EMERGING BIOTECHNOLOGIES DEMAND DEFEAT OF PROPOSED LEGISLATION THAT ATTEMPTS TO BAN GENE PATENTS

By: Gregory C. Ellis[*] [**]

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I. INTRODUCTION

[1] In October 2006, Andrew Fire and Craig Mello won the Nobel Prize in Physiology or Medicine for discovering a process known as RNA interference in the soil nematode *Caenorhaditis elegans*.[1] More commonly known as RNAi, this process has great therapeutic significance for humans because of its ability to specifically and efficiently regulate gene expression.[2] The capacity to easily regulate gene expression will tremendously impact our ability to combat a wide variety of disorders

[*] Gregory C. Ellis was awarded first place in the Fourth Biennial JOLT Writing Competition on the basis of this article. Mr. Ellis is an associate at Townsend and Townsend and Crew, LLP, in San Francisco, California. Mr. Ellis received his J.D. from the University of Washington School of Law in 2008. He earned a Ph.D. from the University of Oregon in Molecular Biology in 2002 and a B.S. in Physiology from Michigan State University in 1995.

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[1] Nobelprize.org, The Nobel Prize in Physiology or Medicine 2006, http://nobelprize.org/nobel_prizes/medicine/laureates/2006 (last visited Sept. 15, 2008).

[2] *See generally* Andrew Fire et al., *Potent and Specific Genetic Interference by Double-Stranded RNA in Caenorhabditis Elegans*, 391 NATURE 806 (1998) (describing discovery of RNAi).

ranging from cancer to infectious diseases.[3] While the mechanism of RNAi was first published within the last decade,[4] three RNAi-based human therapies are already in clinical trails.[5]

[2] In January 2008, just over one year after Fire and Mello's discovery, scientists at the J. Craig Venter Institute published a report describing the first synthetically created bacterial genome.[6] Synthetic biology, as the technology is known, has the potential to create microorganisms capable of producing inexpensive medical therapies, such as malarial vaccines, or even environmentally friendly industrial materials.[7] In addition to other applications, research is currently underway to produce synthetic organisms for use as highly efficient biofuels that would reduce the environmental cost of producing such fuels.[8]

[3] RNAi and synthetic biology are seemingly diverse technologies; however, these two technologies share a common necessity—gene patents. Gene patents are essential to ensure that any useful application will result from either of these technologies. Yet these emerging biotechnologies are not the only applications requiring gene patents. Society has already benefited enormously from gene patents. Biopharmaceutical drugs ("biologics") currently make up 40% of all preclinical candidates and 25%

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[3] *See* Charles X. Li et al., *Delivery of RNA Interference*, 5 CELL CYCLE 2103, 2103 (2006) (describing the versatility of RNAi).

[4] Antonin de Fougerolles et al., *Interfering with Disease: A Progress Report on siRNA-Based Therapeutics*, 6 NATURE REVS. DRUG DISCOVERY 443 nn.1-2 (2007).

[5] *See id.* at 451.

[6] Daniel G. Gibson et al., *Complete Chemical Synthesis, Assembly, and Cloning of a Mycoplasma Genitalium Genome*, 319 SCI. 1215, 1200 (2008), *available at* http://www.sciencemag.org/cgi/rapidpdf/1151721v1.pdf (describing the creation of synthetic genome).

[7] *See* Sapna Kumar & Arti Rai, *Synthetic Biology: The Intellectual Property Puzzle*, 85 TEX. L. REV. 1745, 1746 (2007) (describing potential advantages of synthetic organisms along with the unique intellectual property issues that would arise from their advancement into mainstream biotechnology).

[8] *See also* Lee R. Lynd et al., *How Biotech Can Transform Biofuels*, 26 NATURE BIOTECHNOLOGY 169, 170 (2008) (discussing the benefits of biotechnology with respect to increasing the "land fuel yield" for crops useful as biofuels). *See generally* Biodiesel Times, Genome Transplant Biofuels and Synthetic Genomics, http://biodiesel.rain-barrel.net/genome-transplant-biofuels-and-synthetic-genomics (last visited Sept. 15, 2008).

of all new drug submissions for U.S. market approval.[9] Furthermore, the biologics market is expanding at a rate far greater than the conventional drug market.[10] Research and development for both biologic and conventional drug therapies is quite costly, as a single drug can cost up to $1.7 billion to bring it to market.[11] As a result, the limited period of exclusivity afforded to patents is absolutely indispensable in providing the necessary incentive to invest so heavily in the research and development of most biologic drug therapies.[12]

[4] The promise of most biotechnologies could come to a screeching halt with the adoption of proposed bipartisan legislation that would effectively ban all gene patents. Introduced by Congressmen Xavier Becerra and Dave Weldon, the Genomic Research and Accessibility Act ("GRAA") simply states that "[n]otwithstanding 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."[13] Senator Becerra asserts that "[g]ene patents interfere with research on diagnoses and cures."[14] Gene patents have also caught the imaginative eye of the public. In an op-ed for the *New York Times*, Michael Crichton asserts that "[g]ene patents slow the pace of medical advance on deadly diseases," and that "[y]ou, or someone you love, may die because of a gene patent that should never have been granted in the first place."[15] Some bioethicists have taken a more academic approach by offering legal commentaries that explore the

[9] *See* Stacy Lawrence, *Pipelines Turn to Biotech*, 25 NATURE BIOTECHNOLOGY 1342, 1342 (2007).
[10] *See* Saurabh Aggarwal, *What's Fueling the Biotech Engine?*, 25 NATURE BIOTECHNOLOGY 1097, 1097 (2007).
[11] Liora Sukhatme, *Deterring Fraud: Mandatory Disclosure and the FDA Drug Approval Process*, 82 N.Y.U. L. REV. 1210, 1218 (2007).
[12] *See also* Christopher J. Betti, *Diagnostic Genetic Technologies Left Stranded on First Base: A Need to Unwind the Protection Afforded Gene Patents*, DUPAGE COUNTY BAR ASS'N BRIEF, April 2005, 22, at 23; *cf.* Marcia Angell, *Excess in the Pharmaceutical Industry*, 171 JAMC 1451, 1452 (2007).
[13] Genomic Research and Accessibility Act, H.R. 977, 110th Cong. § 2(a) (1st Sess. 2007) [hereinafter GRAA].
[14] *See* 153 CONG. REC. E315 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra), 2007 WL 433061.
[15] Michael Crichton, Op-Ed., *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, at A23.

legitimacy and subsequent effects of the issuance of gene patents.[16] Prominent scientists have even jumped on the bandwagon.[17] Although the language scientists use does not intentionally evoke the societal fear and paranoia that Crichton employs, both send the same message: gene patents are bad and should not be permitted.[18]

[5] Despite the public outcry, critics ostensibly fail to apprehend gene patents' primary purpose and benefits. In line with this reasoning, there is no convincing empirical evidence that gene patents are slowing the progress of biomedical or commercial research.[19] With respect to diagnostic testing, a great deal of debate has focused on whether gene patents unnecessarily increase the costs of such diagnostic tests.[20] Yet, many opponents of gene patents do not realize that patents that claim methods for diagnosing human genetic disorders comprise only a fraction of the total uses potentially employed by gene patents.[21]

[6] It would be extremely unfortunate if all the beneficial applications of gene patents were compromised at the expense of an overly broad and poorly drafted legislative bill that attempts to address a problem that is overblown and presumptuous. Even if banning gene patents would provide greater access to genetic diagnostic tests, which is itself a questionable notion, what would be the use of knowing that you *might* acquire a genetic condition if potential drug therapies to treat such conditions were never realized as a result of that ban?

[7] If passed, the GRAA would be devastating to the progress of both health care and possibly even the protection of the environment. A better solution would be to pass infringement exemption legislation that only

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[16] *See generally* Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403 (2005) (arguing that gene patents raise bioethical concerns and thus require policy reform).
[17] *See, e.g.*, Who Owns Your Body, Nobel Laureate Opposes Gene Patents, http://www.whoownsyourbody.org/sulston.html (last visited Sept. 15, 2008).
[18] *See, e.g.*, Andrews & Paradise, *supra* note 16, at 404 ("[P]atents for human genetic material are an example of a bad policy that needs to be corrected.").
[19] *See infra* Parts III.A-B.
[20] *See infra* Part III.C.
[21] *See infra* Parts III.C, IV.B for a discussion pertaining to which types of inventions are most commonly associated with gene patents.

targets companies attempting to monopolize diagnostic testing for specific genetic mutations, but without interfering with the commercial needs of companies that plan to develop genome-wide genetic analyses utilizing microchip array technologies.[22] This solution is especially advantageous in light of the technological paradigm shift currently underway from single gene diagnostic testing to genome-wide genetic analyses.[23] Such legislation would avoid interfering with the innovative incentive provided to biologic drug manufacturers as a result of gene patent protection, and would more appropriately address the issues associated with genetic diagnostic tests.

