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BIG AND SMALL FISH IN THE SEA OF PATENT LITIGATION: AN ANALYSIS OF THE *AMP v. USPTO* DECISION AND ITS EFFECT ON LARGE AND SMALL BUSINESSES

Kevin Hershey

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Kevin Hershey[*]

I. INTRODUCTION

On July 29, 2011, the Court of Appeals for the Federal Circuit (hereinafter "CAFC"), in *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office* (hereinafter "*AMP*"), held that human genes with a known function, both as isolated DNA and in the form of complementary DNA ("cDNA"), are patentable subject matter under 35 U.S.C. § 101 (2012).[1] The decision was the first time human DNA was held to be patentable subject matter in a court of law.[2] While the Supreme Court has not yet granted *certiorari* on the decision, the Supreme Court most likely will, because the matter is important to research universities, diagnostic medicine, and pharmaceutical companies. Additionally, the Supreme Court granted *certiorari* in *Diamond v. Chakrabarty*, the first case to hold that a living organism was patentable subject matter.[3] While *Diamond* involved a living organism and *AMP* involves DNA sequences, the two cases involve significant advances in biotechnology and the Supreme Court is likely to take up the issue.

Several problems exist in deciding whether the Supreme Court should affirm or reverse the CAFC's ruling. This article seeks to answer the question of whether or not isolated human DNA should or should not be patentable subject matter, with the primary focus on the impact patents have

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[1] 653 F.3d 1329, 1350 (Fed. Cir. 2011).

[2] Matthew Poulsen, *Jurisprudential and Economic Justifications for Gene Sequence Patents*, 90 NEB. L. REV. 196, 211 (2011).

[3] 447 U.S. 309 (1980).

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on innovation, including commercialization of the technology for businesses. The patentable subject matter inquiry is often too narrowly focused on the idea that patents create an incentive to invent, and removing patentability of a certain subject matter reduces the incentive to invent in that particular field.[4] As with many existing articles, this article agrees that patents do not actually create an incentive to invent. However, this article is different in that it focuses on the difference in the use of patents for innovation in small and large business, namely arguing that patents allow for innovation at the small business level, while a lack of patentable subject matter benefits large businesses. The decision to allow or not allow isolated DNA to be patentable subject matter should consider which business type can bring technology to market the fastest rather than a focus on increasing the incentive to invent.

II. HISTORY OF MAJOR DECISIONS ALLOWING BIOLOGICAL SUBJECT MATTER TO BE PATENTABLE

Patentable subject matter is derived from 35 U.S.C. § 101 (2012), which allows inventors to obtain patents if they "invent[] or discover[] any new and useful process, machine, manufacture, or composition of matter."[5] The statute provides little guidance on what should be considered patentable subject matter, so the issue has largely been decided by the United States Patent and Trademark Office (hereinafter "USPTO"), the courts, and Congress. Congress first allowed living organisms to be patentable subject matter when it passed 35 U.S.C. § 161 (2012) in 1952, allowing those who "invent[] or discover[] and asexually reproduce[] any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, [to] obtain a patent."[6]

In 1980, the Supreme Court in *Diamond v. Chakrabarty* held that genetically modified bacteria constituted patentable subject matter under 35

[4] U.S. DEPT. OF HEALTH & HUMAN SERVS., GENE PATENTS & LICENSING PRACTICES & THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS (2010) [hereinafter SACGHS].

[5] 35 U.S.C. § 101 (2012).

[6] 35 U.S.C. § 161 (2012).

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U.S.C. § 101 (2012).[7] The invention at issue in *Diamond* was genetically modified bacteria which could degrade multiple components of crude oil.[8] While the Supreme Court did not decide whether a genetically modified bacteria was specifically a "composition" or "manufacture," the Supreme Court held the bacteria was patentable subject matter because it was not a "hitherto unknown natural phenomenon, but . . . a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character and use.'"[9]

While bacteria are unicellular organisms and are much less complex than the plants allowed as patentable subject matter under 35 U.S.C. § 161 (2012), it is possible that *Chakrabarty* contributed significantly to the finding that genetically modified multicellular eukaryotic animal organisms could be patented. Perhaps the concept of patenting genetically modified animals became more acceptable once multicellular plants and unicellular animal cells were both patentable. Whatever the reasons, the next significant step in the progression was the USPTO allowing for the patenting of the "oncomouse," a genetically modified animal, in 1988.[10]

Finally, a case was brought in the United States District Court for the Southern District of New York by Molecular Pathology seeking to invalidate seven patents related to the *BRCA1* and *BRCA2* genes.[11] The district court held that the isolated DNA sequences were not themselves patentable subject matter because they were not "markedly different" than what is found in nature, but were merely a purification of what existed in nature.[12]

The CAFC, however, disagreed with the district court and held that the *BRCA1* and *BRCA2* isolated DNA sequences were, in fact, patentable subject matter.[13] The court used several justifications for this decision. One was that the Patent Office has issued patents for isolated human DNA for

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[7] Diamond v. Chakrabarty, 447 U.S. 303, 309–10 (1980).

[8] *Id.* at 305.

[9] *Id.* at 309–10 (1980) (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).

[10] U.S. Patent No. 4,736,866 (filed June 22, 1984).

[11] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 184 (S.D.N.Y. 2010).

