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Equitable Equivalents: Biotechnology and the Doctrine of Equivalents After *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*

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EQUITABLE EQUIVALENTS: BIOTECHNOLOGY AND THE DOCTRINE OF EQUIVALENTS AFTER *WARNER-JENKINSON CO. v. HILTON DAVIS CHEMICAL CO.*[*]

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In the wake of Hilton Davis, patent attorneys can be assured that unless Congress intervenes, the main battleground in 21st-century patent trials will continue to be liability under the doctrine of equivalents.[1]

INTRODUCTION

Biotechnology[2] is big business. In 1996, over 300 publicly-traded biotech companies brought in over 12.4 billion dollars,[3] and

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[*] 117 S. Ct. 1040 (1997).

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[1] Janice M. Mueller, *Crafting Patents for the Twenty-First Century: Maximize Patent Strength and Avoid Prosecution History Estoppel in a Post-Markman/Hilton Davis World*, 79 J. PAT. & TRADEMARK OFF. 499, 506 (1997). A particularly important aspect of the "battleground" is that, under *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, a jury decides infringement under the doctrine of equivalents. 117 S. Ct. 1040, 1053 (1997) (approving of the determination by the Court of Appeals for the Federal Circuit ("CAFC") that the doctrine of equivalents is a question of fact).

[2] This Note will refer to "biotechnology" and "biotech" interchangeably.

[3] John Hodgson & Riku Lähteenmäki, *Public Biotechnology Companies Earn $12.4 Billion, Spend $5.2 Billion*, 15 NATURE BIOTECH. 412, 412 (1997). The figures quoted are for publicly-traded biotechnology companies. *Id.*

spent 5.2 billion dollars on research.[4] Biotech is, however, an industry in which revenues are "hopelessly skewed,"[5] with the five largest companies[6] earning seventy percent of the industry's revenues.[7] Many biotech companies' revenues do not even reach one million dollars, and for many more, research outlays far exceed revenues.[8] While biotech companies can make money from sources other than product sales,[9] most of the largest biotech companies all have major products on the market.[10] Biotech products, like

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[4] *Id.* at 412.

[5] *Id.*

[6] In order of revenues, the five largest biotech companies in 1996 were Amgen ($2.239 billion), Chiron ($1.313 billion), Genentech ($969 million), Quintiles ($538 million) and Genzyme ($511 million). *Id.* at 412-13.

[7] *Id.* at 413.

[8] *See id.* at 412-13. For example, Amylin spent $65 million on research and development while earning $35.8 million; British Biotech spent $47.63 million and earned $13.83 million; Cephalon spent $62.1 million and earned $21.37 million; and COR Therapeutics spent $50.79 million while earning $18.76 million. *Id.* Research expenditures can represent relatively large investments for many companies. *See generally id.* For example, 128 companies spent in excess of $10 million on research in 1996. *Id.* at 413. The excess of research outlays over revenues is normal for younger companies that have not yet begun to produce products. However, not all companies that spend heavily on research suffer paltry revenues. Four of the largest spenders also enjoyed the industry's highest revenues. *Id.*

[9] *Id.* at 413. Biotech companies may derive earnings from interest income from funds generated by public offerings, contract research and royalties. *Id.*

[10] For example, Amgen is marketing Epogen, a drug which stimulates the production of red blood cells. *See* Jennifer Fron Mauer, *New Products Expected to Aid Biotech Products*, WALL ST. J., Jan. 12, 1998, at B12 (noting several large biotech companies and their current products). Chiron currently sells Betaseron, a drug for the treatment of multiple sclerosis. *Id.* Genzyme markets Sepracoat, an antiscarring product. *Id.* Agouron Pharmaceuticals sells a protease inhibitor under the trade name Viracept, a drug for the treatment of AIDS. *Id.* Quintiles has taken a somewhat different approach by providing drug development, testing, and marketing services to other biotech corporations. *See* Bernard Condon, *Annual Report on American Industry Where Time is Almost Priceless*, FORBES, Jan. 12, 1998, at 176 (discussing Quintiles' market niche as a service-provider); David Ranii, *Testing the Limits*, NEWS & OBSERVER (Raleigh, N.C.), Jan. 16, 1997, at C10 (discussing the growth of Quintiles).

products in other industries, are protected by patents.[11] As a relatively new technology and industry, however, biotech has had its share of problems and controversies with the law of patents.[12]

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[11] Patents not only protect against duplication of an invention by a competitor, they also protect investment. Mueller, *supra* note 1, at 506 (discussing "building in equivalency" to patent applications). "[T]he strength of a patent lies not just in the novelty of the claimed technology, but also in the marketplace value of the patent as an asset that can provide broad protection for the client's technology investment for the next 20 years . . . ." Mueller, *supra* note 1, at 506.

[12] For example, the patent code requires an invention to be non-obvious in light of prior art. *See* 35 U.S.C. § 103(a) (1997). However, it was at one time unclear whether a known process for producing a particular molecule of deoxyribonucleic acid ("DNA") makes the molecule itself obvious. *Compare In re* Deuel, 34 U.S.P.Q.2d 1210, 1215 (Fed. Cir. 1995) (holding that a DNA molecule produced by a known process was not obvious), *with Ex parte* Goldgaber, 41 U.S.P.Q.2d 1172, 1181 (B.P.A.I. 1996) (holding that a DNA product produced by a known process *was* obvious). Now, section 103 of the Patent Code specifically disallows rejection of a patent because of the method by which a DNA molecule was produced. 35 U.S.C. § 103(c).

A controversy also exists as to whether unpredictability of some products' activity may legitimately be used to restrict or deny certain patents. *See* Sean Johnston & Leora Ben-Ami, *Unpredictability Factor Narrows Biotech Patents: Courts Have Held Biotechnology Inventions Nonenabled When Results are Deemed Unreliable*, NAT'L L.J., June 16, 1997, at C2 (discussing problems of enablement in biotech patents due to the perceived "unpredictability" of biotechnology). Furthermore, what may be obvious or enabling to a scientist is not necessarily so to a court. *See, e.g., In re Deuel*, 34 U.S.P.Q.2d at 1215, 1216 (focusing on structure in stating that "a prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious" and "[b]ecause Deuel's patent application does not describe how to obtain any DNA except the disclosed cDNA molecules, [the claims in dispute] may be considered to be inadequately supported by the disclosure of the application"); Amgen Inc. v. Chugai Pharm., 927 F.2d 1200, 1212 (Fed. Cir. 1991) (focusing on function in holding that Amgen had not sufficiently enabled a generic claim for DNA sequences encoding erythropoietin analogs, despite the simple convertibility of erythropoietin's protein sequence into a DNA sequence); Kenneth G. Chahine, *Going Beyond the Native: Protecting DNA and Protein Patents*, 15 NATURE BIOTECH. 183, 185 (1997) (discussing the *Amgen v. Chugai* and *In re Deuel* cases).

Recently, the Supreme Court in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*[13] has further muddied the waters by redefining the doctrine of equivalents, previously expanded by the CAFC.[14] Under the doctrine of equivalents, a jury may find that a product infringes the claims[15] of a patent, not because it duplicates the invention literally, but because it performs the same function in the same way so as to achieve the same result as the invention.[16] A broad doctrine of equivalents introduces uncertainty into the scope of patents because it allows a jury to find infringement by an accused product that falls outside a patent claim's literal scope.[17] In an attempt to restrict the application of the doctrine and inject certainty into the scope of patents, the Supreme Court eschewed the CAFC's application of the doctrine to the invention as a whole, holding that the doctrine should instead be applied to each element of a claim.[18] Despite the Supreme Court's ruling, the "rigid 'element-by-element' analysis will not increase the certainty in determining the scope of claims, especially in

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[13] 117 S. Ct. 1040 (1997).

[14] Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512 (Fed. Cir. 1995).

[15] A patent's claims "precisely define the scope of the exclusive rights the patent will confer." DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW § 2D[3] (1992) (describing the aspects of claims).

[16] The Supreme Court recited this three part test (the "function-way-result" test) in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950). The CAFC, in contrast, has emphasized the substantiality of the differences between an accused product and an invention. *Hilton Davis*, 62 F.3d at 1518. Despite this emphasis, however, the CAFC continues to utilize the function-way-result test. *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 114 F.3d 1161, 1164 (Fed. Cir. 1997) (stating that accused process performed "substantially the same function in substantially the same way to reach substantially the same result" as the invention).

[17] The scope of a patent's claims, and therefore the scope of the patent's protection, is a matter of law to be decided by a judge. Markman v. Westview Instruments, Inc., 116 S. Ct. 1384, 1394-96 (1996).

[18] *Hilton Davis*, 117 S. Ct. at 1054. Elements are limitations on, or components of, a patent's claims. *See* CHISUM & JACOBS, *supra* note 15, at § 2F[2][a].

complex fields such as biotechnology."[19] Biotechnology, as an industry relying on difficult-to-produce, technically-complex products, requires that the scope of patent claims be well-defined.[20] Biotechnology, in fact, would benefit from a restricted application of the doctrine of equivalents because application of the doctrine to biotechnology is uncertain and inconsistent, a doctrine of equivalents that is even moderately broad tends to be anticompetitive, and because broad patent claims are already, or should be, available.

This Note argues that the CAFC and Supreme Court interpretations of the doctrine of equivalents in their respective *Hilton Davis* decisions are inappropriate for biotechnology, and that the doctrine should be applied at the discretion of the court, not at the whim of a plaintiff when filing suit. Part I provides an overview of the biotech industry, including biotech products and their development. Part II examines the development of the doctrine of equivalents, with particular focus on the CAFC and Supreme Court *Hilton Davis* decisions. Finally, Part III argues that economics and the nature of the biotech industry require a more narrowly applied doctrine of equivalents. This Note concludes that the doctrine of equivalents should be applied to the biotechnology industry as a doctrine applied by a jury only if a judge rules its use is equitable under the facts of a particular case.

I. BIOTECHNOLOGY - AN OVERVIEW

Biotechnology is the technology of manipulating, *inter alia*, DNA and proteins[21] to produce commercially useful, primarily

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[19] Howard L. Levine, *The Doctrine of Equivalents*, 15 NATURE BIOTECH. 383, 384 (1997).

[20] *See generally* Rochelle K. Seide & Melissa Szanto, *Drafting Claims for Biotechnology Inventions*, *in* INTELLECTUAL PROPERTY LAW INSTITUTE 1995, at 357 (PLI Patents, Copyrights, Trademarks, & Literary Property Course Handbook Series No. 426, 1995) (discussing the specifics of drafting claims for biotech products).

[21] DNA is the molecule which contains all the information a cell needs to perform all of its essential processes. *See* BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 95-101 (1989) (providing a general overview of DNA).

medical and agricultural, products. Biotechnology, particularly in the field of drug development, is a booming industry.[22] In the words of James A. Geraghty, CEO of Genzyme Transgenic Corporation, "Biotechnology seeks to address human suffering. This technology provides the ability to provide a wide range of therapeutics many of which offer the potential to successfully treat serious diseases not treatable any other way."[23] Biotechnology's patentable products now include naturally-occurring and engineered

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DNA is a long, strand-like molecule comprising four different components called nucleotides: adenosine (A); cytosine (C); guanine (G); and thymine (T). *See id.* at 99. DNA is most often represented as a series of these four letters, for example, AATGCAATGT. *See id.* at 97. Some portions of a strand of DNA produce, or code for, specific proteins. *See id.* at 101-02. For example, when a DNA strand encoding a human protein is placed within a plasmid (a small loop of DNA which is copied when a bacterial cell divides, *see, e.g., id.* at 259) the resulting molecule is called recombinant DNA. *Id.* Recombinant DNA can be used to produce commercially-useful protein products.

Proteins are composed of one or more strands of molecules called amino acids. *See id.* at 55, 107-08. The sequence of a DNA molecule determines the amino acid sequence of a protein. The DNA is "read" by a cell as a series of triplets of nucleotides (codons); most codons represent a particular amino acid. *See id.* at 102-03. The cell, therefore, translates DNA into a string of amino acids which constitutes a protein. *See id.* at 104. There are 61 codons which represent 20 amino acids; most amino acids, therefore, are represented by more than one codon. *See id.* at 101-15.

An important concept in understanding the relationship between a protein and the DNA sequence that encodes it is that many changes in the DNA sequence, known as silent mutations, make absolutely no difference in the sequence of the protein. *See id.* at 100. The remainder of DNA sequence changes, however, do affect the protein's sequence; of these substitutions, some will have little or no effect on a protein's functionality, while others will have a major effect, sometimes destroying the protein's functionality altogether. Thus, a researcher may possess a DNA sequence which encodes a protein having a different amino acid sequence as a patented protein, but having a *function* substantially the same as the patented protein.

[22] *See infra* notes 31-35 and accompanying text (describing the recent growth of the drug industry through biotechnology).

[23] James A. Geraghty, *Cloning - Challenges for Public Policy*, CONGRESSIONAL TESTIMONY BY FEDERAL DOCUMENT CLEARING HOUSE, Mar. 12, 1997, *available in* 1996 WL 8219966.

DNA molecules[24] and proteins,[25] antibodies,[26] genetically engineered single-cell organisms,[27] plants,[28] animals[29] and the tools of biotechnological research.[30]

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[24] *See Recent Patent Applications in the Area of Genomics*, 15 NATURE BIOTECH. 385, 385 (1997) (listing patent applications involving DNA sequences).

[25] *See infra* notes 32-47 and accompanying text (giving examples of protein products with medical applications); *Recent Patent Applications in the Area of Peptides*, 15 NATURE BIOTECH. 186, 186 (1997) (listing patent applications involving protein sequences); *Some Patent Applications in Vectors and Expression Systems*, 15 NATURE BIOTECH. 1727, 1727 (1997) (listing patent applications for inventions relating to mass production of proteins).

[26] *See Patent Applications in the Area of Monoclonal Antibodies*, 15 NATURE BIOTECH. 588, 588 (1997) (listing patent applications involving the use of monoclonal antibodies in, *inter alia*, the diagnosis and treatment of cancer).

[27] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303 (1980). Chakrabarty filed a patent application for a bacterium which contained a plasmid enabling it to break down oil. *Id.* at 303. The Supreme Court held that the bacterium itself was patentable under 35 U.S.C. § 101 as a manufacture or composition of matter. *Id.* at 309. *See also Patent Applications in the Area of Expression Systems*, 15 NATURE BIOTECH. 1027, 1027 (1997) (listing recent patent applications involving the production of various biomolecules using microorganisms); *Patent Applications in the Area of Fermentation*, 15 NATURE BIOTECH. 913, 913 (1997) (listing patent applications involving the use of microorganisms in fermentation).

[28] *See infra* notes 46-49 and accompanying text (describing agricultural products).

