THE IMPACT ON AGRICULTURAL RESEARCH BY GENETIC MATERIAL PATENTS AND THE NEED FOR CLARITY AND REFORM IN PATENT LAW FOR GENETIC MATERIAL

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I. INTRODUCTION

It all started with cookie recipes.[1] During the seventh century, Greece issued a one-year monopoly right on cookie recipes.[2] Since that time, patent law has become increasingly complex.[3] The majority of United States patent law is derived from English common law, specifically from the 1602 case, *Darcy v.*

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1. United States Patent and Trademark Office, General Information About Patentable Plants under 35 U.S.C. § 161, http://www.uspto.gov/web/offices/pac/plant/.
2. *Id.*
3. *Id.*

Allin.[4] The language of the lawyer in the case was used by Judge Edward Coke in the decision. The attorney in that case stated:

> When any man by his own charge and industry, or by his own wit or invention doth bring any new trade into the realm, . . . in such cases the king may grant to him a monopoly-patent for some reasonable time, . . . in consideration of the good that he doth bring by his invention to the commonwealth, otherwise not.[5]

By the late 1800s, U.S. patent law had developed significantly and lead to the signing of the 1883 Convention of Paris for the protection of industrial property.[6] The main purposes of which were to protect property rights, thereby increasing invention and developments, and to encourage fair competition.[7] Patent law was codified similarly to the way we know it today in 1952.[8] However, during the 1990s significant changes occurred in the international patent law field with the United States signing the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS").[9] The reason for the increases in international protection for patents under TRIPS was to "promote developmental and technological objectives."[10]

Thus, despite the developments in patent law there has always been a simple, consistent underlying rationale for granting governmental protection to a novel invention or discovery – that is, to foster and encourage research and continuous development of new ideas.[11] The U.S. Constitution states that Congress is empowered to "promote the process of science and the useful arts by securing for limited times to authors and inventors, the exclusive rights to their respective writings and discoveries."[12] Recently, the emergence of sophisticated biotechnology and increased patent protection has created a dichotomy between protecting the discovery or invention and fostering research development.[13] Specifically, academic researchers are left in confusion on how to proceed with their

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4. Biojudiciary.org, History and Introduction to the US patent system, http://www.biojudiciary.org/subpage1.asp?tid=100#footer.

5. *Id.*

6. Convention of Paris for the Protection of Industrial Property, art. 1, Mar. 20, 1883, 21 U.S.T. 1583.

7. *Id.*

8. 35 U.S.C. § 161 (1952).

9. *See* Agreement on Trade Related Aspects of Intellectual Property Rights annex 1C art. 33, Apr. 15, 1994, 33 I.L.M 1125 (extending patent protection from 17 to 20 years).

10. *See id.*

11. Janice Kimpel, *Freedom to Operate: Intellectual Property Protection in Plant Biology and Its Implications for the Conduct of Research*, 37 ANN. REV. OF PHYTOPATHOLOGY 29, 31 (1999).

12. U.S. CONST. art. 1 § 8.

13. Kimpel, *supra* note 11, at 31.

research while not violating a patent when using patented plant genes and genetic sequences.

Most of the theories being offered by the legal community simply are not able to provide adequate definiteness of the law and legal protection to plant genetic researchers. Therefore, an approach is needed that will provide legal protection against infringement that is definite and tailored for the development of the more precise genetic material that is being patented. This note will first focus on the current trends in genetic material patenting, with a brief history of biotechnology patents. Next, this note will examine the dichotomy between the interest of the basic researcher/scientist and the applied researcher/biotechnology company scientist. This note will then examine the current restraints on research as a result of ambiguous laws and adverse court decisions. After looking at those restraints, this note will analyze the currently proffered legal solutions to the problems surrounding genetic material patents and will include a brief discussion of the underlying theories behind patents and the need for modification of those theories in order to protect academic researchers. Finally, this note will offer a comprehensive solution which will attempt to balance the competing interests of academic research and applied research in a corporate setting.

II. BRIEF HISTORY AND CURRENT TRENDS OF BIO-TECHNOLOGY PATENTS

Patented genes and genetic material are all the rage within the biotechnology field.[14] The ability to determine the base sequence of a gene, and thereby its amino acid sequence and resultant protein, is a fairly recent development.[15] However, the concept of patenting a gene or genetic material can be traced back to the 1930 amendments to 35 U.S.C. section 161. These amendments expanded the current patent law to include providing patents for plants which were asexually16 propagated.[17] Asexually propagated plants are known as cultivars, and include such items as new breeds of roses, trees and shrubs.[18] This prototype of

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14. *See* Christina Weschler, Note, *The Informal Experimental Use Exception: University Research After Madey v. Duke University,* 79 N.Y.U. L. REV. 1536 (2004).

15. Biojudiciary.org, Glossary, http://www.biojudiciary.org/glossary/index.asp?flt=f; s*ee also* History of Genetics, Genetics Is the Science of Biological Heredity and Variation, http://www.pssc.ttu.edu/pss3421/hisgen.htm (stating that a pivotal point in plant genetic research came in 1990 when a fully deconstructed genetic sequence of a flowering plant was introduced). *See infra.* figure 1.