[12] *Id.* at 227.

[13] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1358 (Fed. Cir. 2011).

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almost 30 years, and a change in the settled expectations of the inventive community should come from Congress, not the courts.[14] Another issue is that the court used a covalent bond as the boundary between one chemical species and another, arguing that severing the covalent bond creates a new chemical species.[15] In essence, the majority held that when the covalent bonds on either side of the isolated DNA were broken (a necessary step when excising the DNA), the breaking of the covalent bonds created a new, distinct molecule.[16] The court focused more on the structure of the chemical DNA in the cell than the function of the DNA in the cell.[17]

The Supreme Court accepted *certiorari* and immediately remanded the case back to the CAFC.[18] The Supreme Court did not decide the case on the merits, instructing the CAFC to reconsider the case in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[19] When the CAFC reconsidered the case, the court kept its same holding as before.[20] The court held that its holding was still valid in light of *Prometheus*, and kept most of the language from its previous decision intact.[21]

III. IF THE SUPREME COURT GRANTS *CERTIORARI*, HOW SHOULD IT RULE?

A. Arguments That the CAFC Was Incorrect in Holding That the Isolated DNA Was Patentable

The CAFC provided several reason as to why isolated DNA is "markedly different" than DNA in nature. The best argument provided is that isolated DNA is just exons, having the introns excised through natural processes, whereas DNA in nature includes both exons and introns.[22] Another theory the majority put forward was that, when excised from the cell's native DNA, the resulting cDNA or mRNA required the breaking of

[14] *Id.* at 1355.
[15] *Id.* at 1352–53.
[16] *Id.*
[17] *Id.* at 1353.
[18] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct 174 (2012).
[19] *Id.*
[20] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1337 (Fed. Cir. 2012).
[21] *Id.*at 1331.
[22] Ass'n for Molecular Pathology, 653 F.3d at 1352–53.

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covalent bonds on either side native DNA.[23] The court held that the covalent bonds act as the boundary between one molecule and another.[24]

This theory that the cleaving of covalent bonds makes isolated DNA markedly different from DNA in nature is problematic in its use of covalent bonds as the defining point between "naturally occurring" and "markedly different." The dissent discussed an analogy of isolating DNA from living beings compared to isolating elemental lithium from the earth.[25] Lithium exists naturally in the earth as a salt is isolated by processing the salt to create pure elemental lithium.[26] The majority dismissed the analogy, stating that elemental lithium is the same element, whether it is in the earth or isolated.[27] The majority did not want to decide the issue of whether elemental lithium would be patentable or not, and made an enigmatic assertion that if elemental lithium exists in "molecular form" in the earth (i.e., a salt), then it is not the same as purified elemental lithium.[28]

This analysis presents very indefinite boundaries between what is "naturally occurring" and what is "markedly different." It also, as the dissent points out, creates an unusual distinction between different types of bonds, some allowed to mark the boundary between chemical bonds, and others not.[29] The bond in a salt, such as lithium salt, is an ionic bond.[30] Ionic bonds are intramolecular bonds, and though typically not as strong as covalent bonds, serve the same function as covalent bonds.[31] The decision seems to provide little guidance on when the breaking of a bond is sufficient to constitute the creation of a new chemical entity for purposes of

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[23] *Id.* at 1351.
[24] *Id*. at 1352.
[25] *Id*. at 1376 (Justice Bryson, concurring in part and dissenting in part).
[26] *Id.*
[27] *Id*. at 1354.
[28] *Id.*
[29] *Id.* at n.3 (Justice Bryson, concurring in part and dissenting in part).
[30] *Id.*
[31] ROBERT MORTIMER, PHYSICAL CHEMISTRY 898 (2d ed. 2000) (Illustrating how ionic bonded solids typically have a melting temperature of around 170 degrees Celsius, compared to a network covalent bond with a melting temperature of around 1610 degrees Celsius. Mortimer also states that bonds are merely chemical attraction or repulsion, and often put into categories such as ionic chemical bonds, covalent bonds, ion-dipole forces, dipole-dipole forces, hydrogen bonds, ion-induced dipole forces, London dispersion forces, interatomic repulsions, etc. However, there is no such thing as a pure ionic bond, it is rather a degree of polarity in a covalent bond, but it is commonly used in the scientific community, and so for this note will be treated as a distinct type of bond from covalent bonds.).

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patentability. If elemental lithium, purified from its naturally occurring salt form, is not patentable, then is the issue the bond strength? Some covalent bonds are very weak, weaker than ionic bonds, hydrogen bonds, or even Van der Waals bonds, the weakest of intermolecular bonds.[32] If the issue is not bond strength, is there a requirement for how many bonds need to be broken to be considered a "markedly different" molecule? In the case of isolated DNA, only a few covalent bonds are broken at each end. There is no clear test as to when and why the breaking or formation of covalent bonds creates a "markedly different" molecule than one found in nature, or whether breaking or forming other types of bonds creates a patentable entity.

These issues could have drastic effects on the chemical industry. Almost any manufacturing process or chemical process involves the breaking and/or formation of intramolecular bonds. A process as basic as adding table salt (NaCl) to water breaks and creates bonds. The NaCl is dissociated in the water and becomes an aqueous solution of Na^+ and Cl^-. Breaking and forming bonds alone does not make something "markedly different" than in nature because breaking bonds can be very easy, and happens in many natural processes. If someone finds a molecule in nature, and breaks a bond or two, are they thus entitled to a patent, even if the product is the same functionality as in nature? By the reasoning of the CAFC, this appears to be the case.