[29] The most famous example of a genetically engineered animal is the oncomouse, United States patent No. 4,736,866, a mouse genetically engineered to be susceptible to cancer. The mouse contains a recombinant activated oncogene, a gene which, by definition, will cause cancer. *See* CHISUM & JACOBS, *supra* note 15, at § 2C[1][e].

[30] *See Recent Patent Applications in the Area of Chromatography*, 15 NATURE BIOTECH. 802 (1997) (listing patent applications involving methods of separating proteins); *Recent Patent Applications in the Area of Electrophoresis*, 15 NATURE BIOTECH. 1308, 1308 (1997) (listing patent applications involving electrophoresis (the separation of DNA molecules or proteins in an electric field)); *Recent Patent Applications in the Area of Sequencing*, 15 NATURE BIOTECH. 474, 474 (1997) (listing patents involving methods and machinery for DNA sequencing).

A. *Technology and Products*

Biotechnology's hottest research area is searching through the human genome to find targets for new drugs.[31] These medical products are generally naturally-occurring proteins or nucleotide sequences,[32] useful in themselves or as research tools for the development of drugs.[33] For example, the Regents of the University of California hold a patent for the transfer of genes for human insulin and proinsulin[34] into microorganisms in order to facilitate mass production of the two proteins.[35] Genentech, one of the largest biotech companies, used recombinant DNA[36] technology to produce tissue plasminogen activator, a protein that dissolves blood clots within the body.[37] Amgen currently markets Epogen® and Neupogen®, which boost red blood cell and white blood cell counts, respectively.[38]

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[31] *See* Elyse Tanouye et al., *Genetic Giant: Glaxo and SmithKline give Stock Markets Shock Treatment*, WALL ST. J. (Europe), Feb. 3, 1998, at 1 (discussing the "explosion in scientific breakthroughs" brought about by the hunt for human genes which would lead to biological targets for drug action).

[32] *See supra* notes 21-21 for a discussion of DNA and protein.

[33] *See* Tanouye, *supra* note 31, at 1.

[34] These proteins are important for treating diabetes. *See* ALBERTS, *supra* note 21, at 122.

[35] Jeffrey L. Fox, *Insulin Patent Dispute Revisits Old Biotechnology Battleground*, 15 NATURE BIOTECH. 307, 307 (1997) (describing the patent held by the Regents of the University of California).

[36] *See supra* note 21 (defining recombinant DNA).

[37] *See* Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1557-58 (Fed. Cir. 1994) (describing tissue plasminogen activator and its effect on blood clots). A similar product, an anticlotting agent manufactured by Centocor under the trade name ReoPro, enjoys steady sales, and is expected to generate $64 million during the third quarter of 1997 for Centocor's marketing partner, Eli Lilly. *See* Michael Rapoport, *Strong Third Quarter Seen for Agouron, Other Biotech Firms*, SAN DIEGO DAILY TRANSCRIPT, Oct. 7, 1997, at 1A.

[38] Rapoport, *supra* note 37, at 1A (describing the maturing market for Epogen® and Neupogen®). Sales of the two drugs slowed in 1996, causing earnings to drop. Rapoport, *supra* note 37, at 1A. Notwithstanding this drop, Amgen still expects a double-digit increase in earnings in 1997. Rapoport, *supra* note 37, at 1A.

A variety of medical products are currently under development and awaiting approval by the Food and Drug Administration ("FDA").[39] NPS Pharmaceuticals of Salt Lake City is currently developing methods of treating hyperparathyroidism,[40] osteoporosis[41] and central nervous disorders.[42] Aquila BioPharmaceuticals, a relatively new company, is working on drugs to treat feline leukemia, pneumonia, malaria and tick-borne diseases.[43] Immunex Corporation is close to marketing Enbrel®, a drug treatment for rheumatoid arthritis.[44] Lastly, Centocor is close to FDA approval for a drug to treat Crohn's disease, an inflammatory bowel disorder.[45]

Biotechnology is also making great strides in agriculture. Early agricultural applications involved the development of pest- or disease-resistant crops.[46] Disease-resistant animals are also desirable; to this end, Aquila BioPharmaceuticals is currently developing

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[39] *See infra* note 52 (describing the FDA approval process).

[40] Hyperparathyroidism is a malfunction of the thyroid gland which results in an excess of calcium in the blood, which in turn can result in kidney failure. *See* Laura B. Benko, *Utah Cash and Promising Pill Beat Biotech Blues*, INVESTOR'S BUSINESS DAILY, June 26, 1997, at A4 (describing Norcalcin, which treats primary hyperparathyroidism, as one of NPS' successes in 1996). The potential worldwide market for Norcalcin is $1 billion a year. *Id.*

[41] *Id.* Osteoporosis is a gradual decalcification of bones during aging, resulting in weakened and brittle bones. D. L. Glaser & F.S. Kaplan, *Osteoporosis: Definition and Clinical Presentation*, 22 SPINE 12S (1997) (describing the symptomology of osteoporosis).

[42] *Id.*

[43] *See CEO Interview: Dr. Alison Taunton-Rigby President and CEO, Discusses the Outlook for Aguila BioPharmaceuticals*, WALL ST. TRANSCRIPT DIGEST, May 5, 1997, *available in* 1997 WL 8108476 (recounting Dr. Taunton-Rigby's views on Aquila's product development) [hereinafter *CEO Interview*].

[44] *See* Jonathan D. Miller, *Immunex Discovery Shows Promise for Arthritis Relief*, VALLEY DAILY NEWS (Kent, Wash.), July 21, 1997, at C2 (outlining the development of Enbrel®). If approved, Enbrel® could generate in excess of $100 million for Immunex in its first year. *Id.*

[45] *See* Rapoport, *supra* note 37, at 1A (describing expectations of FDA approval of cA2, a drug to treat Crohn's disease). cA2 is the first real possibility of a treatment for the disease, and could generate a billion dollars for Centocor. *See* Rapoport, *supra* note 37, at 1A.

[46] *See* Bill Mintz, *Making Hay with Corn: Texas Firm Leads Way to Edible Vaccines*, HOUS. CHRON., June 18, 1997, at 1.

a drug to prevent bovine mastitis, a disease that poses problems in the dairy industry.[47] Also, another company, ProdiGene of College Station, Texas, is engineering corn to produce industrial quantities of proteins,[48] as well as to produce animal and human vaccines.[49]

B. Development Costs and Problems

The process of bringing a drug to market is lengthy and expensive, and involves several years of testing. For example, the cost to Immunex Corporation to bring a biotechnology product to market is $350 million to $400 million.[50] Contributing to the expense is mandatory compliance with FDA drug testing regulations.[51] Companies developing drugs must closely follow three clinical trial phases mandated by the FDA; these trials together can last more than three years.[52] Moreover, the FDA's pre-approval

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[47] *See CEO Interview*, *supra* note 43.

[48] *See* Mintz, *supra* note 46, at 1 (describing Prodigene's success at mass-producing proteins by genetically modifying corn).

[49] *See* Mintz, *supra* note 46, at 1 (describing the potential for the production of edible vaccines). Agricultural vaccines are delivered to livestock orally. Mintz, *supra* note 46, at 1. The same concept can work in humans if a plant such as corn is genetically engineered to express proteins that resemble proteins found in disease organisms; consumers would vaccinate themselves simply by eating the corn. Mintz, *supra* note 46, at 1. ProdiGene expects to begin animal testing within two years, with human vaccines to follow in approximately eight years. Mintz, *supra* note 46, at 1.

[50] Miller, *supra* note 44, at C2.

[51] *See generally Reinventing and Harmonizing Biotech Regulation: FDA Regulatory Procedures Need Changes to Keep Pace with the Development in the Biotechnology Industry*, BIOPHARM, Sept. 1, 1997, at 16 (outlining various measures for increasing the efficiency of the FDA's regulatory procedures as applied to biotechnology).

[52] *See* Elizabeth M. Rutherford, *The FDA and "Privatization" - The Drug Approval Process*, 50 FOOD & DRUG L.J. 203, 212-13 (1995). The FDA mandates a rigorous set of trials for safety reasons. *Id.* at 212. A drug must first prove itself in nonhuman systems such as cell cultures and in animal models, (typically mice, rats or rabbits). *Id.* This process may take three and a half years. *Id.* The FDA then mandates human trials in three phases. Phase I trials, involving 20 to 80 patients, primarily evaluate the drug's safety over the course of a year. *Id.* at 213. Phase II trials, lasting approximately two years and involving 100-300 patients, evaluate dosing, drug efficacy and side effects. *Id.* If Phase II trials

review process often takes longer than statutorily mandated, further delaying a drug's introduction to the market.[53]

Post-approval regulation, however, has become somewhat less burdensome. To handle an increase in the number of biotech products, the FDA created the Center for Biologics Evaluation and Research ("CBER") in 1987.[54] After encountering problems related to the use of outdated review procedures,[55] CBER instituted changes that have somewhat eased the regulatory burden imposed upon biotech companies.[56]

Another aspect of biotechnology that increases the speculative nature of biotech products is the possible hesitancy of foreign markets to accept products, particularly genetically-manipulated organisms. For example, Ciba-Geigy encountered resistance from the United Kingdom over Ciba's genetically-engineered corn.[57]

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show the drug has the desired effect, Phase III trials, involving several thousand patients, are conducted to confirm data regarding safety and efficacy. *Id.*

[53] *See id.* (noting that the FDA, while statutorily obligated to review drug applications within six months, frequently takes as long as thirty months).

[54] *See id.*

[55] For example, CBER initially used a lot-by-lot analysis of products, which was well suited to the vaccines and blood products with which biotech products had been grouped, but not to the biotech products themselves, which should more appropriately have been treated like conventional drugs. *See id.*

[56] In 1992, the new CBER director reorganized the Center into three units, one specifically for biotech products. *See id.* The resulting differential review procedures better reflected the needs of the biotech industry. *See id.* Further, in 1995, the regulations of biotech and conventional drugs were harmonized. *See id.* The purpose of this and other regulatory changes is to reduce time spent in post-approval regulation so as to free time for processing of product registration applications. *See id.*

[57] John Hodgson, *UK's Ciba Maize Decision "Political"?*, 15 NATURE BIOTECH. 308, 308 (1997). The United Kingdom's objections were supposed by some to be political in nature, but they actually had a sound scientific basis. *Id.* Ciba's corn contained new genes which conferred insect resistance. *Id.* The corn also contained a gene for resistance to ampicillin, a common antibiotic, a gene left over from the process of inserting the insect resistance genes into the corn. *Id.* Some feared that, if the ampicillin-resistance gene were ever transferred from the corn to bacteria, it could be reproduced, making the bacteria resistant to ampicillin and therefore more difficult to kill. *Id.* Ciba's corn is not the only controversial product: "Every single one of the plant biotechnology products that is in the pipeline will provoke further controversy about safety. . . ." *Id.* at 310

However, while such markets can be somewhat speculative at times, they are profitable.

II. THE DOCTRINE OF EQUIVALENTS

A. Purpose of the Doctrine

The United States Constitution gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries."[58] Congress implemented this power by establishing a national patent system.[59] A patent grants the inventor the right to exclude others from making, selling or using[60] his or her invention for fourteen[61] or twenty years.[62]

(quoting John Beringer of the Advisory Committee on Releases into the Environment, a committee advising the Department of Energy).

[58] U.S. CONST. art. I, § 8, cl. 8.

[59] *See* CHISUM & JACOBS, *supra* note 15, at § 2B[1] (describing the early history of U.S. patents).

[60] 35 U.S.C. § 154(a)(1) (1997). Section 154(a)(1) of the Patent Code states "[e]very patent shall contain a short title of the invention and a grant to the patentee . . . of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." *Id.* Currently, there are three types of patents: utility patents, which cover "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," 35 U.S.C. § 101; design patents, which cover the designs of useful inventions, 35 U.S.C. § 171; and plant patents, which cover any asexually—reproduced "new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuberpropagated plant or a plant found in an uncultivated state," 35 U.S.C. § 161. Biotechnological products are classified as compositions of matter, and therefore are covered by utility patents. *See* 35 U.S.C. § 103(b)(1) (referring to the product of a biotechnological process as a composition of matter); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (holding genetically modified bacteria patentable as, *inter alia*, a composition of matter).

[61] 35 U.S.C. § 173 (applying to design patents only).

[62] 35 U.S.C. § 154(a)(2). The twenty-year patent term is for patents issued after June 8, 1995, and the time is measured from the date of filing. *See* Gerald Sobel, *Developments in Patent Law at the Federal Circuit*, 477 PRACTICING L. INST.1071 (1997). For patents in force on June 8, 1995, the patent term is either

Patents are obtained by application to the Patent and Trademark Office.[63] The heart of a patent is the set of claims which define the invention, and the elements which make up those claims.[64]

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the original 17-year term (which began upon issuance of the patent) or the new 20-year term, whichever is longer. *Id.*

[63] Obtaining a patent involves a process called prosecution. *See* 35 U.S.C. § 131 (1997) (requiring examination of patent applications); CHISUM & JACOBS, *supra* note 15, at § 2D[1] (describing the examination process). During prosecution, an application claiming an invention is examined by an examiner at the Patent and Trademark Office. CHISUM & JACOBS, supra note 15, at § 2D[1]. The examiner reviews the prior art, and indicates whether each claim is allowed or rejected. CHISUM & JACOBS, *supra* note 15, at § 2D[1]. To allow the claim, the examiner must determine that the invention is patentable subject matter, 35 U.S.C. § 101, novel, 35 U.S.C. § 102, useful, 35 U.S.C. § 101, nonobvious, 35 U.S.C. § 103, and not statutorily barred, 35 U.S.C. § 102. *See generally* Christine E. Carty, *Biotechnology Patent Applications*, C909 A.L.I.-A.B.A. 195 (1994) (describing claim requirements for biotechnological inventions). Biotechnological inventions must meet the same patentability requirements as other inventions. *Id.*

Potentially patentable biotechnological processes have received special notice in the Patent Code. A "biotechnological process" is defined as

> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to (i) express an exogenous nucleotide sequence [one placed within the cell by artificial means]; (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence [meaning, a process altering natural gene expression]; or (iii) express a specific physiological characteristic not naturally associated with said organism; (B) cell fusion procedures . . . ; and (C) methods of using products defined by [the process].

35 U.S.C. § 103(b)(3).

[64] *See* Paula N. Chavez, *How to Read a Patent Claim*, 475 PRACTICING L. INST. 345, 348 (1997) (explaining the analysis of claim elements). *See also* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 1000-04 (1997) (discussing the scope of patent claims, including the expansion of claims by generic claims, the doctrine of equivalents and inclusion of unanticipated claims, and the limitations of claims by the requirements of novelty and enablement). The claims are part of the specification, which is contained in the patent document.