[8] The purpose of this article is to examine current United States patent law and policy with respect to gene patents, and to argue that the benefits of gene patents far outweigh any disadvantages. Aside from so-called moral opposition against gene patents, which rarely amounts to any meaningful proposals of reform,[24] more commonsensical arguments against gene patents can be divided into two broad categories. First, opponents of gene patents assert that genetic material simply is not patentable subject matter under current U.S. patent law. Second, even if genes are patentable subject matter, critics assert that policy concerns dictate that genetic material should not be patented because of the adverse effects such patents may have. Part II of this article discusses the patentability of genetic material under current U.S. patent law. Part III examines the policies that maintain that gene patents hinder research or prevent reasonable access to genetic diagnostic tests. Part IV demonstrates how gene patents have already benefited society by encouraging the development of biologic drug therapies. Finally, Part V reveals that emerging biotechnologies, including yet-to-be-discovered biotechnologies, will fail to materialize without the acceptance of gene patents.

[22] *See infra* Part III.C for a discussion pertaining to legislation that more appropriately targets issues relating to genetic testing.
[23] Arun Kalyanasundaram et al., *Genomics, Haplotypes and Cardiovascular Disease*, FUTURE CARDIOLOGY, Dec. 17, 2007, *available at* http://www.futuremedicine.com/doi/pdf/10.2217/14796678.3.6.601.
[24] *See* Timothy Caulfield et al., *Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies*, 24 NATURE BIOTECHNOLOGY 1091, 1091 (2006).

II. GENETIC COMPOSITIONS ARE PATENTABLE SUBJECT MATTER UNDER CURRENT U.S. PATENT LAW

[9] Before addressing the more pertinent debate as to whether policy considerations should require legislative action that would preclude gene patents, the standards associated with the patentability of genetic compositions under current U.S. law warrant discussion. This part will provide a brief synopsis of the two most controversial patentability requirements for gene patents: novelty and utility.

A. WHAT IS A GENE PATENT?

[10] As advances in molecular biology have provided greater insight into the complexities of the cellular processes facilitated by macromolecules such as deoxyribonucleic acid ("DNA"), it has become increasingly challenging to accurately define a gene.[25] A generally acceptable scientific definition of a gene is "[a] locatable region of genomic sequence, corresponding to a unit of inheritance, which is associated with regulatory regions, transcribed regions and/or other functional sequence regions."[26]

[11] The phrase "gene patent" does not have any legal basis, but is rather a term used mostly by commentators who address the legitimacy of such patents. The United States Patent and Trademark Office ("USPTO") asserts that a patent may contain claims directed towards an isolated and subsequently purified genetic composition.[27] As far as the USPTO is concerned, however, a genetic composition is broader than the scientific definition of a gene. Nucleic acids are the building blocks of both DNA and ribonucleic acid ("RNA"),[28] and a polynucleotide is basically any DNA or RNA sequence.[29] In practice, patents have been issued for

[25] *See* Helen Pearson, *What is a Gene?*, 441 NATURE 399, 399 (2006) (noting that defining what a gene is has become more difficult as scientists further the knowledge of molecular genetics).
[26] *Id.* at 401.
[27] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001).
[28] See MedicineNet.com, http://www.medterms.com/script/main/art.asp?articlekey=4594 (last visited Sept. 15, 2008), for a basic definition of nucleic acid.
[29] See Answers.com, http://www.answers.com/topic/polynucleotide?cat=health (last visited Sept. 15, 2008), for a basic definition of polynucleotide

polynucleotides that correspond to "a full-length protein encoding gene, a gene fragment, a regulatory region, a cDNA molecule, or a genomic region of unknown function."[30] Furthermore, patented polynucleotides may be either isolated or recombinant.[31] Accordingly, this article will generically refer to a gene patent as a patent that contains claims directed toward a genetic composition that encompasses any polynucleotide sequence, or toward methods that utilize such a composition.[32] This distinction is important considering that the GRAA's definition of what should be prevented from patenting includes any nucleotide sequence.[33]

B. ISOLATED AND PURIFIED GENETIC COMPOSITIONS ARE NOT NATURALLY OCCURRING

[12] Gene patent critics have asserted that genes are products of nature, and therefore do not deserve patent protection;[34] however, the debate as to whether products of nature should be patented existed well before the emergence of gene patents.

[13] The landmark case of *Diamond v. Chakrabarty*[35] was the first Supreme Court decision to address whether bioengineered organisms could be patented. In 1972, Ananda Chakrabarty filed a patent application containing claims directed towards a genetically engineered bacterium capable of breaking down crude oil.[36] Such bacteria do not exist in nature, and were thought to have significant use for treating oil spills.[37] The

[30] *See* Christopher M. Holman, *The Impact of Human Gene Patents on Innovation and Access: A Survey of Human Gene Patent Litigation*, 76 UMKC L. REV. 295, 312 (providing examples of issued patents that claim a variety of different forms of genetic compositions); *see infra* Parts II.B-C (discussing the patentability of genetic compositions).
[31] Holman, *supra* note 30, at 311.
[32] See *id.* at 312, for a comprehensive description of gene patents.
[33] GRRA, H.R. 977, 110th Cong. § 2(a) (1st Sess. 2007).
[34] Andrews & Paradise, *supra* note 16, at 405; Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 261, 263 (2005); Stephanie Arcuri, Note, *They Call That Natural? An Analysis of the Term "Naturally Occurring" and the Application of Genes to the Patent Act*, 40 VAL. U. L. REV. 743, 746 (2006); Crichton, *supra* note 15, at A23.
[35] 447 U.S. 303 (1980).
[36] *Id.* at 305-06.
[37] *Id.* at 305.

patent examiner rejected the claims, asserting that microorganisms are "products of nature," and that living things are not patentable subject matter.[38] The decision of the Court, which arguably provided a legal foundation from which the biotechnology industry has advanced,[39] held that Chakrabarty's live, human-made microorganism was the "result of human ingenuity and research,"[40] and thus should be considered patentable subject matter.[41] In determining that genetically modified bacteria are patentable, the Court provided its now infamous declaration that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[42]

[14] Isolated and purified compositions are not excluded from patentability either. In 1970, hormones isolated and purified from human prostate glands were held to exist in a state not found in nature, and were therefore found to be patentable because the isolated and purified hormones were not considered "naturally occurring."[43] In fact, isolated and purified compositions have been considered novel for almost a century—extracted adrenaline was held to be patentable in 1912.[44] In determining that extracted adrenaline was patentable, Judge Learned Hand asserted that "an extracted product without change," even lacking subsequent purification, is worthy of patent protection.[45] The USPTO applies this rationale to gene patents, maintaining that a genetic composition is not automatically precluded from patent protection as long as the composition is "isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it."[46]

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[38] *Id.* at 306.
[39] *See* Terri A. Jones, Note, *Patenting Transgenic Animals: When the Cat's Away, the Mice Will Play*, 17 VT. L. REV. 875, 883-84 (1993) (noting that the Chakrabarty decision accelerated commercial biotechnology innovation).
[40] *Chakrabarty*, 447 U.S. at 313.
[41] *Id.* at 309-10.
[42] *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399).
[43] *In re* Bergstrom, 427 F.2d 1394, 1401 (C.C.P.A. 1970).
[44] Parke-Davis & Co. v. H. K. Mulford & Co., 196 F. 496, 499 (2d Cir. 1912), *aff'g* 189 F. 95 (C.C.S.D.N.Y. 1911).
[45] Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 103 (C.C.S.D.N.Y. 1911), *aff'd*, 196 F. 496 (1912).
[46] Utility Examination Guidelines, 66 Fed. Reg. at 1093.

[15] Despite almost a hundred years of legislative history and judicial precedent, some commentators still insist that claiming a purified and isolated gene is not novel, but is a "trick of claim drafting" that circumvents a proper interpretation of U.S. patent law.[47] More specifically, these arguments posit that an isolated and purified gene sequence is simply a copy of the naturally occurring sequence, and thus lacks originality.[48] Still, it must be remembered that gene patents are not permitted simply for "sequence data that represent genes as they naturally occur within human chromosomes."[49] Rather, a genetic composition is only patentable if it is useful as a "pharmaceutical drug, screening assay, or other application."[50]

C. STRICT UTILITY REQUIREMENTS MUST BE MET IN ORDER TO OBTAIN PATENT PROTECTION FOR GENETIC COMPOSITIONS

[16] Even if isolated and purified genetic compositions are eligible to meet the novelty standard of U.S. patent law, such compositions must also have utility (i.e., be useful) in order to procure patent protection. Questions as to whether the current utility standard was sufficient, in light of the technology associated with genomic sequencing, arose in the course of two notable events in the 1990s.