An argument not adequately considered by the CAFC or the district court is that isolated DNA, or even complementary DNA (cDNA), is not "markedly different" than in nature because the mechanisms and blueprints for the *BRCA1* and *BRCA2* gene exist naturally. This comports with the "product of nature" argument put forward by the dissent and by the district court, but it needs more thorough examination by the Supreme Court. The method for creating cDNA in a laboratory is well known. The cDNA is created by reverse engineering an mRNA molecule. For each mRNA

[32] For example, the bond dissociation strength of CD-Na is 3.97 kJ/mol. DAVID LIDE, THE CRC HANDBOOK OF CHEMISTRY AND PHYSICS 9–57 (88th ed. 2007). Contrast that number to the typical bond strength of hydrogen bonds, 20 to 25 kJ/mol. IUPAC, COMPENDIUM OF CHEMICAL TERMINOLOGY 1123 (2d ed. 1997). Van der Waals forces, a weak intermolecular force, has a bond strength of about 4.2-8.4 kJ/mol. HARVEY LODISH ET AL., MOLECULAR CELL BIOLOGY § 2.2 NONCOVALENT BONDS (4th ed. 2000).

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molecule, there can be only one possible cDNA molecule. This is so because DNA and mRNA function by using complementary base pairs, with guanine pairing only with cytosine, and thymine (in RNA, thymine is replaced with uracil) pairing only adenine.[33] Because each nucleotide has only one possible counterpart, there is only one possible cDNA molecule for an mRNA strand. There is absolutely no human ingenuity or design in the creation of a cDNA strand. It is the functional equivalent of creating a photograph from a negative. Each color has only one opposite color, and to create a photograph from a negative does not create a new image, it merely creates the exact opposite image.

Not only is the blueprint for the *BRCA1* and *BRCA2* gene given to scientists by the cells, the method of reverse engineering mRNA to cDNA is well known and used in the genetics world. It follows the same basic idea as polymerase chain reaction (PCR), where an excess of nucleotides is put into solution with the mRNA or DNA and a correct transcriptase or reverse transcriptase enzyme. This creates a new DNA molecule using the natural mechanics of DNA replication. While this is an oversimplification of the process, DNA replication is nonetheless and well-known and commonly used process.

Justice Bryson equated the patenting of isolated DNA with the patenting of a leaf snapped from a tree.[34] This is not an ideal analogy because removing the leaf has no clear usefulness. The *BRCA1* and *BRCA2* genes have usefulness as diagnostic tools, whereas a leaf has little benefit or use once removed from the tree. A more apropos analogy might be that of Velcro, a patented product whose idea came from nature. Velcro was designed to imitate a burr's ability to stick to fabric.[35] Even though Velcro was designed to imitate a natural product, the Patent Office issued a patent for Velcro in 1961.[36]

Velcro is patentable because, while inspired by nature, it is a synthesized material which does not exist in a natural form. However, the

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[33] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1335–37 (Fed. Cir. 2011), *judgment vacated sub nom*. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012), *and opinion reinstated* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012).

[34] *Id*. at 1377 (Bryson, J., concurring in part and dissenting in part).

[35] VELCRO®, http://www.velcro.com/About-Us/History.aspx (last visited Sept. 29, 2012).

[36] U.S. Patent No. 3,009,235 (filed May 9, 1958).

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story of Velcro could be rewritten to mimic the *AMP* case much more closely. Had the inventor plucked the burrs and secured them to a fabric rather than inventing an artificial "burr," it would have been much closer to patenting isolated DNA than patenting a leaf plucked from a tree. The burr would have been removed from the stem of the plant. The end of the stem and beginning of the burr is a boundary between two different parts of the plant, just as covalent bonds apparently mark the boundary between different parts of the molecule. The fabric with the attached burrs would be significantly different than anything found in nature, as burrs are not found isolated from the stem and attached to a fabric in nature. While the burrs are altered from their natural state, they serve the same function as in nature—to attach to fabrics and furs. However, it would be hard to argue that this is not a product of nature. Isolating genetic material is the same concept. The isolated DNA performs the exact same function as in nature (i.e., expressing the gene's phenotype), as do burrs attached to fabric.

This argument is presented not to minimize the efforts of those involved in isolating the *BRCA1* and *BRCA2* genes, as the researchers doubtless expended a great amount of time and resources in identifying and developing the isolated DNA. However, intellectual property rights are dependent on the creation of something new, not effort, time, or expenditure of resources involved.[37]

B. The Supreme Court Should Not Be the One to Allow New Subject Matter

The Constitution grants Congress the right to grant patents to promote the progress of science.[38] The justification most often used is that patents offer the incentive to invent. The rationale is that inventors need the motivation of a legal monopoly to prevent others from "free-riding" on their hard work and stealing their invention.[39] However, this is a severe

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[37] *See* Feist Publications, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 364 (1991) (In the copyright context, the Supreme Court held that copyright rewards originality, not effort.).

[38] U.S. CONST. art. I, § 8, cl. 8.

