

Combining the Components of Life: The Application of Patent Extraterritoriality Doctrine to Biotechnology

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INTRODUCTION

Within the past century, scientific advancement has greatly expanded the range of patentable subject matter,¹ famously described as including “anything under the sun that is made by man.”² The discovery of the double-helical structure of deoxyribonucleic acid (DNA) by James Watson and Francis Crick in the early 1950s³ led to the establishment of an entirely new field of science—biotechnology—which also profoundly changed the face of scientific fields such as medicine⁴ and agriculture.⁵ Soon, scientists who had created novel, useful, and nonobvious⁶ inventions utilizing this new technology sought limited-term monopoly⁷ rights under the patent laws of the United States, and the Supreme Court’s 1980 decision in *Diamond v. Chakrabarty*⁸ affixed the Court’s seal of approval on biotech patents.⁹

Inevitably, as soon as patents are granted, accusations of infringement arise. Under the Patent Act, one can infringe another’s patent by usurping a patentee’s rights directly,¹⁰ inducing others to infringe the patent,¹¹ or otherwise contributing to

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1. Inventors may patent “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 35 U.S.C. § 101 (2000).

2. *Patent Law Codification and Revision: Hearings on H.R. 3760 Before Subcomm. No. 3 of the H. Comm. on the Judiciary*, 82d Cong. 37 (1951) (statement of P.J. Federico, Chief Examiner, Patent Office). Natural phenomena, laws of nature, and abstract ideas cannot be patented. *See, e.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).

3. *See* J.D. Watson & F.H.C. Crick, *Molecular Structure of Nucleic Acids: A Structure for Deoxyribose Nucleic Acid*, 171 NATURE 737, 737 (1953).

4. *See, e.g.*, C. Semsarian & C.E. Seidman, *Molecular Medicine in the 21st Century*, 31 INTERNAL MED. J. 53, 53 (2001) (observing that increased scientific understanding of genetic disorders will assist medical researchers in developing pharmaceutical and gene-therapy-based treatments for such diseases).

5. *See, e.g.*, W. Paul Davies, *An Historical Perspective from the Green Revolution to the Gene Revolution*, 61 NUTRITION REVS. 124, 124 (2003) (observing the increasing impact of genetics and biotechnology on agriculture).

6. *See* 35 U.S.C. § 102 (2000) (requiring that a patentable invention possess novelty); 35 U.S.C. § 103 (2000) (requiring that a patentable invention not be obvious “to a person having ordinary skill in the art to which said subject matter pertains”).

7. *See* 35 U.S.C. § 154(a) (2000).

8. 447 U.S. 303, 318 (1980) (holding that a genetically engineered bacterium containing plasmid DNA allowing it to digest crude oil was patentable).

9. *See* Robert G. Sterne & Lawrence B. Bugaisky, *The Expansion of Statutory Subject Matter Under the 1952 Patent Act*, 37 AKRON L. REV. 217, 224 (2004).

10. *See* 35 U.S.C. § 271(a) (2000).

11. *See* 35 U.S.C. § 271(b) (2000).

infringing activities.¹² However, until 1984, the Patent Act only protected patentees from infringement occurring within the United States and its territories or involving the importation of patented products (including those made by patented processes).¹³ Thus, an infringer could avoid United States patent law entirely by conducting some aspect of manufacturing overseas. Such was the case in *Deepsouth Packing Co. v. Laitram Corp.*,¹⁴ in which the Supreme Court held that exporting components of a patented invention that were then assembled into the final product abroad did not constitute infringement.¹⁵

In 1984, Congress responded to *Deepsouth*¹⁶ by enacting 35 U.S.C. § 271(f), which expanded the range of infringing behaviors to include some activities occurring abroad:

(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.¹⁷

Recently, the Court of Appeals for the Federal Circuit expanded the scope of § 271(f),¹⁸ which it initially applied only to the export of tangible components of product patents.¹⁹ In general, product patents are defined as machines, manufactures, or

12. See 35 U.S.C. § 271(c) (2000).

13. See 35 U.S.C. § 154(a)(1) (2000).

14. 406 U.S. 518 (1972).

15. See *id.* at 528–29 (“No wrong is done the patentee until the combination is formed Only when such association is made is there a direct infringement of his monopoly, and not even then if it is done outside the territory for which the monopoly was granted.”) (quoting *Radio Corp. of Am. v. Andrea*, 79 F.2d 626, 628 (2d Cir. 1935)).

16. 130 CONG. REC. 28065, 28069 (1984) (“This proposal responds to the United States Supreme Court decision in *Deepsouth Packing Co. v. Laitram Corp.* . . . concerning the need for a legislative solution to close a loophole in patent law.”) (statement of Rep. Kastenmeier).

17. 35 U.S.C. § 271(f) (2000).

18. The Court of Appeals for the Federal Circuit, created in 1982, has exclusive jurisdiction over appellate patent litigation. See KENNETH J. BURCHFIELD, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 5 (The Bureau of National Affairs, Inc. ed., 1995).

19. See, e.g., *Columbia Univ. v. Roche Diagnostics GmbH*, 150 F. Supp. 2d 191, 204–05 (D. Mass. 2001) (holding that § 271(f) does not apply to process patents, because they do not claim any components that an infringer may combine abroad) (citing *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991)).

compositions of matter.²⁰ Process patents, on the other hand, claim no tangible entity, but instead a series of actions or steps that produce a useful result.²¹ In *Eolas Technologies v. Microsoft Corp.*,²² the court first contemplated applying § 271(f) to process patents²³ and expanded the definition of “component” to include intangible elements of a patented invention (software).²⁴ Expanding § 271(f) liability to intangible components of a patent will affect many different fields of technology, including biotechnology.²⁵ The Federal Circuit has never addressed § 271(f) in a biotech context, but given the increasing number of biotech and pharmaceutical patent disputes,²⁶ it seems likely that the statute will come into play in this context in the future.

This Note predicts how courts might apply § 271(f) to different patented biotech inventions. This is a natural extension of the doctrine²⁷ because biological materials are reproduced in a manner that is very similar to the copying of software,²⁸ often involving informational precursors that do not *physically* become part of a final product and are thus “intangible” in the same manner as software code. Part I examines the basic science of biotechnology and reviews the Federal Circuit’s traditionally narrow approach to patentability and infringement issues involving biotech. Part II summarizes the history of 35 U.S.C. § 271(f), the Federal Circuit cases expanding its

20. DONALD S. CHISUM, CHISUM ON PATENTS § 1.02 (2006).

21. *Id.* § 1.03.

22. 399 F.3d 1325 (Fed. Cir. 2005).

23. “This statutory language did not limit section 271(f) to patented ‘machines’ or patented ‘physical structures.’ Rather every form of invention eligible for patenting falls within the protection of section 271(f).” *Id.* at 1339. Though *Eolas* did not involve a process patent, the court later held that § 271(f) could apply to these patents. See *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 425 F.3d 1366, 1380 (Fed. Cir. 2005) (“[B]ecause § 271(f) governs method/process inventions, Shell’s exportation of catalysts may result in liability under § 271(f).”).

24. *Eolas*, 399 F.3d at 1339. In *Eolas*, the court held that software code on a golden master disk could be a component under § 271(f) because, without this code, “the invention would not work at all and thus would not even qualify as new and useful.” *Id.* (internal quotation marks omitted); see also *Imagexpo, L.L.C. v. Microsoft Corp.*, 299 F. Supp. 2d 550, 553 (E.D. Va. 2003) (holding that the software code on a golden master disk was a component under § 271(f) because it was “the functional nucleus of the finished computer product”).

25. See Dennis Crouch, PATENTLY-O, Dec. 19, 2006, http://www.patentlyo.com/patent/2006/12/microsoft_v_att.html; Dennis Crouch, PATENTLY-O, Oct. 1, 2006, http://www.patentlyo.com/patent/2006/10/supreme_court_1.html.

26. See, e.g., *Company Releases 2005 Report on Biotech and Pharmaceutical Patent Trends*, BIOTECH WK. 345, July 20, 2005, available at 2005 WLNR 11062740 (“Patent litigation has continued at a modest, steady increase, a likely reflection of the continued recognition of the increased value of intellectual property assets. Biotech and pharmaceutical patent litigation appear consistent with this trend.”).

27. See Michael R. Dzwonczyk, *Looking at Federal Circuit Developments 2005: The Year in Review*, 6 HIGH TECH. L.J. 113, 118–19 (2006) (“Is the manufacturer of a host cell transformed in the U.S. and thereafter exported for protein expression and production liable for infringement of a patent claiming a method of producing proteins under § 271(f)?”); Virginia Zaunbrecher, Note, *Eolas, AT&T, & Union Carbide: The New Extraterritoriality of U.S. Patent Law*, 21 BERKELEY TECH. L.J. 33, 55 n.136 (2006).

28. See Andrew Hughes, *The Central Dogma and Basic Transcription*, <http://cnx.org/content/m11415/1.5/> (analogizing the system of genetic transcription and translation to computer processes).

applicability, and the Supreme Court's recent decision in *Microsoft Corp. v. AT&T Corp.* Finally, Part III predicts how modern courts might approach § 271(f) liability in this area and explains why an expansive application of § 271(f) would undermine the Federal Circuit's traditionally narrow approach to biotech patent rights. Part III concludes by explaining why a biotech-specific amendment to § 271(f) would most effectively address this problem.

I. BIOTECHNOLOGY: A PATENT PRIMER

A. *The Central Dogma*

The genetic material of a living organism is composed of polymeric chains of nucleic acids that encode information vital to its survival²⁹ through genes—finite units carrying inherited information about a particular biological function or trait.³⁰ Genes alone do not have any purpose but information storage; the information encoded by a gene sequence must take another form before it can execute any biological function.

The informational content of the genetic code is very similar to that of any other language. From the four standard nucleotide bases contained by DNA—guanine (G), adenine (A), cytosine (C), and thymine (T)³¹—a wide variety of different messages can form. The “words” contained within the “sentence” of any given gene consist of three bases each—short sequences known as “codons”—and correspond to a particular amino acid at a particular location within the protein produced from the gene. Other specialized codons communicate where the protein-coding region of a gene begins and ends.³²

Shortly after the elucidation of the structure of DNA,³³ Francis Crick predicted how cells utilized this genetic information; his theory is now commonly known as the “Central Dogma.”³⁴ In this system, individual genes made of DNA are first transcribed

29. Nucleic acids are composed of heterocyclic nitrogenous bases and are the core building blocks of the genetic code and the information it stores and transfers. See REGINALD H. GARRETT & CHARLES M. GRISHAM, *BIOCHEMISTRY* 327 (Univ. of Va. ed., Sanders College Publishing 2d ed. 1999).

30. *Id.* at 950–51.

