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The Genomic Research and Accessibility Act: More Science Fiction than Fact

By James DeGiulio*

I. OVERVIEW

¶1 This article discusses the recently proposed Genomic Research and Accessibility Act (GRAA), the creation of California Representative Xavier Becerra. If enacted, this legislation will remove DNA from patentable subject matter in a broad stroke. Part one of this article will introduce the gene patent issue and how it has regained the attention of Congress. Part two will present an introduction on the science of DNA, gene patentability and a brief background of the important events leading to the current status of DNA patents. Part three will introduce the language of the GRAA and analyze the reasons why certain scientific groups and members of Congress are convinced DNA must be removed from patentable subject matter. This article will focus on the arguments put forth at a subsequent Congressional hearing on the issue of DNA patentability. Finally, part four will conclude the article by discussing the fate of the GRAA, as predicted by the author.

II. INTRODUCTION

¶2 The first gene patent was granted in 1982 to the Regents of the University of California for construction of a plasmid contained in a bacterium and expression of a gene for a hormone that promotes maternal breast development during pregnancy.[1] Often the topic of controversy, gene patents have recently become the subject of heightened media attention thanks to author and medical doctor Michael Crichton's 2006 book "Next." While researching for his novel, Crichton arrived at some strong opinions on the subject of gene patents and subsequently published them in a recent New York Times column.[2]

¶3 Crichton's article opens by striking fear into the hearts of the public: "You, or someone you love, may die because of a gene patent that should never have been granted in the first place."[3] While certainly an effective strategy in fictional storytelling, Crichton's alarmist assertions about gene patents have minimal scientific facts to support them. After taking his readers through a few of the oft-cited examples of gene patenting

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[1] *Gene Patents and Global Competition Issues*, 26 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, Jan. 1, 2006, *available at* http://www.genengnews.com/articles/chitem.aspx?aid=1163&chid=0.

[2] Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23, *available at* http://www.nytimes.com/2007/02/13/opinion/13crichton.html.

[3] *Id.*

gone wrong (many of which are discussed later in the article), Crichton concludes with an endorsement for Representative Xavier Becerra's GRAA (H.R. 977).[4]

¶4 This comment analyzes the research that is presented in support of the GRAA and the arguments for and against gene patenting. Congress, and society, must decide if such legislation is merely reactive to an outcry of science fiction panic, or is necessary reform based on actual evidence and the needs of public policy.

III. BACKGROUND ON DNA PATENTS

¶5 In order to understand the nature of gene patents, some background on patent law and DNA as patentable subject matter is appropriate. We begin with a brief primer on the science of DNA. This primer is admittedly oversimplified, as the biology of DNA is quite complex. Then we introduce a timeline of the more important events leading to the current status of DNA patents and outline the patentability requirements in the United States and its treatment of DNA to this point.

A. Primer on DNA and Genetics

¶6 DNA is a complex chemical made up of a sequence of nucleotides, each of which contains one of the four bases: adenine, cytosine, guanine and thymine. One of the primary functions of DNA is serving as the source of the information necessary to produce proteins, which in turn provide the functions of a living organism. Humans have around three billion of these nucleotides, arranged in a precise order in our chromosomes.

¶7 A common definition of "gene" is a full-length DNA sequence that encodes a complete protein. Accordingly, the term "gene patent" in this article will refer to a patent that claims at least a DNA sequence that encodes a complete protein or portion thereof. However, as will become clear later, arriving at a precise and accurate definition of "gene patent" is part of the controversy.

¶8 There are various incentives for understanding how DNA processing works. Identification of the function of genes has the potential to provide great therapeutic benefit. In humans, the primary focus is health care, which includes identifying and testing for genetic diseases, producing synthetic therapeutic proteins to replace defective natural proteins, producing other small molecule drugs that interact with particular proteins, and developing therapies to rectify or replace defective genes.[5]

B. DNA Patentability Timeline

¶9 The double-helix structure of DNA was first discovered by Watson and Crick. Interestingly, they refused to patent this structure - a decision that advocates of removing DNA from patentable subject matter are quick to exploit.[6] Since its discovery, DNA has received differing forms of treatment by patent law. However, there are several prominent cases and legislation that define the current state of DNA patents.

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[4] *Id.*

[5] Dianne Nicol, *On the Legality of Gene Patents*, 29 MELB. U. L. REV. 809, 812 (2005).

[6] Melissa L. Sturges, Comment, *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, 243 n.128 (1997).