[17] In 1992, Dr. Craig Venter[51] applied for three gene patents for 6,800 expressed sequence tags ("ESTs").[52] ESTs are short segments of DNA that represent portions of expressed genes, and may be useful for example,

[47] Liivak, *supra* note 34, at 263-64.
[48] *Id.* at 264.
[49] James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?* 37 WILLAMETTE L. REV. 637, 648 (2001) (discussing further requirements beyond mere copying of a gene's sequence that provides for some genetic compositions to be patentable as a result of no longer being naturally occurring).
[50] *Id.* at 648-49.
[51] Craig Venter was the founder of commercially-based Celera Genomics that competed with the federally funded Human Genome Project to complete the sequencing of the human genome. Jonathan Kahn, *What's the Use? Law and Authority in Patenting Human Genetic Material*, 14 STAN. L. & POL'Y REV. 417, 420 (2003).
[52] *See id.* at 420.

to map which sequences in a genome are protein coding genes.[53] Although these applications were ultimately withdrawn, Venter subsequently applied for patents that covered over 20,000 genetic compositions as CEO of Celera Genomics.[54] In doing so, Venter asserted that the patents would be used to later diagnose genetic disorders.[55] The USPTO denied his applications with the implication that simply finding a gene sequence without an established utility does not merit patent protection.[56]

[18] The increased desire for more stringent utility requirements was the result of incidences of opportunistic protection of subsequently discovered uses for some gene patents. For example, in 1995, Human Genome Sciences ("HGS") filed an application for a gene known as HDGNR10.[57] HGS made rather generic claims regarding the utility of its gene: it is useful for "identifying [receptor] antagonists and agonists."[58] What HGS did not know at the time, but was discovered the following year by scientists at the National Institutes of Health ("NIH"), was that the protein encoded by the gene, named CCR5 by the NIH scientists, was identified as a receptor essential for HIV infection.[59] Although HGS was unaware of the true utility of its gene at the time of filing, HGS now enjoys the exclusive right to license the patent to another biotechnology company that is using the CCR5 protein product in an effort to develop an HIV vaccine.[60]

[53] National Center for Biotechnology Information, Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, http://www.ncbi.nlm.nih.gov/About/primer/est.html (last visited Sept. 15, 2008).
[54] *See* Kahn, *supra* note 51.
[55] *See* iBrief, *The Fate of Gene Patents Under the New Utility Guidelines*, DUKE L. & TECH. REV., Feb 28, 2001, ¶ 5 (2001).
[56] *Id.*
[57] *See* Mattias Luukkonen, *Gene Patents: How Useful Are the New Utility Requirements?*, 23 T. JEFFERSON L. REV. 337, 338 (2001).
[58] Sean C. Pippen, *Dollars and Lives: Finding Balance in the Patent "Gene Utility" Doctrine*, 12 B.U. J. SCI. & TECH. L. 193, 195 (2006) (quoting U.S. Patent No. 6,205,154 abstract (filed June 6, 1995)).
[59] *Id.* at 195-96; *see also* Luukkonen, *supra* note 57, at 338 (stating that CCR5 is encoded as an "essential" co-receptor for HIV).
[60] *See* Luukkonen, *supra* note 57; *see* Pippen, *supra* note 588, at 196.

[19] As a result of these events, and in response to criticism that gene patents were being granted too liberally,[61] the USPTO issued new Utility Examination Guidelines ("Guidelines") in January 2001.[62] The Guidelines increased the utility standard for gene patents,[63] and provided that an invention is useful only if it has a "well-established utility."[64] This requires the genetic composition's utility to be "specific, substantial, and credible."[65]

[20] The more stringent utility requirements promulgated by the Guidelines forced stricter examination of patents, allowing only the patenting of useful genetic compositions as required by patent policy. Thus, ESTs must now have a "real world" utility,[66] and will not satisfy the well-established utility requirement put forth by the Guidelines if those ESTs are only useful, for example, as "probes, chromosome markers, or other research tools."[67] Additionally, the Guidelines will function to substantially limit opportunistic patenting that is similar to the approach of the HGS scientists.

[21] Although the Guidelines stopped short of clearly defining what requirements a genetic composition must meet to be useful,[68] the Guidelines ultimately corroborated the USPTO's intent to issue patents claiming genetic compositions under requisite circumstances.[69] This corroboration is based on the USPTO's conclusion that current patent law does not prohibit gene patents.[70] It should be acknowledged, however, that the Guidelines are just that—guidelines that patent examiners should follow when determining whether an invention meets the utility requirement.

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[61] *See* Kahn, *supra* note 51, at 421.
[62] Utility Examination Guidelines, 66 Fed. Reg. at 1092.
[63] *See* Melissa E. Horn, *DNA Patenting and Access To Healthcare: Achieving the Balance Among Competing Interests*, 50 CLEV. ST. L. REV. 253, 257 (2003).
[64] Utility Examination Guidelines, 66 Fed. Reg. at 1098.
[65] *Id.*
[66] iBrief, *supra* note 55, ¶ 28.
[67] *Id.* ¶ 20.
[68] *See* Pippen, *supra* note 58, at 205.
[69] Horn, *supra* note 63, at 257; iBrief, *supra* note 55, ¶ 2.
[70] *Cf.* Pippen, *supra* note 58, at 204.

[22] The Guidelines are not law, and the USPTO clearly acknowledges this fact.[71] Nonetheless, the Guidelines have been substantially indoctrinated into common law, most notably with the Federal Circuit's 2005 *In re Fisher*[72] decision. This decision pertained to a rejected patent application that claimed ESTs that correspond to certain maize genes.[73] The inventor was unaware of the precise structure or function of the genes encoded by the claimed ESTs when he filed the patent application.[74] Despite this lack of functional knowledge, the inventor argued that the uses of the ESTs were not related to the functions of the underlying genes, but could be used as a research tool comparable to a "microscope."[75] While the court acknowledged that the Guidelines were not binding in its decision,[76] the court essentially endorsed the Guidelines in determining that Fisher's ESTs did not have any real world utility based on an asserted "specific and substantial" use.[77]

[23] With respect to current U.S. patent law regarding gene patents, as long as an inventor isolates and subsequently purifies a genetic composition, and can further show that the composition has a non-obvious real world use, the USPTO will issue a patent.[78] Furthermore, the judicial branch has not interpreted current U.S. patent law as a prohibition against gene patents.[79] Thus, this article will proceed with the presupposition that genetic compositions are patentable subject matter.

III. POLICY CONSIDERATIONS STIR THE GENE PATENT DEBATE

[24] As discussed above, genetic compositions are patentable subject matter under current U.S. patent law, and there does not appear to be any indication that such practices will cease without legislative action.

[71] *Id.* at 193.
[72] 421 F.3d 1365 (Fed. Cir. 2005).
[73] *Id.* at 1368.
[74] *Id.*
[75] *Id.* at 1373.
[76] *Id.* at 1372.
[77] *Id.* at 1373; Recent Case, *Patent Law—Utility—Federal Circuit Holds That Expressed Sequence Tags Lack Substantial and Specific Utility Unless Underlying Gene Function is Identified—*In Re Fisher, *421 F.3D 1365 (Fed. Cir. 2005)*, 119 HARV. L. REV. 2604, 2605 (2006).
[78] 35 U.S.C. § 103 (2000).
[79] *See* Holman, *supra* note 30, at 296.

Accordingly, as opposed to questioning the legitimacy of gene patents under the standards of current U.S. patent law, the more relevant question is whether policy arguments that take into account the actual consequences of such patents require action limiting patent protection for genetic compositions.

[25] This article argues that not only should policy concerns prevent a ban on gene patents, but that policy considerations actually *favor* gene patents. Nonetheless, concerns of the possible negative effects of gene patents deserve recognition in order to demonstrate the unsubstantiated trepidation associated with such concerns. Two common arguments exist regarding policy justifications that question gene patents. The first argument asserts that gene patents impede basic or biomedical research and/or commercial innovation. Not only will this section demonstrate that this argument is largely unsupported, but it will also show that such concerns are being unfairly waged against gene patents and are applicable to many types of patents. The second argument in favor of a ban against gene patents asserts that such patents prevent reasonable access to diagnostic testing of genetic disorders.

A. GENE PATENTS DO NOT RESTRAIN BASIC OR BIOMEDICAL RESEARCH

[26] Whereas proponents of gene patents contend that such patents encourage innovation,[80] some critics maintain that gene patents interfere with research and development, and are therefore contrary to patent policy.[81] Such criticisms are largely based on anecdotal evidence gathered

[80] *Id.* *See generally* David E. Adelman & Kathryn L. DeAngelis, *Patent Metrics: The Mismeasure of Innovation in the Biotech Patent Debate*, 85 TEX. L. REV. 1677 (2007) (providing an empirical demonstration that gene patents are not hindering innovation).
[81] *See* 153 CONG. REC. E315 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra), 2007 WL 433061; John F. Merz et al., *Diagnostic Testing Fails the Test*, 415 NATURE 577, 577 (2002); Byron V. Olsen, *The Biotechnology Balancing Act: Patents For Gene Fragments, and Licensing the "Useful Arts,"* 7 ALB. L.J. SCI. & TECH. 295, 334 (1997); Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 149 (2004); Horn, *supra* note 63, at 282; Crichton, *supra* note 15, at A23. *See generally* Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health*

from one third-party survey that sought to determine the full range of genetic data withheld by academic geneticists.[82] The conclusion that gene patents interfere with basic research is based on observations that 21% of surveyed researchers withheld data in order to protect commercial interests in their research.[83] Yet, as soon as a university researcher becomes interested in commercializing his or her research, that research is clearly no longer basic academic research. The survey relied upon, however, is silent as to whether the researchers who were actually prevented from obtaining information or materials because of commercial interests were themselves basic researchers with no commercial ambitions.[84] It is necessary to address this omission before concluding that such data signifies a hindrance on noncommercial biomedical research. Furthermore, it is important to note that the survey was not even unique to gene patents, as it noted that "geneticists were no more likely than other life scientists to report that their requests were denied."[85]

[27] The true test of whether gene patents are hindering noncommercial biomedical research is to examine whether biomedical researchers without commercial interests are prevented from acquiring materials, not whether researchers with commercial interests are withholding materials. Recent surveys of biomedical researchers in universities, government, and nonprofit institutions questioned whether patents could be blamed for blocked access to biomedical research materials.[86] These surveys found that while access to research materials at times may be restricted, "the patent status of the requested material had no significant effect" on why those materials were restricted.[87] In fact, none of those surveyed declared that third-party patents stopped their research and only 1% stated that research was delayed as a result of another party's patent.[88] The survey

Needs, 2 HOUS. J. HEALTH L. & POL'Y 65, 79-81 (2002) (arguing that the rationales that are appropriate for granting patents for some products do not apply to gene patents).