31. See *id.* at 328–29. Thymine is replaced by uracil (U) in RNA. See *id.* at 329.

32. So, for example, the coding DNA sequence

5' ATG CAA GGA TGT ATT ACT GAG CGC CTG TCA TAG 3'

would be transcribed into the following mRNA:

5' AUG CAA GGA UGU AUU ACU GAG CGC CUG UCA UAG 3'

which would be “read” by ribosomes and translated into the following protein:

N-Met—Glu—Gly—Cys—Ile—Thr—Glu—Arg—Leu—Ser-C

AUG serves both as the “start” signal and encodes for the amino acid methionine; UAG is one of three “stop” codons. In addition, the genetic code is degenerate—all amino acids are represented by more than one codon (except for methionine and tryptophan). See *generally id.* at 1073–74. 5' and 3' markers indicate the polarity of nucleic acids, with genes read by cellular machinery from 5' to 3'. N and C markers indicate the polarity of proteins, with translation occurring in an N- to C-terminal fashion. See *id.* at 113–14; JAMES D. WATSON, MICHAEL GILMAN, JAN WITKOWSKI & MARK ZOLLER, *RECOMBINANT DNA* 39–40 (2d ed. 1992).

33. See *supra* text accompanying note 3.

34. GARRETT & GRISHAM, *supra* note 29, at 1014.

into molecules of ribonucleic acid (RNA)³⁵—small and relatively instable³⁶ nucleic acid polymers. These messenger RNA (mRNA) molecules then interact with ribosomes, which facilitate the translation of the genetic code into functional proteins through the assembly of individual amino acids.³⁷

As understanding of the Central Dogma increased, so did researchers' ability to manipulate biological molecules. Genetic sequencing techniques allowed scientists to understand not only individual gene sequences but also the structure and makeup of entire genomes³⁸ and advanced the state of the field considerably.³⁹ One major breakthrough was the discovery of restriction enzymes—proteins that cleave nucleic acid molecules at specific sequences.⁴⁰ In addition to streamlining DNA sequencing,⁴¹ restriction enzymes also allowed researchers to create novel DNA sequences by cutting different molecules of DNA with the same restriction enzyme and then reassembling the fragments to form a chimeric DNA sequence.⁴² Researchers also have utilized restriction enzyme technology to insert foreign genes into cloning vectors and

35. The three major forms of RNA are messenger RNA (mRNA), ribosomal RNA (rRNA), and transfer RNA (tRNA). All of the three major types of RNA are involved in protein synthesis. *Id.* at 1015. However, for the purposes of this Note, mRNA, which is formed from protein-coding genes in an organism's DNA, is the most important, since it serves as an informational precursor to the final protein product encoded by a gene.

36. The instability of mRNA in a cellular environment allows the rate of protein synthesis to be controlled by the rate of transcription of DNA into mRNA. *See id.* Thus, the protein encoded by any given gene will only be produced while the cellular machinery actively transcribes that gene into mRNA, a process which is regulated by features contained by genomic DNA and also by hundreds of different proteins known as "transcription factors." *See generally id.* at 1028–56.

37. *Id.* at 1015.

38. "Genome" refers to all of an organism's genetic material. *See id.* at 23.

39. *See* WATSON ET AL., *supra* note 32, at 63.

40. Restriction endonuclease enzymes, which cut nucleic acid molecules internally at particular sequences, were discovered in various species of bacteria that utilized them as protection against viruses. The enzyme would recognize the viral nucleic acid at a particular sequence (the "restriction site"), cut the nucleic acid at that site, and thus prevent infection by destroying the virus's genetic material. The bacteria's own genetic material would remain untouched due to certain chemical modifications present at the restriction site on its own genome. *See id.* at 64–65.

41. *See id.* at 67.

42. Preferred restriction enzymes used for this purpose are those which create single-stranded "sticky ends" when cutting. For example, the commonly used restriction enzyme *EcoRI* (derived from the bacterium *Escherichia coli*) cuts at the following double-stranded DNA site:

5' G A A T T C 3'
3' C T T A A G 5'

to create the following pieces of DNA with a short single-stranded overhang at the 5' end of the DNA:

5' G A 3' 5' A T T C 3'
3' C T T A 5' 3' A G 5'

Any nucleic acid sequence that has been cut with *EcoRI* enzyme can then be combined with other sequences cut by the same enzyme, allowing the creation of novel nucleic acid sequences. *See id.* at 70–72.

introduce them into different species of cells,⁴³ allowing for the creation of genetically engineered cell lines. The Supreme Court addressed the patentability of such organisms in the landmark case *Diamond v. Chakrabarty*,⁴⁴ in which the inventor had claimed *Pseudomonas* bacteria that contained two such man-made plasmid vectors.⁴⁵

The isolation of genes using recombinant technology not only allowed scientists to learn more about the genes themselves but also opened the door to studying the structure and function of the proteins they produce. Today, scientists utilize a wide variety of protein expression systems to allow for the isolation and study of proteins in the laboratory.⁴⁶ Additionally, technology has enabled scientists to create mutated forms of genes in order to study how individual amino acid residues contribute to the structure and function of a particular protein.⁴⁷

Recombinant DNA techniques also have combined nicely with the use of polymerase chain reaction (PCR), which allows researchers to amplify small samples of nucleic acid (both DNA and RNA) into larger amounts more compatible with laboratory research.⁴⁸ PCR itself and its many variations are claimed by numerous process patents,⁴⁹ but also have aided in the creation of many patented biotech

43. A plasmid is one commonly used vector, consisting of a small, self-replicating piece of circular DNA. Plasmids containing many restriction enzyme recognition sites are highly useful for inserting DNA restriction fragments into the plasmids. These recombinant plasmids can then be introduced into host cells to produce more of the plasmid or to express the protein encoded by the gene. *See id.* at 73–74.

44. 447 U.S. 303 (1980).

45. *Id.* at 305.

46. Many laboratory systems of expressing recombinant proteins are claimed by process patents, causing researchers to lament “multiple licensing agreements [that] may deter companies that do not possess patented in-house technologies from selecting this bacterium as a production host.” Mirna Mujacic & François Baneyx, *Expression, Folding, and Degradation in Escherichia coli*, in *PROTEIN EXPRESSION TECHNOLOGIES: CURRENT STATUS AND FUTURE TRENDS* 85, 86 (François Baneyx ed., 2004). Expression systems are characterized by the use of living cells and an expression plasmid with various characteristics, such as the presence of a particular restriction enzyme site and a strong promoter region (the DNA sequence where the RNA polymerase enzyme binds to begin the process of transcription). *See id.* at 85–92. Common systems used for protein expression involve the cells of bacteria (such as *Escherichia coli*), yeast, insects, and mammals.

47. *See* WATSON ET AL., *supra* note 32, at 192 (describing *in vitro* mutagenesis techniques).

48. *See id.* at 79–80. PCR of DNA generally consists of three steps: first, denaturation (“melting”) of the double-stranded DNA template molecule at high temperatures; second, annealing of primers (short pieces of single-stranded nucleic acid that are complimentary to the endpoints of the sequence to be amplified); and third, synthesis of a new strand of DNA from the original template from a mixture of nucleotides. These three steps are repeated many times in order to exponentially amplify the amount of the target DNA sequence. The key ingredient in PCR is the heat-stable DNA polymerase *Taq*, isolated from *Thermophilus aquaticus*, a bacterial species found in oceanic hot springs, which maintains its functionality despite the high temperatures used for denaturation (about 94°C) that would deactivate most enzymes. *See id.* at 80–85.

49. *See* David McDowell, *The Polymerase Chain Reaction Patents: Going, Going, . . . Still Going*, 99 J. ROYAL SOC’Y MED. 62, 62 (2006). The expiration of the first PCR patents both in the United States and abroad seems likely to expand molecular research given that use of this cornerstone technology will no longer be limited to those who can afford to pay licensing fees on the technology. *Id.* at 63. However, patents on *Taq* polymerase and other variations on PCR,

inventions.⁵⁰ PCR variations can be used to produce DNA from mRNA⁵¹ or to measure the concentration of a certain DNA or mRNA sequence present in a particular sample.⁵²

B. Patents on Biotech Inventions

The biotech revolution has produced inventions that are accompanied by unique patent law issues.⁵³ Still, these inventions must satisfy the basic statutory requirements of novelty, utility, and nonobviousness, and an inventor must provide a sufficient written disclosure,⁵⁴ for patentability. The Federal Circuit has struggled with the application of these requirements to biotech inventions, but has settled on a narrow interpretation of patent rights in this field.⁵⁵

1. Patentable Subject Matter

Professor Rebecca Eisenberg has suggested that many find it difficult to accept the patentability of biotech inventions (especially DNA sequences) because of their informational content. Pure information on its own is unpatentable⁵⁶ unless it is converted into an invention that falls into the categories of patentable subject matter

such as real-time and reverse-transcriptase PCR, are still in force and will continue to affect biotech research. *See id.* at 63–64.

50. *See, e.g.*, U.S. Patent No. 7,153,856 (filed May 26, 2005) (describing the utilization of PCR techniques to assay the tyrosine kinase genes claimed by the patent); U.S. Patent No. 7,154,021 (filed Jan. 5, 2001) (describing the creation of the claimed invention, genetically engineered soybean plants, using PCR techniques). A search using the term “polymerase chain reaction” within the specifications or descriptions of all patents on the United States Patent and Trademark Office’s Web database yielded over twenty-eight thousand results. United States Patent and Trademark Office Full-Text Database Boolean Search, <http://patft.uspto.gov/netahtml/PTO/search-bool.html>.

51. This form of PCR utilizes reverse transcriptase, an enzyme used by retroviruses to produce DNA from an RNA template. GARRETT & GRISHAM, *supra* note 29, at 1008–09; *see also* Ursula E.M. Gibson, Christian A. Heid & P. Mickey Williams, *A Novel Method for Real Time Quantitative RT-PCR*, 6 GENOME RES. 995, 995 (1996) (describing the use of reverse transcriptase in a real-time quantitative PCR protocol to measure amounts of mRNA in a cell).

52. *See* Christian A. Heid, Junko Stevens, Kenneth J. Livak & P. Mickey Williams, *Real Time Quantitative PCR*, 6 GENOME RES. 986, 986–87 (1996) (describing real-time quantitative PCR techniques).

53. The diversity of inventions created by biotech innovation made it difficult for courts to apply a uniform standard in the early days of the biotech revolution. *See* PHILIPPE G. DUCOR, *PATENTING THE RECOMBINANT PRODUCTS OF BIOTECHNOLOGY AND OTHER MOLECULES* 1 (1998).

54. *See* 35 U.S.C. § 112 (2000).

55. *See* BURCHFIEL, *supra* note 18, at 3.

56. *See* Symposium, *Molecules vs. Information: Should Patents Protect Both?*, 8 B.U. J. SCI. & TECH. L. 190, 195 (2002) [hereinafter *Molecules*] (“[T]he subject matter of patents is limited to material products and processes and does not extend to knowledge and information about the world.”). For biotechnology, this seems counterintuitive, as the claimed subject matter (for example, a particular DNA sequence) is likely to be more valuable to scientists for its informational content, which becomes public after a patent is granted, than for any tangible sample of the nucleic acid that can be used in a lab. *See id.* at 198–99.

listed in 35 U.S.C. § 101.⁵⁷ However, despite this, patents claiming a DNA sequence, even without a physical embodiment of that sequence, typically are allowed by the PTO and are enforced by courts because of the link between the tangible nucleic acid and the information it encodes.⁵⁸

Defining the nature of the claimed subject matter of biotech inventions can also be difficult. For example, if an inventor claimed a genetically engineered cell line in a product patent, would such a patent also provide monopoly rights with regard to any processes performed by the cell line? The Federal Circuit addressed this question in *Amgen v. United States International Trade Commission*,⁵⁹ holding that “[a] host cell claim does not ‘cover’ intracellular processes any more or less than a claim to a machine ‘covers’ the process performed by that machine.”⁶⁰

Under the umbrella of product patents, inventors may claim such biological products as proteins,⁶¹ DNA sequences (including both protein-coding sequences and other sequences, such as plasmid vectors optimized for gene expression), and genetically engineered cell lines.⁶² Process claims can include methods of working with genetic material (such as protocols for cell transformation, gene sequencing, or PCR⁶³), cell culture methods, and systems of protein expression and purification.⁶⁴

2. Utility

All patented inventions must possess utility.⁶⁵ PTO Guidelines indicate that for an invention to be patentable, it must possess “specific, substantial, and credible utility.”⁶⁶

57. *See id.*

58. *See* Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 744 (2004).