> The specification shall contain 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

If a product or process reads on all the elements of a claim of a patented product or process, the accused product or process infringes the patent.[65] Any aspect of the invention not claimed in

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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 (setting forth the enablement and best mode requirements for patent claims). While the specification is important to an understanding of the claims, particularly highly technical claims, litigation is based largely on the language of the claims themselves. Chavez, *supra*, at 347.

[65] *See* 35 U.S.C. § 271(a). Section 271(a) states that "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." A patent may be infringed literally or under the doctrine of equivalents. *See* CHISUM & JACOBS, *supra* note 15, at §§ 2F[2][a], [b]; Chavez, *supra* note 64, at 348.

Determination of infringement is a two-step process. *See* Markman v. Westview Instruments, Inc., 116 S. Ct. 1384, 1388 (1996) ("Victory in a patent suit requires a finding that a patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of what the words in the claim mean."). First, a judge determines the meaning and scope of the claims. *Id.* at 1387 ("[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court."). Second, the factfinder determines if the accused product infringes the patent by determining whether the accused product reads on each element of the claim, either literally or substantially under the doctrine of equivalents. *See* Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607-08 (1950) (describing literal and equivalent infringement); Chavez, *supra* note 64, at 348. If the accused product has all of the elements of one claim protecting the invention, the accused product literally infringes the invention's patent. CHISUM & JACOBS, *supra* note 15, at § 2F[2][a]; Chavez, *supra* note 64, at 348. The test for infringement under the doctrine of equivalents, is whether "there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 1045 (1997). Equivalence is not explicitly defined in the Patent Code. *See generally* 35 U.S.C. § 271(a).

Infringement is a mixed question of law and fact. The Supreme Court's decision in *Markman* established that a judge should decide the scope and interpretation of claims as a matter of law. 116 S. Ct. at 1387. The same Court in *Hilton Davis* did not decide whether a judge or jury should determine infringement under the doctrine of equivalents; it did, however, uphold the Federal Circuit's decision that the jury was the proper factfinder. 117 S. Ct. at 1053.

the specification is, theoretically, not protectable.[66] Such a strict and literal reading of a patent, however, harms a patentee because it allows another inventor to make insubstantial modifications which take the modified invention outside of the protection afforded by the patent.[67] Some protection, therefore, is needed against new inventions which do not infringe literally, yet do not embody substantial changes.[68]

The doctrine of equivalents provides such protection.[69] Since the early nineteenth century, courts have allowed patentees to defend patents against "inventors" who have made insubstantial changes to the patentee's claimed invention in an attempt to get around the plain language of the patent.[70] Such equivalent inventions lack the substantial changes required for an invention to be patentable.[71] Thus, even where no literal infringement can be found, the doctrine of equivalents allows a finding of infringement

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[66] The claims in a patent define the invention. *See* Chavez, *supra* note 64, at 347. Patentees are estopped from asserting infringement under the doctrine of equivalents through a claim construction relinquished during the course of prosecution; this is known as prosecution history estoppel. Chavez, *supra* note 64, at 349. At times prosecution history estoppel is applied very stringently. For example, in *Tanabe Seiyaku Co. v. United States International Trade Commission*, Tanabe appealed an International Trade Commission ruling that other companies' processes of producing an imported pharmaceutical did not infringe Tanabe's patented process, which involved an acetone-containing solvent. 109 F.3d 726, 727 (Fed. Cir. 1997). The accused process used butanone, which is chemically very similar to acetone. *Id.* at 729. Tanabe argued the two were equivalent, but the court held that Tanabe's exclusion of butanone from the patent showed that the two solvents were not equivalent. *Id.* at 732. Because Tanabe had given up butanone as an element during patent prosecution, it was estopped from claiming infringement under the doctrine of equivalents. *Id.*

[67] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607 (1950).

[68] *See id.* at 607-08. "Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form." *Id.* at 607.

[69] *See id.* at 608-09.

[70] *See infra* notes 73-75 and accompanying text (discussing three nineteenth-century cases explaining the requirement for substantial differences in a product from an existing invention).

[71] Practically, a product and the invention from which it differs unsubstantially are the same. *Graver Tank*, 339 U.S. at 608.

by a determination that one invention is the substantial equivalent of a patented invention.[72]

B. *History and Development of the Doctrine of Equivalents*

The idea is not new that substantial changes must be made to existing technology before a new invention is patentable. As early as 1814, Justice Story asserted that "[m]ere colorable differences, or slight improvements, cannot shake the right of the inventor."[73] In 1817, Justice Washington stated that "[w]here the machines are substantially the same, and operate in the same manner, to produce the same kind of result, they must be in principle the same."[74] In 1853, in *Winans v. Denmead*, the Supreme Court noted that, while a case of literal infringement is easy to decide, "[i]t is only ingenious diversities of form and proportion, presenting the appearance of something unlike the thing patented, which give rise

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[72] Judge Nies of the CAFC stated that "[t]he doctrine is comparable to the concept of determining the fair use of a copyrighted work." Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1561-62 (Fed. Cir. 1995).

[73] Odiorne v. Winkley, 18 F. Cas. 581, 582 (C.C.D. Mass. 1814)(No. 10,432). Justice Story's charge to the jury focused on effect: "The material question, therefore, is not whether the same elements of motion, or the same component parts are used, but whether the given effect is produced substantially by the same mode of operation, and in the same combination of powers, in both machines." *Id.*

[74] Gray v. James, 10 F. Cas. 1015, 1017 (C.C.D. Pa. 1817)(No. 5718). The court in *Gray* further stated that "[i]f then the jury should be of opinion, that the two machines are the same in principle, it is no defence for the defendants . . . that they have improved [the machine], no matter to what extent." *Id.* at 1017.

to questions."[75] Subsequent Supreme Court decisions reiterated the doctrine.[76]

The modern contours of the doctrine of equivalents were outlined by the Supreme Court in *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*[77] The *Graver Tank* Court outlined a three-part test of equivalency requiring the allegedly infringing product perform the same function, in the same way, to produce the same result as the patented invention.[78] This test is referred to as

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[75] 56 U.S. 330, 342 (1853). *Winans* addressed the infringement of a patent for the design of a railroad coal car able to carry more than its own weight. *Id.* at 332. While the special shape of the hoppers on the plaintiff's car, which resulted in its extra capacity, was cylindrical and conical, defendant's was octagonal and conical. *Id.* at 333. The jury was instructed to determine if the defendant had "constructed cars which, substantially, on the same principle and on the same mode of operation, accomplished the same result." *Id.* at 334. The Court found equivalency through the implied breadth of the plaintiff's claim. *Id.* at 342. The Court stated that "[w]hen a patentee describes a machine . . . he is understood to intend to claim, and does by law actually cover, not only the precise forms he has claimed, but all other forms which embody his invention." *Id.* Thus, "where form and substance are inseparable, it is enough to look at the form only." *Id.* at 343. However, the Court held that form and substance *were* separable; different forms embodying the same substance, therefore, could infringe, even if not literally.

[76] *See* Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929) (stating that an accused product infringes if "there is no substantial departure from the description of the patent, but a mere colorable difference therefrom"); Imhaeuser v. Buerk, 101 U.S. 647, 656 (1879) (finding that a new combination of old ingredients patentable, but mere substitution of an old ingredient with another ingredient that performs the same function infringes the patent on the combination); Union Paper-Bag Machine Co. v. Murphy, 97 U.S. 120, 125 (1877) (holding that two devices are the same if they perform the same work in substantially the same way and accomplish substantially the same result).

[77] 339 U.S. 605, 609 (1950). The invention in question, patented by Linde Air Products Co., was a welding flux containing silicates of calcium and magnesium. *Id.* at 610. Graver Tank's compound contained silicates of calcium and manganese. *Id.* Linde Air Products' flux contained "a major proportion of alkaline earth metal." *Id.* at 613. While magnesium is an alkaline earth metal, manganese is not. *Id.* at 610. Graver Tank's welding flux, therefore, fell outside the literal bounds of Linde Air Products' patent. *Id.* at 612. The Court, however, affirmed the trial judge's holding that the two fluxes were functionally equivalent. *Id.* at 611-12.

[78] *Id.* at 608.

the "function-way-result" test.[79] The Court admitted, however, that the test had been developed in an era of relatively simple technology.[80] Furthermore, the application of the test as outlined was necessarily contextual.[81] The Court stated that

> [w]hat constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case. Equivalence, in the patent law, is not the prisoner of a formula and is not an absolute to be considered in a vacuum. . . . In determining equivalents, things equal to the same thing may not be equal to each other and, by the same token, things for most purposes different may sometimes be equivalents.[82]

Though the doctrine may be considered fair to the patentee, it is apparent that its application sacrifices the certainty and predictability of patents.[83]

One commentator has ascribed to *Graver Tank* the fundamental split between literal and equivalent infringement.[84] "If accused matter falls clearly within the claim, infringement is made out and that is the end of it. . . . [A] patentee may[, however,] invoke [the doctrine of equivalents if] a device '. . . performs substantially the same function in substantially the same way to obtain the same result.'"[85] Prior to *Graver Tank*, the Court had viewed equivalents

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[79] *See, e.g.*, Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1518 (Fed. Cir. 1995).

[80] *See Graver Tank*, 339 U.S. at 609.

[81] *Id.*

[82] *Id.*

[83] Justices Black and Douglas, dissenting in *Graver Tank*, voiced the fear that the doctrine of equivalents introduced undue uncertainty into patents. *Id.* at 617. The two Justices also decried what they perceived to be a new requirement of prescience by businesses. *Id.* A manufacturer could no longer "rely on what the language of a patent claims. He must be able, at the peril of heavy infringement damages, to forecast how far a court relatively unversed in a particular technological field will expand the claim's language . . . ." *Id.*

[84] *See* Robert M. Meeks, *Metaphors of Infringement and Equivalence: The Solution of Our Problems*, 2 J. INTELL. PROP. L. 279, 291 (1994) (noting that this case was the first to differentiate literal from equivalent infringement).

[85] *Graver Tank*, 339 U.S. at 607-08 (quoting Sanitary Refrigerator Co. v. Winters, 280 U.S. 30 (1929)). However, Justice Jackson's comment "that is the

as being part of the claims themselves.[86] Specifications were read broadly so as to protect an inventor's interest in protecting his entire invention, and to fulfill the Constitutional mandate of promoting the useful arts.[87] The dichotomy between literal and equivalent infringement was subsequently "institutionalized" by the creation of the CAFC,[88] which has held that "the scope of patent protection as defined by the claims[] remain[s] the same and application of the doctrine expands the right to exclude to 'equivalents' of what is claimed."[89]

After *Graver Tank*, the CAFC refined the doctrine of equivalents by applying it to each element of a claim, holding that "each element of a claim is material and essential, and that in order for a court to find infringement, the plaintiff must show the presence of every element or its substantial equivalent in the accused device."[90] This approach purported to offer more certainty than

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end of it" was not entirely correct; he subsequently asserted that an accused device reading literally on a patent's claims may not infringe where it "is so far changed in principle . . . that it performs the same or similar function in a substantially different way." *Id.* at 608. This is referred to as the reverse doctrine of equivalents.

[86] *See* Meeks, *supra* note 84, at 287.

[87] Winans v. Denmead, 56 U.S. 330, 341 (1853).

[88] *See* Meeks, *supra* note 84, at 293 (reporting the results of searches on Westlaw and LEXIS revealing many references to "literal infringement" after creation of the CAFC, but few before).

[89] Wilson Sporting Goods Co. v. David Geoffrey & Assoc., 904 F.2d 677, 684 (Fed. Cir. 1990).

[90] Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 935 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 961 (1988) (describing the element-by-element analysis). The court further noted that "[t]o be a 'substantial equivalent', the element substituted in the accused device for the element set forth in the claim must not be such as would substantially change the way in which the function of the claimed invention is performed." *Id.* Subsequent panels of the CAFC utilized and further refined the element-by-element analysis rule. *See* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1259 (Fed. Cir. 1989) ("'Element' may be used to mean a single limitation [of a claim], but it has also been used to mean a series of limitations. In the All Elements rule, 'element' is used in the sense of a limitation of a claim."). Subsequent panels of the CAFC reiterated the all limitations rule that for infringement, each limitation of a claim had to be met literally or substantially. *See* Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992); Becton Dickinson &

the equity analysis, yet other decisions viewed an equitable approach as an exception, not as the rule.[91]

One panel of the CAFC developed an analytical method for determining the extent to which the scope of equivalents was limited by prior art, material a patentee may not claim in obtaining his patent.[92] In *Wilson Sporting Goods v. David Geoffrey & Associates*, the CAFC noted that "it may be helpful to conceptualize the limitation . . . by visualizing a hypothetical patent claim, sufficient in scope to literally cover the accused product."[93] If the hypothetical claim encompassed both the accused product and prior art, then it would be improper to allow the patentee protection for an equivalent which would have been denied by the Patent and Trademark Office over the prior art.[94] The CAFC argued the approach was advantageous because of a closer adherence to traditional rules of patentability and, ostensibly, a more precise analysis than a determination of the accused product's obviousness in light of prior art.[95] The application of this test was, however, limited in subsequent decisions.[96]

Co. v. C. R. Bard, Inc., 922 F.2d 792, 796 (Fed. Cir. 1990); Messerschmidt v. United States., 29 Fed. Cl. 1, 61 (1993) (applying the function-way-result test to all elements of the disputed claims, after considering precedent arguing for an equitable application).

[91] *See* Charles Greiner & Co. v. Mari-Med Mfg., 962 F.2d 1031, 1036 (Fed. Cir. 1992) (noting retention of equitable aspect of the doctrine of equivalents); London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991) (noting that if the doctrine of equivalents were used as the rule, "claims [would] cease to serve their purpose").

[92] *See Wilson Sporting Goods*, 904 F.2d at 684 (describing the hypothetical claim test).

[93] *Id.*

[94] *Id.*

[95] *Id.* at 684-85.

[96] *See, e.g.*, Upjohn Co. v. Mova Pharm. Corp., 951 F. Supp. 333, 337 (Fed. Cir. 1997) (noting that the hypothetical claim test is "preferred, although not mandatory"); Conroy v. Reebok Int'l, Ltd., 14 F.3d 1570, 1576 (Fed. Cir. 1994) (noting that "[w]hile the hypothetical claim analysis is a useful methodology . . . nothing in *Wilson* mandates its use as the only means for determining the extent to which prior art restricts the scope of equivalency . . . ").