16. "Relating to, produced by, or involving reproduction that occurs without the union of male and female gametes, as in binary fission or budding." *THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE* (4th ed. 2000).

17. 35 U.S.C. § 161; *see also* Kimpel, *supra* note 11, at 39.

18. Kimpel, *supra* note 11, at 39.

bio-engineering can be seen as the forerunner to the latest type of plant patents: plant genes and genetic sequences.[19] The advent of patenting a genetic sequence can arguably be found in the 1980 case of *Diamond v. Chakrabarty*, which held that a modified gene was a "product of human ingenuity" and thus patentable material.[20] However, *Diamond* also concluded that naturally occurring genes are not patentable, thus an individual cannot patent their own genes since human genes occur naturally, without human modification.[21] Most of the controversy surrounding this type of patent occurred as scientists' ability to fully deconstruct the gene matured.[22] In the early 1990s, the National Institute of Health ("NIH"), guided by Bernadine Healy, sought patent protection for several expressed sequence tags ("ESTs[23]").[24] Because ESTs are only a small component of a gene sequence, the scientific community was not in favor of such broad patents being granted.[25] After careful review, the United States Patent Office ("USPTO") issued guidelines on how to apply for a gene patent and, specifically, for a patent on an EST.[26] The USPTO guidelines only provide protection for ESTs if they are modified (See figure 2) and have a specific use for developing a new gene sequence.[27] Thus, the current patent law provides for patent protection for most genetic material that has a specific use and is modified by "human ingenuity."[28] Biotechnology companies have taken advantage of this clarification of the law, with a dramatic increase in gene and genetic material patent applications.[29] Between 1980 and 2000, just 2,000 patents were issued for gene and gene sequences.[30] Now, there are more than 70,000 applications pending before the USPTO for similar patents.[31]

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19. *Id.*
20. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
21. *Id.*
22. Charles Schmidt, *Cashing in on Gene Sequences - As the Biotechnology Business Explodes, So Do Attempts to Patent Its Very Foundation,* 4 MODERN DRUG DISCOVERY, May 2001, at 73, 75.
23. ESTs are DNA sequences from active genes in the plant; genes that govern such characteristics as skin color and taste. Press Release, HortResearch, Publication of Apple Gene Sequences, (May 2004).
24. Schmidt, *supra* note 22, at 75; s*ee infra* figure 1.
25. Schmidt, *supra* note 22, at 75.
26. Utility Examination Guidelines, 66 Fed. Reg 1092-02 (Jan. 5, 2001).
27. *Id.*; *see infra* figure 2; *see also In Re Fisher,* 421 F.3d 1365 (Fed. Cir. 2005) (The court held that broad-sweeping lists of potential uses for ESTs would not qualify for patent protection as they were not specific enough to warrant protection).
28. 66 Fed. Reg 1092-02, 1093.
29. *See* Weschler, *supra* note 14, at 1546.
30. Schmidt, *supra* note 22, at 75.
31. *Id.*

An example of this newer type of high-tech "bio-patent" is illustrated by U.S. Patent No. 5,254,800, which protects a DNA sequence that blocks the poly-galacturonase gene in the tomato.[32] This patent protects the use of pTOM36 antisense constructs.[33] The protection of this patent extends, not only to genes which contain the antisense constructs, but also the plant cells, fruits, seeds, and even the tomato plant itself.[34] It is here that we can see the difference between a cultivar plant patent and a DNA sequence patent. The plant patent has been restricted to the plant itself and not to "essential derivations" of it.[35] Thus, a researcher may use all parts of the plant for scientific research and may even use the plant in controlled cross-pollinations to produce new and better hybrids.[36] However, with the latter gene sequence patent there are no parts of the plant that are unprotected by the patent. Therefore, the researcher cannot experiment with any of the genes, seeds or even the plant itself without fear of infringing on a patent.[37] This, combined with the dramatic increase in genetic material patents, is the reason why researchers are rightfully concerned about the future of genetics research.

III. DICHOTOMY BETWEEN THE INTEREST OF RESEARCHERS

Currently, there are two major competing interests in the biotechnology field: the basic researcher/scientist and the applied researcher/biotechnology company scientist.[38] Generally, the first wishes to develop new ideas for the betterment of the scientific community, while the latter wishes to develop the idea for commercial profit (this is not to say one is more noble than the other).[39] Both of these interests have a different perspective on the best approach to patent law. The biotech company researcher wishes to have strictly interpreted patent law protection to ensure profitability from their research, while the basic researcher believes that the best research occurs when there is open and free access to data and new discoveries.[40]

At first blush, there is a conflict between the corporate and academic researcher interests and thus the current tension in the field of gene sequence pat-

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32. Kimple, *supra* note 11, at 39.
33. *Id.*
34. *Id.*
35. *Id.* at 35.
36. *Id.*
37. *Id.*
38. Rebecca Eisenburg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use Exception*, 56 U. CHI. L. REV. 1017, 1017 (1989).
39. *Id.* at 1018.
40. *Id.* at 1035.