[82] *See generally* Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 JAMA 473 (2002) (surveying to what degree and for what reasons geneticists withhold sharing information and materials).

[83] *Id.* at 478 fig.

[84] *Id.* at 473.

[85] *Id.* at 474.

[86] *See* John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCI. 2002, 2002 (2005).

[87] *Id.* at 2003.

[88] *Id.* at 2002.

authors concluded that their "results offer little empirical basis for claims that restricted access to IP is currently impeding biomedical research."[89] Accordingly, there is a paucity of compelling evidence gathered from surveys of basic biomedical researchers that gene patents specifically interfere with strictly academic research.[90]

[28] If gene patents are not dissuading academic investigators who engage strictly in basic research from sharing or receiving data and materials, could researchers nonetheless be held liable if their research infringes upon another's gene patent? It is appropriate to note that patent law does not always prohibit use of a patented invention. There is a common law exception from infringement, known as the experimental use exception, which provides relief from patent infringement if the conduct is "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[91] The experimental use exception has frequently been applied to academic researchers and institutions.[92]

[29] The two-century-old experimental use exception has become even narrower in recent years,[93] leaving many academic researchers to question whether their activities might leave them liable for infringement.[94] In 2002, the Federal Circuit held in *Madey v. Duke*[95] that the experimental use exception did not apply to a private research university[96] despite the

[89] *Id.* at 2003.
[90] See generally *id.*, which demonstrates the failure of biomedical researcher surveys to provide conclusive proof that gene patenting significantly interferes with strictly academic non-commercial research.
[91] Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).
[92] *See* Michael S. Mireles, *Adoption of the Bayh-Dole Act in Developed Countries: Added Pressure For a Broad Research Exemption in the United States?* 59 ME. L. REV. 259, 277-78 (2007).
[93] *See generally* Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921, 922-23 (2006) (discussing the possible impact of *Madey v. Duke Univ.*).
[94] *See generally* Amy Yancey & C. Neal Stewart, Jr., *Are University Researchers at Risk for Patent Infringement?*, 25 NATURE BIOTECHNOLOGY 1225 (2007) (discussing the notion that the traditional practice of ignoring patents by university researchers with no commercial interests might nonetheless leave such researchers liable for infringement).
[95] Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).
[96] *See* Rowe, *supra* note 93, at 944-45.

fact that the university was not directly involved in any commercial ventures related to the patented invention.[97] The reasoning behind this controversial decision was that noncommercial research still advances the university's educational mission to "increase the status of the institution and lure lucrative research grants, students and faculty."[98]

[30] Although it may be advantageous to retain a broad experimental use exception for public sector researchers,[99] it is still unclear how the *Madey* decision will affect academic researcher's ability to use the experimental use exception as a defense against infringement.[100] Some have argued that a de facto experimental use exception nonetheless applies to pre-commercialization researchers.[101] The reasoning behind this notion is that patent holders are unlikely to even be aware of early stage infringing activities taking place among academics, and even if they were aware, "the damages would prove too small to justify the cost of litigation."[102]

[31] Legislation that failed to pass would have protected noncommercial research against infringement of a gene patent.[103] The Genomic Research and Diagnostic Accessibility Act of 2002 ("GRDAA of 2002")[104] provided two provisions that exempted individuals from infringement of gene patents.[105] One provision that pertained to diagnostic tests is discussed below.[106] The other provision would have provided an

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[97] *Madey*, 307 F.3d at 1362-63.
[98] *Id.* at 1362.
[99] *See* David C. Hoffman, Note, *A Modest Proposal: Toward Improved Access to Biotechnology Research Tools by Implementing A Broad Experimental Use Exception*, 89 CORNELL L. REV. 993, 1039 (2004) (arguing that an expansive experimental use exception applied only to public sector researchers would permit noncommercial use of reagents for when equivalent substitutes are unavailable).
[100] Yancey & Stewart, *supra* note 94, at 1227.
[101] *See* Rowe, *supra* note 93, at 950.
[102] *Id.*
[103] *See* Gregory P. Lekovic, *Article: Genetic Diagnosis and Intellectual Property Rights: A Proposal to Amend "The Physician Immunity Statute"*, 4 YALE J. HEALTH POL'Y L. & ETHICS 275, 296-97 (2004) (discussing the legislative history of the Genomic Research and Diagnostic Accessibility Act of 2002).
[104] Genomic Research and Diagnostic Accessibility Act of 2002, H.R. 3967, 107th Cong. (2002).
[105] *See also* Betti, *supra* note 12, at 25-26 (discussing congressional action that would alleviate issues surrounding gene patents and diagnostic testing).
[106] *See infra* Part III.C.

exemption from infringement for those that used patented genetic technologies for noncommercial research purposes;[107] however, the legislation never passed.[108] Nonetheless, as long as an academic researcher has no commercial intentions, it is extremely unlikely, though not impossible, that an academic researcher will find herself in court for infringing a gene patent. At any rate, contentions that gene patents are compromising basic academic research are overstated and not even exclusively based on gene patents.[109]

B. GENE PATENTS ARE NOT COMPROMISING COMMERCIAL INNOVATION

[32] The next concern to address is whether gene patents interfere with innovation when commercialization factors into the equation. Since the passage of the Bayh-Dole Act in 1980, academic researchers have been able to commercialize their research efforts despite funding from the government.[110] The purpose of the Bayh-Dole Act was "to promote the utilization of inventions arising from federally supported research or development."[111] The fact that academic researchers can patent and subsequently license inventions has raised concerns that the public must pay twice for innovation: first through the taxes that funded the research, and then for the high prices enabled by the patent rights.[112] Similar arguments have been raised in regard to gene patents, due to the fact that the Human Genome Project was publicly funded.[113] These claims are only convincing if "the patent arising from the federal funding effectively covers the eventual product that will be brought to market."[114] As this article will demonstrate, most commercialized innovations arising from gene patents are biologic drug therapies that are so far removed

[107] *See* Betti, *supra* note 12, at 25-26.
[108] *Id.* at 25.
[109] *See* Campbell, *supra* note 82, at 478; *see supra* text accompanying notes 89-90.
[110] 35 U.S.C. §§ 200-212 (2000); *see In re* Roche Molecular Sys., 516 F.3d 1003, 1008 (Fed. Cir. 2008) (Newman, J., dissenting) ("The Bayh-Dole Act is intended to promote investment by the private sector in commercialization of federally funded research discoveries for the public good.").
[111] 35 U.S.C. § 200.
[112] *See* Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 NEW ENG. L. REV. 665, 685 (2005).
[113] Andrews & Paradise, *supra* note 16, at 406.
[114] O'Connor, *supra* note 112, at 685.

downstream from the gene discovery phase that public fears of having to pay twice are substantially unwarranted. [115]

[33] The concerns that gene patents reduce commercial innovation are not exclusive to academic researchers that desire to commercialize their research. Public sector researchers that must compete with the intellectual property rights of for-profit corporations, and even the established biotechnology companies themselves, share such concerns. A growing concern among intellectual property commentators arises from what is known as the "tragedy of the anticommons."[116] An intellectual property anticommons is created by patent thickets[117] that allow multiple patent owners to each have a right to exclude others from a scarce resource so that no one individual has an effective privilege of use.[118] Accordingly, technologies requiring many patented components are usually more susceptible to anticommons effects. Patent thickets generally raise concerns that resulting anticommons will block innovation because of "the cost of bringing downstream technologies to market."[119] It is argued that such costs are caused by each upstream patent holder setting up "tollbooths" of high bargaining costs and licensing fees, which subsequently slow the pace of downstream innovation.[120]

[34] One area that has prompted concerns regarding patent thickets is agricultural biotechnology. To exemplify, Golden Rice is a genetically modified crop that has significantly elevated levels of vitamin A because