59. 902 F.2d 1532 (Fed. Cir. 1990).

60. *Id.* at 1538 (internal footnotes omitted).

61. For an in-depth discussion of the patentability of proteins produced by recombinant genetic material, see generally David E. Huizenga, Comment, *P Protein Variants: A Study on the Differing Standards for Biotechnology Patents in the United States and Europe*, 13 EMORY INT’L L. REV. 629, 655–63 (1999).

62. *See* BURCHFIEL, *supra* note 18, at 21–22.

63. *See* McDowell, *supra* note 49, at 63.

64. *See* BURCHFIEL, *supra* note 18, at 25–26. If a gene has been isolated and inserted into a host cell to express the protein it encodes, the following are all patentable: the recombinant protein itself, the isolated genetic material, and the cell line containing the expression vector with the isolated gene. *See id.* at 20.

65. 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and *useful* process, machine, manufacture, or composition of matter, or any new and *useful* improvement thereof, may obtain a patent therefor”) (emphasis added). The utility requirement typically mandates that the inventor demonstrate that the invention possess both operability (the ability to create the result described by the specification) and practical utility (“real-world” benefits provided by the invention). *See* BURCHFIEL, *supra* note 18, at 48–50.

66. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001) (“The utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility.”); *see also* KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT 20–23 (The Bureau of National Affairs, Inc. ed., Supp. 2005) [hereinafter BURCHFIEL SUPPLEMENT].

For example, in *Brenner v. Manson*,⁶⁷ the Supreme Court held that a researcher could not patent a chemical compound merely because it had the potential to exhibit anti-tumor activity without scientific evidence that it actually demonstrated such activity.⁶⁸

The Federal Circuit generally has adhered to this requirement when considering the utility of biotech inventions.⁶⁹ Absolute proof of utility is usually not required—for example, in *Genentech, Inc. v. Chiron Corp.*,⁷⁰ the court held that expert testimony about a method for assaying a particular type of protein activity was sufficient to justify the district court's finding that the claimed recombinant protein possessed practical utility.⁷¹ However, in *In re Fisher*,⁷² the court held that an inventor could not patent expressed sequence tags⁷³ if their utility (and that of the genes from which they were derived) was unknown.⁷⁴

Professor Eisenberg has observed that the value of many biotech patents lies increasingly in their informational content, not in their potential use as templates to produce proteins.⁷⁵ Without knowing specifically the function of a particular gene sequence, an inventor will be ill-equipped to draft claims of the proper scope, to distinguish the sequence from very similar sequences present in the prior art, or to establish sufficient utility for patentability.⁷⁶ Thus, enforcing a strict utility requirement makes sense to prevent overbroad patent protection on DNA sequences of unknown function in order to avoid stifling innovation.

67. 383 U.S. 519 (1966).

68. *Id.* at 531–32. The Court rejected the inventor's argument that structural similarity to a known anti-tumor compound made his claimed compound likely also to exhibit the same properties. "Indeed, respondent himself recognized that the presumption that adjacent homologues have the same utility has been challenged in the steroid field because of a greater known unpredictability of compounds in that field." *Id.* at 532 (internal footnote omitted) (internal quotation marks omitted).

69. *But see* Jordan Paradise, Lori Andrews & Timothy Holbrook, *Patents on Human Genes: An Analysis of Scope and Claims*, 307 SCI. 1566, 1566 (2005) (suggesting that many issued patents on human genes do not have sufficient utility for patentability).

70. 220 F.3d 1345 (Fed. Cir. 2000); *see also* BURCHFIEL SUPPLEMENT, *supra* note 66, at 17–18.

71. *Genentech*, 220 F.3d at 1352.

72. 421 F.3d 1365 (Fed. Cir. 2005); *see also* BURCHFIEL SUPPLEMENT, *supra* note 66, at 18–20.

73. Expressed sequence tags (ESTs) are obtained by sequencing a short stretch (either from the 5' or 3' end) of a DNA clone obtained from a complimentary DNA (cDNA) library. cDNA libraries are created by reverse transcribing mRNAs from a given cell into cDNA and then inserting the cDNA clones into vectors for transformation of bacteria. Each bacterial colony (clone) in the library contains a plasmid with a single cDNA and thus represents a single mRNA from a single gene that was expressed at the time the cDNA library was created. ESTs are useful in identifying genes expressed by a particular type of cell, especially diseased cells. *See* The National Library of Medicine, The NCBI Handbook, Expressed Sequence Tags (ESTs), available at <http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=handbook.section.858>.

74. *Fisher*, 421 F.3d at 1373–74.

75. *Molecules*, *supra* note 56, at 196–97.

76. *See id.* at 198–99.

3. Enablement, Best Mode, and Nonobviousness

The Federal Circuit's strict utility requirement for biotech inventions goes hand in hand with its equally strict disclosure requirements⁷⁷ for this technology. Some commentators have proposed that the Federal Circuit has balanced these requirements by rarely finding biotech inventions unpatentable due to obviousness.⁷⁸

A disclosure must enable others skilled in the art to perform the invention and provide the best mode for doing so. Over the years, the expected abilities of one skilled in the art of biotechnology have changed,⁷⁹ essentially altering the enablement requirements for such inventions. For example, before the advent of recombinant technology, courts required the deposit of a sample of patented microorganisms to satisfy the enablement requirement,⁸⁰ but a deposit is no longer required unless one skilled in the art would need to perform "undue experimentation" to reproduce the invention.⁸¹ Similarly, to satisfy the best mode requirement,⁸² the Federal Circuit has required only "adequate disclosure;" inventors need not provide "a guarantee that every aspect of the specification be precisely and universally reproducible."⁸³ As with the utility requirement, the major justification for the enablement requirement is the concern that inventors might attempt to claim a broad genus of inventions without

77. A patent application must contain a written disclosure, which encompasses a *written description* of the invention, and of the manner and process of making and using it, in such full, clear, concise, and *exact terms* as to *enable* any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the *best mode* contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112 (2000) (emphasis added).

78. An invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2000); *see also infra* note 86.

79. For example, a person of ordinary skill in the art of recombinant technology would be expected to be able to create recombinant organisms using well-known methods. *See BURCHFIEL, supra* note 18, at 172.

80. *Id.* at 171.

81. *See In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988); *Ex parte Humphreys*, 24 U.S.P.Q.2d (BNA) 1255, 1261 (Bd. Pat. App. & Interf. 1992) (requiring deposit of a microorganism containing an antibiotic-producing plasmid for enablement, not simply the deposit of the plasmid); *see also BURCHFIEL, supra* note 18, at 173–75, 200–01. Although deposit is no longer required, it is still a simple method for satisfying both the enablement and best mode requirements for recombinant inventions. *See BURCHFIEL, supra* note 18, at 216; J. Jason Williams, Special Project Note, *Protecting the Frontiers of Biotechnology Beyond the Genome: The Limits of Patent Law in the Face of the Proteomics Revolution*, 58 VAND. L. REV. 955, 975–77 (2005) (observing that the Federal Circuit has relaxed its written description requirements for biotech inventions if inventors deposit the invention publicly) (citing *Enzo Biochem., Inc. v. Gen-Probe Inc.*, 285 F.3d 1013, 1020 (Fed. Cir. 2002), *vacated*, 296 F.3d 1316, 1320 (Fed. Cir. 2002)).

82. *See BURCHFIEL, supra* note 18, at 216.

83. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212 (Fed. Cir. 1991); *see also BURCHFIEL, supra* note 18, at 175–76.

actually making all of the forms of the invention as claimed.⁸⁴ As a result, the Federal Circuit has strictly enforced these disclosure requirements for biotech patents.⁸⁵

Typically, though, if the disclosure requirements in 35 U.S.C. § 112 are satisfied, the Federal Circuit has not found biotech patents void for obviousness.⁸⁶ Interestingly, Professors Dan Burk and Mark Lemley have observed that the court has not imposed the same stringent enablement and best mode requirements upon software patents as it has upon biotech patents.⁸⁷ Disclosing the function of software is sufficient to satisfy § 112; the inventors do not need to disclose more specific features, such as source code.⁸⁸ This makes sense given that biotech inventions incorporate natural elements and are thus inherently unpredictable, while software inventions are entirely man-made and much more predictable in their function.⁸⁹

84. See BURCHFIEL, *supra* note 18, at 187–88. For example, one cannot vaguely claim any DNA sequence producing a particular protein without disclosure of *exact* DNA sequences. Claims to very general methods for creating recombinant organisms raise similar concerns. *Id.* at 188. For a discussion of the dangers of overbroad patent rights in genomic research, see Sandy M. Thomas, *Genomics and Intellectual Property Rights*, 4 DRUG DISCOVERY TODAY 134, 135–36 (1999).

85. See, e.g., *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993). *Fiers* required that a patent on a human DNA sequence disclose the exact sequence and not merely a method of producing the sequence (in this case, by reverse transcription from a particular species of mRNA). *Id.* at 1171; see also *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); BURCHFIEL SUPPLEMENT, *supra* note 66, at 92–95. Citing *Fiers*, the Federal Circuit held that describing an invention as a strain of *E. coli* containing a human insulin gene obtained by reverse transcription of the mRNA corresponding to this gene was not sufficient to satisfy the written description and best mode requirements. *Eli Lilly*, 119 F.3d at 1566–67; see also *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (finding that claims to genetically engineered cyanobacteria were too broad when 150 genera of bacteria were claimed, but only nine genera and one particular species of cyanobacteria were disclosed); *Amgen*, 927 F.2d at 1213 (finding that claims to all DNA sequences capable of producing forms of erythropoietin were too broad); BURCHFIEL, *supra* note 18, at 191–94.

86. The Federal Circuit has only rarely found biotech inventions to be obvious in light of the prior art. See, e.g., *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995) (holding that a prior art reference describing proteins related to cDNAs claimed in the patent at issue did not render those claims obvious); *Vaeck*, 947 F.2d at 494 (holding that a reference suggesting that cyanobacteria serve as good hosts for photosynthetic genes does not render claims to a recombinant cyanobacterium containing non-photosynthetic genes obvious); BURCHFIEL SUPPLEMENT, *supra* note 66, at 52–53; BURCHFIEL, *supra* note 18, at 98–100. *But see Ex parte Goldgaber*, 41 U.S.P.Q.2d (BNA) 1172, 1173, 1176 (Bd. Pat. App. & Interf. 1995) (holding that claims to a DNA clone that was complimentary to a gene was obvious in light of a reference disclosing methods for producing probes that were complimentary to that gene); BURCHFIEL SUPPLEMENT, *supra* note 66, at 53–55. One commentator argues that *Deuel* uprooted years of patent policy, essentially ignoring § 103 in the context of “newly retrieved natural DNA sequences.” DUCOR, *supra* note 53, at 76.

87. Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1167–70, 1178–83 (2002).

88. *Id.* at 1162 (citing *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 934 (Fed. Cir. 1990)).

89. “[U]npredictability in performance of certain species or subcombinations other than those specifically enumerated” is the primary justification for courts’ refusal to enforce chemical patents beyond the exact letter of the claims or disclosure. *In re Smythe*, 480 F.2d

4. Claim Construction and Infringement

To determine if infringement has occurred literally or through the doctrine of equivalents,⁹⁰ a judge⁹¹ must consider the language of each claim, its specification, the prosecution history, and any other relevant evidence in a process known as claim construction.⁹² Not surprisingly, in light of the Federal Circuit's stringent disclosure requirements for biotech patents, the court has interpreted biotech claims narrowly,⁹³ although some district courts and the Federal Circuit have occasionally departed from this general rule.⁹⁴

5. The Big Picture

In general, the Federal Circuit has been loath to enforce biotech patents beyond the exact letter of the disclosure and claims. This would seem to make issues of infringement easy to decide—in general, if something is identical to what is claimed or disclosed in the patent, it infringes, but if it varies *at all* (including by just a few amino acids or nucleotides), it does not. Rare exceptions to this rule do exist, but no federal court has ever held that a patent that only claims a recombinant protein also confers monopoly rights with regard to its associated mRNA and DNA, or that a patent on a particular method for cell transformation or PCR also covers the reagents utilized in that method. Beyond the claims and disclosure, courts cut off protection.

However, such precursors, reagents, or other elements used to create a patented biotech invention could constitute “components” of such a patented invention under § 271(f) given the Federal Circuit's recent expansion of the § 271(f) doctrine, even after

1376, 1383 (C.C.P.A. 1973) (internal footnote omitted).

90. BURCHFIEL, *supra* note 18, at 239–40; *see also infra* note 102.

91. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996) (holding that claim construction “is an issue for the judge, not the jury”).

92. *E.g.*, *Senmed, Inc. v. Richard-Allan Med. Indus., Inc.*, 888 F.2d 815, 818–19 (Fed. Cir. 1989).

93. *See, e.g.*, *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1561–62, 1569 (Fed. Cir. 1994) (defining the term “specific activity” narrowly with reference to an enzymatic patent); *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d 1558, 1563 (Fed. Cir. 1990) (holding that claims indicating that the patented protein corresponded to a particular amino acid sequence limited the claimed invention to only peptides with that *exact* sequence); BURCHFIEL, *supra* note 18, at 245–48.

94. For an example of broad claim construction involving a protein patent, see *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1580–81 (Fed. Cir. 1991) (holding that claim language covering “a human VIII:C preparation” covered both VIII:C that was purified from human plasma and also recombinant human VIII:C). BURCHFIEL, *supra* note 18, at 245. In addition, a recent \$65.2 million district court verdict in favor of Ariad Pharmaceuticals, owner of a very broad patent claiming hundreds of methods of inhibiting nuclear transcription factor NF- κ B, has alarmed many in the pharmaceutical and biotech industries. Ken Garber, *Decision on NF- κ B Patent Could Have Broad Implications for Biotech*, 312 SCI. 827, 827 (2006). Defendant Eli Lilly had obtained patents on two pharmaceuticals that inhibited NF- κ B activity years before the Ariad patent was issued. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, No. 02-11280-RWZ, 2003 WL 21087115, at *1 (D. Mass. May 12, 2003). While the jury verdict has not been reviewed by the Federal Circuit, it is potentially problematic for the manufacturers of hundreds of pharmaceuticals that inhibit NF- κ B in some manner. Garber, *supra*, at 827.

the Supreme Court's limitation of the statute's reach in *Microsoft Corp. v. AT&T Corp.*⁹⁵ As a result, a biotech patent holder might have more extensive rights internationally than within the United States.⁹⁶ Such a development threatens to uproot the traditionally limited enforceability of biotech patents.

II. EXTRATERRITORIAL PATENT PROTECTION: 35 U.S.C. § 271(F)

A. The Famous "Loophole"

Courts and legislators generally agree that patent protection granted within the United States does not extend beyond its territories.⁹⁷ For many years, this limitation was fairly simple to understand. However, after World War II, many American businesses expanded abroad, and international infringement became much more of a concern for many patent holders,⁹⁸ as competitors of a patentee could easily send production of infringing articles overseas and thus avoid liability.

The Supreme Court's 1972 decision in *Deepsouth Packing Co. v. Laitram Corp.*⁹⁹ illustrated a significant gap in United States patent law. Laitram owned several combination patents¹⁰⁰ on machines used to devein shrimp,¹⁰¹ and Deepsouth had manufactured infringing deveining machines and sold them within the United States

95. 127 S. Ct. 1746 (2007).

96. It is interesting to note that the language of § 271(f) is similar to that contained in § 271(b) and § 271(c), statutes governing domestic infringement. Both § 271(b) and § 271(f)(1) require active induction of infringement for liability, and both § 271(c) and § 271(f) assign infringement liability for activities involving components of patented inventions:

Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination, or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C. § 271(c) (2000). However, the Federal Circuit has not addressed the effect of expanding the definition of a § 271(f) "component" on the scope of a § 271(c) "component," and I will not address it in this Note.

97. Even as early as 1870, patent statutes contained territorial limitations on their enforcement. Alan M. Fisch & Brent H. Allen, *The Application of Domestic Patent Law to Imported Software: 35 U.S.C. § 271(f)*, 25 U. PA. J. INT'L ECON. L. 557, 559–60 (2004). Early case law also reflected this limitation. *See, e.g., In re Amtorg Trading Corp.*, 75 F.2d 826, 832 (C.C.P.A. 1935) (holding that use of a patented process in Russia did not infringe the patent, because the patentee did not own a corresponding Russian patent, and United States patent laws did not apply abroad); BURCHFIEL, *supra* note 18, at 311.

98. Fisch & Allen, *supra* note 97, at 561.

99. 406 U.S. 518 (1972).

100. A combination patent protects "an invention that unites existing components in a novel way." BLACK'S LAW DICTIONARY 1157 (8th ed. 2004).

101. "[Shrimp] carry their intestines, commonly called veins, in bags (or sand bags) that run the length of their bodies . . . [I]f the vein is removed, shrimp become more pleasing to the fastidious as well as more palatable." *Laitram Corp. v. Deepsouth Packing Co.*, 301 F. Supp. 1037, 1040 (E.D. La. 1969).

and also internationally. The Supreme Court accepted the district court's finding that Deepsouth had infringed Laitram's patent within the United States,¹⁰² but refused to hold that Deepsouth's international shipment of the components of the patented invention¹⁰³ constituted infringement.¹⁰⁴

When Congress enacted § 271(f) in 1984, the drafters explicitly stated that the new statute was intended to "close a loophole in patent law."¹⁰⁵ The original proposed form of § 271(f) stated:

Whoever without authority supplies or causes to be supplied in the United States the material components of a patented invention, where such components are uncombined in whole or in part, intending that such components will be combined outside of the United States, and knowing that if such components were combined within the United States the combination would be an infringement of the patent, shall be liable as an infringer.¹⁰⁶

One patent official, Gerald Mossinghoff, expressed concern that the proposed statute might prevent the exportation of components "suitable for substantial noninfringing use."¹⁰⁷ He also proposed removing the knowledge requirement,¹⁰⁸ because patent

102. "The patent provisions taken in conjunction with the judgment below also entitle Laitram to the injunction it has received prohibiting Deepsouth from continuing to make or, once made, to sell devenirs throughout the United States." *Deepsouth*, 406 U.S. at 523 (internal quotation marks omitted); see also *Laitram Corp.*, 301 F. Supp. at 1059 (finding that Deepsouth did not literally infringe Laitram's patent, but infringed under the doctrine of equivalents). A court may find infringement under the doctrine of equivalents when a device performs "substantially the same function in substantially the same way to obtain the same result." *Id.* at 1058 (quoting *Sanitary Refrigerator Co. v. Winters*, 280 U.S. 30, 42 (1929)).

103. Deepsouth had shipped deveining machines to international customers completely assembled except for two parts and admittedly did so to avoid liability within the United States, writing to one customer,

We are handicapped by a decision against us in the United States. This was a very technical decision and we can manufacture the entire machine without any complication in the United States, with the exception that there are two parts that must not be assembled in the United States, but assembled after the machine arrives in Brazil.

Deepsouth, 406 U.S. at 523 n.5 (quoting *Laitram Corp. v. Deepsouth Packing Co.*, 443 F.2d 928, 938 (5th Cir. 1971)).

104. "If Laitram has a right to suppress Deepsouth's export trade it must be derived from its patent grant, and thus from the patent statute. We find that 35 U.S.C. § 271, the provision of the patent laws on which Laitram relies, does not support its claim." *Id.* at 526 (internal footnotes omitted). Laitram argued that Deepsouth should be liable for contributory infringement under 35 U.S.C. § 271(c), but the Court held that in the absence of direct infringement under 35 U.S.C. § 271(a), contributory infringement did not take place. *Deepsouth*, 406 U.S. at 526. The Court also rejected the Fifth Circuit's holding that manufacturing the components of Laitram's patent and shipping them abroad with the intent that they be assembled constituted "mak[ing]" the patented invention for the purposes of infringement under 35 U.S.C. § 271(a). *Deepsouth*, 406 U.S. at 525-26.

105. 130 CONG. REC. 28,065, 28,069 (1984) (statement of Rep. Kastenmeier).

106. S. 1535, 98th Cong. § 1 (1984).

107. *Patent Law Improvements Act: Hearing Before the Subcomm. on Patents, Copyrights, & Trademarks of the Comm. on the Judiciary on S. 1535 & S. 1841*, 98th Cong. 26 (1984)

infringement within the United States does not require knowledge.¹⁰⁹ Other hearing witnesses agreed that courts would have an extraordinarily difficult time proving that a party knowingly committed infringement under these circumstances.¹¹⁰

The final enacted version of § 271(f) contains two slightly different subsections, with subsection (1) requiring the international shipment of “all or a substantial portion of the components of a patented invention” in a manner actively inducing the combination of the components abroad, but not requiring knowledge,¹¹¹ and with subsection (2) requiring the shipment of “any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use” with *knowledge* that the component is adapted for use in the invention and intending that the component will be incorporated into the patented invention abroad.¹¹² An infringer’s knowledge and intent to infringe are key in § 271(f)—if present, shipping a single component specially adapted for incorporation into the patented invention is sufficient to cause liability, even if the component is never incorporated into the patented invention, under § 271(f)(2).¹¹³

B. The Early Years of § 271(f)

In the first years after the enactment of § 271(f), courts focused on the subsection’s requirement that an infringer ship “components” abroad, thus applying the subsection only to product patents that contained discrete components,¹¹⁴ especially mechanical devices.¹¹⁵ Later, courts also applied § 271(f) to non-mechanical inventions such as chemical combination patents.¹¹⁶

[hereinafter *1984 Hearing*] (statement of Gerald J. Mossinghoff, Assistant Secretary and Commissioner of Patents and Trademarks, United States Patent and Trademark Office). Mossinghoff also suggested that the bill include an exception to liability for the exportation of staple articles of commerce. *Id.* at 26 (citing 35 U.S.C. § 271(c) (2000)). The enacted version of the bill contains such a limitation in subsection (2). Infringement does not occur if the exported component is “a staple article or commodity of commerce suitable for substantial noninfringing use.” 35 U.S.C. § 271(f)(2) (2000).