enting. *In exempla* Syngenta, a prominent plant biotechnology company, acquired a patent for the novel gene sequence of *Oryza sativa*, a rice genome, in the late 1990s.[41] *Oryza sativa*, subspecies *Indicia*, is the most cultivated subspecies of rice in Asia.[42] Demand for access to the material to develop this discovery in order to make the most of the new information was exceptionally high among scholarly researchers.[43] However, Syngenta was wary of releasing the full sequence to researchers for fear of infringement and loss of profitability. "We had both public and commercial concerns about placing the data into an international database . . . As a result, we agreed with SCIENCE [magazine] to make segments of the draft sequence available through our web site," wrote a spokesman for Syngenta.[44] The scientific community was upset about the lack of access to the full sequence.[45] As a result, the full development of the potential for this new gene sequence was delayed for about two years until full access was given to the scientific community.[46] The developments made with this rice gene sequence will benefit all cereal production and help feed millions in impoverished countries.[47] Syngenta, as a result of the academic research, has been able to better market and unfold the full potential of the gene sequence.[48] It would seem a shameful waste of time to have spent more than two years working out the details of dissemination of the full genetic sequence of the rice genome.

The ostensible tension appears to lessen when similar situations are analyzed more carefully. It would seem that there might be congruence between the commercial researchers' interests and academia. Confluence of similar interests in genetic research seems to be the current trend in modern biotechnology. "The biotechnology revolution has accelerated the commercial development of basic research discoveries and attracted commercial interest in academic biomedical research in its early stages. Academic and industrial scientists may thus have a shared interest . . . in isolating and developing new ways of producing proteins".[49] Consequently, a uniformed approach to biotechnology patent protection should be supported by both types of interests, commercial and academic.

Unfortunately, the patent laws do not reflect the changes in the biotechnology field and are inharmonious with the reality of the situation within the ge-

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41. *See* Nicole Johnston, *Rice Genome Rising Draft Sequences for a Cereal Model Feed Further Investigation*, 18 THE SCIENTIST 4 (2004).
42. *Id.*
43. *Id.*
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. Eisenberg, *supra* note 38, at 1018.

netic research field. Reviewing the history of the current common and statutory patent law structure would, upon a cursory glance, seem to offer protection to the commercial interests and broad access to genetic data for the academic interests.[50] However, upon closer examination, the current patent law regime is outdated and, in some ways, headed in the wrong direction. For example, even though academic researchers desire greater access to patented genetic material for their research (and it would seem that this would be in the best interest of the corporate interests), the long standing, though somewhat esoteric, research exemption is seemingly being abolished by the courts.

Although not directly stated in any statutes, there is the well known common law research exemption.[51] This was first laid out in *Whittemore v. Cutter*, when Justice Story held that "it could never have been the intention of the legislature to punish a man, who constructed a patented machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[52] Although this exemption has never been overruled, it has been further narrowed by the courts. In *Roche Products v. Bolar Pharmaceutical Co.*, the court held that the research exemption was limited to experiments conducted "for amusement, to satisfy the idle curiosity, or for strictly philosophical inquiry."[53] Most recently, in the controversial opinion in *Madey v. Duke University*, the court held that, although Duke did not have an outright commercial objective, the overall purpose of the university's research was to promote the name of the school in order to attract new students. That in turn was a legitimate business objective, thus defeating the experimental use exception.[54] *Madey* would suggest that the experimental use exception is all but dead, eliminating the final vestige of patent infringement protection for academic researchers.[55] It seems as though, in the time of increased need for infringement protection, the courts are actually increasing the vulnerability of the academic researcher.

Before *Madey,* universities were ignoring patents and researching for non-commercial purposes on the theory that they would not be sued, since they were not researching for business profits. Even if they were sued, the experimen-

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50. *See e.g.* Whittemore v. Cutter, 29 F. Cas. 1120, 1122 (D. Mass. 1813) (holding that common law would support the notion of protection for research and development); 35 U.S.C. § 161 (granting protection to the inventor for commercial use).

51. Whittemore, 29 F. Cas. 1120.

52. *Id.* at 1121.

53. Roche Prods. v. Bolar Pharmaceutical Co., 733 F.2d. 858, 863 (Fed. Cir. 1984).

54. Madey v. Duke Univ., 336 F. Supp. 2d 583 (M.D.N.C 2004). It should be noted that even a broad interpretation would not have helped Duke in this case, but the lasting effects of this ruling on the experimental use exception are troublesome.

55. Madey, 336 F.Supp.2d at 592.

tal use exception would apply.[56] Now researchers are legitimately confused and do not know the extent of their legal liability. Furthermore, university researchers are frustrated by the restraints this places on research in light of the heavily protected gene sequence patents.[57] Therefore, the current status of patent law is not sufficient to protect the interests of the academic researcher in light of the voluminous amount of gene sequence patents being issued.