[39] Nicole Boutros, *Race to the Cure: Why Gene Patents Pave the Way for Breast Cancer Research*, 19 AM. U. J. GENDER SOC. POL'Y & L. 1009, 1011 (2011) ("Eliminating genetic researchers' ability to patent isolated gene sequences will destroy the incentives that led to their successes in the first place."); Tina Saladino, *Seeing the Forest Through the Trees: Gene Patents & the Reality of the Commons*, 26 BERKELEY TECH. L.J. 301, 315 (2011) ("If the government did not provide patent

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oversimplification of the motivations of invention, and ignores the hurdles associated with bringing a new technology to the market.

1. Patents May Not Create Much Incentive, Particularly in the Academic Field

Arguably, patents are not essential to invention. In a historical context, the current model for patents began in Venice in March 19, 1474.[40] Some have gone so far as to opine that modern patent statutes are just footnotes of the original Venetian law.[41] By no means were humans living in caves and squalor, using sticks and stones until the Venetians found a way to incentivize invention. When Leonardo da Vinci, one of the greatest inventors of all time, sketched ideas in the *Tratado de Estatica y Mechanica en Italiano*,[42] he did so without the motivation of patents, rather, he did so because of his passion as an artist and inventor.

History is filled with important discoveries and inventions which came without the incentives for patents. For example, Penicillin, one of the most important discoveries of the 20th century, was not patented because patent protection in England was seen as "a repugnant sign of commercialism."[43] Even without the motivation of obtaining a patent, or even further, with the hatred of patenting, England still made some of the most significant contributions to modern day science.

To understand invention and discovery in the sciences, it is imperative to look at the invention process, since not all invention or discovery comes to fruition in the same way. Genetic research is somewhat different than many types of invention. Research is not done in an inventor's garage or workshop, the research is done mostly at universities due to the high risk and cost for uncertain results.[44] In a report generated by the Secretary's

protection for isolated gene sequences, laboratories would have little incentive to invest in the cost of pursuing such research knowing that others could take from their findings and profit with little investment.").

[40] CRAIG A. NARD, THE LAW OF PATENTS 9 (2d ed. 2011).

[41] *Id.*

[42] LEONARDO DA VINCI, TRATADO DE ESTATICA Y MECHANICA EN ITALIANO (photo. reprint 1974) (1493).

[43] NARD, *supra* note 40, at 535.

[44] *See* Julia Carbone et al., *DNA Patents and Diagnostics: Not a Pretty Picture*, 28(8) NATURE BIOTECHNOLOGY 784, 785 (2010) ("In addition, most gene patents relevant to diagnostics are held by

Advisory Committee on Genetics, Health, and Society (SACGHS), the SACGHS noted that most basic genetic research is funded by government organizations.[45] Government funding is primarily through grants, and the government does not have a financial interest in the discoveries. At the early stages of research, success is highly variable, and that is why the government, and not private venture companies, funds the research. Universities are generally more interested in publishing papers than getting patents (*see infra*). Research is primarily completed at universities because there is a large cost associated with scientific research, and large universities are capable of attracting government funding. These universities are typically more interested in advancing research than obtaining patents and commercializing technologies. Most universities are not set up to manufacture, market, and sell a patented product, or even sell a patent, rather they are in the business of discovery and education through cutting edge research.

The SACGHS report concluded that most basic genetic research is completed for factors other than profiting from the discovery, such as curiosity, career ambitions, and desire to advance understanding of health and disease.[46] Many university scientists are motivated by the opportunity to publish in prestigious journals such as *Science*, *Nature*, or *Cell*.[47] It is for this reason that some universities are, informally of course, called "publish or perish" universities.[48] In these universities, the faculties' tenure and job security depends on their ability to generate publications. Their research is spurred on by pressures to publish, not pressures to produce a patent. In the academic field, publication in prestigious journals is associated with success in the field. A large number of publications means more publicity and often greater chances of winning grants. This allows researchers to

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universities on the basis of research funded by public money." A majority of patents belong to universities, suggesting that is where most of the basic research is being performed.)

[45] SACGHS, *supra* note 4, at 2.

[46] SACGHS, *supra* note 4, at 90.

[47] *See Fix the PhD*, NATURE 472, 259–60 (2011), *available at* http://www.nature.com/nature/journal/v472/n7343/full/472259b.html ("Yet many academics are reluctant to rock the boat as long as they are rewarded with grants (which pay for cheap PhD students) and publications (produced by their cheap PhD students).").

[48] Daniele Fanelli, *Do Pressures to Publish Increase Scientists' Bias? An Empirical Support from US States Data*, PLoS ONE 5(4) (2010), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2858206/?tool=pmcentrez.

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develop their research further and make more significant discoveries, increasing the prestige of their university. For these reasons and others, the SACGHS report concluded that patents do little to incentivize invention in the field of genetic research.[49]

Genetic discoveries can be incredibly lucrative for pharmaceutical companies, however there is an enormous disconnect between the industry and academia. The academic community, where much of this research is done, seems to give very little thought as to whether or not their research tools and results are patented.[50] Indeed, there is very little evidence of an actual "anticommons" effect in academia.[51] The anticommons effect is a theory in intellectual property where more than one person or entity owns property rights, but none own exclusive rights.[52] For example, if pastures were divided into lots among a group of farmers, the ownership of individual lots would prevent farmers from being able to effectively farm because the other lots would block their access to things like water or new pastures. The surrounding lots would effectively limit the farmers to their own lots and nothing else. In genetic research, this would be akin to one holding a patent on a gene sequence, and another holding a patent on the method for making the DNA. One would be able to exclude the other from practicing their invention, and since each need the other's method or product to practice their own inventions, it effectively shuts both out of doing anything. Under such a regime, invention is difficult because inventors are unable to use each other's inventions, and overall progress is impossible.