108. *1984 Hearing*, *supra* note 107, at 26–27.

109. Knowledge is not required for liability for the direct infringement of a patent. 35 U.S.C. § 271(a) (2000). Knowledge *is* required for contributory infringement of a patent, but without an act of direct infringement resulting from the act of contributory infringement, an infringer cannot be held liable. 35 U.S.C. § 271(c) (2000).

110. *See, e.g., 1984 Hearing*, *supra* note 107, at 61–62 (statement of Bernarr R. Pravel, president, American Intellectual Property Law Association).

111. 35 U.S.C. § 271(f)(1) (2000).

112. 35 U.S.C. § 271(f).

113. *Id.*

114. *See* Fisch & Allen, *supra* note 97, at 567–68. The idea that § 271(f) was meant to apply only to product patents is supported by statements made during the pre-enactment hearing. *See, e.g., 1984 Hearing*, *supra* note 107, at 60–62 (discussing the implications of proposed § 271(f) under the heading “Product Patent Rights”).

115. *See, e.g.,* T.D. Williamson, Inc. v. Laymon, 723 F. Supp. 587, 593 (N.D. Okla. 1989) (holding that shipping most of the components of a patented mechanical invention to Venezuela, where they were combined into the final invention, violated § 271(f)(1)); Fisch & Allen, *supra* note 97, at 568 n.50.

116. *See* Fisch & Allen, *supra* note 97, at 568–70. Recently, courts have rejected the

However, courts refused to apply § 271(f) to process patents for many years due to its explicit requirement that components of a patented invention be *combined* abroad to constitute infringement. For example, in *Standard Havens Products, Inc. v. Gencor Industries, Inc.*,¹¹⁷ the Federal Circuit refused to apply § 271(f) to a company's foreign sales of a machine that utilized a patented process.¹¹⁸ One common justification for this refusal to apply § 271(f) to process patents was another infringement statute, 35 U.S.C. § 271(g),¹¹⁹ which assigns liability for the import, but not the export, of any product made by a patented process.¹²⁰

Courts also refused to extend § 271(f) liability to design patents, as such patents are composed of a single, indivisible unit and thus do not contain multiple "components" per se.¹²¹ The Federal Circuit also refused to endorse § 271(f) liability when no *physical* components of a patented invention were exported from the United States, even when the alleged infringer had exported the instructions to assemble infringing items abroad.¹²²

C. Expanding § 271(f) Liability

In recent years, the Federal Circuit expanded the application of § 271(f) to inventions containing intangible "components," starting with its decision in *Eolas Technologies, Inc. v. Microsoft Corp.*¹²³ Eolas owned a software product patent¹²⁴ and

argument that § 271(f) only prohibits the export of components of mechanical combination patents. *See, e.g.,* Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 95 Civ. 8833, 2001 U.S. Dist. LEXIS 16895, at *6–*9 (S.D.N.Y. Oct. 18, 2001) (determining the identity of components of a chemical product patent under § 271(f)); W.R. Grace & Co.-Conn. v. Intercat, Inc., 60 F. Supp. 2d 316, 321 (D. Del. 1999) ("Nowhere in the statute or its legislative history is there a limitation to components of machines and other structural combinations."); Lubrizol Corp. v. Exxon Corp., 696 F. Supp. 302, 325 (N.D. Ohio 1988) (issuing a preliminary injunction preventing defendant from supplying a patented lubricant additive from the United States "for combination in a lubricating composition outside the United States").

117. 953 F.2d 1360 (Fed. Cir. 1991).

118. *Id.* at 1374.

119. "Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer . . ." 35 U.S.C. § 271(g) (2000).

120. *See, e.g.,* Enpat, Inc. v. Microsoft Corp., 6 F. Supp. 2d 537, 538–39 (E.D. Va. 1998). One district court found that § 271(g) provided evidence that Congress knew how to draft a statute to protect against extraterritorial infringement of process patents and, therefore, must have intended § 271(f) to apply only to product patents. *Id.*; *see also* Fisch & Allen, *supra* note 97, at 572. In *Enpat*, the court rejected several arguments later embraced by the Federal Circuit in cases such as *AT&T* and *Eolas*. *See* discussion *infra* Part II.C. Despite the fact that the process patent involved "components" such as a computer server, the court concluded that § 271(f) only applied to the assembly of components of a product patent abroad. *Enpat*, 6 F. Supp. 2d at 539.

121. *See, e.g.,* Aerogroup Int'l, Inc. v. Marlboro Footworks, Ltd., 955 F. Supp. 220, 232 (S.D.N.Y. 1997) (holding that § 271(f) does not apply to a design patent for a shoe sole).

122. *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117–18 (Fed. Cir. 2004). Even given the recent expansion of § 271(f) liability, the Federal Circuit has never held that § 271(f) applies to design patents. *See id.* ("[T]here can be no liability under § 271(f)(1) unless components are shipped from the United States for assembly.").

123. 399 F.3d 1325, 1338–40 (Fed. Cir. 2005).

124. U.S. Patent No. 5,838,906 (filed Oct. 7, 1994).

alleged that Microsoft's Internet Explorer browser infringed several of its claims.¹²⁵ Section 271(f) was invoked because Microsoft had shipped golden master disks containing the Windows operating system (which included Internet Explorer) to international computer manufacturers that would then install Windows and Internet Explorer on new computers.¹²⁶ The court observed that the plain language of § 271(f) does not impose a tangibility requirement upon components¹²⁷ and found that since the unpatented software code contained on the golden master disks was essential to Eolas's patented product, it could constitute a component of the final patented invention for the purposes of § 271(f).¹²⁸

Later in 2005, in *Union Carbide Chemicals & Plastics Technology Corp. v. Shell Oil Co.*,¹²⁹ the Federal Circuit held that a catalyst¹³⁰ could be a component of a patented chemical process under § 271(f).¹³¹ The district court had held that Shell directly and contributorily infringed Union Carbide's process patent with its catalysts that performed the patented process, but excluded Shell's international sales of these catalysts from its calculation of damages due to its conclusion that § 271(f) "[did] not apply to process claims."¹³² The Federal Circuit held that § 271(f) could apply to process patents and remanded the case for a calculation of damages that accounted for Shell's sales of its infringing catalysts abroad.¹³³

The court revisited *Eolas* in *AT&T Corp. v. Microsoft Corp.*¹³⁴ and went even further in attaching § 271(f) liability to intangible components of a product patent, affirming a district court judgment that held Microsoft liable for infringement of AT&T's software patent by installing Windows on foreign computers from *copies* of

125. *Eolas*, 399 F.3d at 1325.

126. *Id.* at 1331.

127. *Id.* at 1338–40.

128. *Id.* at 1339 ("Without this aspect of the patented invention, the invention would not work at all and thus would not even qualify as new and 'useful.'"). Also, the court first considered the application of § 271(f) to process patents: "This court cannot construct a principled reason for treating process inventions different than structural products." *Id.*

129. 425 F.3d 1366 (Fed. Cir. 2005).

130. A catalyst helps to increase the rate of a chemical reaction, "may or may not actually take part chemically in the reaction," and usually will not be incorporated into the final reaction product. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 350 (1993).

131. *Union Carbide*, 425 F.3d at 1381.

132. *Id.* at 1369.

133. *Id.* at 1381. Several members of the court dissented vigorously from the denial of rehearing en banc, noting, "A component of a process is a step in the process; it is not the physical material to be used in the process." *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 434 F.3d 1357, 1358 (Fed. Cir. 2006). However, the court also has observed that process patents seem less likely to be infringed under § 271(f). *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1322 (Fed. Cir. 2005) ("[I]t is difficult to conceive of how one might supply or cause to be supplied all or a substantial portion of the steps of a patented method in the sense contemplated by the phrase 'components of a patented invention' in section 271(f) . . .").

134. 414 F.3d 1366 (Fed. Cir. 2005). AT&T alleged that Microsoft had infringed its patent on a particular type of "speech codec" (software for digitizing and replaying speech) through features in its Windows operating system. *Id.* at 1367–68 & n.1.

golden master disks exported from the United States,¹³⁵ not the exported disks themselves. Microsoft unsuccessfully argued that the software copied from the golden master disks it had shipped abroad was manufactured abroad and thus was not “supplied from the United States.”¹³⁶ In rejecting this argument, the court observed that making copies was inherent in the nature of software, and thus, “the act of copying is subsumed in the act of supplying, such that sending a single copy abroad with the intent that it be replicated invokes § 271(f) liability for those foreign-made copies.”¹³⁷

Microsoft appealed the Federal Circuit’s decision to the Supreme Court, and the Court granted certiorari on October 27, 2006.¹³⁸ Microsoft’s petition for certiorari first questioned whether software code should be considered a component under § 271(f),¹³⁹ arguing that the expansion of liability under § 271(f) “eviscerate[s] the well-established ‘right’ of American software companies ‘to compete with an American patent holder in foreign markets,’”¹⁴⁰ exposing companies such as Microsoft to increased international liability and encouraging them to relocate research facilities abroad to avoid § 271(f) liability.¹⁴¹

Microsoft also argued that intangible attributes of an invention cannot be considered components under § 271(f) because they are not “constituent part[s]” of the invention¹⁴² and cannot be “combined” with anything in the strictest sense of the word.¹⁴³ Finally, Microsoft disputed the panel’s finding that the copies of the golden master disk made abroad were supplied from the United States and thus infringed under § 271(f).¹⁴⁴ Judging from the number of amicus curiae briefs filed in the case, Microsoft’s position had more supporters than the expansive position adopted by the Federal Circuit panel.¹⁴⁵

135. *Id.* at 1370. The court rejected Microsoft’s argument that the software code simply created the invention and thus was not a component for the purposes of § 271(f). *Id.* (citing *Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1118 (Fed. Cir. 2004)).

136. *Id.*

137. *Id.* (internal quotation marks omitted).

138. *See* *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 467, 467 (2006).

139. Petition for Writ of Certiorari at 12, *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746 (2007) (No. 05-1056), 2006 WL 403897. Microsoft argued that software code actually constitutes design information and the Federal Circuit’s expansion of liability would also necessitate that “blueprints, formulas, and methodologies” would be components under § 271(f). *Id.*

140. *Id.* at 11 (quoting *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972)).

141. *Id.* at 11–12.

142. *Id.* at 15–16 (quoting WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 466 (1993)).

143. The dictionary definition cited by Microsoft defines “combine” as “to join in physical or chemical union.” *Id.* at 16 (quoting WEBSTER’S THIRD NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 452 (1993)).