IV. RESTRAINTS ON RESEARCH

Currently researchers are very unsure of their rights, duties and liability under the current system of laws.[58] In a recent study of university agricultural researchers, "48% experienced difficulties in obtaining genetic material, 45% indicated that this interfered with their research activity, and 28% felt that it hampered their ability to release new varieties."[59] A major factor contributing to the confusion is the lack of definiteness of the law.[60] Courts have yet to lay down a specific exception and have not clarified the extent of "flow through" patent rights in DNA material patents.[61] As this note will show, the case law surrounding DNA material patent rights and the rights of researchers can only be described as murky. Furthermore, the Legislature has yet to fully address the issue.[62] Although the latest guidelines for utility laid down by the USPTO are a step in the right direction, they still fall short of adequately informing researchers of their right to research. [63] Thus, there has emerged with these DNA material patents, a need for clearly laid out infringement protection for agricultural researchers.

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56. *See* Beth Arnold, *Navigating Gene Patent Minefields*, BIO-IT WORLD, Nov. 12. 2002 (stating that it would be likely that a university would not be sued if they did not try to profit from the research). This statement looks like precarious legal advice in the wake of *Madey* since potential revenues derived from tuition from students attracted as a result of the research would be the potential damages in the claim. For private universities, this sum could be very large.

57. *See id.*

58. Kimpel, *supra* note 11, at 31.

59. *See* Dwijen Rangnekar, *Can TRIPs Deter Innovation? The Anticommons and Public Goods in Agricultural Research* (Int'l Workshop on Governance of Biodiversity as a Global Pub. Good, Working Paper, 2004) (the study comprised 25 universities and 41 crops).

60. *See* JOHN WALSH ET AL., RESEARCH TOOL PATENTING AND LICENSING AND BIOMEDICAL INNOVATION 6 (2002).

61. *Id.*

62. Sandra Schmieder, *Scope of Biotechnology Inventions in the United States and in Europe – Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System,* 21 SANTA CLARA COMP. AND TECH. L.J. 163, 182 (2004).

63. See 66 Fed. Reg. 1092-02.

V. CURRENT PROFFERED LEGAL SOLUTIONS

During the last five years, more scholarly papers have been written on the subject of the experimental use exception than in the previous two-hundred years.[64] This prolific amount of written material on a rather obscure point of common law is evidence of an underlying concern that current patent law is incongruent with needs of modern research. Several theories as to how to approach the exception have been given. However, many of these theories simply are not compatible with gene sequence and gene fragment patents.

One such theory, posited by Katherine Strandburg of DePaul University, is the experimental use exception should be granted to those who use patented material to perform research on that material but not to those who perform research with the patented material.[65] Such a concept would easily apply to tangible property. But, even as Strandburg admits, genetic material presents problems of the exact nature of what role a patented gene plays in the research process.[66] For example, if the researcher utilizes the rice gene by inserting it into the genome of another cereal crop, has the gene become a tool for research on the grain or is inserting the gene in the grain performing research on the gene? The answer to this question is extremely fact intensive and would likely provide little predictive help to protect researchers if the research exemption were based on that rationale.

In another recent New York University Law Review note, a non-legal, informal exception to intellectual rights is offered.[67] This theory suggests that universities are not likely to be sued by private corporations, thus continued ignorance of the law will become an informal protection to the academic researcher who performs non-profit research.[68] This has been the advice in the past from many prominent attorneys.[69] However, this comes with pitfalls, as the note admits. If the researcher is sued, their liability will be enforced by the court.[70] The legal malpractice ramifications of advising a client to break the law are chilling. Additionally, this "break the law and lie low" approach presents the problem in

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64. This figure was a result of searching various law review articles and treatises on Westlaw and Lexis Nexus.

65. Katherine Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 151 (2004).

66. *See id.* (discussing recombinant gene factors and how they're used in various ways in academic research).

67. Weschler, *supra* note 11.

68. *Id*.

69. Arnold, *supra* note 56 (stating "[i]f you're infringing a patent, can't develop an effective design-around, . . . the best strategy may be to lie low").

70. Weschler, *supra* note 11.

disbursement of ideas and publication of research results.[71] Obviously, the less a patent holding company knows of any infringement the better.[72] Furthermore, genetic sequence patent holders jealously guard their patents and are not likely to ignore the precedent set in *Madey* that potentially sets up tuition fees and grant awards of the researcher as potential damages. In this changing landscape of genetic patents, preemptive measures must be taken to protect the researcher before they are sued, not after.

A. *The Outcry for a Paradigm Shift in Patent Law*

The underlying economic theory for patent protection is promoting research. However, the assumption has been among commercial entities and the legislature, that providing economic incentive is the way to achieve this goal.[73] This theory is largely based on theory of the internalization of externalities.[74] Thus, when public property is subjected to private control pursuant to the protection of a patent, incentives are increased for research and development.[75] This increase in research is due to the knowledge that a researcher's discoveries will not be automatically disseminated to the public, but remain under his/her control.[76]

However, intellectual property does not fit this theory, because of the nature of genetic material.[77] For instance, internalizing an invention and removing it from the private sector rewards the inventor who spent countless hours developing that product. Gene sequences, however, are granted patents before the bulk of the research and development is done because the first step is to modify the gene then discover its potential.[78] However, the patent is granted at the first

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71. *Id.*

72. Unless, of course, you have direct permission, but then the court likely would hold that the researcher had a license. Weschler asserts that this type of cooperation would eliminate the danger of being sued, but this is nothing more than asserting that a licensed researcher wouldn't be likely to be sued. In many cases, the exemption for researchers is needed for those that are in fact infringing on the patent without the existence of a research license. Weschler, *supra* note 11.

