January 2002


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I. INTRODUCTION

CellPro, a biotechnology company in Seattle, Washington, developed an extraordinary device. Its Ceprate system separates stem cells from blood and enables the reintroduction of healthy stem cells into patients who have undergone debilitating radiation treatment. This device was so effective that it cured CellPro’s own CEO, Rick Murdock, of his deadly form of cancer. The Food and Drug Administration (FDA) approved CellPro’s Ceprate system for sale in the United States, but it is not on the market.

The Ceprate system is not for sale because the United States District Court for the District of Delaware found that CellPro willfully infringed four patents in the creation of the Ceprate device. Those four patents were initially found to be invalid in a jury trial. However, the district court overturned the jury’s decision by granting the patents’ assignees and licensees’ motion for judgment as a matter
of law ("JMOL") using de novo review. After its own de novo claim construction, the district court remanded the case to another jury. That jury trial found CellPro had willfully infringed the patents. That decision was upheld on appeal and as a result CellPro dissolved, along with its Ceprate system. This cancer-curing device was shelved.

Rick Murdock comments on his experience with CellPro, Ceprate, and the district court in his book, Patient Number One. He describes the entire process as "a sham, a kangaroo court... about as real as pro wrestling." Rightfully upset, Murdock was on the losing side of the case that destroyed the very technology that saved his life. Stem cells continue to help biomedical research gain significant ground in the fight against cancer and other life-threatening diseases. Yet the rush by scientists to patent their discoveries creates tension between open scientific research, and exclusivity and profit protection. This tension is all the more evident when life-saving technology is at stake because it is difficult to morally justify restricting technology that could eradicate debilitating diseases for the sake of exclusive intellectual property rights. Is Murdock right? Was his experience with the justice system a sham? Is the district court's review of jury verdicts too powerful? Maybe Markman has changed the patent review system too much.

The opinion in Markman anticipated the possibility of "certainty in claim construction... early settlements, reduced litigation costs, and increased judicial efficiency." In practice however, it has had

10. Id. at 185.
12. See MURDOCK & FISHER, supra note 1, at 288–89.
13. Id. at 291.
14. See MURDOCK & FISHER, supra note 1.
15. Id. at 244.
16. See id. at 268–71.
the opposite effect.20 The Federal Circuit now reverses approximately forty percent of the claim constructions it reviews on appeal.21 Litigation is not reduced as anticipated, since "[p]arties are much less willing to settle knowing that there exists a forty percent chance that the Federal Circuit will reverse the claim construction and remand the case for trial under a new construction."22 If reality after Markman is a system fraught with uncertainty and added expense,23 one cannot help but agree with Murdock. After all, the patent system was created to "promote the progress of science and useful arts" by protecting rights of inventors.24 Congress created the United States Court of Appeals for the Federal Circuit as a court with exclusive jurisdiction over patent-related appeals.25 Congress hoped to avoid forum shopping and create certainty in patent cases.26 Further adding to the confusion is that the United States Constitution protects the right to a trial by jury.27 Unless Congress takes the Federal Circuit one step further by creating an even more highly-specialized patent court system, a jury should be allowed to continue its fact-finding function in patent claim construction without the threat of de novo review by the Federal Circuit.

II. PATENT PROTECTION AND BIOMEDICAL RESEARCH

The Constitution attributed to Congress the role of promoting "the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."28 The Framers found value in the right of an inventor to protect the property interests in his invention29 and sought to protect the inventor.30 A patent system was seen as a way of protecting the public's interest in innovation and allowing the public to benefit from that innovation.31 Such public benefits are the "protection of investments in inventions and expansion of the public

20. Id. at 1270–71.
21. Id. at 1270.
22. Id. at 1274.
23. See id. at 1270–74.
27. U.S. CONST. amend. VII.
30. Id. at 1263.
31. Id. at 1259.
domain by encouraging the disclosure of trade secrets." In areas like medicine, where the goals of research and invention are eliminating life-threatening human disease, the question remains whether the rush to patent places "undue constraints on knowledge in the public domain."

One such example is the wealth of research on human and animal stem cells. Multi-cellular life starts with a single cell. That cell divides, specializes, and becomes an entire human being. As cellular division progresses, specialized pluripotent cells develop that "can give rise to cells that have a particular function," such as becoming a heart cell or a lung cell. One of the best-understood stem cells so far is the blood stem cell. From blood stem cells one can "grow an entire immune system and all the blood cells necessary to circulate oxygen to the tissues." Scientists hope to locate these pluripotent cells, since their discovery could unlock the key to human development.