C. *The CAFC Expands the Doctrine of Equivalents*

The CAFC eschewed both the element-by-element approach and the hypothetical claim test in choosing a broad application of the doctrine in its controversial decision in *Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*[97] The CAFC held that, based on *Graver Tank*, the test for infringement under the doctrine of equivalents was the "substantiality of the differences between the claimed and accused products or processes."[98] The CAFC further held that any plaintiff may assert infringement under the doctrine of equivalents,[99] and that equivalence was a question of fact for the jury to decide.[100] Tellingly, the CAFC stated that "[t]he trial judge does not have [equitable] discretion to choose whether to apply the doctrine of equivalents when the record shows no literal infringement."[101] Judge Plager, in a dissent joined by Judges Archer, Rich and Lourie, however, argued strongly for an equitable application of the doctrine wherein the trial judge would have discretion in its application.[102]

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[97] 62 F.3d 1512, 1521-22 (Fed. Cir. 1995).

[98] *Id.* at 1517. While holding that the determinative factor was the substantiality of differences between accused and patented products or processes, the CAFC still clung to the function-way-result test as a means of assessing that substantiality. *Id.* at 1518. The court noted that evidence of the interchangeability of patented and accused products and processes was also relevant to an infringement analysis. *Id.*

[99] *See id.* at 1521-22 (noting that the manner in which evidence arises regarding the substantiality of differences between an invention and an accused product depends upon how the parties frame their arguments, and that a court must admit the evidence if it is relevant to a determination of infringement, and noting one Supreme Court case, in which the Court stated that the doctrine was available to all patentees, as "inimical to the hypothesis that the doctrine is equitable").

[100] *Id.* at 1521 ("[I]nfringement under the doctrine of equivalents is an issue of fact to be submitted to the jury in a jury trial with proper instructions, and to be decided by the judge in a bench trial.").

[101] *Id.* at 1522. This holding, according to the CAFC, flowed logically from the finding that equivalence was a legal basis for recovery, not an equitable one, and that equivalence was a question of fact. *Id.* at 1521-22.

[102] *Id.* at 1536-45.

Hilton Davis involved a process patent which covered a method for the purification of dyes.[103] Both Hilton Davis and Warner-Jenkinson produced dyes.[104] Hilton Davis obtained a patent for the ultrafiltration method of purification, which was much more efficient than the old "salting-out" method.[105] During the prosecution of the patent, Hilton Davis added the element "at a pH of approximately 6.0 to 9.0" to the claimed process.[106] Warner-Jenkinson developed and used a similar ultrafiltration process, operating at a pH of 5.[107] As a result, Hilton Davis sued for infringement and prevailed at the trial level under the doctrine of equivalents.[108] Notably, the trial judge refused Warner-Jenkinson's efforts to establish equivalency as an equitable doctrine.[109]

On appeal, the CAFC reviewed the factual basis for the finding of infringement under the doctrine of equivalents, specifically, the difference in pH between Hilton Davis' and Warner-Jenkinson's processes.[110] Hilton Davis argued that there was an infringement because its patent claimed a lower pH limit of "approximately 6.0,"

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[103] *Id.* at 1515.

[104] *Id.*

[105] *Id.*

[106] *Id.* pH refers to the acidity or alkalinity of a solution. Low pH indicates an acidic solution and high pH indicates a basic solution. This modification was added to differentiate the Hilton Davis patent from one issued to another patentee whose process operated at pH 11-13. *Id.* at 1515-16.

[107] *Id.* at 1516. The disputed claims in Warner-Jenkinson's patent and in Hilton Davis' patent contained most of the same elements, including equivalent pressures, pore sizes for the filtering membrane and sequence of filtration steps. *Id.* at 1515-16.

[108] *Id.* at 1516. The court also issued a permanent injunction against Warner-Jenkinson, preventing it from practicing ultrafiltration "except at pressures above 500 p.s.i.g. and pHs above 9.01." *Id.* Warner-Jenkinson had begun using its filtration method without knowledge of Hilton Davis' patent. *Id.* Though intent plays no role in finding infringement, *id.* at 1520, the district court awarded Hilton Davis only 20% of the award it sought because Warner-Jenkinson had not willfully infringed. *Id.* at 1516.

[109] *Id.* at 1523.

[110] *Id.* at 1524.

and Warner-Jenkinson's process operated at a pH of 5.0.[111] The court decided that the jury appropriately found that pH 5.0 was equivalent to "approximately 6.0."[112]

The CAFC then took the "opportunity to restate — not to revise — the test for infringement under the doctrine of equivalents."[113] The CAFC, relying particularly on the Supreme Court's *Graver Tank* decision,[114] reiterated the simple assertion in *Graver Tank* that "[a] finding of equivalence is a determination of fact."[115] However, in citing the *Graver Tank* Court, the CAFC ignored the fact that *Graver Tank* did not hold that a jury must be the finder of fact.[116] In fact, *Graver Tank* was originally a bench trial, and therefore the trial judge was the factfinder.[117]

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[111] *Id.* (recounting the testimony of Dr. Cook, the inventor for Hilton Davis Chemical Co., that pH 5 would have the same effect as pH 6 in the process).

[112] *Id.* The court emphasized that the difference in pH would have no effect on the function of the membrane in filtering the dye. *Id.* This determination of equivalence, however, has problems. pH represents the concentration of hydrogen, or H+, ions in solution. *See* IRWIN H. SEGEL, BIOCHEMICAL CALCULATIONS 14-15 (1989). Each numerical decrease in pH represents a tenfold increase in H+ concentration; therefore, a solution of pH 5 has a tenfold higher concentration of H+ ions than a solution of pH 6. *Id.* In determining infringement, equivalence is a measurement of the substantiality of functional differences between the invention and the accused product. *See Hilton Davis*, 62 F.3d at 1518. Nevertheless, it is somewhat disturbing that two processes which possess an element differing in some aspect by an order of magnitude can be deemed equivalent. Judge Lourie of the CAFC expressed this view in *Genentech Inc. v. Wellcome Foundation Ltd.*, arguing that a court could not reasonably hold that a protein containing 446 amino acids infringes a claim to a protein with 527 amino acids. *See* 29 F.3d 1555, 1570 (Fed. Cir. 1994) (Lourie, J., concurring).

[113] *Hilton Davis*, 62 F.3d at 1516.

[114] *Id.* at 1517-19.

[115] *Id.* at 1520 (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)).

[116] *Graver Tank*, 339 U.S. at 609-10.

[117] *Id.* at 611. *See also* Jeff Kuehnle, Hilton Davis Chemical Co. v. Warner-Jenkinson Co.: *Opening the Floodgates on Nonliteral Patent Infringement Through the Doctrine of Equivalents*, 48 BAYLOR L. REV. 589, 597 (1996). The CAFC allowed that a judge in a bench trial could determine equivalency. *See Hilton Davis*, 62 F.3d at 1521. However, the CAFC maintained that if a jury trial was properly requested the case had to go to a jury. *Id.* at 1525.

The CAFC also rejected the concept of an equitable application of the doctrine of equivalents.[118] The CAFC acknowledged that the *Graver Tank* Court had addressed fairness when it explained that the doctrine protected the patentee against unfair deprivation of protection against insubstantial changes in the patented invention.[119] Equity, then, reflected only "general fairness"[120] not a doctrine which would grant the trial judge discretion over whether it should be applied.[121] However, in support of its argument that the doctrine was one of law and not equity, the CAFC could cite only Supreme Court cases decided in an era of much simpler technologies.[122]

Judge Plager's dissent in *Hilton Davis* questioned the court's interpretation of the doctrine of equivalents as a doctrine of law. Judge Plager stated that "[t]he majority essentially blesses the

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[118] *Hilton Davis*, 62 F.3d at 1521. The court stated that

> [b]y referring to the doctrine as a doctrine of fairness, neither the Supreme Court nor this court has invoked the myriad implications of an alternative to legal remedies. In addition, neither the Supreme Court nor this court has invoked equity in the technical sense of a set of principles originating in England to compensate for the historically harsh rules of common law.

Id. The CAFC in part framed the equitable approach as one in which the court first decided whether the defendant had intended to copy the patented process. *Id.* at 1523.

[119] *Id.* at 1521 (referring to the explanation in *Graver Tank* that the doctrine of equivalents achieved an "equitable" result).

[120] *Id.* The court cited a number of its previous decisions in which it had labeled the doctrine of equivalents an equitable doctrine. *Id.* at 1521 n.2 (citing Texas Instruments Inc. v. U.S.I.T.C., 988 F.2d 1165, 1173 (Fed. Cir. 1993); Charles Greiner & Co. v. Mari-Med Mfg., 962 F.2d 1031, 1036 (Fed. Cir. 1992); London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991); Perkin-Elmer Corp. v. Westinghouse Elec. Corp., 822 F.2d 1528, 1532 (Fed. Cir. 1987); Loctite Corp. v. Ultraseal, Ltd., 781 F.2d 861, 870 (Fed. Cir. 1985), *overruled on other grounds by* Nobelpharma AB v. Implant Innovations, Inc., 46 U.S.P.Q.2d 1097 (Fed. Cir. 1998)).

[121] *Id.* at 1522.

[122] *Id.* at 1521, 1526 (citing Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42 (1929); Royer v. Schultz Belting Co., 135 U.S. 319, 325 (1890); Seymour v. Osborne, 78 U.S. (11 Wall.) 516, 556 (1871); Taylor v. Boston, 74 U.S. (7 Wall.) 327 (1869); Winans v. Denmead, 56 U.S. (15 How.) 330, 338 (1853)).

continued unfettered use of the doctrine of equivalents, at the discretion of a jury, noting that in some cases at least the ritual chant [of function-way-result] will be quite sufficient justification for a rewriting of the claimed limitations."[123] Judge Plager was unconvinced that the court had at all established the doctrine as a legal remedy,[124] arguing instead that the doctrine was in fact an equitable remedy available to mitigate the harshness of the literality of claim drafting.[125] Whereas the claims defined a patentee's statutorily-protected rights, a court, "in the exercise of its extraordinary equity power" could provide a patentee protection not afforded by statute.[126] Judge Plager made a good argument, therefore, that the application of the doctrine of equivalents should be at the discretion of a court, an argument ignored by the Supreme Court when it heard the case.

D. The Supreme Court Refines the Doctrine of Equivalents

In *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*,[127] the Supreme Court upheld and refined the doctrine of equivalents.[128]

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[123] *Id.* at 1537 (Plager, J., dissenting). Judge Plager appeared quite suspicious of jury decisions, particularly because juries give general verdicts with little reasoning behind them. For example, Judge Plager quoted the jury's finding in the *Hilton Davis* case: "We the jury, unanimously find that plaintiff Hilton Davis has proved by a preponderance of the legal evidence that defendant Warner-Jenkinson has infringed [claims 1, 2, 3, 13, 14]." *Id.* at 1538 n.3.

[124] *Id.* at 1541.

[125] Judge Plager argued strongly that the language of the patent statute prohibited the doctrine of equivalents. *See id.* at 1539-40. For example, Judge Plager argued that 35 U.S.C. § 112 directs that the specification shall cover what is distinctly claimed. *Id.* at 1539. Judge Plager also noted that at several points, Congress had opportunities to incorporate the doctrine of equivalents into the patent statutes by the simple addition of "and equivalents thereof" to the statutory language defining claims, but failed to do so. *Id.* That failure, Judge Plager opined, reflected Congress' desire for exactitude in patent claiming, an exactitude diminished by application of the doctrine in every case. *Id.* at 1539-40. As a result, he argued, the doctrine of equivalents, a judge-made doctrine which softened the literality of claims, had to be equitable in nature. *Id.*

[126] *Id.* at 1540.

[127] 117 S. Ct. 1040 (1997).

[128] *Id.* at 1054.

Petitioner Warner-Jenkinson argued that the doctrine should be eliminated because it had not survived the 1952 Patent Act.[129] Warner-Jenkinson further argued that the doctrine violated the requirement that "the outer limits of each patent monopoly must be defined with precision in the claims set forth in the patent,"[130] and that "[t]he Federal Circuit's 'insubstantial differences' standard . . . deprives the public, including other firms and inventors, of the clear notice of patent boundaries that Congress has commanded."[131] Further, Warner-Jenkinson reasoned, the 1952 Patent Act contained no endorsement of the doctrine of equivalents; therefore, the doctrine should be abandoned.[132] The Court responded that the doctrine had indeed survived the 1952 Patent Act, and pointed to the failure of similar arguments in Justice Black's dissent in *Graver Tank*.[133]

The Court was, however, concerned with the potential for an overbroad application of the doctrine, noting that "the doctrine of equivalents, as it has come to be applied since *Graver Tank*, has taken on a life of its own."[134] Acknowledging that such an application of the doctrine conflicted with the public notice functions of patents,[135] the Supreme Court held that the doctrine

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[129] *See* Brief for Petitioner at 10-12, Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040 (1997) (No. 95-728).

[130] *Id.* at 11.

[131] *Id.*

[132] *Id.* at 42-44. The Court also noted that pre-1952 Patent Act precedent had survived passage of the Act. *Hilton Davis*, 117 S. Ct. at 1048 (citing Aro Mfg. Co. Convertible Top Replacement Co., 365 U.S. 336, 342 (1961)).

[133] *Id.* at 1047 (referring to Justice Black's dissent in *Graver Tank & Mfg. Co. v. Linde Air Products Co.* that the doctrine of equivalents was inconsistent with the Patent Code's requirement of clear and distinct claims).

[134] *Id.* at 1048-49.

[135] Claims contained within a patent notify the public of what is patentable by defining the invention and what constitutes infringement. *See* CHISUM & JACOBS, *supra* note 15, at § 2D[3][d] (describing the properties of claims). This public notice function is essential to the functioning of the patent system. *See* London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991). "[C]laims must be 'particular' and 'distinct' . . . so that the public has fair notice of what the patentee and the Patent and Trademark Office have agreed constitute the metes and bounds of the claimed invention. Notice permits other parties . . . to design around the patent." *Id.* The Supreme Court noted in *Hilton Davis* that

of equivalents was to be applied to each element of a claim.[136] Because each element is material to a patent's claims, equivalency had to be determined for each element, rather than between an invention and an accused product.[137] After *Hilton Davis*, a patentee claiming infringement must show literal or equivalent infringement of each element of a claimed invention, not simply the invention as a whole.[138]

The Supreme Court was unconcerned as to whether a "function-way-result" test[139] or some other test was used, as long as "the test is probative of the essential inquiry: Does the accused product or process contain elements identical or equivalent to each claimed element of the patented invention?"[140] The Supreme Court explicitly left to the CAFC the actual application of the doctrine.[141] Since *Hilton Davis*, the CAFC has not had the opportunity to apply the newly-defined doctrine of equivalents in a case involving a biotechnological invention.

The Court also emphasized that prosecution history estoppel was an important limitation on the application of the doctrine of equivalents.[142] In *Hilton Davis*, it was not clear to the Court from the prosecution history why the patentee Hilton Davis had set the

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"[t]here can be no denying that the doctrine of equivalents, when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement." 117 S. Ct. at 1049.

[136] *Hilton Davis*, 117 S. Ct. at 1049.