73. *See* Mark Lemley, *Property, Intellectual Property, and Free Riding* (Stanford University Stanford Law and Econ. Olin Working Paper No. 291, Aug. 2004).

74. This theory asserts that as publicly shared information or property is transferred to private ownership, the incentive for development and innovation increase. Michael A. Heller, *The Boundaries of Private Property*, 108 YALE L.J. 1163, 1164 (1999).

75. *Id.*

76. Lemley, *supra* note 73.

77. Lemley, *supra* note 73; *see also* Michael A. Heller & Rebecca S. Eisenburg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research,* 280 SCI. 698, 701 (1998) [hereinafter *Anticommons*].

78. Lemley, *supra* note 73.

step, thus the incentive to further research is only there for the sole owner of the patent, providing an overall decrease in the amount of research that will take place.[79] This inefficient allocation of resources is inherent in holding to a model that no longer works with genetic material.[80]

The ultimate result of adhering to a patent paradigm that does not apply to DNA sequence patents is what modern scholars are calling the "tragedy of the anti-commons".[81] This is the opposite of the traditional economic theory of the tragedy of commons which occurs when there is over consumption of a resource.[82] The tragedy of the anti-commons is exactly the opposite, and occurs when there is under consumption of goods because the resources are owned by too few persons.[83] This theory goes along with the Bentham model of Utilitarianism as applied to property rights.[84] When a gene sequence is discovered that provides a benefit to a large part of society, then the greatest utility of the gene should be sought after.[85] If one researcher owns all of the rights to the gene and all essential derivations thereof, then the maximum utility is not afforded to society if the owner does not disseminate that information to the public.[86] Thus, there is an outcry for a major change in the rationale of the laws governing patentability of genetic material.[87] Although there is much demand, there is little in the way of clear, concise suggestions that have a workable solution.

Some go so far as to suggest that genetic material should not be patented at all.[88] Those asserting this theory argue that genetic material is a public good and privatization provides no creative incentives.[89] One such theory, offered by a recent Tennessee Law Review article, suggests that as recombinant genes are patented, access to the genetic code as a whole is restricted.[90] This in turn violates the Supreme Court's case law that laws of nature should remain public do-

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79. *Id.*
80. *Id.*
81. Schmieder, *supra* note 62, at 182; *see also Anticommons, supra* note 78, at 70.
82. *See* Terry Anderson & Fred McChesney, PROPERTY RIGHTS: COOPERATION, CONFLICT, AND LAW, 255 (Princeton Univ. Press 2003).
83. Rangnekar, *supra* note 59.
84. Anderson, *supra* note 82, at 32.
85. *See id.*
86. *See* Peter Drahos, A PHILOSOPHY OF INTELLECTUAL PROPERTY 201 (Dartmouth Publ'g Co. Ltd. 1996).
87. Peter Lee, Note, *Patents, Paradigm Shifts, and Progress in Biomedical Science*, 114 YALE L.J. 659, 661 (2004).
88. Lawrence Busch, *Eight Reasons Why Patents Should Not Be Extended to Plants and Animals,* 24 BIOTECHNOLOGY AND DEV. MONITOR 24 (1995).
89. *Id.*
90. Eileen Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 708 (2004).

main.[91] But before one suggests that DNA material be exempted from patent protection, one should apply a form of felicific calculus.[92] When this is applied it can be seen that there are many competing interests that must be factored in. Although the researcher and the public will gain utility from the discovery of new genetic sequences, there must be enough incentives for the costly process of discovering a new, useful DNA sequence.[93] Some studies indicate that the costs of developing a pharmaceutical drug can reach as high as $802 million.[94] A wholesale abandonment of case law and statutory law upholding DNA material patentability would not fit within any form of known property philosophy, as the initial researcher's utility is ignored in this scenario.[95]

A modification of this theory and one propounded by a recent student note, suggests that a broad research exception be allowed for a limited time after a patent is granted, to allow for the dissemination of vital information into the researching marketplace.[96] At first blush, this theory seems to provide a nice solution. It comprises a paradigm shift in patent theory in allowing upstream work on the patented material to be performed, while providing long-term patent protection incentive to create.[97] However, this largely leaves out several factors, such as the amount of time it takes to perform research. Also, it raises unanswered questions, such as what kind of research is to be protected, what happens once a university has a commercially viable product as a result of that research and, perhaps most importantly, how is it to be accomplished?

The bottom line is there needs to be a practicable theory offered that balances the competing interests of the initial researcher and the follow-up researcher. A shift in the paradigm theory of patent law is needed but cannot be seen that any one solution or, as my note suggests, even a prominent feature in a solution to the murky waters of DNA material patent law.

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91. *Id.* at 765.

92. *See* Anderson, *supra* note 82, at 32-33.