¶10 Arguably, the most important event in the development of gene patents was the decision in *Diamond v. Chakrabarty*, where the Supreme Court held that recombinant microorganisms are patentable, which opened the door for patents on living things.[7] The Supreme Court held that living organisms fall within the realm of patentable subject matter as long as they are "a nonnaturally occurring manufacture or composition of matter – a product of human ingenuity."[8]

¶11 The Federal Circuit confirmed DNA satisfied the *Chakrabarty* test in *Amgen, Inc. v. Chugai Pharmaceutical Co.*, holding that "purified and isolated" gene sequences are different from those occurring in nature.[9] Amgen's inventor did not have the "mental picture" of the erythropoietin gene until the gene had been isolated. Importantly, the Federal Circuit understood and confirmed that DNA is a chemical, stating that "[a] gene is a chemical compound, albeit a complex one."[10]

¶12 In 1980, Congress passed the Bayh-Dole Act,[11] which encouraged universities to patent and commercialize inventions derived from government research grants.[12] The Bayh-Dole Act further provided for the efficient transfer of patents on inventions arising from federally-funded research into the private sector, and granted university professors the right to file for patents on federally funded discoveries. Accompanying the enactment of Bayh-Dole, and in the years subsequent to its passage, federal financial commitments dedicated to biomedical research dramatically increased. As a consequence of these governmental actions, the number of patents assigned to universities increased from 264 in 1979 to 3,259 in 2003.[13]

¶13 These events led to the 1990 founding of the Human Genome Project, the goal of which was to code three billion nucleotides contained in the human genome and to identify all the genes present in it. The Project's efforts have led to the discovery of approximately 35,000 genes. The mid-1990s was a period of growth in DNA-related patents in the United States, at a rate of 50 percent per year.[14] Today, the biotechnology sector in the United States has reached gargantuan proportions, expanding from $8 billion in 1992 to $50.7 billion in 2005.[15]

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[7] 447 U.S. 303 (1980).

[8] *Id.* at 309.

[9] 927 F.2d 1200 (Fed. Cir. 1991).

[10] *Id.* at 1206.

[11] 35 U.S.C. §§ 200-12 (2000).

[12] *See generally* Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE 989 (2007).

[13] Roger Klein, *Gene Patents Jeopardize Genetic Testing*, 27 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, May 1, 2007, *available at* http://www.genengnews.com/articles/chitem.aspx?aid=2092&chid=0.

[14] Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091 (2006).

[15] *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the Subcomm. on Courts, the Internet and Intellectual Property of the H. Comm. on the Judiciary*, 110th Cong. 61 (2007) [hereinafter *Gene Patent Hearings*] (statement of Jeffrey P. Kushan, Biotechnology Industry Organization).

C. Stricter Standards for Patentability

¶14 To decide whether the GRAA has merit, it is essential to have a base understanding of patent standards and how they have been applied to DNA. The United States Patent and Trademark Office will approve a patent on an invention if it satisfies the statutory requirements of being "useful, novel, and non-obvious."[16] Generally, the standards for patenting inventions have become stricter due to the evolving jurisprudence in the doctrines of inherent anticipation and obviousness.

¶15 For a gene to be patentable, it must be useful.[17] Typically the utility standard has been easily met; however, in 2001, the PTO issued guidelines that demanded applicants identify a specific, substantial and credible utility for their inventions.[18] The guidelines require the disclosure to have a scientifically credible basis of support. The heightened utility requirements of the PTO guidelines were supported by the Federal Circuit in 2005 in *In re* Fisher, which held that the mere potential for use in discovering a gene was not sufficient to satisfy the specific and substantial utility requirements of § 101.[19]

¶16 To receive patent protection, the invention must be novel. Under 35 U.S.C. § 102, this equates to not being anticipated by the prior art. An invention is anticipated if a prior art reference expressly or inherently discloses each and every limitation of the claimed invention.[20] The evolution of inherent anticipation may make it more difficult for the applicant to obtain gene patents. The doctrine of inherent anticipation may preclude an applicant from claiming certain fragments of a gene if that gene is disclosed by prior art.

¶17 To receive patent protection, an invention must also be nonobvious at the time of the invention to one of ordinary skill in the relevant art under 35 U.S.C. § 103. In *KSR International Co. v. Teleflex Inc.*, the Supreme Court disapproved of the manner in which the Federal Circuit applied the accepted teaching, suggestion, or motivation (TSM) test and suggested a less rigid application.[21] The Court emphasized looking at secondary considerations, but did not provide a clear standard.[22] This relaxing of the obviousness standard may make it more difficult to obtain gene patents. A recent example is *In re Kubin*,[23] where the Federal Circuit found that a DNA sequence was not patentable because, under *KSR*'s obvious-to-try standard, the prior art's disclosure of the NAIL protein and antibody for NAIL rendered the DNA sequence of the gene obvious.

¶18 The Patent and Trademark Office along with the decisions in the Federal Circuit and Supreme Court have raised the bar for obtaining patents on DNA. Thus, obtaining patents over DNA is more difficult than it has have ever been. Despite the adjustments to the patentability standards of DNA, some legislators believe that a more dramatic change is needed to address the issue. As a result, there has been a recent push for legislative action barring DNA from patentable subject matter altogether, which is the goal of the GRAA.