144. *Id.* at 18. Judge Rader dissented on these grounds from the Federal Circuit panel’s decision in *AT&T*, arguing that sending the golden master disk abroad was the only action that could be considered “supplying” under § 271(f). *AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366, 1373 (Fed. Cir. 2005) (Rader, J., dissenting).

145. Numerous parties filed amicus curiae briefs in support of Microsoft. *See, e.g.*, Brief Amici Curiae of Intellectual Property Professors in Support of Reversal, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3740618 (Dec. 15, 2006); Brief of Amicus Curiae Yahoo! Inc. in Support of Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3723904

D. Microsoft at the Supreme Court: Curtailing the Expansion of § 271(f)

The Supreme Court decided *Microsoft Corp. v. AT&T Corp.* on April 30, 2007,¹⁴⁶ with seven Justices voting to reverse the Federal Circuit and with Justice Ginsburg delivering the majority opinion.¹⁴⁷ Justice Stevens was the lone dissenter.¹⁴⁸ The majority boiled its analysis down to two key questions: “First, when, or in what form, does software qualify as a ‘component’ under § 271(f)? Second, were ‘components’ of the foreign-made computers involved in this case ‘supplied’ by Microsoft ‘from the United States’?”¹⁴⁹ In addressing these questions, the Court considered two different possibilities for conceptualizing software—first, as “software in the abstract: the instructions themselves detached from any medium,”¹⁵⁰ and, second, as “a tangible ‘copy’ of software, the instructions encoded on a medium such as a CD-ROM.”¹⁵¹

The majority adopted the first definition of software (or, “the notes of Beethoven’s Ninth”)¹⁵² and held that software in this form could not constitute a component under § 271(f) because “any software detached from an activating medium . . . remains uncombinable.”¹⁵³ As a result, the Court held that the copies of Windows that were made abroad from golden master disks exported from the United States and then were installed onto foreign-made computers could not infringe AT&T’s patent under § 271(f) because they were not themselves “supplied from the United States.”¹⁵⁴

(Dec. 15, 2006); Brief of Shell Oil Company as Amicus Curiae in Support of Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3740358 (Dec. 15, 2006); Brief of Amicus Curiae Eli Lilly and Co. in Support of Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3740360 (Dec. 15, 2006); Brief of Intel Corp. as Amicus Curiae in Support of Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3740361 (Dec. 15, 2006); Brief of Amazon.com, Inc., Mentor Graphics Corp. & Wacom Tech. Corp. as Amici Curiae in Support of Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3723905 (Dec. 14, 2006). Other parties, such as the American Intellectual Property Law Association, filed amicus briefs that only disagreed with the Federal Circuit that copies of the master disk made abroad are “supplied” from the United States. Brief of American Intellectual Property Law Ass’n as Amicus Curiae in Support of Neither Party, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3746711, at *11 (Dec. 15, 2006).

146. 127 S. Ct. 1746 (2007).

147. Justice Ginsburg authored the majority opinion except as to footnote 14. *Id.* at 1750.

148. Justice Stevens sided with the Federal Circuit panel due to his belief that its decision took into account Congress’s intent in enacting § 271(f) to protect not only physical items such as the deveining knife in *Deepsouth*, but also software in the abstract. *Id.* at 1762–63 (Stevens, J., dissenting). “[I]f a disk with software inscribed on it is a ‘component,’ I find it difficult to understand why the most important ingredient of that component is not also a component.” *Id.* at 1763.

149. *Id.* at 1753–54.

150. *Id.* at 1754. Justice Ginsburg analogized this concept of “software” to the “notes of Beethoven’s Ninth Symphony.” *Id.*

151. *Id.* (analogizing this concept of “software” to “[s]heet music for Beethoven’s Ninth”).

152. *Id.*

153. *Id.* at 1755.

154. *Id.* at 1757 (“Under this formulation, the very components supplied from the United States, and not copies thereof, trigger § 271(f) liability when combined abroad to form the patented invention at issue.”). Justice Ginsburg also favorably cited Judge Rader’s dissenting opinion protesting that supplying a component and copying a component were different actions

In his concurrence, Justice Alito opined that Microsoft did not infringe AT&T's patent under § 271(f) because "no physical object originating in the United States was combined with these computers"¹⁵⁵ Justice Alito would have only found § 271(f) infringement if the Windows CD-ROM needed to be present in a computer's CD-ROM drive for the software to function properly—or, in other words, if the CD-ROM disk were *physically* combined with the computer.¹⁵⁶

After *Microsoft*, information on its own cannot qualify as a "component" under § 271(f). However, as long as an information-based component of an invention is exported in a physical form that could be used to create the final invention abroad, § 271(f) infringement can still occur.

III. SECTION 271(F) AND BIOTECH

Given the unique dual nature of many biotech inventions (in that they are tangible, but also serve as an intangible medium for information storage and transmittal),¹⁵⁷ changes in the § 271(f) doctrine will affect biotech patents, but in a manner distinct from both mechanical and software patents. Applying the statute to biotech inventions could be very confusing given the current state of the doctrine. As a result, this Part concludes that a biotech-specific amendment to § 271(f) would lend force to the policies underlying § 271(f) without requiring courts to reanalyze the scope of the statute's application in the complicated field of biotechnology.

A. Biology, Chemistry, and Extraterritoriality

Several district court cases illustrate the complexity that has accompanied the application of § 271(f) to biotech and chemical patents in the past.

1. Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.

In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*,¹⁵⁸ one district court began its analysis by identifying the patented chemical compound's § 271(f) components¹⁵⁹ from the perspective of one of ordinary skill in the art of organic

and the ease of copying computer software did not mean that copying was the same as supplying for the purposes of § 271(f) infringement. *Id.* at 1756–57 (citing *AT&T Corp. v. Microsoft Corp.*, 414 F.3d 1366, 1373–74 (Fed. Cir. 2005) (Rader, J., dissenting)). The Court also relied upon the general presumption against extraterritoriality to justify its finding of non-infringement. *Id.* at 1758.

155. *Id.* at 1762 (Alito, J., concurring).

156. *Id.*

157. See Symposium, *Use of Patented Research Tools Abroad: Loophole or Liability?*, 8 B.U. J. SCI. & TECH. L. 218, 219 (2002) (analogizing information contained by the genetic code to the informational content of software).

158. 95 Civ. 8833, 2001 U.S. Dist. LEXIS 16895 (S.D.N.Y. Oct. 18, 2001).

159. *Id.* at *9–*11. The court held that § 271(f) applied to chemical patents, despite the fact that chemical compounds are "not generally described as having components." *Id.* at *6–*9. However, the court also observed that "conceptually it is difficult to apply 35 U.S.C. § 271(f) to patents for chemicals" because atoms, the smallest constituents of matter, make up patented molecules. *Id.* at *7 n.3.

chemistry, concluding that the core chemical structure and its side chains¹⁶⁰ fit the bill.¹⁶¹ The court then rejected Bristol-Myers Squibb's claims under § 271(f)(1) because only one of these components (the side chain, in the form of its precursor molecule) had been supplied from the United States.¹⁶²

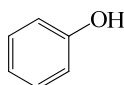
One can extend the logic of *Bristol-Myers Squibb* to cases involving biotech product patents, especially those claiming macromolecules such as genes and proteins. Such molecules are considerably more complex than the small molecule at issue in *Bristol-Myers Squibb* and thus would contain thousands of individual components as defined in that case. As a result, following the *Bristol-Myers Squibb* court's analysis to the letter would be unmanageable in the context of biological macromolecules.¹⁶³

Redefining "components" from the viewpoint of a person of ordinary skill in the art of biotechnology leads to several possible results. Genes are formed from individual nucleotides, and proteins are formed from individual amino acids;¹⁶⁴ so one might classify these constituents as § 271(f) components. On a broader scale, researchers also could classify large regions of gene or protein sequences as components of patented products under § 271(f). For example, distinct sections of a protein, known as domains,

160. An example (not the structure at issue in *Bristol-Myers Squibb*) of a simple core chemical structure is a benzene ring:



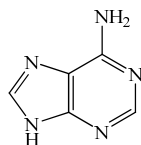
A common side chain is an alcohol group: OH-
Under the court's analysis in *Bristol-Myers Squibb*, these "components" make up the following compound (phenol):



161. *Bristol-Myers Squibb*, 2001 U.S. Dist. LEXIS 16895, at *9-*10. The court's conclusion resulted from the testimony of both parties' expert witnesses, who testified that the core structure and its side chain were the two "parts" or "components" of the patented molecule. *Id.* at *10.

162. *Id.* at *11-*14. Section 271(f)(1) requires that a "substantial portion" of the components be supplied from the United States for infringement to occur. A single component supplied from the United States is not sufficient to trigger § 271(f)(1) liability. *Id.* (citing *Windsurfing Int'l v. Fred Ostermann, GmbH*, 668 F. Supp. 812, 819-20 (S.D.N.Y. 1987)).

163. Consider, for example, what would occur if a court followed *Bristol-Myers Squibb* in classifying all of the attributes of a single nucleic acid base, adenine, as § 271(f) components of a recombinant DNA invention:



Likely, each of the rings would be a component, in addition to the amine (NH₂) side chain. Considering that all bases would thus contain three or four components, a typical gene that is 1200 nucleotides in length would contain approximately five thousand components. See WATSON ET AL., *supra* note 32, at 42-43.

164. See *supra* text accompanying notes 31-37.

often have specific functions that are enzymatic or structural in nature.¹⁶⁵ Furthermore, a particular amino acid sequence encoding a membrane-spanning protein domain¹⁶⁶ serves as a component of a complete protein in the same manner that a side chain is a component of a small molecule—the amino acid sequence is essential to certain properties of the protein.¹⁶⁷

Similarly, many genes also contain distinct functional units. These functional units can occur within the protein-coding region itself as exons¹⁶⁸ or within nontranscribed genetic sequences, including introns,¹⁶⁹ regulatory sequences such as promoter regions, and other control regions.¹⁷⁰ From this perspective, one can see how inventions created with the tools of biotechnology¹⁷¹ could be made up of distinct genetic or protein components that form the final product¹⁷² but are larger than single nucleotides or amino acids.

In addition to classifying physically distinct regions of a molecule as components under § 271(f), *Bristol-Myers Squibb* contains an additional layer of analysis. After deciding that the core structure and the side chain of the patented compound were its § 271(f) components, the court then assumed that precursor molecules (the compounds from which the patented compound was produced) to each of these components *also* were components under § 271(f).¹⁷³ Classifying both intangible elements and unpatented precursor molecules as § 271(f) components opens the door to conferring this crucial status on unpatented precursors that are used to create a patented biotech invention *but do not become a physical part of it*. In the biotech context, such unpatented precursor “components” might include a DNA sequence encoding a

165. See GARRETT & GRISHAM, *supra* note 29, at 120–26.

166. See *id.* at 115.

167. Membrane-spanning domains are essential to the formation of many different proteins that interact with membranes, such as ion transporters. See *id.* at 301–03. Another example of a protein domain with a distinct function is the heme-binding protein domain contained within the oxygen-transport proteins hemoglobin and myoglobin. See *id.* at 480–81.