93. Schmieder, *supra* note 63, at 182.

94. Lee, *supra* note 87, at 661; *see also* A Joint Committee of Science, Technology and Economic Policy Board and Science, Technology, and Law Program: Committee on Intellectual Property in Genomic and Protein Research Innovation (Feb. 27, 2004) (transcript *available at* http://www7.nationalacademies.org/step/Genomics_Committee_Meeting_1_transcript.pdf) [hereinafter *Committee*].

95. *See* Anderson, *supra* note 82, at 32-33.

96. Lee, *supra* note 87, at 661.

97. *Id*.

VI. MUCH NEEDED CHANGES

As this note has shown, there is much confusion in the current field of DNA material patenting and DNA research.[98] Different theories have been proffered and analyzed. Each of these theories, for the most part, has a measure of validity. However, what appears to be the fundamental problem is that each suggests a single solution, where each offered solution really is only an aspect of what this author believes to be the ultimate solution. The confusion in this field, as noted above, is due to the many competing interests and the inapplicability of former patent law theory to DNA material.[99] Therefore, any solution must be comprised of various sectors, each making sacrifices, in order to bring maximum utility to society. Thus the solution offered in this note is broken down into four sections: a quasi paradigm shift in patent theory, statutory improvement, development of compulsory licensing, and increased university responsibility.

A. *Quasi Paradigm Shift*

The reason this note does not suggest that a wholesale change in underlying patent law theory is needed is due to the fact that the existing theory does not need changing as much as it needs to be expanded. As noted earlier, the main problem is that DNA patents are granted early in the research process, so the need to zealously guard the rights of the patentee is decreased as there are greater needs to foster upstream research and development of the new DNA material.[100] Given the great expense of developing new DNA sequences and ESTs, some protection is needed to secure a lucrative property interest in the initial research to ensure that enough incentive remains to encourage continued experimentation in order to create new, useful recombinant genes. At the same time, courts and the legislature need to understand that a danger exists of under consumption of useful data and information.[101] Thus, to a certain extent, a need does exist for shift in the approach to patent protection. The practical outworking of any shift in the underlying theory behind patent laws will likely be found in the approach that Congress takes in drafting a statutory scheme that is more carefully tailored to genetic material patents. The implication for any new statutory scheme would be to relax the heavy protection of upstream research in favor of more protection of specific predicted or actual end results of the genetic material that is patented. Protection needs to be restricted in the sense that protection must be narrower

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98. Walsh, *supra* note 60, at 6; *see also Committee*, *supra* note 94.
99. Schmieder, *supra* note 62, at 182.
100. Lemley, *supra* note 73.
101. Rangnekar, *supra* note 59.

and more defined than the current approach, which is ambiguous and too expansive.

B. *Statutory Improvement*

Part of the reason there is lack of clarity in the courts is the current patent law schema pertaining to DNA material.[102] Although improvement has been made, more improvement is needed. The need for a codified research exemption is paramount as is the need for a more rigorous test to determine utility. This concept is not without empirical evidence supporting it as a viable solution. German statutory law serves as a possible example of how this could be achieved.[103] In Germany's Draft to Implement the Directive of the EU European Patent Convention, the legislature stated that any biotechnology patents "shall be determined 'narrowly and precisely, strictly coupled to its function' " ("enge und praezise Funktionszuordnung").[104] Under this statutory scheme, simply designating a recombinant DNA sequence as "useful for the development of rice" would not be acceptable.[105]

The German Legislature has also codified a broad research exception that allows for research not intended for commercial development and to promulgate scientific knowledge.[106] Even research that has a commercial intent is protected with a "cross patent," available for the initial creator of the biotechnology.[107] The United States should attempt to create a statutory scheme that matches the definiteness that German and EU law contains.[108]

One suggestion would be to provide a statutory safe harbor that would allow for research that has not, nor intends to, market any results of the research to be liable for patent infringement. Furthermore, Congress should act in a decisive way to prohibit grant money and tuition fees to be available as recoverable damages in a suit against a university. This latter suggestion comes with a duty of responsibility on the part of university researchers that will be explored below. Improved statutory law will enable the researching field to be certain of their rights and legal exposure.

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102. *Committee*, *supra* note 94.
103. Schmieder, *supra* note 62, at 199.
104. *Id.*
105. *Id.*
106. *Id.* at 214.
107. *Id.* at 214-15.
108. *See e.g.* Schmieder, *supra* note 62.

C. *Development of Compulsory Licensing*

Compulsory licenses are being haled by some as the primary solution to the DNA material patent/research dilemma.[109] Although, as should be clear by now, this note does not accept that as the sole solution, the usefulness of compulsory licenses should be explored. The underlying theory behind this is that if a patent inhibits dissemination of an invention to the public to the public's detriment, another should be allowed to exploit its potential.[110] Traditionally, courts have issued this type of license only in the instance where the patentee has neglected to develop the patent.[111] More recently, however, a development in this area has been occurring.[112] The traditional notion of the courts intervening only when a patent is undeveloped is being replaced by the idea that a biotechnology patent should be developed by researchers to benefit the public.[113] TRIPS and EU law has developed to promote public welfare through the means of such licenses.[114] A potential problem with relying solely on this, without the other changes, is that the costs of licenses can be great.[115] Additionally, while it could foster research, it would ultimately pass these increased costs to the consumer and, in some cases, derail the research effort altogether. However, with all the other changes in the system, this could very well provide a much needed solution where research would encroach on legitimate patent property rights.