[115] *See infra* note 162 and accompanying text.
[116] *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998) (describing how the "tragedy of the commons" metaphor helps to explain an "anticommons" in which resources are underused as a result of blocking patents).
[117] The phrase "patent thickets" is often used either interchangeably, or in conjunction with, the phrase "tragedy of the anticommons." *See* Kenneth Neil Cukier, *Navigating the Future(s) of Biotech Intellectual Property*, 24 NATURE BIOTECHNOLOGY 249, 250 (2006); Yancey & Stewart, *supra* note 94, at 1225-26.
[118] *See* Heller & Eisenberg, *supra* note 116, at 698.
[119] Yancey & Stewart, *supra* note 94, at 1225-26.
[120] Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing The Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV 303, 418 (2002); *see* Heller & Eisenberg, *supra* note 116, at 698-99.

of the transgenic expression of beta-carotene.[121] There is a prediction that the impact of Golden Rice could save millions of lives annually in the developing world.[122] The development of Golden Rice required an astonishingly large array of patent-protected technologies; it called for seventy patent-protected technologies belonging to over thirty public and private sector entities.[123] Fortunately, these patent-holding entities cooperated by offering free licenses in order to promote distribution of the crop to the developing world.[124] Still, it is uncertain at this time whether similar patent holders will be as cooperative in sharing other agricultural biotechnologies intended for food security in the developing world.[125]

[35] In regard to human gene patents, critics have warned that gene patent thickets will "increase the costs of genetic diagnostics, slow the development of new medicines, stifle academic research, and discourage investment in downstream R&D."[126] The United States has patented one-fifth of human genes, according to one study.[127] This has prompted gene patent opponents, including Congressman Becerra, to claim that one-fifth of your genome is "owned" by someone else.[128] Unfortunately, such

[121] *See generally* Jacqueline A. Paine et al., *Improving the Nutritional Value of Golden Rice Through Increased Pro-Vitamin A Content*, 23 NATURE BIOTECHNOLOGY 482 (2005) (describing the preferential accumulation of beta-carotene in rice through the transgenic expression of the phytoene synthase gene from maize in combination with the Erwinia uredovora carotene desaturase gene).
[122] *See* Stanley P. Kowalski & R. David Kryder, *Golden Rice: A Case Study in Intellectual Property Management and International Capacity Building*, 13 RISK 47, 51-52 (2002).
[123] *See* Ronald P. Cantrell et al., *The Impact of Intellectual Property on Nonprofit Research Institutions and the Developing Countries They Serve*, 6 MINN. J. L. SCI. & TECH. 253, 269 (2004).
[124] *Id.* at 270; *see* Remigius N. Nwabueze, *What Can Genomics and Health Biotechnology Do For Developing Countries?*, 15 ALB. L.J. SCI. & TECH. 369, 394 (2005).
[125] *See* Gregory C. Ellis, *Intellectual Property Rights and the Public Sector: Why Compulsory Licensing of Protected Technologies Critical for Food Security Might Just Work in China*, 16 PAC. RIM L. & POL'Y J. 699, 708 (2007) (raising concerns that China's public sector agricultural biotechnology industry might be disadvantaged because of foreign competition resulting from China's strengthening intellectual property laws).
[126] Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCI. 239, 239 (2005).
[127] *Id.*
[128] 153 CONG. REC. E315 (daily ed. Feb. 9, 2007) (statement of Rep. Becerra), 2007 WL 433061; *see also* Crichton, *supra* note 15, at A23.

estimates are significantly overstated.[129] Because human gene patents may include a variety of functional uses from simple gene fusions to complex hybridization arrays, it is improper to assume each patent claiming a human genetic composition confers ownership to that respective human gene.[130] In fact, the abovementioned study showed that some genes have as many as twenty patents attributed to that one gene's sequence.[131] Anxieties of having "one-fifth" of your genome "owned" are further undermined by the fact that there have only been six lawsuits alleging infringement of a human gene patent as identified in the aforementioned study.[132]

[36] Apart from the fact that many human genes comprise sequences that the United States claims through patents, there is limited empirical evidence that gene patents adversely affect innovation.[133] For example, a recent empirical study ultimately challenges the "the widely held belief that the rapid growth in biotechnology patenting over the last decade is impeding innovation."[134] The study argues that simply counting patents leads to false predictions and unrealistic expectations.[135] Instead, the authors examined "investigations of broad patent trends, patterns of patent ownership, and the distribution of patents across PTO patent subclasses."[136] The results showed a continuous entry of new patent owners, that biotechnology patents were diffuse among owners, and biotechnology patent applications were rising.[137] As a result, the authors concluded that "overall biotechnology innovation is not being impaired by the growth in patents issued each year."[138] For now, while the thicket of gene patents may be increasing, the resulting anticommons has not yet become tragic. Moreover, concerns of slowed innovation because of patent thickets are not exclusive to gene patents as there are also

[129] *See* Holman, *supra* note 30, at 299.
[130] *See id.* at 315-16.
[131] Jensen & Murray, *supra* note 126, at 239.
[132] Holman, *supra* note 30, at 353.
[133] *See* Caulfield, *supra* note 24, at 1093-94.
[134] Adelman & DeAngelis, *supra* note 80, at 1679.
[135] *Id.*, at 1679-80.
[136] *Id.*, at 1681.
[137] *Id.*, at 1729.
[138] *Id.*

predictions that there will be slowed innovation of semiconductors and software.[139]

C. GENE PATENTS AND DIAGNOSTIC TESTS

[37] The increased cost of tests, which could indicate increased susceptibility to genetic disorders, is the most widely acknowledged negative effect of gene patents.[140] Although there is almost no empirical data that genetic tests, or the clinical knowledge resulting from them, are negatively affected by gene patents,[141] nonetheless, such tests could be desirable in order to determine susceptibility to various genetic disorders.[142] Additionally, genetic tests will have increased use in the future as a way to create personalized medicine that will determine which drugs will be most efficacious for individual patients.[143] The poster child example of a gene patent's supposed detriment to society that has sparked intense public debate derives from patents owned by a Utah biotechnology company known as Myriad Genetics ("Myriad").

[38] Myriad owns patents that relate to methods and materials used to isolate and detect a gene known as BRCA1 that confers higher susceptibility to breast and ovarian cancer.[144] Women who carry a germ-line mutation of BRCA1 have an approximately 85% risk of developing breast cancer and a 60% risk of developing ovarian cancer over the course of their lifetime.[145] Myriad also holds patents to another breast cancer susceptibility gene known as BRCA2. The patents to these two genes have allowed Myriad to develop diagnostic tests to detect cancer-causing mutations in the two genes.[146] Many opponents of gene patents find it egregious that Myriad charges up to $3,000 to test for mutations in these

[139] *See* Yancey & Stewart, *supra* note 94, at 1226.
[140] *See* Betti, *supra* note 12, at 25; *cf.* Roger D. Klein, *Gene Patents and Genetic Testing in the United States*, 25 NATURE BIOTECHNOLOGY 989, 989 (2007).
[141] *See id.*
[142] *See id.* at 990.
[143] *See generally* Dan Jones, *Steps on the Road to Personalized Medicine*, 6 NATURE REVS. DRUG DISCOVERY 770 (2007) (demonstrating how genetic data can be used to determine patients' response to drug therapies).
[144] U.S. Patent No. 6,162,897 (filed May 2, 1997).
[145] *See* Bernadine Healy, *BRCA Genes-Bookmaking, Fortunetelling, and Medical Care*, 336 NEW ENG. J. MED. 1448, 1448 (1997).
[146] Betti, *supra* note 12, at 24.

two genes.[147] This is about three times as much as other labs could charge notwithstanding Myriad's patents.[148] For these reasons, commentators have asserted that gene patents "impede access to appropriate health care and violate individual rights,"[149] or that gene patents "counter[] the goals of the healthcare system."[150]

[39] Solutions have been offered to remedy unnecessarily expensive diagnostic tests for genetic disorders. One solution is a limited infringement exemption, which was likely modeled after the surgical use exemption[151] and was included in the previously discussed GRDAA of 2002 that failed to pass.[152] In addition to exemption from infringement for noncommercial research, the GRDAA of 2002 would have also exempted a health care provider against infringement for noncommercial diagnostic testing of genetic disorders.[153]

[40] The GRDAA of 2002 is not as ideal as it first appears. First, some commentators have voiced concern that the medical procedure exemption has resulted in undeveloped medical procedures.[154] Because the GRDAA of 2002 was modeled after the medical procedure exemption, similar concerns of undeveloped innovation may occur with diagnostic genetic tests. Second, such legislation does not take into consideration commercial DNA array technology, which has been pioneered by the

[147] W. Nicholson Price II, *Patenting Race: The Problems of Ethnic Genetic Testing Patents*, 8 COLUM. SCI. & TECH. L. REV. 119 (2007); Medical News Today, *Myriad Genetic Launches Direct-to-Consumer Advertising of Breast Cancer Gene Test in Northeastern Cities*, Sept. 13, 2007, http://www.medicalnewstoday.com/articles/82147.php.
[148] Price, *supra* note 147, at 126-27.
[149] Andrews & Paradise, *supra* note 16, at 404.
[150] Paradise, *supra* note 81, at 148-49.
[151] *See generally* Bradley J. Meier, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. LEGIS. 265 (1997) (providing an overview of the medical use exemption following its recent passage).
[152] *See supra* Part III.A.
[153] *See* Betti, *supra* note 12, at 24.
[154] *See generally* Emily C. Melvin, Note, *An Unacceptable Exception: The Ramifications of Physician Immunity from Medical Procedure Patent Infringement Liability*, 91 MINN. L. REV. 1088 (2007) (arguing that a lack of patent protection for medical procedures will result in fewer available medical procedures available to society).

biotechnology company Affymetrix.[155] DNA arrays allow the screening of hundreds of gene mutations at one time.[156] Therefore, instead of asking whether an individual has a mutation in gene X, one could theoretically screen that person's entire genome at once for all known mutations. The problem is that separate patent owners, not unlike Myriad, would own most of these mutations. Although the previous section argued that gene patents have not created a patent thicket that is significantly hindering innovation,[157] genome-wide diagnostic DNA arrays could create an anticommons effect in the near future.