[137] *Id.*

[138] *Id.* The Court credited Judge Nies of the CAFC for reconciling the Supreme Court positions that the doctrine of equivalents is desirable and that a court has no right to expand a claim beyond its limitations. Nies had proposed accomplishing this goal by requiring that the doctrine of equivalents be applied to a claim element-by-element. *See id.* (citing Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1573-74 (Fed. Cir. 1995) (Nies, J., dissenting)).

[139] As outlined in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950).

[140] *Hilton Davis*, 117 S. Ct. at 1054.

[141] *Id.* "[W]e see no purpose in going further and micro-managing the CAFC's particular word-choice for analyzing equivalence. We expect that the CAFC will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations . . . ." *Id.*

[142] *Id.* at 1049-50.

lower pH bound for its ultrafiltration process as "approximately 6.0."[143] The lower pH limitation had been added during prosecution after the examiner had objected to the original claim, which conflicted with a previous patent.[144] The Court, therefore, enunciated a rule that where, as in the current case, no explanation had been given for the added, limiting element, "the court should presume that the [Patent and Trademark Office] had a substantial reason related to patentability for including the limiting element added by amendment."[145] Since each element contained within a claim was material,[146] and since Hilton Davis had not provided evidence to demonstrate that estoppel was precluded, the Supreme Court remanded the case to the CAFC.[147]

The Court left unanswered, however, the question of whether judge or jury should be the factfinder. Noting that Warner-Jenkinson's comments on the question went "more to the alleged inconsistency between the doctrine of equivalents and the claiming requirement than to the role of the jury in applying the doctrine,"[148] the Court declined to address the issue.[149] The Court, having redefined the doctrine of equivalents to its satisfaction, remanded the case to the CAFC.

On remand, the CAFC, in an uncharacteristically brief decision, again upheld the jury's verdict that Warner-Jenkinson's process infringed Hilton Davis' patent under the doctrine of equivalents.[150] In doing so, the CAFC retreated into an amalgam of the function-way-result test and the insubstantial differences test, holding that "one of ordinary skill in the art would know that performing ultrafiltration at a pH of 5.0 will allow the membrane

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[143] *Id.* at 1050.

[144] *Id.* The previous patent disclosed an ultrafiltration process operating at pH greater than 9.0; it was not clear to the Court why the lower limit of "approximately 6.0" was added. *Id.*

[145] *Id.*

[146] *Id.*

[147] *Id.* at 1054.

[148] *Id.* at 1053.

[149] *Id.*

[150] Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 114 F.3d 1161, 1164 (Fed. Cir. 1997).

to perform substantially the same function in substantially the same way to reach substantially the same result as performing ultrafiltration at 6.0."[151] As to the question, however, of whether Hilton Davis was estopped by prosecution history from claiming infringement of the lower pH bound element, the CAFC remanded the case to the district court to decide.[152]

The Supreme Court may have refined the doctrine of equivalents by instituting an element-by-element approach, but the Court is perceived to have left the matter as confusing as before.[153] One commentator has averred that the establishment of the element-by-element analysis will "do nothing to dispel any of the current uncertainty and confusion regarding the doctrine of equivalents."[154] This is certainly true with respect to the biotech industry.[155] Natural product cases in which consumer-produced

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[151] *Id.* at 1164.

[152] *Id.*

[153] Professor Donald Chisum of the Santa Clara University School of Law suggested that the Supreme Court's decision was an attempt at peacemaking between the factions of the CAFC (the CAFC *Hilton Davis* decision was 7-5). *See* Victoria Sind-Flor, *High Courts [sic] Punts on Equivalents*, NAT'L L.J., Mar. 17, 1997, at A6 (describing sources of confusion regarding the doctrine of equivalents). The Supreme Court left unresolved whether a judge or jury would act as factfinder to hear questions of equivalence, and the framework for deciding equivalence. *See Hilton Davis*, 117 S. Ct. at 1053.

[154] Levine, *supra* note 19, at 384. *See also* Robert D. Bajefsky & Howard W. Levine, *Impact of* "Hilton Davis" *on Biotech is Unclear*, NAT'L L.J., June 16, 1997, at C9 (discussing the uncertainties inherent in the element-by-element rule).

[155] *See, e.g.*, Bajefsky & Levine, *supra* note 154, at C9 (noting the difficulty of applying the Supreme Court's version of the doctrine of equivalents to one type of biotechnology product); Levine, *supra* note 19, at 384 (describing implications of the *Hilton Davis* decision for the biotech industry). It is arguable that an element-by-element approach provides no more guidance than the more expansive CAFC approach. For example, the Supreme Court and the CAFC both considered a single element, the lower pH bound of the ultrafiltration process, in arriving at their respective decisions. *See Hilton Davis*, 117 S. Ct. at 1050; Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1524 (Fed. Cir. 1995). Similarly, in *Genentech, Inc. v. Wellcome Foundation*, it was one element, the activity of FE1X, to which the doctrine of equivalents was applied. 29 F.3d 1555, 1563-65, 1567-69 (Fed. Cir. 1995). Micron Separations, which submitted an amicus brief in support of Warner-Jenkinson, had also been

metabolites are elsewhere patented also remain confusing.[156] In general, "[d]issatisfaction with the doctrine of equivalents has arisen despite general adherence to an all-elements rule, which seems unlikely, by itself, to satisfy concerns about the unpredictability of equivalence analysis."[157] The concerns about the doctrine of equivalents are well-founded. Part III of this Note discusses several reasons why the biotechnology industry does not need even a moderately broad doctrine of equivalents.

III. THE BIOTECHNOLOGY INDUSTRY DOES NOT NEED A BROAD DOCTRINE OF EQUIVALENTS

Judge Plager's dissent in the CAFC's *Hilton Davis* decision suggested a semi-equitable approach to the application of the doctrine of equivalents by which a judge would examine the substantiality of differences between an invention and an accused product and, based on that examination, decide whether the

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involved in extensive litigation over a single element of another company's patent, which the CAFC held Micron had infringed under the doctrine of equivalents. *See* Brief of Amicus Curiae Micron Separations in Support of Petitioner at 5, Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040 (1997)(No. 95-728) (describing the litigation); Pall v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995) (deciding the litigation). The element-by-element approach may be a refinement of the doctrine of equivalents, but the refinement has not improved the resolution of these cases over the previous, broader, CAFC approach.

[156] The question is whether a chemical product's metabolite, produced within a consumer after ingestion, is the substantial equivalent of an existing patented product with the same chemical structure; an element-by-element approach adds no guidance to this problem. An example of such a product is terfenadine, sold as Seldane®, an allergy medication. *See* Arthur R. Whale, *Liver Cited as Infringer*, NAT'L L.J., May 12, 1997, at C29. Marion Merril Dow held the patent for terfenadine. *Id.* Just before its patent expired, Baker Norton applied to the FDA for approval to market terfenadine after expiration of Dow's patent, and the FDA agreed. *Id.* Dow sued, however, because terfenadine is broken down in the body into a metabolite, TAM, for which Dow still had an active patent. *Id.*

[157] Stephen L. Sulzer & Leo J. Jennings, *Doctrine of Equivalents is not Limited to Piracy*, NAT'L L.J., May 12, 1997, at C32.

doctrine is available to a plaintiff.[158] This limited approach to the doctrine of equivalents would work best for biotech products, particularly DNA and protein products, because broad patents are possible for biotech products,[159] the function-way-result test does not fit biotech products well,[160] juries may have difficulty understanding the concepts at issue,[161] and a broad doctrine of equivalents, even one utilizing an element-by-element approach, tends to suppress competition.[162]

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[158] *Hilton Davis*, 62 F.3d at 1543-44 (Plager, J., dissenting). Judge Plager stated that this determination of availability was separate from the question of relief under the doctrine, a question left to a jury. *Id.* at 1544. Judge Plager admitted that this approach may have problems in that a judge, in making the initial determination of availability, may make some of the same function-way-result determinations the jury would make. *Id.* This criticism, however, is hollow in that judges frequently make evidentiary determinations while looking through a jury's eyes, for example, while weighing the evidence involved in a summary judgment motion. Also, Judge Plager's approach would allow a judge to discourage the use of the doctrine (when not actually meritorious) as an intimidation factor by the plaintiff. Judge Plager had even suggested eschewing the doctrine of equivalents altogether. *See id.* at 1543; *supra* Part II (outlining reasons why this option would be undesirable). In addition, Judge Nies of the CAFC also held the doctrine of equivalents to be a mixed question of law and fact. *Id.* at 1563 (Nies, J., dissenting).

[159] *See infra* Part III.A (describing how claims can be drafted broadly to encompass equivalents).

[160] *See infra* Part III.B (describing how the doctrine of equivalents does not easily apply to biotechnological inventions).

[161] *See infra* Part III.C (describing how juries have difficulty understanding complex technical evidence such as might be presented at trial in a case involving alleged infringement of a biotech patent).

[162] *See infra* Part III.D (describing how the doctrine of equivalents can act to discourage competition). It should be noted that the Biotechnology Industry Organization, in its amicus brief to the Supreme Court, strongly supported the doctrine of equivalents as applied to the biotech industry. *See generally* amicus brief for the Biotechnology Industry Organization, Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 117 S. Ct. 1040 (1997) (No. 95-728).

A. *Claims May Be Drafted Broadly To Encompass Equivalents*

A strong objection to consistent application of the doctrine of equivalents to infringement actions involving biotechnological inventions is that broad patent constructions are already available.[163] It is therefore possible to include many potential equivalencies in a patent claim's language.[164] The process of obtaining

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[163] Broad patents may utilize specific claims so that potential equivalencies may be included in the language of the claims. Such specificity is important; the Supreme Court has said:

> [T]he patent laws require that an applicant for a patent . . . "shall particularly specify and point out the part, improvement, or combination which he claims as his own discovery." This provision was inserted in the law for the purpose of relieving the courts from the duty of ascertaining the exact invention of the patentee by inference and conjecture, derived from a laborious examination of previous inventions, and a comparison thereof with that claimed by him.

Keystone Bridge Co. v. Phoenix Iron Co., 95 U.S. 274, 278 (1877). *See, e.g.*, Shayana Kadidal, *Digestion as Infringement: The Problem of Pro-Drugs*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 241, 245-48 (1996) (discussing the claiming of a spectrum of chemical compounds all metabolized to the same active compound in the body). After *Hilton Davis*, William H. Dippert, a patent attorney with Cowan, Liebowitz & Latman, P.C. advised using qualifiers such as "about" or "approximately" or relying on value ranges in claims to "give your client a better chance of equivalence." Dominic Bencivenga, *Proving Infringement: Supreme Court Establishes Equivalence Test*, N.Y. L.J., May 8, 1997, at 5.

[164] For example, consider the ultrafiltration process at issue in *Hilton Davis*. *See* Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1515 (Fed. Cir. 1995). Hilton Davis could have protected itself by replacing the imprecise lower limit "approximately 6.0" of the patent's claim with definite language, such as "pH 5.0" or by replacing the range with "at any pH below 9.0."

An example of a patent which encompasses many equivalents is found in *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996). Genentech held a patent on a process for the production of recombinant human growth hormone (hGH). *Id.* at 1556. The patent claimed:

> A method for producing human growth hormone which method comprises [1] culturing bacterial transformants containing recombinant

a patent involves correspondences with a patent examiner.[165] The potential patentee desires broad claims, while the examiner tries to limit the claims in accordance with patentability.[166] An inventor

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plasmids which will, in a transformant bacterium, express a gene for human growth hormone unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto, and [2] isolating and purifying said expressed human growth hormone.

Id. at 1558. This claim is very general and inclusive, encompassing every type of bacterium which could be transformed, every type of plasmid capable of carrying the hGH gene, arguably any sequence of DNA which would produce hGH, and practically every method of isolation or of purification of the products. In one broad stroke, the number of potential equivalent processes is vastly reduced. Bio-Technology General's ("BTG") process produced the protein by expression of the hGH gene within bacteria, which resulted in inactive hGH collecting in clumps called inclusion bodies. *Id.* at 1557. The inclusion bodies were separated from the bacteria and the hGH reactivated. *Id.* BTG's process, however, was held to infringe upon the Genentech patent because, despite substantial differences between the two processes, BTG's process performed essentially the same function in the same way so as to achieve the same result as Genentech's process. *Id.* at 1558-60. The strength of Genentech's claim lay in the broad scope of its claim's language.

[165] *See* CHISUM & JACOBS, *supra* note 15, at § 2D[1] (describing the patent examination process).

[166] *See* Stephen G. Whiteside, Note, *Patents Claiming Genetically Engineered Inventions: A Few Thoughts on Obtaining Broad Property Rights*, 30 NEW ENG. L. REV. 1019, 1021 (1996). If the examiner allows the claims, they become part of the issued patent. *See* CHISUM & JACOBS, *supra* note 15, at § 2D[1]. A patent examiner may disallow a claim for overbroadness; in this case, the inventor has tried to claim too much. *See* Whiteside, *supra*, at 1053-70 (discussing generic claims). Equivalencies disallowed during prosecution for lack of enablement cannot, by prosecution history estoppel, be infringed by subsequent inventors.

The scope of claims is frequently limited by material that is already patented or part of the public domain; such material constitutes "prior art." *See* CHISUM & JACOBS, *supra* note 15, at § 2C[5] (discussing what constitutes prior art); Whiteside, *supra*, at 1034-36 (discussing the inability of an inventor to claim prior art under the doctrine of equivalents). Prior art includes prior patents, publications describing the art included in the inventor's current patent application, anything in public use or on sale in the United States, and certain trade secrets. *See* CHISUM & JACOBS, *supra* note 15, at § 2C[5]. Prior art can determine what is not patentable on grounds of obviousness, 35 U.S.C. § 103(a) (1997), or lack of novelty, 35 U.S.C. § 102(a),(b),(d),(e),(g). For example, the

tries to claim what he has actually invented in a manner that encompasses as many minor variations on the invention as possible.[167] Broad claims are still expressed in specific terms; specificity of claiming, even when the claims are broad, is critical in that it gives competitors notice of what has been patented.[168] Thus, an inventor may claim many equivalents and still give sufficient notice of what he has patented.

Inventors patenting DNA molecules or proteins may make generic claims.[169] This means that an inventor can claim classes of elements when only one member of the class is used in the invention, as long as the claim "[is] of a scope appropriate to the invention disclosed by an applicant,"[170] and the language of the claim is sufficiently enabling.[171] When an applicant satisfies these

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upper pH limit on the Hilton Davis patent was set at 9.0 so as to avoid infringing a previous patent. Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 1045-46 (1997). The previous patent represented prior art.

[167] Whiteside, *supra* note 166, at 1024, 1050-56 (discussing broad claiming for genetically engineered organisms and the effect of the doctrine of equivalents thereupon). Claims reflecting only the inventor's work are too narrow in scope because they do not effectively prevent a competitors' development of useful variants of the work. Whiteside, *supra* note 166, at 1024.