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[16] *See generally* 35 U.S.C. §§ 101-13 (2000).
[17] 35 U.S.C. § 101 (2000).
[18] Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).
[19] 421 F.3d 1365 (Fed. Cir. 2005).
[20] *See* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576-78 (Fed. Cir. 1991).
[21] 550 U.S. 398 (2007).
[22] *Id.*
[23] 561 F.3d 1351 (Fed. Cir. 2009).

IV. THE GENOMIC RESEARCH AND ACCESSIBILITY ACT

¶19 On February 7, 2007, Congressmen Xavier Becerra, a Democrat of California, and Dave Weldon, a Republican of Florida, introduced the GRAA to the House of Representatives. Representative Becerra's introductory statement illustrates the motivation for the bill, which seeks to "end the practice of gene patenting" by giving "guidance to the [PTO] on what is not patentable – in this case, genetic material, naturally-occurring or modified."[24] In Becerra's view, this bill will "correct the regulatory mistake" that allows genes to be patented.[25]

¶20 The language of the GRAA is extremely broad, reading, "Notwithstanding any other provision of law, no patent may be obtained for a nucleotide sequence, or its functions or correlations, or the naturally occurring products it specifies."[26] Though the purpose of the bill is to remove DNA from patentable subject matter, the bill is not limited to banning patents on DNA. As the text reads, the statute promulgates a ban on patenting "the naturally occurring products [a nucleic acid] specifies."[27]

¶21 Read literally, the GRAA would ban patenting of all naturally-occurring proteins produced by any means, including many critical therapeutic proteins such as hemoglobin, erythropoietin, albumen, and human growth hormone. It would also ban any diagnostic assay that depended on detection of genetic polymorphisms, which are the genetic basis for many important diseases. Dr. Kevin Noonan, a Chicago patent attorney, astutely notes: "In short, the bill would eliminate patent production for the molecules that are expected to provide the pipeline of new drugs for the next twenty years."[28] Indeed, any trained scientist should realize that the language is so overbroad that it has the potential to cripple the biotechnology industry. *Intellectual Property Today* columnist Steven Ludwig commented that "[w]hen I first read the scope of the exclusion, I thought I must have read it wrong."[29]

¶22 On March 1, 2007, the bill was referred to the Subcommittee on Courts, the Internet and Intellectual Property. Though not explicitly in response to the GRAA, on October 30, 2007 Representative Howard L. Berman held a hearing, entitled "Stifling or Stimulating: The Role of Gene Patents in Research and Genetic Testing."[30] In his introduction, Representative Berman introduced the controversy over DNA patents and some of the arguments for and against them before turning the floor over to four individuals who presented testimony.[31] The testimony given at this hearing provided a framework to analyze the merits of the GRAA. The GRAA can be contextualized by analyzing the arguments and supporting research on both sides of the gene patent controversy.

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[24] 153 CONG. REC. E315-16 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra).

[25] *Id.*

[26] H.R. 977, 110th Cong. § 2 (1st Sess. 2007).

[27] *Id.*

[28] Posting of Kevin E. Noonan to Patent Docs, *The Continuing Threat to Human Gene Patenting*, http://www.patentdocs.org/2007/10/the-continuing-.html?cid=86709402 (Oct. 16, 2007, 23:52 CST).

[29] Steven R. Ludwig, *Attacking Gene Patents: Interesting Conversation – Bad Policy*, INTELL. PROP. TODAY, Jan. 2008, at 8.

[30] *Gene Patent Hearings*, *supra* note 15.

[31] *See Gene Patent Hearings*, *supra* note 15, at 1-3 (statement of Rep. Howard L. Berman, Chairman of the Subcommittee on Courts, the Internet and Intellectual Property).

V. THE ISSUES WITH GENE PATENTING

¶23 Four members of the biotechnology research community gave testimony at the hearing: Marc Grodman, CEO of Bio-Reference Laboratories; Jon Soderstrom, managing director of the Office of Cooperative Research at Yale University and President-Elect for the Association of University Technology Managers (AUTM); Lawrence Sung, a professor at the University of Maryland and partner at Dewey & LeBoeuf LLP; and Jeffrey Kushan, who presented testimony on behalf of the Biotechnology Industry Organization. Each member discussed various arguments regarding DNA patent reform. Though each member endorsed some type of gene patent reform, none presented testimony in favor of the sweeping reform embodied in the GRAA.

A. Patenting Life?

¶24 Representative Becerra's statement introducing the GRAA claims that "one-fifth of the blueprint that makes you . . . me . . . our children . . . all of us . . . who we are is owned by someone else. And we have absolutely no say in what those patent holders do with our genes."[32] This argument has been the media darling and most inflammatory argument against gene patenting—that someone else can own your genes. Indeed, Michael Crichton, as a strong supporter of the GRAA, chastises the current system that disallows donations of patented genes to a scientist of one's choosing. He blasts this disconnect, claiming "[the] gene may exist in your body, but it's now private property."[33] Further, web sites such as www.whoownsyourbody.org spark public anxiety over the idea that corporations own parts of their bodies through gene patents. As Crichton has shown, this is great material for best-selling science fiction novels, but the question is whether it has any actual scientific or legal merit.