168. An exon is a region of a eukaryotic gene which is represented in the final mRNA and exits the nucleus for translation in the cytoplasm of a cell. Regions of a gene that are removed from the final mRNA are known as introns. See WATSON ET AL., *supra* note 32, at 137. The exon/intron organization of eukaryotic genes allows for greater efficiency in genetic information storage, as a single gene may produce several different mRNAs based on differential splicing. See *id.* at 140. In some cases, exons even correspond to functional protein domains when expressed. *Id.* at 140–41.

169. See *supra* note 168.

170. A promoter region of DNA binds to RNA polymerase enzyme to initiate transcription of a gene. See WATSON ET AL., *supra* note 32, at 51.

171. See DUCOR, *supra* note 53, at 62 (describing the creation of chimeric biotech inventions, such as genes or expression vectors, by combining large portions of preexisting genetic material); *supra* notes 40–45 and accompanying text.

172. For example, if researchers are interested in creating a chimeric hybrid of genes A and B, and both genes contain the same restriction site, they could cut the genes with that restriction enzyme and then combine the 5' end of A with the 3' end of B to create a patentable invention. The final A-B hybrid would contain physical parts of both precursors, and, thus, the precursors would be classified as components under § 271(f).

173. See *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 95 Civ. 8833, 2001 U.S. Dist. LEXIS 16895 (S.D.N.Y. Oct. 18, 2001), at *11.

patented recombinant protein or an expression vector used in the creation of a patented cell line.

In light of the Federal Circuit's very specific disclosure requirements for biotech patents and its reluctance to allow biotech patent enforceability beyond the exact letter of the claims or disclosure,¹⁷⁴ this approach should disturb the reader. Courts could prohibit the export of unpatented biological precursors, thus allowing more substances to be protected by the patent abroad than would be protected within the United States.

Even after the Supreme Court's *Microsoft* decision somewhat curtailed the expansion of § 271(f), subsection (f)(1)'s requirement that exported components be "combined" abroad for extraterritorial liability remains almost nonexistent. Instead, an exported component must only be utilized to manufacture a patented product abroad,¹⁷⁵ but not necessarily "combined" with anything, to violate the statute.¹⁷⁶ Just like software on a master disk, an unpatented gene sequence is not *combined* with anything per se to produce a patented protein, but instead indicates the design of the final product to a cell's transcription and translation machinery.¹⁷⁷ Eliminating the combination requirement seems likely to move the Federal Circuit even further away from its previously narrow construction of biotech patents.¹⁷⁸

The expansion of the definitions of "component" and "combination" also greatly affects the scope of § 271(f)(2) in its application to biotech product patents. Subsection (f)(2) only requires intent to combine at least one specially adapted component "in a manner that would infringe the patent if such combination occurred within the United States,"¹⁷⁹ but when the court has already stripped "combination" of all its usual meaning, all that remains is the requirement that an infringer intend to utilize the component in some manner to form the final invention for § 271(f)(2) liability. Not requiring proof of assembly for liability under this subsection alleviates the burden of proof on the patentee, but allowing liability for infringement, even if actual combination has not taken place, further expands the rights of biotech patent holders, rights that the Federal Circuit has previously limited.

174. See *supra* Part I.B.

175. See *Molecules*, *supra* note 56, at 196 ("A 'tangible' now seems to mean 'useful,' rather than something material."); *supra* Part II.D.

176. Of course, after *Microsoft*, the exported component *itself* must be utilized for the production of the final product to invoke § 271(f). Copies of a component made abroad do not violate the statute. However, the Court did not contest the fact that if the exported disks themselves had been utilized to install Windows and Internet Explorer on the foreign computers, Microsoft would have clearly violated § 271(f), despite the fact that the software has not really been "combined" per se with anything except the hardware and software on the computer. See *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746, 1755 (2007).

177. See *supra* notes 34–37 and accompanying text.

178. See *supra* Part I.B.

179. 35 U.S.C. § 271(f)(2) (2000); see also *Waymark Corp. v. Porta Sys. Corp.*, 245 F.3d 1364, 1367–68 (Fed. Cir. 2001) (holding that § 271(f)(2) only requires intent to combine, thus not requiring proof of actual combination).

2. *Columbia University v. Roche Diagnostics GmbH*

The expansion of § 271(f) liability will also affect biotech process patents in unique ways. One district court decision, *Columbia University v. Roche Diagnostics GmbH*,¹⁸⁰ addressing § 271(f) infringement of biotech process patents would likely have turned out differently today after the combined decisions of *Eolas*, *AT&T*, and *Union Carbide*.¹⁸¹

In *Columbia*, the court held that the export of a protein-producing cell line did not infringe a process patent claiming the cell line production method, because § 271(f) did not apply to process patents, and thus, the exported materials were not components under the statute.¹⁸² *Columbia* had unsuccessfully argued that these actions infringed its patent under § 271(f) because the exported cell line and the protein it produced were “the functional equivalent” of components because they contained “substantially all the components needed to manufacture the EPO protein and create new cells and products.”¹⁸³

If *Columbia* were decided today, its outcome would be different. A court could easily classify attributes of patented inventions (including process inventions after *Union Carbide*) as components under § 271(f), though they do not easily fall within the dictionary definition of “component.” Thus, a judge could classify the exported cell line, which the patentees claimed was the “functional equivalent” of a component, as a component under § 271(f), therefore opening the door to liability under subsections (f)(1) and (f)(2) if their other requirements were satisfied.

B. Biotech and Extraterritoriality Today

Expanding the definition of “component” under § 271(f) could produce a wide variety of outcomes in a biotech context, depending on how a particular judge decides to define this term. As discussed in Part III.A, many different ways of breaking biotech inventions into “components” exist. In addition, the application of the statute becomes even more confusing when one considers the wide variety of biotech-based inventions

180. 150 F. Supp. 2d 191 (D. Mass. 2001).

181. Components of both patented processes and products could be intangible for § 271(f) analysis, especially with regard to fields of technology in which products and processes are interchangeable. “[S]ound policy again counsels against varying the definition of ‘component of a patented invention’ according to the particular form of the part under consideration, particularly when those parts change form during operation of the invention as occurs with software code.” *Eolas Techs., Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1339–40 (Fed. Cir. 2005). Biotech inventions also fit this mold, as product and process patents often cover much of the same technology. For example, a product patent could cover a recombinant protein itself, while a process patent might cover the expression system used to produce the protein.

182. *Columbia*, 150 F. Supp. 2d at 204–05 (citing *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 953 F.2d 1360, 1374 (Fed. Cir. 1991); *Aerogroup Int’l, Inc. v. Marlboro Footworks, Ltd.*, 955 F. Supp. 220, 231 (S.D.N.Y. 1997)). The court held that for infringement under § 271(f), components themselves must be noninfringing and uncombined in some manner upon export before being combined into a “greater, infringing compound” after export. *See id.* at 204 n.35.

183. *Id.* at 204.

and how differences in their composition could cause the strength of § 271(f)'s protection to vary.

For purposes of this analysis, I will consider five distinct varieties of biotech inventions: DNA-based inventions created using PCR techniques, DNA-based inventions created using recombinant techniques (e.g., restriction enzymes), proteins produced from laboratory-engineered genes, genetically engineered cell lines that perform some special function (e.g., produce a particular protein or contain some particular plasmid), and laboratory methods.

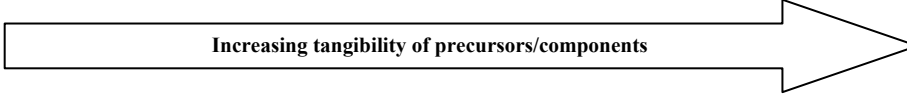
The tangibility of precursors to these inventions falls generally into three categories, illustrated in Figure 1. First, inventions with completely intangible precursors or components—those that are purely informational and serve only as a template for identical copies—would include PCR-based inventions, including cell lines created using PCR and methods performed using PCR. These precursors are similar in nature to the exported golden master disk in *Microsoft*, copies of which were made abroad and then were utilized to install Windows onto foreign computers. The initial exported copy itself was not installed onto any computers.

Next, inventions with dual-nature precursors would include all patents claiming recombinant proteins. Precursor DNA must be “combined” with cellular protein expression machinery to produce the final protein product. Precursors to these inventions are equivalent to the golden master disk in *Eolas*, which was exported from the United States and then used to install Windows on the foreign computers itself.¹⁸⁴ Such inventions could also include cell lines that produce proteins in this manner and methods incorporating these techniques.

Finally, inventions with completely tangible precursors would include what I term “recombinant inventions”—those created through recombinant DNA technology such as restriction enzymes. For example, when a chimeric gene is created with restriction enzymes and ligase, the two “halves” of the gene become a *physical* part of the final product.¹⁸⁵ As above, this category also could include engineered cell lines containing genes created using this recombinant technology and any methods utilizing these techniques.

184. See *Eolas*, 399 F.3d at 1338–39.

185. See *supra* note 172.



Inventions with completely intangible precursors (not “combined” in any sense to form the final product)	Inventions with dual-nature precursors (“combined” in the <i>Microsoft</i> sense to form the final product, but do not <i>physically</i> become part of the final product)	Inventions with completely tangible precursors (<i>physically</i> combined with other components to form the final product)
PCR inventions	Proteins created from laboratory-created gene sequences	Recombinant inventions
Cell lines (those created by PCR)	Cell lines (those producing a recombinant protein)	Cell lines (those containing recombinant DNA sequences such as plasmids)
Methods performed involving PCR techniques	Methods of recombinant protein expression	Methods of creating recombinant inventions

Figure 1. Tangibility of the components of different biotech inventions.

1. Pre- and Post-*Microsoft* Approaches to Biotech Extraterritoriality

The flaws in both the Federal Circuit’s pre-*Microsoft* approach and the approach taken by the Supreme Court in that case are illustrated by the results that would occur when applying these schemes to the three broad categories of biotech inventions illustrated in Figure 1. Consider the first category. A sample of DNA that is exported and later amplified abroad using PCR techniques in order to produce a patented invention abroad would have been considered a component under the Federal Circuit’s *AT&T* decision, but not by the Supreme Court majority that reversed it.

In a biotech context, *Microsoft* draws a line at whether the PCR is performed in the United States or abroad (or, whether the exported component itself or a copy of it made abroad is used to create the patented invention). If it is performed abroad, the would-be infringer is free from infringement liability. If not, the patentee can sue under § 271(f). However, PCR is a relatively simple procedure that can be performed in several hours in any modern biology laboratory, and to draw a line between PCR performed in the United States and PCR performed abroad seems absurd, especially when drawing that line could mean millions of dollars in infringement damages.

Both pre- and post-*Microsoft*, the statute seems to clearly prohibit the export of precursors to the second category of inventions (those with a dual intangible/tangible nature), such as DNA that is later used to produce a protein abroad. However, as discussed in Part III.A, allowing the use of unpatented precursor molecules to violate § 271(f) runs contrary to the Federal Circuit’s traditionally narrow biotech patent protection.¹⁸⁶ If the DNA used to produce a patented protein is unpatented and thus unprotected in the United States, its export should not invoke infringement liability, and yet such exportation would do just that under the current § 271(f) doctrine.

