two competing versions of the facts, *Myriad* generated six. There are several possible reasons for this case's fecundity in terms of narrative generation.

First, the story of the discovery and exploitation of the BRCA genes is one that spans decades, from the early scientific discoveries of the 1980s through the pricing and reimbursement debates of today. Long spans of time, as illustrated by *Figure 1*, offer numerous points at which different sub-narratives within a larger sequence of events can begin and end.

Second, the *Myriad* case, and the broader debate over gene patenting in the U.S., involved a host of actors beyond the parties to the case being litigated. Thus, in addition to the patent holder and the laboratories and researchers against which it threatened to assert its patents, the case engaged patients, advocacy groups, bar associations, prominent scientists, legal scholars, biotechnology companies, and the federal government.<sup>281</sup> Each actor in this diverse collection derived from the vast set of available facts surrounding the *Myriad* case and gene patenting more generally a particular narrative tailored to its own perspective, arguments and goals. In this respect, *Myriad* can be viewed as an experimental test bed of narrative formation, in which each and every available narrative could have come forward through the engagement of one party or another. And given the long timeframe and large number of parties involved, it is remarkable that *only* six narrative types emerged from this rich broth.

The six narratives generated by the *Myriad* case, while rooted in the circumstances surrounding *Myriad*'s patents on BRCA1/2, may typify broader categories of narrative that extend beyond this single case.<sup>282</sup> That is, the Science, Pioneer, Administrative, Access, Dystopian and Anti-

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<sup>281</sup> See Appendix 1, *infra*, for a complete list of parties filing *amicus* briefs at various stages of the *Myriad* litigation.

<sup>282</sup> Narrative types have been identified in other fields of legal scholarship, particularly environmental law. See, e.g., Michael Burger, *Environmental Law/Environmental Literature*, 40 *ECOLOGY L.Q.* 1, 21-39 (2013) (categorizing representations of the wolf in litigation literature (the scientific wolf, the historic wolf and the mythic wolf)); Michael Burger, *Recovering from the Recovery Narrative: On Glocalism, Green Jobs and Cyborg Civilization*, 46 *AKRON L. REV.* 909, 910 (2013) (identifying environmental law/ecocriticism "storylines" such as pastoral, wilderness, toxic discourse, apocalypse and recovery (citing, *inter alia*, GREG GARRARD, *ECOCRITICISM* (2004) and CAROLYN MERCHANT, *REINVENTING EDEN: THE FATE OF NATURE IN WESTERN CULTURE* (2003)). Daithi Mac Sithigh has also suggested that such narrative types may be evidenced in the debate over network neutrality.

Commons Narratives of the *Myriad* case are merely exemplars of more generalizable narrative types sharing similar attributes. *Table 3* illustrates how the six narrative categories developed in the *Myriad* case may have broader applicability to other cases involving scientific research, discovery and innovation.

Table 3  
Narrative Typology in Innovation Cases

<b>Narrative Type</b>	<b><i>Myriad</i> Case</b>	<b>General Case</b>
<b><i>Science</i></b>	Many parties engaged in the race to sequence the BRCA genes, and the ultimate discovery of the gene's sequence was not scientifically significant	How the scientific community addressed a significant scientific or technological challenge
<b><i>Pioneer</i></b>	Myriad invested significant resources and developed novel techniques to sequence the BRCA genes	Innovation by one or more parties, leading to a significant technological innovation
<b><i>Administrative</i></b>	Patenting the BRCA genes was consistent with well-established PTO practice and the ordinary course of business	Exploitation of known administrative channels to protect innovation
<b><i>Access</i></b>	Myriad's pricing of its BRCA1/2 diagnostic tests prevents access by many individuals and thus endangers lives	Broadening availability and access to the fruits of innovation
<b><i>Dystopian</i></b>	Patenting genes may have unanticipated and dire social and ethical consequences	Social and ethical consequences of unbridled technological advancement
<b><i>Anti-Commons</i></b>	Patenting genes will lead to a multiplicity of patents covering basic biomedical principles and will make further research in the field more difficult	Multiplicity of barriers that will make further research and innovation more difficult

It is not difficult to imagine narratives hewing to this taxonomy in cases involving areas as diverse as genetically modified organisms, human cloning, climate change, artificial intelligence and self-driving vehicles. Each of these fields is characterized by scientific or technological innovation and, as such, is likely to draw on many of the same narrative sources and worldviews that arose in *Myriad*. Thus even a case far

removed from the realm of patent law, but involving the introduction of novel technologies to the market, is likely to occasion the emergence of narratives that can broadly be classified as Science, Pioneer, Administrative, Access, Dystopian and Anti-Commons.