¶25 This argument is known as the "universal heritage" argument, and its basic premise is that the human genome is part of every person, so it should belong to all humanity. The emphasis is placed on preserving the territory for future generations rather than focusing on current economic interests.[34] Universal heritage theorists argue that genes are the product of millions of years of evolution and are thus the property of all mankind, not any one individual.[35]

¶26 In support of the universal heritage argument, the Canavan disease case is frequently presented. Indeed, it is introduced by Becerra and Crichton, and is cited often by writers who oppose gene patents.[36] In that case, a family afflicted by a rare genetic disorder initiated an effort to find the gene mutation for the disease. They raised money, collected DNA samples, and recruited genetic researchers to investigate the disease. They were successful, and the gene was identified in the late 1990s. The researcher and his employer, Miami Children's Hospital, obtained a patent on the gene and began charging royalties on a genetic test to screen for the disease. Patient groups filed suit in 2000, contending misappropriation of trade secrets by using their children's DNA

[32] *See* 153 CONG. REC. E316 (daily ed. Feb. 9, 2007).
[33] *See* Crichton, *supra* note 2.
[34] *See* Sturges, *supra* note 6, at 248.
[35] *See* Mark A. Chavez, *Gene Patenting: Do The Ends Justify the Means?*, 7 COMPUTER L. REV. & TECH. J. 255, 264 (2003).
[36] *See* Crichton, *supra* note 2.

without consent to obtain a patent. In 2003, a confidential settlement was reached allowing certain laboratories to continue collecting royalties but allowing institutions, doctors, and scientists free use of the patented sequences. Opponents of gene patents argue that researchers never would have found the gene without the efforts and the DNA samples of the afflicted.[37]

¶27 Jeffrey Kushan addressed this sensitive issue during the hearing. First, he noted the important distinction that patents are not granted on genes or sequences, but novel chemical molecules. Consequently, the term "gene patents" is a misnomer.[38] Following *Chakrabarty* and *Amgen*, genes as they exist in nature cannot be patented.[39] Only after conducting research and establishing the utility of nucleic acids can they be patented. Under the PTO Guidelines[40] and *In re Fisher*,[41] the function or role of a gene must be elucidated before a practical application can be derived from the DNA comprising the gene. The utility threshold of DNA can only be met upon the finding of a practical application, such as enabling commercial production of a desired protein the DNA encodes, or providing the basis of a clinical diagnostic tool.[42]

¶28 Kushan's argument illustrates that technically any person's DNA is outside of patent claims. Since DNA must be isolated from the genome to qualify for patentability, it is impossible for any corporation or university holding a patent on a gene to own any person's DNA. However, Representative Becerra dismisses the Federal Circuit holding in *Amgen* that patent claims to nucleic acids require that they are "isolated" or "purified and isolated"[43] as "mere wordplay".[44] Wordplay or not, it is clear that no company owns anyone's particular genes. Companies own a patent on isolated DNA sequences with a practical application.

B. Effect of Gene Patents on Innovation

¶29 The rallying cry of opponents of gene patents is that they stifle innovation. Indeed, Becerra invokes this argument in support of the GRAA, stating "[r]esearch into disease cures is impeded when the holder of a patent on the disease gene prohibits other scientists from undertaking research involving that gene. Patent holders have shut down genetic disease research projects at major universities."[45] This argument represents the most dominant policy concern against gene patenting.

¶30 At the outset of the hearing on gene patenting, Representative Howard Berman cited the examination of gene patents' role in stimulating or stifling research as the central purpose of the hearing.[46] Berman mentioned that there is anecdotal information

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[37] Denise Caruso, *Someone (Other Than You) May Own Your Genes*, N.Y. TIMES, Jan. 28, 2007, at 3.3.

[38] *See* Kushan, *supra* note 15, at 64.

[39] *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980) and *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) for a discussion.

[40] *See* Utility Examination Guidelines, *supra* note 18.

[41] 421 F.3d 1365 (Fed. Cir. 2005).

[42] *See Gene Patent Hearings*, *supra* note 15, at 65 (statement of Jeffrey P. Kushan, Biotechnology Industry Organization) (discussing *In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995).

[43] *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1200 (Fed. Cir. 1991).

[44] *See* Becerra, *supra* note 24, at E316.

[45] Xavier Becerra, *Talking Points*, http://becerra.house.gov/HoR/CA31/Issues/genepatents.htm (last visited Feb. 20, 2008).

[46] *See Gene Patent Hearings*, *supra* note 15, at 2.

that suggests researchers have discontinued research because of the threat of lawsuit by patent holders, but then acknowledges that there is data suggesting just the opposite.[47] The two sides of this argument are well addressed by the various testimonies at the hearing, and we will examine the available evidence to determine which side is best supported by the data.