[168] *See supra* note 135 (describing the public notice function of patents).

[169] *See* Whiteside, *supra* note 166, at 1069 (discussing the limits of generic claims). *See also* Carty, *supra* note 63, at 209-10 (discussing how some biotechnological patents need several representations of the invention to satisfy the statutory enablement requirement).

[170] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1214 (Fed. Cir. 1991)

[171] *Id.* (referring specifically to claimed DNA sequences). The idea is that one may substitute nucleotides in a DNA molecule or amino acids in a protein, while altering the functionality of either molecule unsubstantially. *See supra* note 21 (discussing proteins). The specification, which includes the claims, must enable a person of ordinary skill in the relevant art to make and use the invention described in the claims. 35 U.S.C. § 112 (1997); *see also* CHISUM & JACOBS, *supra* note 15, at 2D[3][a] (describing enablement). Enablement is therefore a limitation to broad claims. For example, in *Amgen v. Chugai Pharm. Co.*, the CAFC noted that applicants were entitled to broad generic claims. 927 F.2d at 1213. Amgen attempted to claim all erythropoietin gene analogs, but the CAFC held that Amgen had described the making of too few analogs for the claim to be enabling. *Id.* Another example arises when a bacterial expression system involves a poorly-characterized bacterial type; an applicant may not necessarily claim that the expression system includes all species within that type. *See In re*

requirements, he has effectively encompassed all variants which could be construed as equivalents to the invention, even under the most liberal definition of equivalency.[172] For example, an inventor may claim all the DNA variants which encode a specific amino acid sequence.[173]

Another method for accomplishing broad claims is to define elements of a claim in terms of function, not simply in terms of structure.[174] For example, since a monoclonal antibody is a protein which reacts with other molecules, it may be described by its functionality only, that being reactivity,[175] or by both its chemical characteristics and its functionality.[176] Similarly, a DNA

Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991) (holding that since cyanobacteria were a poorly-characterized group of bacteria, a claim involving an expression system using one cyanobacterial species could not encompass all cyanobacterial species). Nevertheless, if sufficient enablement for analogs is shown, many (or all) of them may be claimed along with the invented molecule. *See id.* at 496.

[172] Such a claim may not, however, encompass useful variants of the claimed molecule in which sections were deleted or new components added, or in which a functional fragment was used, as long as the new invention has a different functionality than the patented one.

[173] *See* Whiteside, *supra* note 166, at 1069.

[174] *See* Mueller, *supra* note 1, at 507. Mueller suggests "us[ing] plenty of broad, functional language to describe what each element of the invention does, and why it does it, and how it interacts with other elements, and not just what the element is." Mueller, *supra* note 1, at 507. Such descriptions form the basis for accusations of equivalency against later-developed technology. Mueller, *supra* note 1, at 507. *See also* Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 1053 (1997) (holding that infringement under the doctrine of equivalents is to be determined at the time of infringement, not at the time the patent was issued).

[175] For example, a claim could read "High affinity monoclonal IgM antibodies immunoreactive with antigen X." Seide & Szanto, *supra* note 20, at 449. Such a claim refers only to the antibody's action. Seide & Szanto, *supra* note 20, at 449.

[176] For example, a claim could read "A monoclonal antibody which lyses human C cells in vitro in the presence of complement, said antibody recognizing an antigenic determinant on the surface of human C cells having a molecular weight of about 50-60 kD as determined by SDS-Page electrophoresis on a 10% polyacrylamide slab gel." Seide & Szanto, *supra* note 20, at 451. A monoclonal antibody may also be claimed by the process of making it, a description of the epitope (the part of another molecule recognized by the antibody) and activity,

molecule may be claimed by its sequence, or by its function of producing a particular amino acid sequence.[177] In general, claims of DNA molecules that encompass the encoded protein's functions are broader than those that encompass only sequence or chemical characteristics.[178]

The patentee is protected, as well, against claims that are initially drafted too narrowly.[179] The Patent Act allows for the reissue of claims in broader terms when the defect in the claim is attributable to failure to draft claims broadly enough to encompass the invention.[180] Therefore, despite the relative unpredictability of biotechnology, the patentee has the benefit of some hindsight to protect his or her invention.

With the availability of broad claim drafting, inventors have no real need for ready access to the doctrine of equivalents. In general, if an accused product or process is an equivalent to a patented product or process, the patent's claims likely could have been drafted more broadly to encompass that equivalent. Conversely, prosecution history estoppel prevents patentees from claiming works which were disallowed during the patenting process.[181] Both broad claim drafting and prosecution history estoppel argue against easy availability of the doctrine to a patentee.

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by association with the cell line which produces it, or simply by its producing cell line. Seide & Szanto, *supra* note 20, at 444, 449-50. Since monoclonal antibodies are themselves highly specific in action, claims for them may be broadened by describing only the antibody's activity, without regard to how or by which cell line it was produced. Seide & Szanto, *supra* note 20, at 444.

[177] *See* Seide & Szanto, *supra* note 20, at 454-55 (describing claims for DNA molecules).

[178] *See, e.g.*, Diana Sheiness, *Patenting Gene Sequences*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 121, 127-28 (1996) (discussing DNA claims of varying breadth and increasing the breadth by including a functional element).

[179] *See* 35 U.S.C. § 251 (1997) (outlining the reissue of defective patents; "[w]henever any patent is, through error without any deceptive intention, deemed wholly or partially invalid by reason . . . of the patentee claiming . . . less than he had a right to claim in the patent, the Commissioner shall . . . reissue the patent . . . "); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1574-75 (Fed. Cir. 1991) (outlining the court's view of patent reissue).

[180] *See* 35 U.S.C. § 251 (1988) (describing the reissue process).

[181] *See supra* note 66 (discussing prosecution history estoppel).

B. *The Doctrine of Equivalents is Not Readily Applied to Biotech Products*

The "function-way-result" test as outlined in *Graver Tank*[182] and accepted by the Supreme Court in *Hilton Davis* does not apply easily to biotechnology.[183] This failure of the test reflects the unusual properties of the molecules and processes involved in biotechnology, whereby an inventor may take several different paths to reach the same result. Similarly, the substantial similarities test espoused by the CAFC is difficult to apply to biotechnological products. In general, as the Supreme Court and CAFC have articulated its application, the doctrine of equivalents is not easily applied to biotech products.

The difficulties posed by the function-way-result test become apparent when considering, for example, a protein product which has a useful medical application. The protein can be purified from some natural source, or it can be produced artificially. To produce it artificially, a researcher will require a gene for the protein, a

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[182] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608-09 (1950).

[183] Judge Lourie of the CAFC noted that the function-way-result test does not apply well to chemistry:

> New chemical compounds differ structurally from old compounds (that is what makes them new) and yet they may perform the same function (have the same use), provide the same result, and do so in the same way. The fact that they do so in the same way does not make them substantially the same in the way they are defined, i.e., by structure.

Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1546 (Fed. Cir. 1995) (Lourie, J., dissenting). Judge Lourie's discomfort with the application of the doctrine of equivalents to chemistry speaks to biotechnology as well, since many biotech patents are similarly described in terms of structure, that is, the DNA or protein sequence. *See generally* Whiteside, *supra* note 166 (describing the claiming of DNA molecules by structure). Changes in the structure of either, which results in chemically distinct molecules, may result in molecules that perform the same function in the same way to achieve the same result. *See supra* note 21 (describing the effect of modifications of DNA and protein sequence on protein function).

DNA vector for the gene,[184] and a microbial system for its production, most likely a bacterium.[185] The gene/vector combination transforms the bacterium genetically.[186] The researcher then induces the transformed bacteria to produce useful quantities of the protein.[187] This protein will have a certain characteristic activity.[188] The researcher then claims this protein in his or her patent.

Infringement questions arise, however, if a competitor tries to produce a competing protein product. Since many, perhaps millions, of sequence-unique genes may encode the exact same protein,[189] a competitor can construct a new, artificially-produced gene to encode the protein. Alternatively, the competitor can modify the existing gene to produce a protein with a different sequence, but one which has a similar activity to the claimed protein.[190] A competitor may alter the gene so that it contains all the preferred codons[191] for the bacteria producing the protein, increasing production of the protein. In each case, a competitor

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[184] This vehicle is usually a small circle of DNA known as a plasmid. *See* ALBERTS, *supra* note 21, at 259.

[185] *See* ALBERTS, *supra* note 21, at 265-66 (describing the use of bacteria to produce proteins in the laboratory).

[186] *See* ALBERTS, *supra* note 21, at 265.

[187] *See* ALBERTS, *supra* note 21, at 265.

[188] A protein's useful activity consists of its ability to accelerate useful biochemical reactions. ALBERTS, *supra* note 21, at 125 (describing the catalytic activity of a class of proteins called enzymes); *see also* Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1557 (Fed. Cir. 1994) (describing artificially-produced tissue plasminogen activator and its effects on blood clots); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1203 (Fed. Cir. 1991) (describing the effect of the protein erythropoietin on the production of red blood cells).

[189] *See, e.g., Genentech*, 29 F.3d at 1562-63, 1565-67 (discussing the different activities of two variants of tissue plasminogen activator, t-PA and FE1X).

[190] *See id.* at 1559 (describing a claim by Genentech of infringement of its patent for recombinant tissue plasminogen activator (t-PA) by two artificially-produced t-PAs with sequences different from that patented by Genentech).

[191] *See supra* note 21 (describing codons and the conversion of a DNA sequence into a protein sequence).

may attempt to patent both the protein product and the method for making it.[192]

In these scenarios, it is not clear how the doctrine of equivalents would be applied. If the accused protein's sequence exactly matches the patented protein, there is literal infringement.[193] But if there are significant sequence changes, there is no literal infringement, particularly if the activity of the accused protein differs significantly from the patented one. It then becomes difficult to tell if the new protein infringes under the doctrine of equivalents. If a protein's sequence or activity is a material element in a claim, it is not clear how much difference between the claimed and accused sequences or activities is "substantial."[194] If the sequences themselves are material elements, discerning equivalence can be problematic as well.

The question of equivalent infringement by a product previously patented, but produced by a different process, was addressed in *Scripps Clinic & Research Foundation v. Genentech, Inc.*[195] Scripps Clinic was the holder of a patent for the production of human Factor VIII:C.[196] Scripps Clinic engaged in the production of Factor VIII:C by purifying it from human or porcine blood.[197] Several of the claims at issue referred to the Factor's purification from "plasma" and the separation of VIII:C from VIII:RP, a second protein.[198] Five other claims at issue in the case were product-by-

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[192] *See, e.g., Genentech*, 29 F.3d at 1558 (reciting claims contained in Genentech patents for both tissue plasminogen activator and the process for creating it).

[193] This assumes that the patent contains a recitation of the protein's sequence. The patent may, however, contain only a description of the protein's functionality. *See, e.g., id.* (reciting one patent claim of "Human plasminogen activator, having thrombolytic properties . . . and having a specific activity of 500,000 IU/mg").

[194] *See infra* note 229 (discussing several problems associated with a range of activity element in one claim at issue in *Genentech, Inc. v. Wellcome Foundation*).

[195] 927 F.2d 1565 (Fed. Cir. 1991).

[196] *Id.* at 1568. Factor VIII:C is a clotting factor found in the blood. *Id.* It is useful in place of whole blood in the treatment of hemophilia. *Id.* at 1568-69.

[197] *Id.* at 1569.

[198] *Id.* at 1570 (referring to claims 24-27).

process claims.[199] Genentech, however, developed a new and useful method of producing human Factor VIII:C through recombinant DNA technology.[200] Scripps Clinic argued that Genentech's human Factor VIII:C infringed both its product[201] and product-by-process claims.[202] The district court granted Scripps summary judgment on its product claims, but not for its product-by-process claims.[203]

The CAFC, however, held that summary judgment was inappropriate for the product claims, as there was a genuine question of material fact as to the purity and specific activities of the VIII:C produced by the two processes.[204] The CAFC also held that, as a matter of law, "the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."[205] This broad view, however, was rejected the following year by a different panel of the CAFC in *Atlantic Thermoplastics Co. v. Faytex Corp.*[206] That panel held that the process recited in a product-by-process claim is a material element of the claim.[207] The conflict between the two cases is not yet completely settled.[208]

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[199] Product-by-process claims are claims that describe the product by the method in which it is produced. *See* CHISUM & JACOBS, *supra* note 15, at § 2D[3][d][vi] (describing product-by-process claims).

[200] *Scripps Clinic & Research Found.*, 927 F.2d at 1580.

[201] *Id.*

[202] *Id.* at 1583.

[203] *Id.* at 1580, 1583.

[204] *Id.* at 1580.

[205] *Id.* at 1583. Judge Newman's rationale for this holding was that claims were to be construed the same way when determining validity as when determining infringement. *Id.*

[206] 970 F.2d 834, 839 n.2 (Fed. Cir. 1992).

[207] *Id.* at 846-47. This panel of the CAFC rejected the earlier attempt in *Scripps* to equalize the construing of claims during patent prosecution and during litigation on a claim. *Id.*

[208] *See, e.g.*, Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7, 10 (D. Mass. 1993) (following, despite "the confused state of the record," the CAFC's decision in *Atlantic Thermoplastics Co.*); Dekalb Genetics Corp. v. Northrup King Co., No. 96 C 50169, 1997 WL 587492, at *2 (N.D. Ill. Aug. 14, 1997) (expressly following *Scripps Clinic & Research Found.* over *Atlantic Thermoplastics Co.*) Most courts, however, follow *Atlantic Thermoplastics Co.*

Scripps Clinic & Research Foundation and its subsequent rejection by *Atlantic Thermoplastics* represent two conflicting interests in biotechnology. *Scripps Clinic & Research Foundation* is rational in that the inventor of a biologically useful molecule should be able to patent that molecule regardless of the method by which it is made. The case also upholds the desirable broad claiming that can make biotech patents valuable assets. The holding on product-by-process claims, however, leads to the illogical result that two completely different processes could be equivalent.[209] Conversely, an adherence to the *Atlantic Thermoplastics* holding on product-by-process claims reduces the value of biotech patents utilizing such claims, and leads to the illogical result that the same molecule may be patented by two different inventors.[210]

A case that further underscores the difficulty in applying the doctrine of equivalents to biotechnology is *Genentech, Inc. v. Wellcome Foundation*.[211] The protein product in controversy was tissue plasminogen activator ("t-PA"), which is medically useful for dissolving life-threatening blood clots.[212] Genentech held three patents on natural and recombinant t-PA, and several means of producing it.[213] Genentech sued the Wellcome Foundation for producing and importing met-t-PA, a form of t-PA which differed from Genentech's t-PA by only one amino acid.[214] Genentech also sued a co-defendant, Genetics Institute ("GI"), for producing FE1X, a form of t-PA which lacked significant protein segments found in Genentech's t-PA, yet still retained blood clot-dissolving

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[209] Under the function-way-result test, the two processes could not be said to result in production of the molecule in the same "way."