Deciphering the cell-specialization process through stem cell research would not only augment the understanding of human development, but would also increase the likelihood of curing many diseases. Although stem cells are powerful and crucial to development, they are "very rare and difficult to locate." Dubbed the "Holy Grail," biomedical researchers are still working to isolate stem cells in the hope they can be cultured, grown, and used to repair damaged cells. Many life-threatening diseases and chronic disorders result from "disruption of cellular function" and the "destruction of tissues of the body." Stem cells are a potential

32. Id. at 1260. See also DONALD CHISUM ET AL., PRINCIPLES OF PATENT LAW 70–81 (2d ed. 2001).
33. Dawson, supra note 19, at 1260.
35. Id.
36. Id.
37. Id.
38. MURDOCK & FISHER, supra note 1, at 25.
40. PRIMER, supra note 34.
43. PRIMER, supra note 34.
“renewable source of replacement cells”\textsuperscript{44} that, if isolated, could regenerate an “entire immune system” and make organ and tissue transplants “safe and reliable.”\textsuperscript{45} Key stem cell-related treatment would focus on “human development abnormalities” or the “regulation of uncontrolled cellular growth associated with cancer” with the ultimate goal of “new drug targets and test potential therapeutics.”\textsuperscript{46} If stem cell research is allowed to continue,\textsuperscript{47} future discoveries could promise treatments, or even cures, for spinal cord injuries, heart disease, Parkinson’s disease, Alzheimer’s disease, arthritis, and other debilitating human diseases.\textsuperscript{48}

One example of the drive to research and patent stem cell procedures is Stem Cells, Inc. (StemCells), a Palo Alto, California company. The focus of StemCells’ research is brain, liver, and

\begin{itemize}
\item \textsuperscript{44} Id. \\
\item \textsuperscript{45} MURDOCK \& FISHER, supra note 1, at 25. \\
\item \textsuperscript{46} Statement of National Institutes of Health Before the Senate Appropriations Subcomm. on Labor, Health and Human Services, Education and Related Agencies, (Aug. 1, 2001) [hereinafter Statement] (statement of Maria C. Freire, Ph.D., Director, National Institutes of Health Office of Technology Transfer), at http://www.nih.gov/news/stemcell/080101freire.htm. \\
\item \textsuperscript{47} Even though stem cell research may lead to the cure of some of the most threatening of human diseases, their source has caused political controversy that has restricted research. In order to find these cells, researchers must go back in time to the early stages of human development, when the body’s systems are being formed—the embryonic stage. Krieger, supra note 39, at 1F. Until August 25, 2000 there was a ban in the United States on federally funded stem cell research derived from human fetal tissue. \textit{Id.} \textit{See generally} National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976 (Aug. 25, 2000), corrected 66 Fed. Reg. 69,951 (Nov. 21, 2000), withdrawn 66 Fed. Reg. 57,107 (Nov. 14, 2001), available at http://www.nih.gov/news/stemcell/stemcellguidelines.htm. At the same time, the government of the United Kingdom, supported by the British Medical Association, proposed a lifting of a similar ban in the UK. Georgina Kenyon, \textit{UK Medical Group Backs Stem Cell Research}, REUTERS HEALTH, Nov. 17, 2000. Prior to the November 2000 presidential election, there was growing concern among the stem cell research community that a conservative presidential administration would reintroduce the ban and further hamper important research. Interview with George Dunbar, Former President and CEO, StemCells, Inc., in Los Gatos, Cal. (Aug. 25, 2000). As feared, federal funding for stem cell research was limited in 2001. Federal research grants will only be available to further research on stem cell lines in existence prior to 2001. Future funding is limited out of the fear that taxpayer money would be used to “sanction or encourage further destruction of human embryos that have at least the potential for life.” President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), available at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html. However, the United States is not the only country favoring a limit to stem cell research. A recent vote of the German Parliament “signifies a tightening of restrictions for researchers.” Lucian Kim, \textit{Germany Tightens Stem-Cell Imports}, \textit{CHRISTIAN SCI. MONITOR}, Feb. 1, 2002, at http://www.csmonitor.com/2002/0201/p08s01-woeu.htm. \\
\item \textsuperscript{48} PRIMER, supra note 34. \textit{See also} Nowak, supra note 17.
\end{itemize}
pancreatic stem cells.\textsuperscript{49} Using stem cells that have "already committed themselves to become brain cells," StemCells hopes that once implanted these cells will "connect with other neural cells and set up the brain's circuitry."\textsuperscript{50} Thus far, researchers have successfully injected and grown new working neural tissues in laboratory mice, coming closer to the re-growth of human brain tissue.\textsuperscript{51} They are in the preclinical phase of testing the efficacy of these procedures to cure degenerative brain diseases by literally re-growing healthy tissue.\textsuperscript{52} A scientist from StemCells repaired a mouse's liver using stem cells derived from mouse bone marrow, further evidencing the potential of such technology.\textsuperscript{53} A hope of stem cell researchers is to develop a "source of highly defined engraftable human cells capable of extensive liver regeneration" as an alternative to liver transplants.\textsuperscript{54}

However, the search for cures, albeit humanitarian, is not the focus of most biomedical companies since products and sales are what propels the market economy.\textsuperscript{55} The force of profit-driven companies is the patent; "the financial lifeblood of biotech."\textsuperscript{56} Biotechnology companies are not left out of the rush to patent since the holding of \emph{Diamond v. Chakrabarty}\textsuperscript{57} allowed the patenting of man-made biological material. The United States Supreme Court held that the meaning of "manufacture" and "composition of matter" from Title 35 of the United States Code, section 101\textsuperscript{58} included biological organisms created by genetic engineering.\textsuperscript{59} The Court concluded that it was Congress's function, "not the courts["]," to
"define the limits of patentability." Focusing on congressional testimony, the Court interpreted congressional intent for patentable subject matter to include "anything under the sun that is made by man."