1. Effect of Gene Patents on Research

¶31 In an oft-cited article published in the highly influential journal *Science*, Michael Heller and Rebecca Eisenberg hypothesized that patents upstream of final products could create an "anticommons" effect, encumbering research progress and access to resources, thus making it difficult to acquire sufficient intellectual property and stifling innovation.[48] They predicted that permitting gene patenting would restrict progress, inhibit academic freedom, and prevent scientists from working cooperatively. Although no empirical evidence was cited, the idea quickly gained a good deal of attention.

¶32 E. Jonathan Soderstrom addressed the anticommons hypothesis as it relates to gene patents. Soderstrom pointed to several studies (discussed independently throughout this article) which show that "the licensing of DNA patents at US academic institutions has not led to the decline in academic cooperation and technology transfer that many observers have feared."[49]

¶33 At the hearing, Jeffrey P. Kushan expanded on Soderstrom's points against gene patents' role in stifling innovation. Kushan included an article written by Ted Buckley, the BIO director of Economic Policy, which contains some interesting empirical evidentiary findings that refute the "anticommons" effect feared by gene patent opposition.[50]

¶34 Buckley suggested that if the anticommons were occurring, we would expect the amount of research and development to decline. However, since 1998, research and development of publicly traded biotech companies has increased over 60%, and between 1995 and 2005 the amount of venture capital funding for biotechnology companies has increased 300%.[51] Employment in the biotechnology sector has increased 21% since 1998.[52] Thus, instead of seeing what one would expect from an industry experiencing an anticommons effect, one observes an industry that is increasing research and development levels, as well as increasing employment.

¶35 If the anticommons were occurring, research would be increasingly difficult, and the number of innovative therapies would be expected to decrease. Buckley observed that the number of biological compounds entering preclinical trials in 2005 was 37%

[47] *Id.*

[48] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

[49] *See Gene Patent Hearings*, *supra* note 15, at 27 (statement of E. Jonathan Soderstrom, J.D., Ph.D., Managing Director, Office of Cooperative Research).

[50] Ted Buckley, The Myth of the Anticommons (May 31, 2007) (unpublished manuscript, on file with the Biotechnology Industrial Organization), *available at* www.bio.org/ip/domestic/TheMythoftheAnticommons.pdf.

[51] *Id.*

[52] *Id.* at 3.

higher than in 1998,[53] cutting against the anticommons theory that gene patents are stifling research.

¶36 Other studies have revealed that minimal research-blocking effects of patents have been found. The National Academy of Sciences surveyed 414 academic researchers from universities, non-profits, and government labs to examine how patents have impacted their research.[54] Interestingly, only 5% of these researchers regularly check for patents on knowledge inputs related to their research.[55] Only 1% of academic respondents stated that they had experienced delays on their projects due to patents on knowledge inputs.[56] Even in areas of patent-intensive research where issues of access to intellectual property should be evident, only 3% of respondents reported stopping a project in the past two years because of a patent.[57] The report concluded that there is "[n]o evidence that widespread assertion of patent rights on genes has significantly hampered biomedical research."[58]

¶37 Advocates of reform are convinced that the rate of DNA patent infringement litigation is rising, providing another stifling cost to innovation. This perception is derived from three reports warning of the consequences of industry stifling innovation.[59] Further, *Madey v. Duke University*[60] opened the door for infringement assertions against universities and other public research institutions. Since universities and public research institutions are generally less well funded than the private sector, the hefty cost of litigation is thought to hamper innovation at these crucial centers for biomedical research.

¶38 Professor Lawrence M. Sung addressed this issue at the hearing. He is an advocate for change in gene patenting, yet his proposal falls short of the scope of the GRAA. In response to the *Madey* fears, Sung proposed that the statutory clinical trial exemption in the patent infringement statute section[61] should be expanded to include an exemption for research use.[62] This proposal would immunize academic researchers and their institutions from patent infringement and establish a right to use patented technology for basic research without fear of litigation.[63] Sung conceded that legislation may be needed in order to restore the balance between the interests of commercial exclusivity and public access to genetic technology. However, perhaps in a thinly veiled response to the GRAA, he warned, "the potential for unintended consequences in any change to patent

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[53] *Id.*

[54] John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002, 2002-03 (2005).

[55] *Id.*

[56] *Id.*

[57] *See id.*

[58] *See Gene Patent Hearings*, *supra* note 15, at 27 (statement of E. Jonathan Soderstrom, J.D., Ph.D, Managing Director, Office of Cooperative Research).

[59] *See* Ann E. Mills & Patti Tereskerz, *DNA-based Patents: An Empirical Analysis*, 26 NATURE BIOTECHNOLOGY 993, 993, 995 nn.7-9 (2008) (concluding that "[t]he perception of rising rates of litigation derives from three reports warning of dire consequences if industry is unable to innovate and successfully commercialize new products" and citing those three reports).

[60] 307 F.3d 1351 (Fed. Cir. 2002).

[61] 35 U.S.C. § 273 (2000).

[62] *See Gene Patent Hearings*, *supra* note 15, at 7 (statement of Lawrence M. Sung, Ph.D).