[210] The Supreme Court noted that an accused product falling within the literal scope of a claim may avoid infringement if it is "so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way . . . . " Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 608-09 (1950). This is known as the reverse doctrine of equivalents. *See Scripps*, 927 F.2d at 1581. The CAFC noted that a defendant had to differentiate between his product and a patent's claims in terms of function in order to prevail under the reverse doctrine of equivalents. *Id.*

[211] 29 F.3d 1555 (Fed. Cir. 1994).

[212] *Id.* at 1557.

[213] *Id.* at 1559.

[214] *Id.* at 1559 n.4.

activity of t-pa.[215] The jury found that both companies had infringed Genentech's patent under the doctrine of equivalents.[216] The CAFC held that the lower court should have granted GI judgment as a matter of law that FE1X did not infringe Genentech's patent on t-PA.[217]

The Wellcome Foundation decided after trial to discontinue production of their t-PA.[218] Thus, the question of infringement of Genentech's patent on t-PA by met-t-PA under the doctrine of equivalents was not addressed by the CAFC.[219] Genentech's claims to its recombinant t-PA were drafted broadly and referred to the t-PA's activity rather than its structure.[220] However, had Genentech recited an amino acid sequence for the t-PA in its claims, it is arguable that Genentech would have had a claim of infringement by equivalence against the Wellcome Foundation because the difference between Wellcome's met-t-PA and Genentech's t-PA, the addition of methionine, would be insubstantial.[221] Under an element-by-element analysis, however, Genentech, before arguing to a jury that the Wellcome met-t-PA differed unsubstantially from Genentech's t-PA, would have had to first argue what constituted an element of the claim, a matter currently unclear.[222]

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[215] *Id.*

[216] *Id.* at 1560.

[217] *Id.* at 1569.

[218] *Id.* at 1560.

[219] *Id.*

[220] *Id.* at 1558.

[221] *See* Whiteside, *supra* note 166, at 1049-50.

[222] *See* Bajefsky & Levine, *supra* note 154, at C9 (discussing the problematic application of the "all elements" rule to protein and DNA sequences). It is not clear whether the protein sequence itself comprises one element of the claim, or if each amino acid of the protein sequence is an element. Bajefsky & Levine, *supra* note 154, at C9. Under the CAFC conception of the doctrine of equivalents, the factfinder may be able to find infringement more easily than under the Supreme Court's element-by-element analysis, because it could look at the invention - the t-PA - as a whole to determine infringement under the function-way-result test. In an element-by-element analysis, however, a factfinder would have to determine the equivalence of the sequences exclusive of the equivalence of the t-PA's function, a different element than the sequence.

It is even less clear whether a factfinder using an element-by-element analysis would find equivalence between Genentech's t-PA and GI's FE1X, since a much greater disparity exists between their respective sequences.[223] A factfinder would have to determine if the *sequence* of GI's FE1X performed the same "function in the same way so as to achieve the same result" as Genentech's t-PA's sequence, regardless of t-PA's function, a separate element. If the CAFC adopted a rule that each amino acid in a sequence is an element, GI's FE1X sequence would lack a large number of elements contained in the Genentech t-PA. An equivalence question, therefore, might never reach the jury.[224] Ironically, examining the whole protein for equivalence of function may not be an option under an element-by element analysis. The element-by-element refinement to the doctrine of equivalents, therefore, has created at least as much confusion as it has cured.

Another example of equivalence problems arises when the specific activity of a protein is an element of a claim. In *Genentech*, Genentech's t-PA had a specific activity of 500,000 IU/mg plus or minus 25%, or a specific activity of 375,000 IU/mg to 625,000 IU/mg.[225] FE1X, however, had an activity range of

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Although Genentech did not recite a protein sequence when claiming its recombinant t-PA, the CAFC decided the case as if it had. The CAFC noted that Genentech's specification in one of the patents litigated upon gave several different apparent definitions of "tissue plasminogen activator." Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1563-65 (1994). Of the four definitions, the CAFC chose the narrowest, "t-PA produced through recombinant DNA technology but having the same structure as natural t-PA." *Id.* at 1563. Thus, the CAFC in effect imposed upon Genentech's claim an element of structure which in future litigation would be considered an element in and of itself. Indeed, the district court that first heard the case interpreted the phrase "tissue plasminogen activator" in the claims to mean "the full length amino acid sequence of human t-PA plus any 'naturally-occurring allelic variant' thereof." *Id.* at 1560.

[223] *See id.* at 1559 n.4.

[224] *See* Bajefsky & Levine, *supra* note 154, at C9 (describing the effects of the element-by-element analysis on the presentation of a sequence-element-infringement issue to a factfinder).

[225] *Genentech*, 29 F.3d. at 1563. The specific activity of an enzyme is generally expressed as a particular number of International Units per milligram of enzyme, or IU/mg. IRWIN H. SEGEL, BIOCHEMICAL CALCULATIONS 282 (2d ed. 1976). "One International Unit (IU) is the amount of enzyme which catalyzes

208,000 IU/mg to 299,000 IU/mg.[226] The figure of 500,000 IU/mg for Genentech's t-PA was added to distinguish it from prior art.[227] The CAFC held that the activity of FE1X fell outside the range of activity of Genentech's t-PA,[228] and that FE1X was "thus outside the permissible range of equivalents through the application of prosecution history estoppel."[229] Presumably if the average of the accused protein's activity had fallen within the patented protein's equivalence range, it would have infringed upon the patent.

It is not clear, however, if infringement by equivalence could have been found if the activity ranges had overlapped slightly. For

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the formation of [one micromole] of product per minute under defined conditions." *Id.* A protein's activity will depend upon the method or assay used to determine that activity. *See Genentech*, 29 F.3d at 1562-63, 1566 (discussing two assays for determining the activity of t-PA, the bovine fibrin binding assay and the chromogenic substrate assay). When comparing the activities of two proteins, it is important to use the same assay in testing both. *Id.* at 1566.

[226] *Id.*

[227] *Id.* at 1563.

[228] *Id.* at 1567.

[229] *Id.* at 1565-66. It should be noted that the range "plus or minus 25%" is arbitrary. The CAFC recounted the testimony of Dr. Collen, who stated that "the 'consensus attitude' of those who work in the area is that, if an assay [for protein activity] is performed 'properly and carefully', the resulting measurement for native t-PA should be 500,000 plus or minus 25%." *Id.* at 1567 n.32. However, the activity reported depended entirely upon the assay used. *Id.* at 1566 (differentiating the bovine fibrin binding assay and chromogenic substrate assay). The activity of FE1X was reported using a chromogenic substrate assay. *Id.* The reported activity for FE1X was 350,000 IU/mg to 450,000 IU/mg. *Id.* at 1565-66. However, the t-PA was tested using the bovine fibrin plate assay. *Id.* at 1566. By this assay, FE1X had an activity of 440,000 IU/mg. *Id.* Although the plaintiffs argued that the two assays gave comparable results, the court held otherwise. *Id.* Had the court accepted the published activity of FE1X, it likely would have held that FE1X infringed Genentech's patent. However, the court ignored the published figures and held that "the only evidence in the record which is probative on the question of the specific activity of [the FE1X] is the testimony of plaintiff's expert Dr. Mann," who testified that the range of activity of FE1X was 208,000 IU/mg to 299,000 IU/mg. *Id.* This figure fell outside Genentech's t-PA's range of activity; thus, there was no infringement under the doctrine of equivalents. *Id.* at 1567. Clearly, the arbitrariness of the court's choice of what evidence to believe in this case protected GI from liability for infringement.

example, if the average activity of the accused t-PA had been 310,000 IU/mg, an average well outside the equivalence range of the patented t-PA, the upper end of its equivalence range would have been 387,500 IU/mg and within the patented protein's equivalence range. Also unclear is the question of how much overlap between activity ranges would constitute equivalence. The answers are not forthcoming under either the CAFC's or the Supreme Court's conception of the doctrine of equivalents.[230] It is apparent, however, that proteins with higher activities are accorded a greater range activity, and therefore a greater range of equivalents. This might provide companies with an incentive to exaggerate claims of activity in order to claim more under this element.

C. *Juries May Have Trouble Understanding the Concepts at Issue*

As biotechnology has matured as an industry, biotech companies, particularly the larger ones, have become more litigious.[231]

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[230] The CAFC's emphasis on substantiality of difference is of no help because the CAFC has not defined substantiality in reference to activity ranges. *See generally id.* Likewise, an element-by-element approach provides no relief because a protein's activity range is a single element, and the question therefore reduces to one of substantiality of difference.

[231] *See generally* WILLIAM S. FEILER ET AL., AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION BIOTECHNOLOGY LITIGATION REPORT NO. 5 (1997) (describing the status of patent litigations in biotechnology over the last 20 years). Feiler marks the beginning of the biotechnology litigation era with the filing of the case *Diamond v. Chakrabarty*. *Id.* at Preface (noting Diamond v. Chakrabarty, 571 F.2d 40 (Cust. & Pat. App. 1978)). Since then, 259 cases have been filed; many are still pending. *Id.* The pace of litigation picked up in the mid 1980s, with at least 15 actions a year from 1987 to date. *Id.* A high of 44 actions were filed in 1996. *Id.* The largest companies have filed the most suits. For example, Genentech has filed 24, Amgen 16, De Kalb Genetics 12, Monsanto 11 and Cetus 11. *Id. See also* Lynn H. Pasahow, *Patent and Trade Secret Biotechnology Litigation*, C886 A.L.I.-A.B.A. 37, 42 (1993) (stating that "[m]any biotech companies are controlled by venture capitalists . . . [and that t]hese people are often greater risk-takers, and are more willing to litigate in order to try to achieve exceptional future returns rather than eliminate risks by settling and allowing their future profits to be diluted"). The pace of patent litigation in

With this increased tendency to sue comes the increased likelihood that large, scientifically-complex cases will come to trial. Since equivalence is a matter of fact to be determined by a jury,[232] a jury of laypersons will have to sift through factual material completely unfamiliar to them.[233] The jury is a cornerstone of the American legal system, but it is a weak foundation on which to lay the doctrine of equivalents.[234]

Several studies have shown that juries have serious problems understanding cases when they involve factual material that is complex, unfamiliar, or both.[235] In particular, juries had trouble

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general is increasing; one Chicago-area publication reported in 1997 that patent cases there had increased 25% since 1992 to 1,840 suits. *See* H. Lee Murphy, *Patently Offered: Lawsuits Rise Over Corporate Cribbings*, CRAIN'S CHI. BUS., Apr. 14, 1997, at 4.

[232] Warner-Jenkinson Co. v. Hilton Davis Chemical Co., 117 S. Ct. 1040, 1053 (1997) (approving the CAFC's holding that equivalency was a question of fact for the jury). *See also* Sind-Flor, *supra* note 153, at A6 (noting that juries will likely now have a free hand to decide equivalence questions). Kenneth R. Adamo, a patent attorney, commenting on the Supreme Court's acquiescence to the Federal Circuit's decision to leave equivalence questions to the jury, said "Justice Thomas did a surprisingly good job, but he dropped the ball on that issue." Sind-Flor, *supra* note 153, at A6.

[233] Jurors may have the cultural background and experience to understand a new set of facts in a trial involving homicide or the question of liability in an auto accident because they have seen accounts of murders on television or have experienced accidents. Jurors may easily understand what motivates a person to murder, or what would lead to liability in an accident. Most jurors, however, have no such familiar points of reference for the factual technical aspects of biotechnology upon which they may base a verdict of infringement.

[234] *See infra* notes 235-242 and accompanying text (discussing problems juries have understanding technically complex evidence).

[235] *See* Joe S. Cecil et al., *Citizen Comprehension of Difficult Issues: Lessons From Civil Jury Trials*, 40 AM. U. L. REV. 727, 752-76 (1991) (describing problems juries have in understanding material presented in complex trials). The Special Committee on Jury Comprehension of the American Bar Association's Litigation Section studied jury decisionmaking in complex cases. *Id.* at 752. The volume of evidence was not important when familiar issues were at stake. *Id.* at 753-54. For example, in a sexual harassment action, jurors felt comfortable with the volume of evidence. *Id.* However, a trade secrets case proved problematic in that jurors "had trouble deciding one of the claims because of the large volume of evidence they had to consider." *Id.* at 754. Jurors differed widely in their

understanding technical or scientific evidence,[236] in part because of a lack of a technical background.[237] This disturbing weakness is exacerbated by the tendency of many courts to "discourage the selection of technically competent and highly educated individuals for jury service."[238] This trend is particularly troubling considering that the Supreme Court in *Hilton Davis* reaffirmed the jury's role in deciding infringement under the doctrine of equivalents.[239]

Jury trials pose other problems as well. Neither the Supreme Court nor the CAFC has defined for a jury "insubstantiality of differences."[240] Findings of equivalency, as determinations of

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ability to understand a complex case's issues, with several jurors becoming utterly confused. *Id. See also Confronting the New Challenges of Scientific Evidence: VI. Addressing the Problems of Complex and Scientific Evidence*, 108 HARV. L. REV. 1481, 1583, 1585 (1995) (describing problems in the comprehension of scientific evidence).

[236] Cecil, *supra* note 235, at 756. Judges and juries both perceive scientifically complex evidence as causing juror confusion. Cecil, *supra* note 235, at 757. In particular, jurors may not interpret statistical evidence correctly, even failing to differentiate in one case between statistical evidence strongly implicating a defendant's guilt and similar evidence pointing only weakly to guilt. Cecil, *supra* note 235, at 757-58, 760. Moreover, jurors may misunderstand quantitative evidence as well. Cecil, *supra* note 235, at 760.

[237] *Confronting the New Challenges*, *supra* note 235, at 1585 (addressing the problems lay jurors have with understanding technically-complex evidence). One jury foreman noted "If you can find a jury that's both [sic] a computer technician, a lawyer, an economist, knows all about that stuff, yes, I think you could have a qualified jury, but we don't know anything about that." ILC Peripherals Leasing Corp. v. IBM Corp., 458 F. Supp. 423, 447 (N.D. Cal. 1978) (involving an assertion by Memorex that IBM had attempted to monopolize various computer markets).

[238] *Confronting the New Challenges*, *supra* note 235, at 1585. Further, courts often "routinely excuse doctors, dentists, lawyers, and professionals from jury duty." *Confronting the New Challenges*, *supra* note 235, at 1585 n.13.

[239] Eugene C. Rzucidlo, *Patent Prosecution: Be Careful What You Say*, 15 NATURE BIOTECH. 1305, 1305 (1997) (noting that after the Supreme Court decisions of *Markman v. Westview Instruments*, 116 S. Ct. 1384 (1996), and *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 117 S. Ct. 1040 (1997), patent applications, once written for technically-trained patent examiners, must now be written for the judges and juries who will decide the scope of patent claims).