D. *University Responsibility*

"I think it's disingenuous for us in universities to file patents, prosecute them aggressively, and then turn around and say, 'hey, don't sue us. We're just researchers.' "[116] There is a need for universities to become the starting point of patent responsibility.[117] Universities should be leading the way in being responsible in applying for patents. It is hypocritical for them to complain of overly-broad patents when they have several of the same in the name of the university.[118] Universities are in the position to foster research and lead the way in encouraging

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109. *Id.* at 182.
110. Kurt Saunders, *Patent Nonuse and the Role of Public Interest as a Deterrent to Technology Suppression,* 15 HARV. J.L. & TECH. 389, 441 (1992).
111. *Id.*
112. *Id.*; *see also* Schmieder, *supra* note 62, at 182.
113. Schmieder, *supra* note 62, at 182.
114. *Id*.
115. *Committee*, *supra* note 94.
116. *Id.*
117. *Id.*
118. Schmieder, *supra* note 62, at 182.

the public and the legislature to make the needed changes in DNA material patenting.[119] Dr. Collins from the National Academies talks of how he and fellow researchers have established a "pro-bono" collection of data, open to all researchers.[120] The only rule is that one cannot patent anything that is contained in the genetic database or essential derivations of it.[121] Although, at the moment, the "no patent rule" is just enforced by the honor system and "click licenses," the hope is that continued contributions to this database will be a boon to researchers everywhere, which provides patent free sequences and ESTs ripe for development.[122] With a more eleemosynary attitude on the part of university researchers regarding genetic material, non-commercial research could flourish greatly.

VII. CONCLUSION

Although the current landscape of this sector of the law is murky and ambiguous, there is hope in remembering that, as a society, we are in the early stages of the genetic revolution in agricultural research and development.[123] This note suggests that a slight shift in underlying patent theory is needed to make way for a statutory scheme for genetic material patents that makes sense and provides predictive guidance to basic researchers, yet provides the proper incentives for further invention. This, coupled with a development in the way compulsory licenses are used and a concerted effort on the part of universities to promote responsibility in the patenting of genes and gene sequences, would provide the starting point towards achieving a statutory scheme for genetic material patents that is clear, concise, and, above all, helpful in providing predictive help to the researcher. There is much hope for the future. In the meantime, researchers should be careful and not continue to ignore patent laws in the face of recent adverse verdicts. Rather, take to heart the changes this note suggests and encourage Congress to take on the task of protecting and fostering research in the United States.

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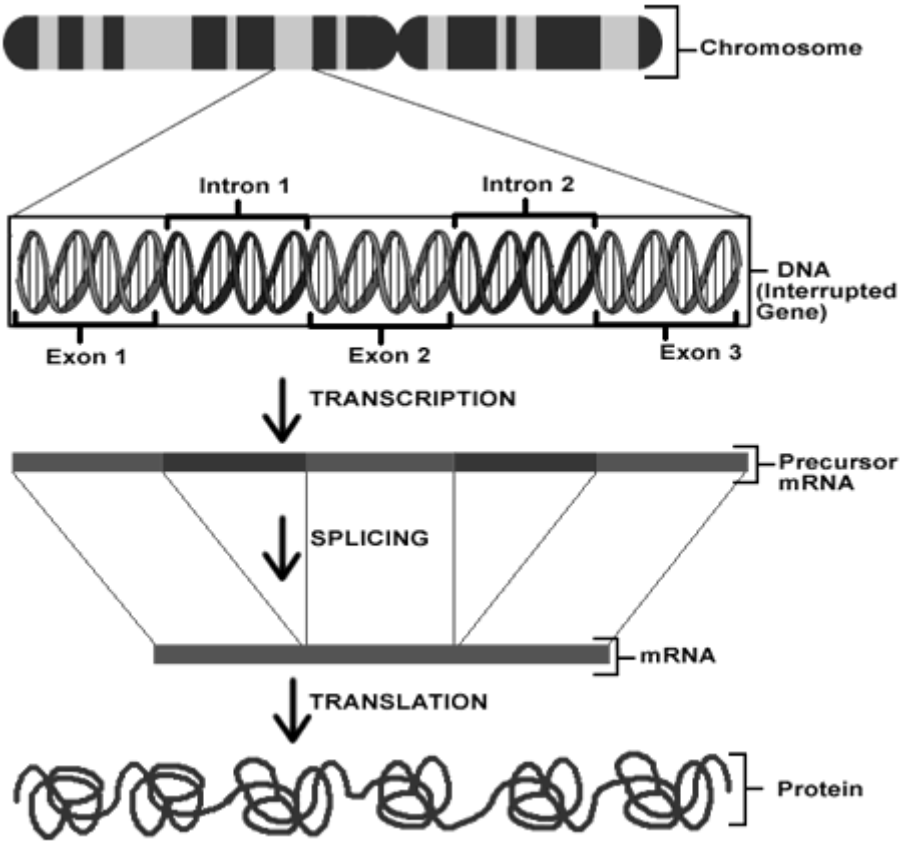
119. *Committee*, *supra* note 95, at 21.
120. *Id.*
121. *Id.*
122. *Id.*
123. *Id.*