[63] *Id.* at 13.

laws, which may have disparate impact upon various technologies and industries, strongly suggests that such action should be approached with careful deliberation."[64]

¶39 In 2008, Ann Mills and Patricia Tereskerz conducted a study to determine whether or not the rates of DNA-based patent litigation are actually rising.[65] They analyzed 211 cases involving DNA-based patents issued between 1982 and 2005, finding that in 163 of these 211 cases (77%), a complaint was filed with no further action being taken.[66] The authors suggested that the results "should call into question whether the perception of rising litigation rates is valid for some industries and whether this argument can continue to be used to justify patent reform without additional research."[67] The authors warned against broad scope legislation, especially "when passage of such legislation may be accompanied by introducing uncertainty as to patent validity, which may in turn discourage investment in younger industries and ultimately stifle innovation and commercialization."[68] This evidence weakens the argument for the necessity of a radical legislative response such as the GRAA. Indeed, the authors explicitly warned against such a response.

¶40 The passage of the GRAA would compromise the status of the United States as the world leader in biotechnology and pharmaceutical innovation. Patents on genes and recombinant or transgenic organisms have been vital to America's preeminence in the biotechnology and pharmaceutical industries.[69] A recent *Washington Post* article by Joseph Fuller and Brock Reeve warns of the complacency of innovation in the United States.[70] American pharmaceutical companies account for sixty percent of global sales, and seventy-five percent of biotechnology sales.[71] However, just thirty years ago, half of the top ten pharmaceutical companies in sales were European, and in the early 1980's European companies invented half of the world's new drugs.[72] Fuller and Reeve credit the passage of the Bayh-Dole Act and the *Diamond v. Chakrabarty* decisions as the source of this change in leadership.[73] In contrast, Europe did not permit patents on living organisms until 1988, and the European Union did not encourage state-funded universities to pursue patenting.[74] Fuller and Reeve warn that the restrictions placed on stem cell research in the United States could lead to falling behind other countries that do not have such expansive restrictions.[75] It is not a far-fetched assumption that the passage of the GRAA could have a negative effect on the position of the United States as the world leader in biotechnology and pharmaceutical innovation.

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[64] *Id.* at 14.
[65] Mills & Tereskerz, *supra* note 59.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *See* Posting of Kevin E. Noonan to Patent Docs, *The Continuing Value of Biotech Patenting*, http://patentdocs.typepad.com/patent_docs/2007/02/the_continuing_.html (Feb. 4, 2007, 16:24 CST).
[70] Joseph Fuller & Brock Reeve, *Will We Lose in the Stem Cell Race?*, WASH. POST, Feb. 3, 2007, at A15, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/02/02/AR2007020201525.html.
[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] *Id.*

¶41 The empirical evidence presented by Soderstrom and Kushan at the hearing refute the argument that research is stifled by gene patents. The study by Mills further confirms that the existence of gene patents in specific areas does not deter decisions to choose research focus in these areas. Though the *Madey* decision may leave universities vulnerable to patent infringement suits, the levels of litigation are not rising as feared. A dramatic response such as the GRAA would cause significant economic harm, including the risk that the United States falls behind the rest of the world in biomedical advancement.

2. Effect of Gene Patents on Research Sharing

¶42 The sole argument that Becerra provides data to support is that gene patents have a negative effect on the sharing of research materials. Becerra relies on a 2003 study that surveyed 1,077 doctoral students and postdoctoral fellows.[76] He states:

> Forty-seven percent of geneticists have been denied requests from other faculty members for information, data, or materials regarding published research. The practice of withholding data detrimentally affects the training of the next generation of scientists. Almost one fourth of doctoral students and postdoctoral fellows reported they have been denied access to information, data and materials.[77]

¶43 Indeed, a recent study confirms data that shows problems with material transfer agreements are more prevalent than patents. In this 2005 survey of 414 biomedical researchers in universities, government, and nonprofit institutions, 19% of the respondents reported that their most recent request for material was denied.[78] When the reason for noncompliance was analyzed, the patent status of the requested material had no significant effect on noncompliance.[79] However, access to materials was more problematic in patented technologies than the random sample, with thirty percent of researchers not receiving their last requested materials.[80]

¶44 The sharing problem presented by Becerra is perhaps his best-supported argument. However, this problem is likely to be prevalent to all biotechnology and pharmaceutical patents, and not specific to DNA patents. Becerra's lone study compared life science with computer science and chemical engineering, but the existence of patents was not discussed. Research endeavors in life science as compared to computer science and chemical engineering are quite different. It is inappropriate to assume the only difference between these two disciplines is the ownership of patents.

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[76] Christine Vogeli et al., *Data Withholding and the Next Generation of Scientists: Results of a National Survey*, 81 ACAD. MED. 128 (2006).

[77] 153 CONG. REC. E315-16 (daily ed. Feb. 9, 2007).

[78] *See* Walsh, *supra* note 54.

[79] *Id.* at 2003.