Consider, for example, a case involving the assignment of tort liability in a fatal highway accident caused by a self-driving vehicle.<sup>283</sup> The Science Narrative might focus on the community of innovators that converged to enable the solution of previously intractable problem of automated road navigation. The positive light in which this community is portrayed, and the value that it contributed to society, might tend to lessen the odds that the developers would be held liable for the damage caused by the vehicle. The Pioneer Narrative might focus on the ingenuity and financial commitment of the vehicle's developers, also tending to exonerate them from liability. The Administrative Narrative might address the positive results of mandatory safety testing conducted by the National Highway Safety Transportation Administration, again tending to diminish the designers' liability. The Access Narrative, on the other hand, might focus on the victims' injuries and need for compensation (in this case, access not to the technology, but to a part of the profit generated by it in the form of redress). The Dystopian Narrative would evoke a future of high-speed chaos on the nation's highways, also tending to favor liability. The Anti-Commons Narrative, however, with its emphasis on fractionalization of interests, might focus more on the impact that tort liability might have on the industry, favoring larger insurance pools rather than liability for individual vehicle vendors. *Table 4* offers a comparison of the doctrinal outcomes supported by each narrative type in this example with the outcomes supported in *Myriad*.

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<sup>283</sup> See, e.g., John Villasenor, Products Liability and Driverless Cars: Issues and Guiding Principles for Legislation (2014), available at <http://www.brookings.edu/research/papers/2014/04/products-liability-driverless-cars-villasenor>.

Table 4  
Narratives and Outcomes – Gene Patenting and Self-Driven Vehicles

<b>Narrative Type</b>	<b>Gene Patenting Case</b>	<b>Self Driving Vehicle Case</b>
<i>Science</i>	No patents	Designer not liable
<i>Pioneer</i>	Patents	Designer not liable
<i>Administrative</i>	Patents	Designer not liable
<i>Access</i>	No Patents	Designer liable
<i>Dystopian</i>	No Patents	Designer liable
<i>Anti-Commons</i>	No Patents	Designer liable

Note that in this example, the litigation outcomes supported by each narrative type are largely aligned in the same manner as they are in the *Myriad* gene patenting case. Thus, the Pioneer and Administrative Narratives generally tend to favor the innovator (gene sequencer/car designer), while the Access, Dystopian and Anti-Commons Narratives tend to favor a broader public interest.

Interestingly, the doctrinal outcome of the Science Narrative is not consistent with the alignment seen in the other five narratives. In the case of gene patenting, the Science Narrative disfavors patenting, thus aligning it with the Access, Dystopian and Anti-Commons Narratives. In the vehicle liability case, however, the Science Narrative seems to favor the developer, thus aligning it with the Pioneer and Administrative Narratives. This reversal suggests that the narrative structures identified in this article are not necessarily outcome determinative. Rather, they typify stories that may be told about situations involving technology and innovation, but may at times support different stakeholder groups when disputes about such technologies arise.

## CONCLUSION

Narratives are integral to the legal system, particularly to the adjudication of disputes. Narratives form the basis on which judicial decisions are made, and thus influence not only the outcome of individual cases, but the direction in which the law develops. An understanding of the narratives that are told with respect to important cases in the development of the law is fundamental to understanding those developments, as well as the future direction of legal development.

Six distinct narratives (Science, Pioneer, Administrative, Access,

Dystopian and Anti-Commons) emerged from the decades-long dispute involving Myriad Genetics and its patents on the BRCA1/2 genes. These narratives played a significant role in both the argumentation of the *Myriad* case, as well as the judicial opinions that were issued at all stages of the litigation. Both the lengthy time frame of the *Myriad* dispute, as well as the large number of actors engaged in the dispute, suggest that these six narratives represent the full complement of distinct narratives concerning the case. If our perspective is expanded beyond *Myriad* itself, one can also consider the six narrative types that emerged in *Myriad* as constituting a taxonomy of narrative types within the broader realm of disputes involving new technology, scientific discovery and innovation.

**Appendix 1***Narrative Inputs to Courts in Myriad**[Note: Anti-Commons Narrative still to be added]*

<b>Brief/Declaration</b>	<b>Narrative<sup>284</sup></b>	<b>Court<sup>285</sup></b>
<b><i>Parties</i></b>		
Plaintiffs	Science Access	SDNY CAFC SCOTUS
Defendants (Myriad Genetics, Univ. Utah Res. Fndn.) <sup>286</sup>	Pioneer Administrative	SDNY CAFC SCOTUS
<b><i>Amici Curiae</i></b>		
U.S. Government (Dept. of Justice)	Doctrinal Only	CAFC SCOTUS
AARP	Access	CAFC SCOTUS
Academics in Law, Med., Health Policy and Clinical Genetics	Access	CAFC SCOTUS
Am. Bar Assn. (ABA)	Administrative	SCOTUS
Am. Intel. Prop. Law Assn. (AIPLA)	Administrative	CAFC SCOTUS
Am. Med. Assn. (AMA), et al	Access	SDNY CAFC SCOTUS
Alnylam Pharmaceuticals	Pioneer	CAFC
Andrew Chin	Doctrinal only	CAFC
Animal Health Inst. and Merial Ltd.	Pioneer	CAFC SCOTUS
Assn. Am. Physicians & Surgeons	Pioneer	SCOTUS
Biotechnology Indus. Org. (BIO)	Pioneer	SDNY CAFC SCOTUS
Boston Patent Law Assn.	Administrative	SDNY CAFC SCOTUS

<sup>284</sup> All briefs also include one or more doctrinal arguments, which are not the focus of this article. I have indicated doctrinal arguments in this table only when the submitting party has limited its arguments exclusively to doctrinal arguments without offering an underlying or supporting narrative.