[41] If the GRDAA of 2002 had passed, DNA array manufacturers such as Affymetrix would still have had difficulty manufacturing their arrays because commercial entities would not have been exempted from infringement. The result would have been extremely large transaction costs,[158] and is likely the reason that Affymetrix is the only notable biotechnology company that is actually opposed to gene patents.[159] If similar legislation were to pass that provided infringement exemptions for commercial entities in addition to noncommercial entities with respect to genetic diagnostic tests, companies such as Myriad would no longer be able to monopolize individual genetic mutations, while companies such as Affymetrix would then be able to manufacture genome-wide genetic screens. Thus, an infringement exemption for genetic tests that is inclusive towards commercial entities would not leave innovative diagnostic arrays undeveloped. Of equal importance, extending a diagnostic testing exemption to commercial entities would curb an anticommons effect that might result from genome-wide diagnostic testing.

[42] Another solution offered to remedy unnecessarily expensive diagnostic tests involves issuing compulsory licenses of gene patents for diagnostic tests, which would force patent holders to license their gene

[155] *See generally* Elizabeth Pennisi, *The Ultimate Gene Gizmo: Humanity on A Chip*, 302 SCI. 211, 211 (2003) (describing the science behind gene chip arrays).
[156] *Id.*; *see* Betti, *supra* note 12, at 26.
[157] *See supra* Part III.B.
[158] Betti, *supra* note 12, at 26.
[159] Tom Abate, *Do Gene Patents Wrap Research in Red Tape?*, S.F. CHRON., Mar. 25, 2002, at E1.

patent regardless of the patent holder's desires.[160] Compulsory licenses, however, have never been granted in the United States out of fears that such licenses will compromise innovation, and are probably only useful in limited circumstances.[161] In effect, compulsory licenses are not realistic options to ensure adequate access to genetic tests.

[43] Regardless of whether some individuals unfortunately have to pay a little more for genetic tests, what many opponents of gene patents seem to miss is that the purpose and benefit of gene patents extend far beyond the simple development of diagnostic tests. Gene patent critics have asserted that gene discovery does not require the same incentive to innovate as drug discovery.[162] Yet these assertions confuse the patent policy designed to promote incentive to innovate with the incentive to discover genes.

[44] In reality, most gene patent claims are not methods intended to diagnose genetic disorders.[163] On the contrary, gene patents have

[160] Betti, *supra* note 12, at 26. *See generally* Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument For Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001) (arguing that broader licensing opportunities and experimental use exemptions will alleviate some of the negative effects associated with gene patents).

[161] *See generally* Ellis, *supra* note 125, at 708 (arguing that China's unique public-sector driven agricultural biotechnology industry in combination with the properties of such technology creates a paradigm in which compulsory licenses may not adversely affect innovation).

[162] Andrews, *supra* note 81, at 77; Andrews & Paradise, *supra* note 16, at 405.

[163] The exact percentage of gene patents that claim methods for diagnosing human mutations is unknown. Such imprecision is a result of the fact that patents claiming methods of genetic testing use claim language that has many meanings and/or purposes. For example, some diagnostic test patents use the word "screening" to signify that a diagnostic screen is being conducted against a specific human mutation; however, many gene patents that have nothing to do with diagnostic tests also use the word "screening." In an attempt to approximate how many gene patents claim diagnostic tests for genetic mutations, the author searched the DNA Patent Database for human gene patents from the past ten years that claim methods using any of the following words: diagnostic, predisposition, screen, screening, detecting, risk, or presence. While approximately one-fourth of the human patents found in the database include one of those words, because many inventions that are not diagnostic tests also use these words, one-fourth is likely to be a gross over-estimation. In randomly sampling hits (n=50) to determine which hits actually claimed methods for testing for genetic mutations, the author determined that one-half (n=24) of the hits claim methods for diagnostic tests, bringing the approximation between 10 and 15%. If one considers the fact that roughly one-fifth of all gene patents

provided the necessary incentive to innovate many drugs currently on the market that simply would not exist without such patents.[164] Moreover, because many individuals choose *not* to be tested for genetic disorders out of fear of genetic discrimination,[165] and further considering the fact that the reliability of many genetic tests is questionable,[166] one should wonder how critical genetic tests really are to public health. The remainder of this article will demonstrate that not only are diagnostic tests a small subset of products that arise out of gene patents, but also that therapeutic drugs that are arguably more valuable to society depend heavily on the existence of such patents.

IV. GENE PATENTS ARE CRITICAL FOR BIOTECHNOLOGY DRUG DEVELOPMENT

[45] Before the criticisms and subsequent counterarguments relating to the necessities of gene patenting are addressed, a basic understanding of the essential nature of patents as they relate to pharmaceutical drug innovation shall be discussed. This paradigm can then be extended to the biotechnology industry. Similar to small molecule pharmaceutical drug discovery, patents containing gene sequences will provide crucial incentives for biologic drug discovery.

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have the word "human" in their claims, the total number of gene patents that claim methods for human genetic diagnostic testing is likely to be closer to around 2-3%. Importantly, it must further be stressed that the patents examined that do claim methods for diagnosing human genetic disorders almost always claimed non-diagnostic methods, including therapeutic applications. This fact further substantiates the argument posited by this article that gene patents have numerous applications beyond mere diagnostic testing for genetic mutations. While such approximations lack scientific precision, it nonetheless demonstrates the notion that diagnostic tests comprise only a fraction of all inventions claimed by gene patents. *See* DNA Patent Database, http://dnapatents.georgetown.edu/search/searchadvdnag.htm (last visited Oct. 12, 2008).

[164] *See infra* Part IV.B.

[165] *See generally* Paul Steven Miller, *Genetic Discrimination in the Workplace*, 26 J.L. MED. & ETHICS 189 (1998) (discussing potential consequences of discrimination resulting from disclosure of potential yet undiscovered genetic disorders).

[166] *See* Michael J. Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS J. 23, 37-41 (2000).

A. THE NECESSITY OF PATENTS IS WELL ESTABLISHED FOR PHARMACEUTICAL INNOVATION

[46] Patent law in the United States is enabled by the U.S. Constitution, and is intended "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[167] The intent of the patent system is simple—to encourage innovation.[168] Patents encourage innovation because the period of exclusivity[169] afforded by patents provides financial incentive for inventors "to engage in desirable behavior."[170] More importantly, this period of exclusivity promotes innovation by allowing an inventor to recoup the costs of researching and developing a product without any concern that an innovative product will be exploited by free riders who did not have to invest in the necessary research and development.[171] As a result, it is probably fair to say that as more investment is required for research and development for any given invention, periods of exclusivity become more critical in order to provide incentive to innovate. Patents further benefit the public by encouraging disclosure.[172] Inventors and the public reach a bargain so that inventors receive a private right in the form of a patent in exchange for public disclosure of inventions.[173]

[47] Patent protection is particularly critical for the incentive to innovate pharmaceutical drug therapies. In the context of this article, pharmaceutical drugs are "conventional drugs," which are small molecule, chemically synthesized compounds that are claimed by chemical composition patents, not gene patents.[174] Exclusive patent rights are more

[167] U.S. CONST. art. I, § 8, cl. 8.
[168] *See* ROGER E. SCHECHTER & JOHN R. THOMAS, PRINCIPLES OF PATENT LAW 9-12 (2d ed. 2004).
[169] The period of exclusivity for a U.S. patent is twenty years from the date of filing the application. 35 U.S.C. § 154(a)(2) (2000).
[170] SCHECHTER & THOMAS, *supra* note 168, at 9.
[171] *See id.* at 9-12; Rowe, *supra* note 93, at 946-47.
[172] Betti, *supra* note 12, at 22-23.
[173] All patent applications are published eighteen months after filing. Thus, inventions that are never issued patents are nevertheless still disclosed to the public. 35 U.S.C. § 122(b); *see id.*; Hoffman, *supra* note 99, at 996.
[174] *See* Tam Q. Dinh, *Potential Pathways for Abbreviated Approval of Generic Biologics Under Existing Law and Proposed Reforms to the Law*, 62 FOOD & DRUG L.J. 77, 90-92

critical to the pharmaceutical industry than most other industries because research and development costs are extremely expensive and time-consuming.[175] Incredibly, the cost of bringing a single pharmaceutical drug to market, which can take up to fifteen years, ranges between $800 million to $1.7 billion.[176] Arguably, a pharmaceutical company will not put forth that large of an investment risk without the assurance that those costs can be recovered.