The fact that there is no empirical evidence of anticommons does not mean the Supreme Court should decide upon patentable subject matter ignoring the anticommons issue. The absence of anticommons at this point in time does not mean that it will never be a problem. If pharmaceutical or large biotech companies begin to enforce patents more strictly, and make

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[49] SACGHS, *supra* note 4, at 1–2.

[50] Matthew Poulsen, *Jurisprudential and Economic Justifications for Gene Sequence Patents*, 90 NEB. L. REV. 196, 229 (2011) ("In the United States, for example, only 1% of the respondents indicated that they abandoned a research project due to an existing patent. Further, in their 2005 study, Zhen Lei, Rakhi Juneja, and Brian Wright found that only about 10% of respondents indicated that they inquired as to whether or not a research tool used in their work was patented.").

[51] *Id.*

[52] *Id.* at 227.

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more inquiries into academia, they could do serious damage to research because the atmosphere for anticommons is already in place. In fact, this happened with the current *AMP* case, where Myriad sent cease and desist letters to the University of Pennsylvania, and left "many researchers with the (wrong) impression that Myriad would not tolerate any form of research."[53] Again, just because there is not currently a problem with the anticommons, there may be at some point in the future, and it should certainly be part of the discussion about whether or not isolated genes should be patentable subject matter.

Patents in the field of genetic research provide little incentive to invent and create circumstances ripe for the anticommons, but that should not be the end of the inquiry. Patents should also be viewed in light of whether or not they promote the commercialization of new inventions. Patents are particularly important in the biotechnology field because of the large costs associated with bringing a biotechnology product to market.

2. Patents May Not Help Commercialize New Inventions in the Genetics Field

When analyzing whether or not isolated DNA should be patent eligible, the question should ultimately boil down to, "what infrastructure best allows for the innovation and advancement of technology, as well as gets new technology to the public the most efficiently?" Some have proposed different schemes such as mandatory licensing, research exemptions, or limiting gene patents to exclude upstream patents.[54] This

[53] Carbone et al., *supra* note 44, at 788.

[54] *See* SACGHS, *supra* note 4, at 97 (Recommendations included creating an exemption from liability for research, creating more transparency in licensing, and creating a special advisory board for licensing.); Carbone et al., *supra* note 44, at 791 (Recommendations included securing more funding in university tech transfer offices and better practices in tech transfer offices. Additionally, Carbone recommended clearer research exemptions and opposition proceedings in patent law, as well as more agency oversight as recommended by SACGHS.); Janice Mueller, *Facilitating Patient Access to Patent-Protected Genetic Testing*, 6 J. BUS. & TECH. L. 83, 94 (2011) (Recommendations included either creating an outright exemption from liability for patent infringement, or at least some form of mandatory nonexclusive licensing with remuneration to the patentee.); Andrew S. Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access*, 9 NW. J. TECH. & INTELL. PROP. 377 (2011) ("These considerations suggest that not only are DNA sequence patents not required for innovation in the development of gene-based molecular diagnostics, but also they actually hinder the advancement and clinical adoption of personalized medicine.").

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paper will focus on the commercialization aspect of diagnostic genetic tests, such as the *BRCA1* and *BCRA2* genes, and how patents will likely help or inhibit commercialization. The Supreme Court must look beyond whether or not isolated DNA is a product of nature and should consider how its decision will affect the progress of science. Even if the Supreme Court considers the economic impact of isolated DNA, the issue is important enough that Congress should take up the issue and conduct a complete investigation.

The economic impact of gene patents is an important consideration. In this case alone, the *BRCA1* and *BRCA2* gene sequences relate to breast cancer. Breast cancer cost $13.86 billion in treatment and care in the United States in 2006.[55] Breast cancer research spending reached $1 billion in 2007.[56] In 2012, the American Cancer Society estimates that there will be 226,870 new cases of invasive breast cancer in women, 63,000 new cases of *carcinoma in situ*, and 39,510 deaths from breast cancer.[57] The American Cancer Society also estimates that 1 in 8 women will have invasive breast cancer in her life, and the chance of dying from breast cancer is 1 in 36 women.[58] Breast cancer's economic cost and its impact on women and their families is mammoth in scale. If the *BRCA1* and *BRCA2* sequences are able to better diagnose breast cancer and reduce the costs by even 10%, this would result in billions of savings in the healthcare industry. Many other cancers and health related problems are linked to genetics, and whether or not isolated DNA is patentable will have a profound effect on the economy and healthcare industry by impacting other potential genetic marker testing.

To begin the analysis of the economic impacts of the patentability of isolated DNA, it is important to distinguish between "invention," and "innovation." Innovation is much broader than invention, as innovation includes commercializing the invention and gaining acceptance of the

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[55] NATIONAL CANCER INSTITUTE, http://progressreport.cancer.gov/doc_detail.asp?pid=1&did=2009&chid=95&coid=926&mid (last visited Mar. 14, 2012).