[240] Richard Zachar of the Chicago firm of Vedder Price Kaufman &

fact, are reversible only under the "substantial evidence" standard, under which a jury's findings of fact may not be disturbed on appeal unless the court on appeal finds that no reasonable juror could have made the finding.[241] Additionally, post-trial motions for new trials under Rule 50 of the Federal Rules of Civil Procedure can delay a final resolution.[242]

The court system itself has been criticized as a forum for evaluating scientific evidence.[243] Because experts for each party act as advocates for their respective party's position, rather than as neutral observers, scientific evidence may be incompletely presented.[244] In addition, lawyers present only evidence favorable

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Kammholz, an intellectual property attorney for 28 years, said "The million-dollar question is: How do you know what insubstantial is? It's left for juries to decide." Murphy, *supra* note 231, at 4. Other issues left unresolved by the courts and left for juries are what constitutes a claim element, what it "take[s] to vitiate a claim, and what kind of equivalent undermines an invention," Bencivenga, *supra* note 163, at 5 (quoting patent attorney Kate Murashige of Morrison & Foerster, Washington D.C.).

[241] Read Corp. v. Portec, Inc., 970 F.2d 816, 821 (Fed. Cir. 1992) (discussing the standard of review of a jury's findings of fact).

[242] *See* FED. R. CIV. P. 50; Avern Cohn, Letter to the Editor, 15 IPL NEWSLETTER 28 (Summer 1997) (noting the time involved in deciding a Rule 50 motion). The filing of a motion for new trial as a matter of law under Rule 50 of the Federal Rules of Civil Procedure is common after a jury-decided patent case, and can take longer to decide than a similar inquiry following a bench trial. *Id.* While bench trials are not necessarily better than jury trials, adherence to jury trials in the context of a readily-available doctrine of equivalents can therefore lengthen litigation.

[243] *Confronting the New Challenges of Scientific Evidence*, *supra* note 235, at 1586 (discussing the problems of experts in trials).

[244] *Confronting the New Challenges*, *supra* note 235, at 1586. One perceived problem is that of dueling experts, some of whom may be "willing to testify to virtually anything for the right price." *Confronting the New Challenges*, *supra* note 235, at 1586. Generally this should not be a real problem in patent actions, as the experts tend to be the developing scientists themselves rather than hired experts. *See, e.g.*, Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1563 n.17, 1566 n.32 (Fed. Cir. 1994) (testimony given by Dr. Collen of Leuven Research & Development, a plaintiff, and Dr. Goeddel of Genentech, both of whom worked directly on the development of t-PA). However, pride in work and the sometimes high monetary stakes of an infringement action can create pressures to provide desired testimony. Sometimes the confusion simply reflects conflicting

to their clients' positions. If experts and attorneys present deliberately incomplete evidence, a jury may fill in gaps with common experience.[245] This gap-filling for scientific evidence, however, is not possible when jurors have little or no scientific experience.[246]

A judge is in a better position to determine a factual issue of equivalency. The Supreme Court in *Markman v. Westview Instruments, Inc.*,[247] held that a judge must construe the scope of a claim as a matter of law.[248] "The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis."[249] In construing the meaning of claims, a judge must take into account evidentiary matters.[250] For example, the district court judge in *Genentech* construed Genentech's claim for "tissue plasminogen activator" to mean "the full length amino acid sequence of human t-PA plus any 'naturally-occurring allelic variant' thereof."[251] Thus, a judge is in a position relatively early in litigation to determine, based upon the particular art in question, if there is any

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data. Such confusion between experts is illustrated in *Genentech* with respect to the confusion in the determination of the activity of the proteins in question. For a discussion of *Genentech* and the confusion of the range of activity of t-PA, see *supra* Part III.B.

[245] *See Confronting the New Challenges*, *supra* note 235, at 1587.

[246] *See Confronting the New Challenges*, *supra* note 235, at 1587.

[247] 116 S. Ct. 1384 (1996).

[248] *Id.* at 1393-96 (analyzing the Court's role in interpreting claim language). *See generally* Frank M. Gasparo, Note, Markman v. Westview Instruments, Inc. *and Its Procedural Shockwave: The Markman Hearing*, 5 J.L. & POL'Y 723 (1997) (outlining the evidentiary and procedural implications of the *Markman v. Westview Instruments, Inc.* decision).

[249] *Markman*, 116 S. Ct. at 1395.

[250] *Id.* at 1395 ("[I]t often becomes necessary that [judges] should avail themselves in the light furnished by experts relevant to the significance of [unfamiliar] words and phrases.").

[251] Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1560 (quoting Genentech, Inc. v. Wellcome Found., 14 U.S.P.Q.2d 1363, 1369 (D. Del. 1990)). The CAFC held that "human tissue plasminogen activator" meant "natural t-PA," *id.* at 1565, but did not disturb the district court's ruling on the inclusion of naturally-occurring variants within that definition. *Id.* at 1565 n.27.

merit to an assertion of infringement under the doctrine of equivalents.[252]

This reasoning applies to the appeals process as well. The CAFC was created to hear patent cases, as well as a limited number of other matters.[253] It has exclusive appellate jurisdiction over patent cases arising in lower district courts.[254] Because of this narrow jurisdiction, the CAFC's judges are presumed to have more experience in understanding the language and constructions of patent claims than other courts, and arguably more than a jury of laypersons.

The jury, therefore, is a weak link in the determination of equivalence in questions involving biotechnology. This weakness is evident under either the CAFC's or the Supreme Court's view of the doctrine of equivalents. If a juror is confused under the CAFC's view as to whether an accused product or process is substantially equivalent to a patented product or process, that juror will likely be as confused in determining under the Supreme Court's view whether the accused product or process is the substantial equivalent of each element of a patent's claim, since each element is viewed in the context of the entire invention. The Supreme Court's view provides no relief because, as in *Hilton Davis*, the dispute centered around a potentially difficult-to-understand element. The alternative, allowing a judge to first decide if a plaintiff may invoke the doctrine of equivalents, is the more reasonable approach.

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[252] Judge Plager of the CAFC noted that before 1870, "the date when inventors were first statutorily required to particularly and distinctly claim their invention[,] . . . the scope of protection turned on the embodiments disclosed in the specification. Courts read these specifications broadly, to include equivalents, in order to give the patentee the full scope of an invention." Hilton Davis Chemical Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1537 (Fed. Cir. 1995).

[253] Federal Court Improvements Act of 1982, 96 Stat. 25 (1982) (codified as amended in 28 U.S.C. et. seq.).

[254] *See* 28 U.S.C. § 1295(a)(4)(A), (B) (1997).

D. *The Doctrine of Equivalents, Even One Utilizing an Element-By-Element Approach, Acts to Suppress Competition*

The application of patent law to biotechnology has occasionally proved problematic.[255] The doctrine of equivalents also creates economic problems for the biotechnology industry because it may not significantly reduce the risk of illegitimate competition while at the same time affording larger companies a legal weapon to use against smaller companies.

Judge Newman of the CAFC noted in her concurrence to *Hilton Davis*[256] that the purpose of the doctrine of equivalents was to "adjust[] the relationship between the originator and the second-comer who bore neither the burden of creation nor the risk of failure."[257] However, the development of new biotechnologically-produced drugs is nearly as burdensome and risky for second-comers as for innovators because every new drug, no matter how similar to a patented drug, must pass through the FDA's extensive approval procedure.[258] Judge Newman also noted that "the patentee . . . may be encouraged [to develop new products] by the broader commercial protection of the doctrine of equivalents."[259] However, much of the development in biotechnology does not necessarily respond primarily to risk and the potential scope of claims.[260] For example, university research laboratories, which

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[255] *See supra* note 12 (discussing several problems arising from the application of patent law to biotechnology).

[256] *Hilton Davis*, 62 F.3d 1512, 1529 (Fed. Cir. 1995)(Newman, J., concurring).

[257] *Id.* at 1531. According to Judge Newman, the risk of innovation in technical fields tends to be high, and a policy of literal claim reading unduly lowers the risk of innovation to competitors as opposed to pioneering inventors. *Id.* at 1532. The doctrine of equivalents ostensibly protects the innovator from opportunistic, unsubstantially-innovating competitors, thereby encouraging substantial innovation. *Id.*

[258] For a discussion of FDA-mandated drug trials see *supra* Part I.B.

[259] *Hilton Davis*, 62 F.3d at 1533.

[260] *See* Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 793 (1992).

perform research for prestige and to expand general knowledge, work under government grants and are not constrained by profit motive.[261] Many biotech companies work in alliance with such research labs. Thus, application of the doctrine of equivalents may not be important for encouraging or reducing the risk of biotechnological product development, while providing increased potential for anticompetitive acts by larger companies.

A problem facing small competitors is that of predatory litigation by larger companies.[262] Since patent owners are allowed to enforce their patent rights through litigation, a large company may use the threat of litigation, or extended litigation, to frustrate competitors.[263] Such use of litigation acts to control a market and suppress competition.[264] It can also be a source of income for the

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[261] *Id.* at 793.

[262] *See generally* Michael Paul Chu, *An Antitrust Solution to the New Wave of Predatory Patent Infringement Litigation*, 33 WM. & MARY L. REV. 1341, 1341 & n.3 (1992) (discussing the use by companies of patents as "swords to cut down their competitors" in areas involving high-technology, including "manufacturers of computers, semiconductors, and consumer electronics"). The same problems will arise in biotechnology because both industries spend a great deal on research and development, and the potential markets are large. *See supra* notes 4-11 and accompanying text (describing research expenditures by several companies in 1996).

[263] *See* Chu, *supra* note 262, at 1341-42. For example, Texas Instruments ("TI") sued nine other corporations for alleged infringements of chip manufacturing processes; TI garnered $191 million in 1987 from the actions. *See* Chu, *supra* note 262, at 1341. Richard Agnich, senior vice president and general counsel of TI considered litigation an "untapped resource" that TI had, until then, "been underutilizing." Chu, *supra* note 262, at 1341.

[264] Chu, *supra* note 262, at 1352. Such litigation can "force competitors to pay higher royalties or even drive them out of the market completely." Chu, *supra* note 262, at 1352. The cost of patent litigation can be quite high. Litigation between Du Pont and Cetus over the polymerase chain reaction cost Cetus approximately $3.2 million. *See* Pasahow, *supra* note 231, at 39. Litigation between Xoma and Centocor cost both parties an aggregate of $12 million. Pasahow, *supra* note 231, at 39.

Some costs, however, are not monetary. During the litigation between Xoma and Centocor, both companies may have lost regulatory approval for their disputed products because of testimony introduced at trial attacking the studies supporting the patent applications. Pasahow, *supra* note 231, at 40. Also, Genetics Institute, in losing litigation between itself and Genentech, was "unable

large company.[265] Smaller companies on the receiving end suffer burdensome legal costs, and are forced to divert precious research funds to nonproductive uses.[266] Innovation suffers, and monopoly, already a strong tendency in the industry, is encouraged.[267]

The doctrine of equivalents, available to any plaintiff, can only serve to encourage monopolization and predatory litigation because it encourages a lack of clarity in the scope of claims, increasing the potential for infringement by competitors developing products similar to patented ones. Biotechnology, an industry with many small players and a few large companies, may be particularly prone to litigation of this type.[268] Predatory litigation, however, would be less of a threat if an assertion of infringement under the doctrine were available only after a judge had reviewed the case and held the assertion valid.

Aside from threats of litigation, the uncertainty introduced into the scope of claims fostered by the doctrine acts to discourage

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to continue its separate existence, and allowed itself to be acquired by American Home Products." *See* Pasahow, *supra* note 231, at 40. Ironically, the uniformity of patent interpretation brought about by the creation of the CAFC "actually transformed the strongest protective aspects of the patent system into weapons for offensive use against legitimate competition." Chu, *supra* note 262, at 1351-52.

[265] Chu, *supra* note 262, at 1352. "The mere defense of a patent and challenge of an allegedly infringing device are no longer exclusive motivations. . . . [F]irms recently have realized that huge damage awards in patent infringement suits can conveniently boost the trickle of royalties." Chu, *supra* note 262, at 1352. One temptation for a firm bringing successful suits is to rely on such suits as a source of income. Chu, *supra* note 262, at 1352.

[266] Chu, *supra* note 262, at 1353. Litigation costs can be substantial burdens to new companies. The cost of a preliminary court action may cost a company $100,000, which may represent a year's profit for a smaller company. *See* Murphy, *supra* note 231, at 4.

[267] Pasahow, *supra* note 231, at 41. "[M]any biotechnology companies believe that monopoly rights are necessary to justify the investment necessary to develop and obtain approval for a therapeutic drug." Pasahow, *supra* note 231, at 41 (paraphrasing the testimony of Kirk Raab, CEO of Genentech, before a Congressional committee). The worth of a company may also depend heavily upon an anticipated monopoly position. Pasahow, *supra* note 231, at 41.

[268] *See supra* notes 4-11 and accompanying text (describing the relative sizes of public corporations in biotechnology).

product development. While broad patents help protect investment, "patent scope should not extend further than necessary to accomplish this objective, because patents restrict distribution of the invention and reduce incentives to make improvements."[269] In fact, one economic model of patents argues that, since biotech companies derive funds from sources other than patented products, "patent scope should be just broad enough to allow the inventor to recover the cost of the inventions."[270]

CONCLUSION

The biotech industry suffers under a confusing doctrine of equivalents, whether a court applies the broad CAFC application or the Supreme Court's element-by-element approach. Both approaches act to confuse the interpretation of claims within biotech patents, and therefore act to suppress competition and new product development. However, the doctrine of equivalents serves a useful purpose in protecting a patentee. The Supreme Court has stated that "[t]he essence of the doctrine [of equivalents] is that one may not practice a fraud on a patent."[271] The best solution, therefore, is to retain the doctrine, but as a purely equitable remedy available in exceptional cases. Its potential availability will protect patentees who have legitimate need of the doctrine's application, while its limited use will reassert desired certainty into patents and discourage nonmeritorious litigation.

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[269] Ko, *supra* note 260, at 793.

[270] Ko, *supra* note 260, at 795. The model described is the "incentive-to-invent" model of how patents stimulate innovation. Ko, *supra* note 260, at 791-73. The theory balances incentive to innovate with burdens on other inventors by suggesting that patent scope be broad enough to recover the cost of innovation, but no more. Ko, *supra* note 260, at 795. Strictly applied, this model is somewhat too restrictive, since profit is an acceptable and desirable goal of a free market; nevertheless, it properly takes into account the negative effect overly broad patents have on potential competitors. Ko, *supra* note 260, at 793.

[271] Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950).