[80] *Id.*

C. Genetic Testing and Public Health

¶45 Genetic testing involves comparing a patient's DNA sequence with a reference sequence. The Human Genome Project has made reference sequences freely available. Research investments have focused on development of novel test instruments, methods, and reagents.[81] It is generally well accepted that genetic diagnostics have provided advancement for overall public health.

¶46 Becerra mentioned gene patent effects on genetic testing in his introductory remarks to Congress, stating: "Gene patents interfere with research on diagnoses and cures. Half of all laboratories have stopped developing diagnostic tests because of concerns about infringing gene patents. One laboratory in four has had to abandon a clinical test in progress because of gene patents."[82]

¶47 Becerra relies on a 2006 study that investigated the effect of gene patents on various stages of research.[83] After finding very little evidence of any limitations on most research projects, the study turned to gene patents that cover a diagnostic test. In this case, 25% of labs had abandoned one or more genetic tests as a result of patents.[84] The patentee sees unlicensed lab testing as competition with his commercial activity. Hence, it is not surprising that owners are asserting their patent rights.[85]

¶48 Marc Grodman, CEO of Bio-Reference Laboratories, supports Berreca's concerns over gene patent effects on genetic testing. He presented arguments as to why he believed that "exclusive licensing of genetic associations" should be barred.[86] Grodman presented two points of focus. First, Grodman argued that exclusive licensing runs contrary to public health. Second, he proposed a remedy to the problem, which lies within the Bayh-Dole Act.[87]

¶49 Grodman posited that competition in genetic testing is critical to public health. He succinctly stated, "In the area of genetic testing, exclusivity is a formula for mediocrity."[88] In one illustration, Grodman discussed the highly publicized *Myriad* case, which, like the *Canavan* case mentioned earlier, has become an often-cited case for patent reform.[89] A genetic test for hereditary breast and ovarian cancer, based on full DNA sequencing of BRCA1 and BRCA2 genes to identify mutations, was developed by Myriad using an exclusive license from the University of Utah, which holds the patents on these genes.[90] Grodman argued that these tests were not as comprehensive as they could have been if other researchers were permitted to create a better test. Further, the test is expensive, in the range of $3,000, reducing the number of people who can afford the test.[91] To reinforce that the problem is not isolated to breast cancer, Grodman

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[81] *See* Klein, *supra* note 13.
[82] 153 CONG. REC. E315-16 (daily ed. Feb. 9, 2007).
[83] *See* Caulfield, *supra* note 14, at 1092.
[84] *Id.*
[85] *Id.*
[86] *See Gene Patent Hearings*, *supra* note 15, at 107.
[87] *Id.* at 35.
[88] *Id.* at 41.
[89] *Id.* at 40.
[90] *Id.* at 34.
[91] *Id.*

submitted an appendix listing problems encountered due to exclusive licensing in the area of neurological disorders.[92]

¶50 The Myriad gene patent controversy undoubtedly provides a cautionary example of the negative potential of gene patents. An analysis of the policy reports published after 2002 shows that the Myriad story was, by far, the most referenced gene patent controversy.[93] The Myriad story was often used as a specific justification for patent reform.[94] However, many policy reports and suggested reforms receive very little media attention, and one study provides data suggesting that the media coverage was responsible for driving a political agenda.[95]

¶51 Grodman's solution to the exclusive licensing problem falls well short of the scope of the GRAA. His proposal is to exercise the "march-in" powers of the Bayh-Dole Act,[96] which empowers the federal agency funding the research (usually the National Institute of Health in most academic research settings) and provides licenses to other interested parties when the "health or safety needs" of the American people are not being "reasonably satisfied" by the patent holder or its exclusive licensee.[97] Lawrence Sung also echoed Grodman's calling for exercise of Bayh-Dole march-in rights.[98]

¶52 Interestingly, the NIH has never exercised its "march-in" powers, and has denied formal requests to march in.[99] However, in these cases, the denials involved pharmaceuticals rather than genetic testing.[100] Grodman contrasted genetic testing and pharmaceuticals, pointing out convincingly that several drugs can effectively treat a disease, but most diseases only deal with one or a handful of genes. The licenses would still be profitable by establishing a reasonable royalty.[101] Grodman hedged his proposal: "I am not asking for a free ride; all I am asking for is the ability to compete fairly and benefit the public and my company."[102]

¶53 One 2006 study suggests that the prevalence of exclusive licensing seems to be overstated.[103] The survey of technology transfer of DNA inventions reveals that universities actively promote licensing patent rights to biotechnology companies, but rarely grant exclusive licenses.[104] Further, the report finds that the exclusive licenses granted are limited in nature, most frequently by "field of use" restrictions.[105]

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[92] *Id.* app. B.

[93] Timothy Caulfield et al., *Myriad and the Mass Media: The Covering of a Gene Patent Controversy*, 9 GENETICS IN MED. 850 (2007).

[94] *Id.*

[95] *Id.*

[96] 35 U.S.C. § 203 (2000).