[56] *Breast cancer research nears $1B spent*, USA TODAY, Jan. 1, 2007, *available at* http://www.usatoday.com/news/nation/2007-01-21-komen-anniversary_x.htm.

[57] AMERICAN CANCER SOCIETY, http://www.cancer.org/Cancer/BreastCancer/OverviewGuide/breast-cancer-overview-key-statistics (last visited Mar. 14, 2012).

[58] *Id.*

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product in the marketplace.[59] David Teece outlined three important factors in commercializing a new technology including the appropriability regime, the complementary assets, and the dominant design paradigm.[60]

Appropriability is where patents come into play. An appropriability regime involves the innovator's ability to prevent imitators from taking value from the innovation by copying or "inventing around" the innovation. An appropriability regime includes things like patents and trade secrets.[61] Patents are merely a factor in the appropriability regime, and courts must break away from the conventional thinking that patents equal progress. While strong appropriability makes it easier to gain a market share, it is not essential, and weak appropriability regimes can be overcome by implementing a solid business strategy based more on the complementary assets.[62]

Complementary assets are the ancillary requirements for bringing an innovation to market. These assets can include machinery to manufacture the good, marketing channels, distribution channels, modes of disseminating information, brand recognition, etc.[63] When the appropriability regime is weak, it is important to gain control over the complementary assets and gain the market share by strategy, rather than through legal monopoly.[64]

Complementary assets are incredibly important, arguably as important or even more important than appropriability. A strong appropriability regime carries no guarantees of successful innovation without the complementary assets in place to disseminate the technology. Perhaps the quintessential example of a strong appropriability regime with lacking complementary assets is the Segway. The Segway had several patents protecting its invention, giving it a strong appropriability regime.[65] The

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[59] *See* David Teece, *Profiting from Technological Innovation: Implications for Integration, Collaboration, Licensing and Public Policy*, 15 RES. POL'Y 285 (1986), *available at* http://www.mbs.edu/home/jgans/tech/Teece-1986.pdf (discussing how innovation requires acceptance by and diffusion into the market).

[60] *Id.* at 286.

[61] *Id.* at 287.

[62] *Id.* at 290.

[63] *Id.* at 288.

[64] *Id.* at 297.

[65] U.S. Patent No. 6,415,879 (filed Mar. 21, 2001); U.S. Patent No. 6,651,766 (filed May 22, 2001).

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strength of the appropriability regime is evidenced by the fact that there are no imitators, everyone knows the mechanical, gyroscope self-moving transport device as the Segway. However, the Segway never reached the status its inventors and investors thought it would.[66] The venture capitalist who backed the Segway said cities would be redesigned around the Segway.[67] The complementary assets however, such as highway and road design, sidewalk design, and the infrastructure already in place at existing cities, presented enormous hurdles for Segway. Even with a strong appropriability regime, they were unable to capture the market because of the almost non-existent complementary assets. Appropriability in this case just ensured no one else, even had they obtained the complementary assets, was able to take the innovation. In the end, the strong appropriability regime helped to ensure the product did not gain any market traction.[68]

In contrast to the Segway, the computer industry, particularly the PC industry, is one with little appropriability and high complementary assets.[69] The manufacturers of individual components often enjoy a high appropriability because they are able to protect their trade secrets and obtain patents.[70] In contrast, systems manufacturers such as HP and IBM have a weak appropriability regime because they do not invent new systems, they simply build systems from existing modular components. Because system manufacturers have a weak appropriability regime, they must rely on complementary assets instead.[71] Microsoft did a better job of capturing complementary assets than Intel, and it caused Intel to eventually sell its business to Lenovo.[72]

While complementary assets are very important, this article does not seek to minimize the importance of a strong appropriability regime. A combination of a strong appropriability regime and control of the complementary assets is the ideal situation. This is something Apple was

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[66] Mark Gimein, *Reinventing The Wheel, Slowly*, BLOOMSBURG BUSINESSWEEK, at 56 (Sept. 11, 2006), *available at* http://www.businessweek.com/magazine/content/06_37/b4000411.htm.

[67] *Id.*

[68] *Id.*

[69] Jason Dedrick et al., *Who Profits from Innovation in Global Value Chains?: A Study of the iPod and Notebook PCs*, INDUS. & CORP. CHANGE 81, 101 (Feb. 2010), *available at* http://pcic.merage.uci.edu/papers/2008/WhoProfits.pdf.

[70] *Id.*

[71] *Id.*

[72] *Id.*

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able to do by keeping its operating system and its source code secret and protected.[73] Combined with complementary assets including successful marketing, a strong appropriability regime allowed Apple to be the dominant market player in goods such as MP3 players (i.e., the iPod), tablets (i.e., the iPad), and MP3 sales (i.e., iTunes).[74] A strong appropriability regime allows those with complementary assets to be the dominant market player, for big or small businesses. However, when there is strong appropriability and no complementary assets, it can work to stifle the technology and prevent it from getting to market, such as the Segway. When deciding whether or not patents will contribute to the progress of technology and commercialization, it is important to consider how a strong or weak appropriability could affect the market for new technologies.