[48] The necessity of patent exclusivity for pharmaceutical drugs has been the center of much debate. Some patent advocates have suggested that in light of the fact that a large portion of a drug's patent term is caught up in pre-clinical and clinical trials, "[t]he twenty-year life of a patent from the time of application is a very short window within which a drugmaker may recoup its research and development costs."[177] In contrast, some critics have asserted that patents are unnecessary because the large expenditures on marketing demonstrate that pharmaceutical companies do not need a period of exclusivity to recover research and development costs.[178] Arguments such as the latter misconstrue causal sufficiency with necessity. The only reason why the capital exists to market the drug is because a patent allowed for the development of the drug in the first place. Without patents, not only would marketing cease, but development of new drugs would as well.

[49] While it may be true that some blockbuster drugs have provided handsome profits for the drug companies, such drugs are few and far between. Additionally, the exclusivity term associated with a patent further allows for the recovery of the development costs for potential drugs that never reach the market. On average, only one out of every 5000

(2007) (providing a brief description of traditional drugs in comparison to biologic drugs).

[175] *See* Betti, *supra* note 12, at 25-26; Roberto Mazzoleni & Richard R. Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL'Y 273, 274-76 (1998).

[176] Sukhatme, *supra* note 11, at 1218.

[177] Paul T. Nyffeler, Comment, *The Safe Harbor of 35 U.S.C. § 271(e)(1): The End of Enforceable Biotechnology Patents in Drug Discovery?*, 41 U. RICH. L. REV. 1025, 1025 (2007).

[178] *See* Angell, *supra* note 12.

to 10,000 screened compounds becomes an approved drug.[179] Though society pays upfront by allowing a pharmaceutical drugmaker exclusive control of the drug at first, society ultimately benefits as a result of being provided with the innovated product.

B. BIOLOGICS CURRENTLY ON THE MARKET REQUIRED GENE PATENTS

[50] Bioethicists have asserted that "while patents on certain products related to health care are appropriate—such as patents on drugs—the rationales for granting such patents do not apply to patents on genes."[180] These opponents will further proclaim that "[t]he discovery of genes does not require the same commercial incentives as drug development."[181] These assertions could not be further from the truth, especially considering the fact that patents claiming methods for diagnosing human genetic disorders comprise only a fraction of the total uses resulting from gene patents.[182] In actuality, gene patents do require the same commercial incentives as drug development because gene patents *are* required for drug development—biologic drug development.

[51] Biologics, also known as biopharmaceuticals, are essentially drugs that are biological products derived from a living organism or cell, or by recombinant DNA technology.[183] Thus, as opposed to conventional small molecule drugs that are a result of chemical composition patents, biologics are drugs that are usually protected by gene patents. Biologics are also drugs that would be negatively affected by the GRAA. Examples of biologics on the market are growth factors, monoclonal antibodies, hormones, cytokines, fusion proteins, blood factors, recombinant enzymes, recombinant vaccines, anticoagulants, and nucleic acids.[184] Biologics are

[179] BUREAU OF LABOR STATISTICS, U.S. DEP'T OF LABOR, PHARM. AND MED. MFG., *available at* http://www.bls.gov/oco/cg/cgs009.htm (last visited Sept. 15, 2008).
[180] Andrews, *supra* note 81, at 67.
[181] Andrews & Paradise, *supra* note 16, at 406.
[182] *See supra* note 163 and accompanying text.
[183] Dinh, *supra* note 174, at 82.
[184] Aggarwal, *supra* note 10, at 1097.

used to treat a variety of disorders including but not limited to: cancer, AIDS, influenza, hepatitis, diabetes, and cardiovascular disease.[185]

[52] Sales of biologics are extremely significant for the drug market and are not dwarfed by conventional drugs. In 2006, biologics brought in over $30 billion in sales in the United States.[186] In 2007, 42% of all products in world-wide preclinical testing were protein-based biologics.[187] As of 2001, there were 1,457 biotechnology companies in the United States alone.[188] Furthermore, biologics are expected to continue to have a significant role as drug therapies.[189] Biologics experienced an annual growth rate of 20% between 2001 and 2006, although during the same time period, conventional pharmaceuticals in the United States only experienced an annual growth rate of 6-8%.[190] Thus, a significant proportion of drug therapies that are potentially available to the public consist of biologic drug therapies.

[53] The incentive required to research and develop a biologic drug is no less than it would be for a traditional pharmaceutical drug. In actuality, it is more. Because of the "greater complexity in their manufacture, biologics typically cost much more than chemically synthesized, small-molecule drugs."[191] Similar to conventional drugs, biopharmaceutical manufacturers will not even consider investing in the research and development required to bring a biologic to market without the guarantee that their investing expenditures can be recovered.[192] Similarly, as opposed to "big-pharma," many biotechnology companies are start-ups requiring venture capital in order to innovate their biologics. In 2007, over $7 billion in venture capital was invested in biotechnology start-

[185] *See* Gary Walsh, *Biopharmaceutical Benchmarks 2006*, 24 NATURE BIOTECHNOLOGY 769, 775 fig.3 (2006) (providing an update on new arrivals to the biopharmaceutical market).
[186] Lawrence, *supra* note 9, at 1342.
[187] *Id.*
[188] Klein, *supra* note 140, at 989.
[189] Dinh, *supra* note 174, at 78-79.
[190] Aggarwal, *supra* note 10, at 1097.
[191] Dinh, *supra* note 174, at 79.
[192] Betti, *supra* note 12, at 23.

ups.[193] In order to secure venture capital, bioentrepreneurs absolutely must obtain patent protection over their biological product.[194]

[54] Biologics are not without unique issues, usually pertaining to whether biosimilar generic drugs can be safely manufactured. Most biologics are currently regulated by and require approval under the Public Health Service Act ("PHSA").[195] For conventional drugs, the Food and Drug Administration ("FDA") abbreviates approval for generic drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA").[196] In contrast, the PHSA does not expressly provide a mechanism for abbreviated approval of a biologic.[197] As a result, most biologics unfortunately do not have generic counterparts following expiration of the respective drug's patent term.[198] Nonetheless, there is much debate as to whether the FDA can and should approve generic biologics under the FDCA regardless of whether the biologic was originally approved under the PHSA.[199] Pioneers argue that the FDA should not approve generic biologics.[200] This is because unlike conventional small molecule drugs, "biological sources cannot be accurately characterized or reliably produced."[201] Current legislation, however, would provide the FDA with express authority to abbreviate approval of a biologic drug.[202] This complicated debate is important to note. Because generics do not exist for most biologics, many biopharmaceutical drug makers are receiving a de facto patent term extension.[203] This could result in higher costs to

[193] *See* Stacy Lawrence, *2007—A Banner Year for Biotech*, 26 NATURE BIOTECHNOLOGY 150, 150 (2008).
[194] Betti, *supra* note 12, at 23; Klein, *supra* note 140.
[195] Dinh, *supra* note 174, at 84.
[196] *Id.* at 77.
[197] *Id.* at 85.
[198] *Cf. id.* at 79; William L Warren et al., *Abbreviated Approval of Generic Biologics*, 26 GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (2006), *available at* http://www.genengnews.com/articles/chitem.aspx?aid=1936.
[199] *See generally* Carole S. Ben-Maimon & Rob Garnick, *Biogenerics at the Crossroads*, 24 NATURE BIOTECHNOLOGY 268 (2006) (providing the pros and cons of implementing an abbreviated regulatory framework for biologic generics).
[200] Dinh, *supra* note 174, at 77.
[201] *Id.*
[202] Warren, *supra* note 198.
[203] Dinh, *supra* note 174, at 79; Warren, *supra* note 198.

patients, insurance companies, health plan providers, and taxpayers.[204] Although ultimately outside the scope of this article, legislation that would provide a mechanism to bring safe and affordable generic biologics to all patients should be vigorously supported and subsequently adopted.

[55] The impact biologics have on the drug market simply cannot be ignored. Because biologics are industrially more complicated than conventional drugs, unique issues persist. Like all recently introduced technologies, the biotechnology industry still requires the fine-tuning necessary to provide the most efficient drugs possible. At any rate, it appears as though biologics are steadily becoming more prominent in the repertoire of drug therapies available to society. As a result, such technologies should be vigorously pursued and not compromised at the expense of a limited number of diagnostic genetic tests.