<sup>285</sup> Indicates whether brief/declaration was filed with the U.S. District Court for the Southern District of New York (SDNY), the Court of Appeals for the Federal Circuit (CAFC), or the U.S. Supreme Court (SCOTUS). Unless otherwise indicated, all CAFC briefs were filed in the 2011 proceeding.

<sup>286</sup> Omits procedural arguments made by defendant U.S. Patent & Trademark Office (PTO), which was dismissed from case by CAFC.

<b>Brief/Declaration</b>	<b>Narrative<sup>284</sup></b>	<b>Court<sup>285</sup></b>
Canavan Foundation, et al	Access Cautionary	CAFC SCOTUS
Cancer Council Australia	Access	CAFC SCOTUS
CLS Bank Int'l	Doctrinal only	SCOTUS
Coalition for 21 <sup>st</sup> Century Medicine	Pioneer	SDNY CAFC SCOTUS
Croplife Int'l	Pioneer	CAFC SCOTUS
Anada Mohan Chakrabarty	Doctrinal only	SCOTUS
Larry Geier, William Harb, et al	Pioneer	SCOTUS
Eileen M. Kane	Doctrinal only	CAFC SCOTUS
Eric S. Lander	Doctrinal only	SCOTUS
Ethics & Religious Liberty Comm'n of the Southern Baptist Conv. and Prof. D. Brian Scarnecchia	Access Cautionary	CAFC SCOTUS
Fifteen Law Professors <sup>287</sup>	Doctrinal only	SCOTUS
Fed. Circuit Bar Assn.	Doctrinal only	CAFC SCOTUS
Federation des Conselies en Propriete Intellectuelle	Doctrinal only	CAFC SCOTUS
Genedx and Law Professors	Access	SCOTUS
Genetic Alliance	Pioneer	SDNY CAFC
Genformatic LLC	Science	SCOTUS
Genomic Health, Inc.	Pioneer	SDNY CAFC
Gilead Sciences, Elan Pharmaceuticals	Pioneer	CAFC SCOTUS
Immatics Biotechnologies	Pioneer	CAFC SCOTUS
Info. Soc'y Proj. - Yale Law Sch.	Access	CAFC (2012)
Inhouse Patent Counsel, LLC	Pioneer	SCOTUS
Inst. of Prof. Reps. Before the European Patent Off.	Doctrinal only	SCOTUS
Intel. Prop. Clinic - UNH School of Law	Doctrinal only	CAFC SCOTUS
Intel. Prop. Owners Association (IPO)	Pioneer	CAFC SCOTUS
Int'l Ctr. for Technology Assessment	Access	SDNY CAFC SCOTUS
Invitae Corp.	Pioneer	SCOTUS
James D. Watson	Science	CAFC SCOTUS

<sup>287</sup> The author was a signatory to this brief.

<b>Brief/Declaration</b>	<b>Narrative<sup>284</sup></b>	<b>Court<sup>285</sup></b>
Jeffrey A. Lefstin	Doctrinal only	SCOTUS
Juhasz Law Firm	Doctrinal only	SCOTUS
Kali N. Murray and Erika R. George	Pioneer	CAFC SCOTUS
Kane Biotech	Pioneer	CAFC
Knowledge Ecology Int'l (KEI)	Access	CAFC SCOTUS
Lynch Syndrome Int'l	Access	SCOTUS
Mark Gatschet and Richard Knight	Doctrinal only	CAFC
MPEG LA	Pioneer	SCOTUS
Nanobusiness Commercialization Association	Pioneer	SCOTUS
Nat'l Women's Health Net., Asian Communities for Reproductive Justice, et al	Access	SDNY CAFC SCOTUS
National Venture Capital Association	Pioneer	SCOTUS
New York Intel. Prop. Law Assn.	Administrative	CAFC (2012)
Novartis Corp.	Pioneer	CAFC
Pharmaceutical Research & Manufacturers of Am. (PhRMA)	Pioneer	CAFC SCOTUS
Philadelphia Intel. Prop. Law Assn.	Administrative	SCOTUS
Robert Cook-Deegan, Christopher M. Holman	Doctrinal only	CAFC
Rosetta Genomics, George Washington Univ.	Pioneer	SDNY CAFC
Sigram Schindler Beteiligungsgesellschaft	Doctrinal only	SCOTUS
Target Discovery, Inc.	Pioneer	CAFC SCOTUS
Universities Allied for Essential Medicines	Pioneer	CAFC
Univ. of Baltimore/Johns Hopkins Ctr. for Med. & Law and Gregory Dolin	Pioneer	SCOTUS
<b><i>Selected Declarations Submitted to District Court</i></b>		
Lisbeth Cerani (Plaintiff)	Access	SDNY
Patrice Fortune (Plaintiff)	Access	SDNY
Haig H. Kazazian, Jr.	Access	SDNY
Shobita Parthasarathy	Science Access	SDNY
Mark Skolnick	Pioneer	SDNY
John Edward Sulston	Science	SDNY