Complementary assets in the pharmaceutical industry include manufacturing facilities, testing capabilities, distribution channels, customer goodwill, etc. While it is true that the costs of obtaining complementary assets for genetic tests are much lower than for drugs and other pharmaceuticals,[75] the costs can still be prohibitive. If the Supreme Court overrules the court of appeals and affirms the district court, the lack of patents in the genetic testing realm can potentially also increase the cost of marketing, since DNA patents themselves can offer improved marketing.[76] This means that the complementary assets for bringing a genetic test to market put smaller companies at a significant disadvantage. Without the appropriability of patent protection, complementary assets become much more important. A strong appropriability regime also allows smaller companies to obtain outside funding more easily[77] since investors will be less worried that another company will be able to steal the market share through control of the complementary assets. Therefore, smaller companies trying to enter the market will be more likely to lose out to

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[73] *Id.* at 102.
[74] *Id.*
[75] *See* Robertson, *supra* note 54, at 37–38.
[76] *Id.* at 32.
[77] *See* Jacob D. Moore, *The Forgotten Victim in the Human Gene Patenting Debate: Pharmaceutical Companies*, 63 FLA. L. REV. 1277, 1293 (2011) ("For many biotechnology companies, patents are the only means of convincing investors to fund lifesaving genetic research.").

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incumbents who control the complementary assets, especially when those assets are specialized.[78]

The question of whether to patent comes down to who can get a product to market faster and better. On one hand, large companies have the assets and capital to be able to scale up much faster than smaller companies that must obtain outside funding and may not be as familiar with the Food and Drug Administration's (FDA) procedures. However, the quick scale-up which larger companies can achieve can also be a disadvantage, as small companies which must proceed more slowly are able to make adjustments along the way. Alternatively, there could be a combination of large and small businesses working together at different phases, where the large businesses who control the complementary assets would buy the appropriability regime of small companies.[79] This is currently done quite frequently, such as when Eli Lilly purchased the IP rights to insulin from Genentech.[80] If, however, isolated DNA is not held to be patentable, small businesses will most likely lose the opportunity to create and sell isolated DNA, or to sell the rights to a larger company. Larger companies could therefore run smaller companies out of business if the larger companies control the complementary assets.

The Constitution says Congress can promote the progress of science, not that they must promote the single most progressive option. Congress seems to favor protecting small business, particularly with the passage of the America Invents Act (AIA) in 2011. The AIA has several provisions designed to help small businesses. For example, Section 32 allows for small businesses to receive patent assistance on a pro bono basis.[81] Additionally, Section 10 establishes a micro entity status, which allows very small businesses to receive significant fee reductions.[82] Lastly, Section 28 establishes the Patent Ombudsman for Small Businesses Program.[83] If the Supreme Court takes any guidance from Congress, it should consider

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[78] Teece, *supra* note 59, at 292.

[79] Joshua S. Gans & Scott Stern, *The Product Market and the Market for "Ideas": Commercialization Strategies for Technology Entrepreneurs*, 32 RES. POL'Y 333, 334 (2003).

[80] *Id.* at 343.

[81] Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in 28 U.S.C. § 1454; 35 U.S.C. §§ 123, 257, 298–99, 321–29).

[82] *Id.*

[83] *Id.*

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carving an exception for isolated DNA because allowing small businesses to capture a strong appropriability regime would allow small businesses to protect against larger companies overtaking the market through domination of complementary assets.

This section aims to illustrate the difficulty in trying to improve the progression of science. The issue is not as black and white as whether patents incentivize or dis-incentivize innovation. The question is very complex, and while others have attempted to answer the question on their own,[84] the large amount of academic work emphasizes the complexity. The issue becomes particularly complex in the field of genetic research and biotechnology because innovation is very difficult in the field of biotechnology.[85] The decision should therefore not be made by the Court, but should be made by Congress, or through traditional administrative agency rule-making procedures with a public comment period.

However, Congress should decide whether or not to allow patents of isolated DNA. Even if Congress agrees with the Supreme Court's ruling, it should still consider the issue with a full investigation and make a law confirming or changing the Court's ruling. The Supreme Court is not as well equipped to decide the issue as Congress. In the recent case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court considered whether a method for determining thiopurine drug dosage was patentable subject matter.[86] The court avoided the question of whether or not patents in the medical diagnostics field would increase or decrease innovation, arguing that the Court "must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where

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[84] *See generally* Matthew Poulsen, Ph.D., *Jurisprudential and Economic Justifications for Gene Sequence Patents*, 90 NEB. L. REV. 196 (2011).

[85] *See* Moore, *supra* note 77, at 1293–94 ("[Bringing a pharmaceutical to market involves] the process of research, development, and marketing of a [drug, which takes an estimated] average of nearly ten years and between $500 million and $2 billion to complete. [L]ess than one percent of biotechnology research ventures ever make it to the marketplace. [T]he average biotechnology company will not be profitable until their successful products have been on the market for over twelve years. Indeed, only about five percent of biotechnology companies are even profitable at all.").

[86] 132 S. Ct. 1289 (2012).

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necessary."[87] The Court was absolutely correct in this statement, and Congress should take up the issue.