FIGURE 1[124]



The figure above illustrates an unmodified gene and one that would not be protected by a patent. Because of the instability of mRNA, to modify a gene, a scientist uses an enzyme called reverse trancriptase to convert mRNA into cDNA, a much more stable compound. This creates an expressed DNA sequence because the introns are removed during the process from the mRNA. [125] Unlike the pictured gene, the expressed sequence can be patented because it has undergone manipulation, provided the manipulation produces a novel result. A good explanation of DNA and the intent of bio-developers is given in *In Re Fisher*:

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124. MyDNA.com, Expressed Sequence Tags, http://www.mydna.com/genes/genetics/genetics101/primer_est.html.

125. *Id.*

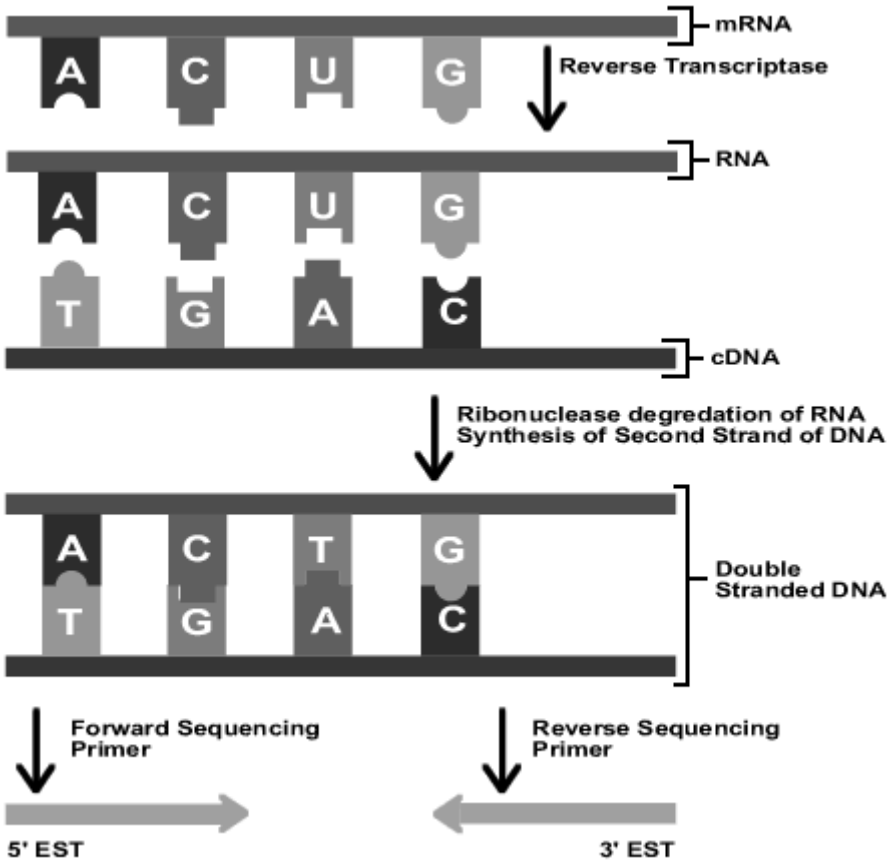
Genes are located on chromosomes in the nucleus of a cell and are made of deoxyribonucleic acid ("DNA"). DNA is composed of two strands of nucleotides in double helix formation. The nucleotides contain one of four bases, adenine ("A"), guanine ("G"), cytosine ("C"), and thymine ("T"), that are linked by hydrogen bonds to form complementary base pairs (*i.e.,* A-T and G-C).

When a gene is expressed in a cell, the relevant double-stranded DNA sequence is transcribed into a single strand of messenger ribonucleic acid ("mRNA"). Messenger RNA contains three of the same bases as DNA (A, G, and C), but contains uracil ("U") instead of thymine. mRNA is released from the nucleus of a cell and used by ribosomes found in the cytoplasm to produce proteins.

Complementary DNA ("cDNA") is produced synthetically by reverse transcribing mRNA. cDNA, like naturally occurring DNA, is composed of nucleotides containing the four nitrogenous bases, A, T, G, and C. Scientists routinely compile cDNA into libraries to study the kinds of genes expressed in a certain tissue at a particular point in time. One of the goals of this research is to learn what genes and downstream proteins are expressed in a cell so as to regulate gene expression and control protein synthesis. An EST is a short nucleotide sequence that represents a fragment of a cDNA clone. It is typically generated by isolating a cDNA clone and sequencing a small number of nucleotides located at the end of one of the two cDNA strands. When an EST is introduced into a sample containing a mixture of DNA, the EST may hybridize with a portion of DNA. Such binding shows that the gene corresponding to the EST was being expressed at the time of mRNA extraction.

421 F.3d 1365, *1367 (Fed. Cir. 2005).

FIGURE 2[126]



126. *Id.*