186. See *supra* Part I.B.

The final category of inventions, those created using completely tangible precursors, would quite clearly have fallen within the ambit of the statute almost from its inception.¹⁸⁷ If two different DNA molecules are digested with a restriction enzyme and used to create a new, chimeric molecule, the precursor DNA molecules *physically* become part of the final invention and would thus be considered components in the true sense of the word. Considering the precursors of such inventions to be components under § 271(f) is the only situation that does not seem to uproot the Federal Circuit's narrow biotech patent protection.

2. Potential Legislative Responses

The preceding analysis indicates how § 271(f) might produce confusing results even when applied to different types of inventions within the same field of technology. Indeed, many agree that Congress should consider amending or repealing § 271(f) in light of its poorly defined language¹⁸⁸ and its potentially harmful economic effects.¹⁸⁹ Members of Congress seem eager to tackle the problem—in 2005, a proposed amendment to § 271(f) that failed to pass would have required that components be tangible,¹⁹⁰ and another current bill proposes the complete repeal of § 271(f).¹⁹¹ However, in introducing the 2006 bill, Senator Orrin Hatch offered little justification for the need to repeal § 271(f) except for the vague statement that § 271(f) “benefits foreign manufacturers and patentees in some situations.”¹⁹²

Others have suggested that increased international protection of the rights of United States patentees makes § 271(f) obsolete.¹⁹³ The most significant agreement addressing international patent protection is commonly known as TRIPS,¹⁹⁴ which became effective in 1995 between members of the World Trade Organization.¹⁹⁵ TRIPS

187. See *supra* Part II.B.

188. See Catherine Tornabene, Note, *The Export-Import Dilemma: Inventions and Employment Abroad*, 58 HASTINGS L.J. 153, 176 (2006).

189. See Donald S. Chisum, *Reforming Patent Law Reform*, 4 J. MARSHALL REV. INTELL. PROP. L. 336, 347 (2005).

190. The proposed amendment would have added a third subsection to § 271(f):

(3) An item supplied in or from the United States is not a “component” under this section unless the item is a tangible item that is itself combined physically with other components to create the combination that is alleged to infringe.

Subcomm. on Courts, the Internet, and Intellectual Property, 109th Cong., Patent Reform Act of 2005, § 10 (2005), available at <http://patentlaw.typepad.com/patent/DraftPatentStatuteDDC.pdf>.

191. See Brief for the Petitioner, *Microsoft Corp. v. AT&T Corp.*, No. 05-1056, 2006 WL 3693463, at *29 n.7 (citing Patent Reform Act of 2006, S. 3818, 109th Cong. § 5 (2006)).

192. 152 CONG. REC. S8829, S8830 (daily ed. Aug. 3, 2006) (statement of Sen. Hatch).

193. See Zaunbrecher, *supra* note 27, at 52–53; cf. Harold C. Wegner, *Microsoft Extraterritoriality: “Mutiny . . . Heresy”*, 25 BIOTECHNOLOGY L. REP. 659, 667 (2006) (explaining that § 271(f) and the need for true international patent protection resulted from the same policy considerations of protecting innovation abroad).

194. General Agreement on Tariffs and Trade–Multilateral Trade Negotiations (the Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

195. Paroma Basu, *International Patent Law: Boon or Bane of Biotech?*, 23 NATURE BIOTECHNOLOGY 13, 13 (2005).

mandated minimum standards of protection for all forms of intellectual property in WTO member countries, thus addressing the significant problem of very weak patent protection in many developing countries that previously made them ideal locations to utilize technology patented in other nations.¹⁹⁶

However, while TRIPS certainly has decreased the prevalence of international patent infringement, its reach is still not absolute. A grace period built into TRIPS gives less-developed signatory countries a longer period of time in which to become compliant, thus making these locations more attractive to those seeking to avoid the patent laws of TRIPS-compliant nations in the next decade.¹⁹⁷ As a result, complete reliance on this system (as suggested by some supporting § 271(f)'s repeal) seems unlikely to solve all the problems of extraterritorial patent infringement in the short-term future.

i. Tangibility-Based § 271(f) Amendment

Thus, throwing out § 271(f) completely seems premature. Congress instead could amend the statute to simplify its application to new technologies.¹⁹⁸ One option would be to create more general tangibility requirements for components in one of three ways, illustrated in Figure 2. First, Congress could allow the term “component” to apply to all unpatented elements of a patented invention, regardless of tangibility. (This would overrule *Microsoft*.) Such an approach gives courts little guidance in determining what is properly classified as a component of a patented invention under § 271(f).

Another option would be to allow “component” to apply only to unpatented elements that are at least somewhat tangible. This would apply the Supreme Court's holding in *Microsoft* to other fields of technology besides software. Completely intangible components, such as source code (or an initial DNA sample used in PCR), would be excluded under such a regime, but code on a physical disk or dual-nature precursors to biological molecules (such as unpatented DNA that encodes a patented protein) could be components. Finally, the statute could be redrafted to allow “component” to apply only to unpatented elements that are *physically* incorporated into the final patented invention. (This is Justice Alito's proposed approach in his *Microsoft* concurrence.)¹⁹⁹

196. *See id.*

197. *See id.* For example, nations in sub-Saharan Africa have until January 2016 to become TRIPS-compliant. *Id.*

198. After all, the range of patentable subject matter under 35 U.S.C. § 101(a) has always expanded to encompass new technologies. *See, e.g.,* *Diamond v. Diehr*, 450 U.S. 175, 192–93 (1981) (holding that a process accomplished through the use of computer software was patentable subject matter); *Diamond v. Chakrabarty*, 447 U.S. 303, 309–10 (1980). Thus, the rest of patent doctrine, especially infringement doctrine, must expand accordingly to accommodate the new technology.

199. *Microsoft Corp. v. AT&T Corp.*, 127 S. Ct. 1746, 1762 (2007) (Alito, J., concurring).

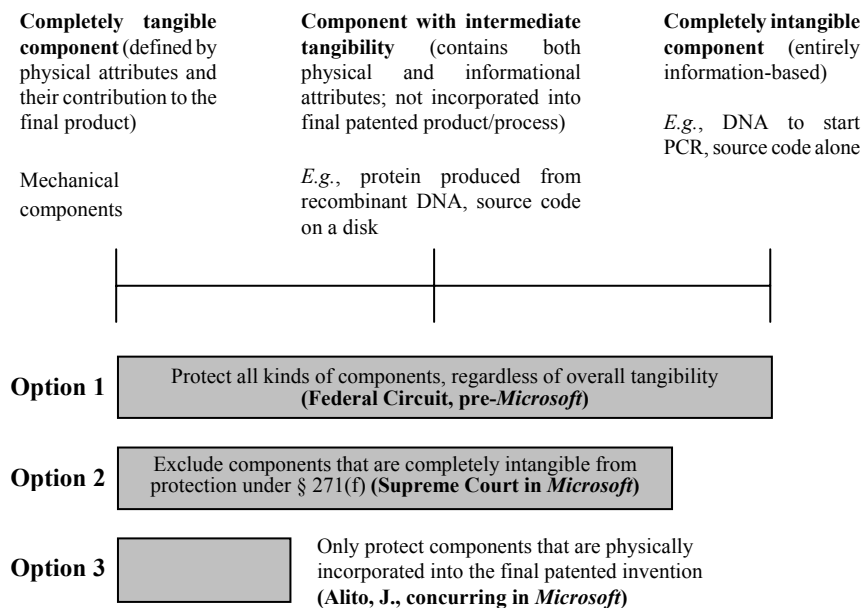


Figure 2. Continuum of tangibility for redrafted § 271(f).

The third option could be a beneficial choice for biotech, given the generally narrow approach to these patents adopted by the Federal Circuit and other courts.²⁰⁰ Many biological precursors that likely would be classified as components under an expansive interpretation of § 271(f)²⁰¹ are themselves patentable if they meet the statutory requirements, and so to extend protection to include unpatented precursors (that are either barred from patentability or off-patent) that are not physically incorporated into the final patented product would contradict many years of biotech jurisprudence. This option would not completely exclude biotech patents from § 271(f) protection, but would only apply to components that physically became part of the final patented invention.

Although such a tangibility-based amendment to § 271(f) might ease the statute's application to biotechnology, it would probably not solve the problems discussed in this Note permanently, as technology continues to advance and to pose new, unforeseen challenges in patent law.

ii. Technology-Based § 271(f) Amendment

A second option could be to create technology-specific § 271(f) variations. Although TRIPS prohibits signatory countries from varying levels of patent protection for different technologies,²⁰² Congress has previously created patent provisions that help alleviate special issues posed by inventions in particular fields.²⁰³ On balance, this

200. *See supra* Part I.B.

201. *See supra* Part III.B.1.

202. TRIPS, *supra* note 194, at art. 27.

203. Although much of the Patent Act utilizes broad language in order to encompass

seems to be the best option to address biotech patent issues caused by the expansion of § 271(f) liability, as it allows the specific nuances of this technology to be addressed in the § 271(f) context without relying on a generic provision that may affect different technologies in different ways.

Such a biotech-specific addendum to § 271(f) could add a third subsection to define the scope of the statute with regard to these patents:

(3) For patents disclosing or claiming a patented invention which is primarily manufactured or performed using genetic material (DNA or RNA), proteins, cell-culture or cloning techniques, or other processes involving site-specific genetic manipulation techniques, a substance supplied in or from the United States is not a “component” under this section if it is an unpatented informational precursor from which the patented invention is produced or with which a patented process is performed and it is not physically incorporated into the final, patented invention.²⁰⁴

CONCLUSION

Adding subsection (3) to § 271(f) would eliminate the possibility of conferring international patent protection that exceeds domestic patent protection upon unpatented precursors such as DNA samples used abroad to create or practice patented biotech inventions.²⁰⁵ However, it still would protect against the export of components that are incorporated physically into a final patented invention abroad. Thus, § 271(f) still would apply to biotech inventions, albeit within a very limited context that allows policies underlying the Federal Circuit’s narrow interpretation of these patents²⁰⁶ to retain force.

The nature of technology mandates that Congress take action regarding this issue. The statute clearly cannot be left as it is, inviting wildly divergent and increasingly expansive interpretations²⁰⁷ based on its vague language and relatively uninformative legislative history.²⁰⁸ Indeed, whenever new, previously unforeseen fields of technology arise in the future, Congress could enact technology-specific subsections similar to the one proposed in this Note addressing § 271(f) that would ease the statute’s application to inventions in those fields of technology.

This approach could help Congress alleviate future problems in interpreting the broad language of § 271(f) without scrapping or redrafting the entire system, which, on the whole, still provides useful protection for United States patents when other systems of international patent protection might fail.

technologies not yet invented, Congress also has included technology-specific provisions in areas in which interpretation of the law has been confusing or inequitable. *See, e.g.*, 35 U.S.C. § 271(e)(1) (2000) (permitting importation of patented inventions “solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products”).

204. This proposed subsection incorporates language from 35 U.S.C. § 271(e)(1) and draft § 271(f)(3) from the Patent Reform Act of 2005. *See* source cited *supra* note 190.

205. Unpatented biological precursors might also include physical components of a precursor product, such as a protein produced from a chimeric gene. *See supra* notes 164–72 and accompanying text.

206. *See supra* Part I.B.

207. *Compare supra* Part II.B with *supra* Part II.C.

208. *See supra* Part II.A.