V. A BAN ON GENE PATENTS WOULD PREVENT RECENT ADVANCES IN BIOTECHNOLOGY FROM MATERIALIZING

[56] This article has thus far demonstrated the critical role patents play in bringing biotechnological innovation to market. Without patents, biotechnology companies would likely rely solely on trade secrets.[205] This would result in severely reduced instances of innovative advancement for all biotechnologies requiring substantial investment costs.[206] Opponents of gene patents that have failed to appreciate this reality have further failed to appreciate that emerging biotechnologies that may benefit society will fail to innovate without robust patent protection. While no one can predict exactly what technological innovation the future holds, this section will exemplify just two emerging biotechnologies that surely would be harmed by passage of the GRAA: RNAi and synthetic biology.

[204] Dinh, *supra* note 174, at 79.
[205] Michael John Gulliford, *Much Ado About Gene Patents: The Role of Foreseeability*, 34 SETON HALL L. REV. 711, 730 (2004) (demonstrating the less than optimal options biotechnology companies would have without patents).
[206] *See id.*

A. RNAi

[57] One biologic drug therapy necessitating gene patents, which is expected to reach the market in coming years, centers around the technology known as RNA interference ("RNAi"). RNAi is employed in nature by many organisms from fungi to mammals and it functions as a natural mechanism to silence gene activity.[207] RNAi was first coined by Andrew Fire and his colleagues, who discovered that injection of double-stranded RNA into the nematode *C. elegans* interfered with the function of the endogenous gene corresponding to the specific RNA sequence that was injected into the worm.[208] This discovery allowed scientists to harness this naturally occurring mechanism in order to develop an easy and specific method to manipulate gene expression.[209]

[58] Being able to manipulate gene expression has tremendous therapeutic benefits. In addition to its research applications, RNAi has a potentially therapeutic role benefiting "a wide variety of diseases, including malignant, infectious and autoimmune diseases."[210] Furthermore, RNAi is desirable because it reduces side-effects and secondary harm by utilizing naturally occurring mechanisms.[211]
One of the current difficulties with RNAi technology is that the progress that has been made in understanding siRNA[212] *in vitro* in mammalian cell lines has not necessarily translated to *in vivo* activity.[213] The greatest

[207] *See* Scott E. Martin & Natasha J. Caplen, *Applications of RNA Interference in Mammalian Systems*, 8 ANN. REV. GENOMICS HUM. GENETICS 81, 82 (2007) (describing the scientific discovery of RNAi).
[208] Fire et al., *supra* note 2, at 806.
[209] *See id*.
[210] Li et al., *supra* note 3.
[211] *See* Reese McKnight, *RNA Interference: A Critical Analysis of the Regulatory and Ethical Issues Encountered in the Development of a Novel Therapy*, 15 ALB. L.J. SCI. & TECH. 73, 78-80 (2004) (describing the advantages of RNAi over traditional gene therapy).
[212] RNAi terminology if often used synonymously with siRNA (small interfering RNAs). To distinguish, RNAi refers to the mechanism of silencing gene expression, whereas siRNA and miRNA (microRNAs) refer to the physical components of RNA that act as the effector molecules to induce gene silencing. When discussing the potential therapeutic application of RNAi with respect to mammalian cells, siRNA is the terminology most commonly employed. But RNAi is the terminology more often used when broadly discussing the technology as a whole.
[213] *See* de Fougerolles et al., *supra* note 4, at 446.

hurdle is currently with drug delivery.[214] Nonetheless, there already exists "[t]hree different RNAi therapeutics [that] are currently under clinical investigation, with several more poised to enter trials soon."[215] The earliest clinical applications of RNAi are for respiratory syncytial virus (RSV) infection and age-related macular degeneration (AMD).[216]

[59] In spite of the uncertainties of RNAi, the technology is rapidly advancing. In 2006, there was a 170% increase over 2005 in RNAi patents issued.[217] RNAi is further expected to contribute significantly to the breadth of biologics available, and new RNAi-focused market entrants are joining the biotechnology industry monthly.[218] Additionally, Merck bought a RNAi-focused company known as Sirna Therapeutics for $1.1 billion in 2006.[219] Patents are undoubtedly fueling the explosion of RNAi technology. Like DNA, RNA is composed of nucleotide sequences. Thus, patents claiming compositions or methods associated with RNAi would unfortunately be banned if Congressmen Becerra and Weldon's GRAA becomes law.

B. SYNTHETIC BIOLOGY

[60] Synthetic biology is another emerging biotechnology whose success will ultimately depend on the acceptance of gene patents. Synthetic biology is the synthesis of biologically based and complex systems that do not display functions that exist in nature.[220] Synthetic biology has numerous beneficial applications, including the potential production of unlimited and inexpensive supplies of medically relevant drugs for diseases such as malaria.[221] Synthetic biology has environmental applications as well, more particularly with respect to biodiesel

[214] *Id.* at 446, 451.
[215] *Id.* at 451.
[216] *Id.* at 443, 451.
[217] *See* Stacy Lawrence, *Biotech Patents Still Strong*, 25 NATURE BIOTECHNOLOGY 1341, 1341 (2007).
[218] *See* Randall Osborne, *Companies Jostle for Lead in RNAi, Despite Uncertainties*, 25 NATURE BIOTECHNOLOGY 1191, 1191 (2007) (discussing the emergence of new RNAi focused companies into the biotechnology industry).
[219] *Id.*
[220] *See* Kumar & Rai, *supra* note 7, at 1746.
[221] *Id.*

production, which aims to lessen the environmental impact of producing these fuels.[222] Because high lipid content is a desirable trait for biodiesel production, synthetic genome production could create microorganisms with all the necessary lipid production pathway genes in order to regulate highly efficient lipid production.[223]

[61] Synthetic biology is making rapid advances. In early 2008, the first bacterial genome was successfully synthesized.[224] The synthesized genome is comprised of 582,970 nucleotide base pairs and was modeled after the bacterium *Mycoplasma genitalium*.[225] Like many areas of biotechnology, synthetic biology is not without criticism. Previously raised concerns include suggestions that rogue states or terrorist organizations might use such technologies for bioterrorism.[226] Such concerns are completely legitimate and deserve careful scrutiny. A comparison of the advantages of such technology to the possible negative effects and questions as to whether synthetic biology deserves to be vigorously pursued, however, should be debated elsewhere. If critics of synthetic biology desire leverage to attain their goals, the patent system is not the proper forum. This article has already demonstrated that gene patents are unfairly targeted as causes of some of the possible negative effects of intellectual property protection, even though most of these putatively negative side effects are not even specific to gene patents.[227] The potential advances synthetic biology can make towards public health and the environment could be enormous, and must not be sacrificed at the expense of far-reaching legislation that is ultimately targeted towards problems, which in reality are relatively insignificant.

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[222] *See generally* Timothy Searchinger et al., *Use of U.S. Croplands for Biofuels Increases Greenhouse Gases Through Emissions from Land Use Change*, 319 SCI. 1238 (Feb. 7 2008), *available at* http://www.sciencemag.org/cgi/rapidpdf/1151861v1.pdf (demonstrating that current biofuel production may not be as efficient as previously acknowledged due to the enormous efforts required to produce the necessary crops that will be modified into biofuels).

[223] Biodiesel Times, *supra* note 8.

[224] Andrew Pollack, *Researchers Announce A Step Toward Synthetic Life*, N.Y. TIMES, Jan. 25, 2008, at A17.

[225] Gibson et al., *supra* note 6, at 1215.

[226] Kumar & Rai, *supra* note 7, at 1747.

[227] *See supra* Part III.

VI. CONCLUSION

[62] The GRAA sponsored by Congressmen Becerra and Weldon is unnecessary and would have ruinous effects on health care and possibly even the environment. Gene patents are not compromising basic research and commercial innovation. While it may be true that development of diagnostic tests is inexpensive and probably does not demand the same periods of exclusivity that patent policy affords to other technologies, diagnostic tests only make up a fraction of the possible uses for gene patents. Most other applications that depend upon gene patents absolutely require the patent's period of exclusivity to ensure innovative incentive.

[63] This article concedes to some degree that patients are sometimes unfairly forced to pay more for genetic tests than could be provided by their health care providers. This article further concedes that issues exist with respect to the high costs of brand-name drugs. Nevertheless, the GRAA completely oversteps its bounds in addressing issues relevant to gene patents. A much better solution would be legislation similar to the GRDAA of 2002 that provides infringement exemptions for non-commercial research and diagnostic testing. Even so, the GRDAA of 2002 was not perfect, as diagnostic testing is experiencing a paradigm shift such that diagnostic tests will likely exist mostly on genome-wide arrays in the near future. When this occurs, commercial entities such as Affymetrix, which would not have been exempt from infringement had the GRDAA of 2002 passed, might have difficulty maneuvering around the individual gene patents protecting respective diagnostic tests. If the GRDAA of 2002 is revived with infringement exemptions for genetic diagnostic tests that extend to commercial activities, companies will no longer be able to monopolize tests for individual genetic mutations. Genome-wide diagnostic array tests, however, would become commonplace for genetic testing and would not be left undeveloped. More importantly, such legislation would directly address the pertinent issues, and would not interfere with the most important and widely used application of gene patents—biologic drug innovation.