3. While the Supreme Court Should Accept Certiorari *and Make Its Ruling, Congress Should Take up the Issue Due to Isolated DNA's Importance in Commerce and Healthcare*

Congress should consider the issue of whether or not isolated DNA should be patentable because they are in the best position to do so, and have the time and resources to consider many factors. Even if isolated DNA is considered a product of nature, Congress can still allow it to be patentable subject matter. After all, Congress is empowered by the Constitution to grant patents although patentable subject matter has often been left to the courts.

To understand this relationship, it is important to look at patents in a historical context. Historically, patents were issued for almost any monopoly, whether or not the patentee actually invented the product.[88] Patents were given by the English Crown, which led to abuses of power, where the Crown had granted monopolies to its cronies.[89] It was under this context that Thomas Jefferson, who was diametrically opposed to monopolies, wrote the patent statute 35 U.S.C. § 101 (2012).[90] Perhaps it is for this reason that Thomas Jefferson avoided making any specific laws about what could or could not be patented, and instead left those decisions to the judicial system.[91] The point made in Part III that isolated DNA is a product of nature is a reference to the judicially created rule that products of nature cannot be patented.[92] As such, the issue has largely been decided by the courts, but because isolated DNA is so important to the economy and the healthcare system, Congress should conduct a full inquiry and analyze

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[87] *Id.* at 1305.

[88] JANICE M. MUELLER, PATENT LAW 22 (3d ed. 2009).

[89] *Id.*

[90] Bilski v. Kappos, 130 S. Ct. 3218, 3245 (2010) ("Thomas Jefferson was . . . 'the author of the 1793 Patent Act.'")

[91] *Id.*

[92] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1349 (Fed. Cir. 2011) ("Supreme Court precedent establishes that a product of nature is not patent eligible even if, as claimed, it has undergone some highly useful change from its natural form.").

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the issue. Congress can carve an exception to the product of nature rule, and should do so if they find it beneficial to society.

There are significant benefits to allowing Congress or the USPTO to make decisions using administrative agency procedures.[93] Not only would Congress or the USPTO be in a better position to determine whether patents really will increase innovation or not, there is an element of the general public to consider. The CAFC relied on the settled expectations of the inventing community.[94] However, relying on the settled expectations of the inventing community rather than the general public is a poor choice. A large part of the inventing community has a very real economic interest in allowing patents, because patents contribute to an appropriability regime which can make it easier for innovators to capture value from their invention. Patents balance the interests of the inventing community against the general public,[95] but the courts seem to ignore the interests of the general public. The general public could voice its opinion through a comment period or the legislative process, rather than gambling on whether or not the courts will hear their concerns.

Gene patents have a significant effect on the general public and on healthcare. The debate rages on, some saying that patenting isolated DNA hurts patient access to genetic tests, others argue it helps patient access.[96]

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[93] *See* Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1760 (2011).

[94] *Ass'n for Molecular Pathology*, 653 F.3d at 1355.

[95] Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 63, 119 S. Ct. 304, 310, 142 L. Ed. 2d 261 (1998) ("[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time. The balance between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other, has been a feature of the federal patent laws since their inception.").

[96] Marisa Pins, *Impeding Access to Quality Patient Care and Patient Rights: How Myriad Genetics' Gene Patents Are Unknowingly Killing Cancer Patients and How to Calm the Ripple Effect*, 17 J. INTELL. PROP. L. 377, 398–400 (2010) (allowing patents on *BRCA1* and *BRCA2* genes ruins patient access and quality of care); Andrew Robertson, *The Role of DNA Patents in Genetic Test Innovation and Access*, 9 NW. J. TECH. & INTELL. PROP. 377, 26 (2011) ("Without broad licensing, the availability of alternative testing techniques, medical second opinions, and testing verification is severely limited. This critique of patenting is related to the reduced incentives that monopoly holders have to introduce newer, cheaper, or alternative tests."); *contra* Peter Edwards, AMP v. Myriad: *The Future of Medicine and Patent Law*, 12 MINN. J.L. SCI. & TECH. 811, 843 (2011) ("Moreover, without the patent incentive, many genes with important medical implications would never have been sequenced, and thus thousands of patients would be without the benefit of decades of medical research.").

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Previous articles have discussed whether or not, as a whole, patents stifle or promote innovation in the biotechnology field. This article is not intended to supplant or discredit any of the previous articles, but is intended to illustrate the effects of patents on commercializing technologies, and how allowing patents will likely favor small businesses, and not allowing patents will favor larger businesses in the biotechnology field. This is but one factor the Supreme Court should consider, and more importantly, a factor that Congress should consider if it decides to take up the issue of isolated DNA patents.

IV. CONCLUSION

The economic and social implications of gene patenting are incredibly complex issues which need a long, thorough analysis before, as a country, we decide to allow isolated genes to be patentable subject matter or not. There is a split in academia, the district court, and the court of appeals about whether or not isolated DNA is a product of nature or a new invention. Whether isolated DNA is or is not a product of nature, the Supreme Court must understand that the patentability of isolated DNA has a profound effect on the economy and can affect millions of lives. Patenting isolated DNA should be analyzed as much as possible before a decision is made, and another avenue, such as allowing the legislature to make the decision, or creating a comment period by the USPTO, would be a better route to determine whether or not it is in the country's interest to allow patents of isolated DNA. The Supreme Court should accept *certiorari* in this case, and should make a ruling with all the knowledge they can muster, but the decision should be reviewed by Congress and Congress should create law based on their findings.

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