[97] *See Gene Patent Hearings*, *supra* note 15, at 42 (statement of Dr. Marc Grodman, Chair of the Board and CEO, Bio-Reference Laboratories, citing 35 U.S.C. § 203(a)(2)).

[98] *Id.* at 10 (statement of Lawrence M. Sung, Ph.D).

[99] *See* Johns Hopkins Univ. v. Cellpro, Inc., 152 F.3d 1342 (Fed. Cir. 1998).

[100] *Id.*

[101] *See Gene Patent Hearings*, *supra* note 15, at 43-44 (statement of Dr. Marc Grodman, Chair of the Board and CEO, Bio-Reference Laboratories).

[102] *Id.* at 41.

[103] Lori Pressman et al., *The Licensing of DNA Patents by US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31 (2006).

[104] *Id.*

[105] *Id.*

¶54 If gene patents can be read to cover genetic testing, then granting exclusive rights to genetic testing could be found to hurt public health. Dr. Roger D. Klein, a medical doctor, attorney, and genetic testing advocate, admits that "given that almost all disease has a genetic component, this state of affairs bodes poorly for the future of healthcare generally."[106] However, Klein goes on to suggest that the legal threats on genetic testing may lack substance. Current United States law does not permit patents on human genes or patents on correlations between genetic variants, which dates back to the prohibition of patenting of natural phenomena.[107] The Supreme Court, most recently in *Diamond v. Diehr*, has repeatedly affirmed the natural phenomenon doctrine.[108]

¶55 Recently, the Supreme Court had an opportunity to rule on a case with direct implications for the validity or enforceability of gene-related patents that have restricted the development and implementation of genetic testing. In October 2005, the Court granted certiorari in *Laboratory Corporation of America v. Metabolite Laboratories, Inc.*[109] The claim at issue was a method for detecting a cobalamin or folate deficiency in animals by testing a body fluid for an elevated level of total homocysteine. Review was granted only with respect to whether a method correlating results can validly claim a scientific relationship used in medical treatment such that, after looking at a test result, a doctor infringes the patent merely by thinking about the relationship. Regrettably, after oral argument, the Supreme Court dismissed the case. Three justices, led by Justice Breyer, would have heard the case and would have found the patent invalid. Justice Scalia commented, "[B]ut here what [claim] 13 involves is simply discovery of the natural principle that when . . . there is the presence of one substance in a human being, there is a deficiency of two other ones. That's just a natural principle."[110]

¶56 The natural principle doctrine prevents patenting of biological relationships between genetic changes and physical characteristics that are at the heart of genetic testing.[111] According to Klein, so long as the courts do not expand the scope of gene-related patents to include genetic testing, there is likely no legal risk to pursue these diagnostics.

¶57 Becerra's argument that exclusive licensing has a negative impact on genetic testing may have some merit. However, it is questionable whether gene patents are the source of these problems. The GRAA is likely an overbroad response to this problem, and most commentators, including Grodman, argue that less invasive legislation is more appropriate.

VI. CONCLUSIONS

¶58 The GRAA faces an uphill battle. Read literally, the language of the bill is far too broad. In essence, the bill would ban patenting on all naturally-occurring proteins

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[106] Klein, *supra* note 12, at 989.
[107] O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853).
[108] 450 U.S. 175 (1981).
[109] 546 U.S. 975 (2005) (granting the petition for writ of certiorari).
[110] Transcript of Oral Argument, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921 (2006) (No. 04-607), *available at* http://www.supremecourtus.gov/oral_arguments/argument transcripts/04-607.pdf.
[111] *See* Klein, *supra* note 12, at 990.

produced by any biological means. It would also ban any diagnostic tool that relied on the identification of mutations in the genetic code. This would include a ban on patenting all natural, therapeutic proteins and any diagnostic assay that depended on detection of genetic polymorphisms. The bill would eliminate patent production for the molecules that are expected to provide new drugs, crippling the biotechnology industry in the process. The GRAA does reference the important need for careful regulation regarding overbroad DNA patents, though a more detailed and less reactive legislation should be explored.

¶59 Becerra simply does not know enough about the problem, as illustrated by the unreasonably broad sweep of the GRAA. The proposals by the witnesses at the hearing reflect the concern that enacting revolutionary legislation is unwise. According to Grodman and Sung, the solution may be available though currently available legislative means. Indeed, all of the testimony heard at the October 2007 hearing warned of the delicate nature of this type of legislation and that much more research and deliberation is needed before this Act or any other is passed.

¶60 The evolution of the stricter patentability standard, coupled with the available statutory regulation, is enough to handle the problems that the GRAA is proposed to solve. While we should applaud Becerra's recognition of need for reform, the indirect and debilitating effects of the GRAA will vastly outweigh the potential resolution of the issues Becerra presents. Congress must prioritize analysis of scientific data before voting on such legislation, rather than responding to inflammatory editorials from newspapers and isolated, media-friendly case studies.