StemCells is one of many companies to capitalize on the holding of Chakrabarty. In point of fact, StemCells researchers recently patented both a process to separate stem cells for laboratory growth and a model for identifying progenitor cells. In total, StemCells "owns or has exclusive license to twenty-five issued U.S. patents ... as well as fifteen U.S. applications." The existence of patents combined with limiting licensing agreements can significantly hamper scientific research. There is concern that a patent holder may "exercise its rights through licensing in a manner inconsistent with the advancement of basic research." Stuart Orkin, of Harvard Medical School, referred to stem cells and stem cell research as "therapeutic gold" based on the potential for development of new drugs. Yet patents on stem cell isolation techniques limit access to that gold, potentially at the expense of beneficial medical research. Patents may hold great economic value to their holders, but there is equally significant value to society when research is "widely available to scientists" and researchers. So while science advances through open access to research, business advances through the restriction of access. However, the National Institutes of Health (NIH) believes effective negotiation and "[s]trategic licensing" can "provide for the continuing availability of exclusively licensed subject matter to researchers in order to ensure progress of biomedical research." This solution offered by the NIH does not eliminate the conflict, and it is this very tension between research goals and exclusive patent rights, combined with a failure to

60. Id. at 315.
61. Id. at 309.
63. Id. For example, one patent covers the method for isolating and growing human neural stem cells.
64. Statement, supra note 46.
65. Stem Cells, supra note 53.
66. Statement, supra note 46.
67. Id.
negotiate a license, that is at the heart of the CellPro patent infringement case.

III. THE CELLPRO PATENT INFRINGEMENT CASE

During the 1980s scientists on opposite coasts of the United States were working independently on techniques for isolating stem cells. Two groups were actively attempting to discover successful procedures that would isolate stem cells. One research group, at Johns Hopkins University, patented its procedures, while the other group, in Seattle, did not. The Seattle group used its technology, formed CellPro, and took a working therapeutic device through clinical trials. They gained approval for sale by the FDA for the device. The Johns Hopkins group that patented the procedure licensed this technology to Baxter Healthcare, who had not been successful themselves in creating a similar device. CellPro's attorneys analyzed Johns Hopkins' patents and believed them to be invalid. After licensing negotiations failed between Baxter and CellPro, Baxter, the putative licensee, sued CellPro for patent infringement. A jury agreed with CellPro's attorneys that the Hopkins' patents were invalid, but the judge, with the power to construct the patent claim, reversed the verdict.

A. The Civin Patents

Curt Civin, a researcher at Johns Hopkins University Oncology Center, was working in the 1980s on the blood stem cell isolation problem to create "a purified, cancer-free suspension" to be used to treat leukemia patients after radiation treatment. Civin focused specifically on the functionality of antibodies in blood cell labeling.

68. MURDOCK & FISHER, supra note 1, at 25.
70. MURDOCK & FISHER, supra note 1, at 27–28.
71. Id. at 240.
72. Id. at 270.
74. MURDOCK & FISHER, supra note 1, at 52–54, 70–71.
77. MURDOCK & FISHER, supra note 1, at 25.
79. Id. at 308.
He hoped to create an antibody to bind with a specific antigen on a blood stem cell so the stem cell, once bound, could be identified from other surrounding cells. Thinking there may be a specific antigen on immature blood cells, Civin repeatedly experimented with different antibodies until he discovered an antibody that bound immature blood cells effectively. Civin named his newly discovered “biological homing pigeon the My-10 antibody.”

On the opposite coast, a researcher from Seattle was working on the same problem and developed a stem cell binding system similar to Civin’s that ultimately evolved into CellPro’s Ceprate device. Irwin Bernstein, at the Fred Hutchinson Cancer Research Center in Seattle, discovered a monoclonal antibody. His antibody, the 12.8 antibody, bound to a different site on a blood stem cell than Civin’s My-10 antibody. Bernstein’s antibody also possessed properties different from the My-10 antibody. Specifically, the 12.8 antibody bound to biotin. This gave the 12.8 antibody greater laboratory utility, since the ability to bind to biotin allowed the 12.8 antibody to be used in experiments with primates. This factor took the researchers in Seattle one step further than Civin’s research. Biotin binds solidly with the protein avidin. After binding the antibody to biotin, the antibody could be bound to stem cells. This mixture of blood cells could then be passed through a separating device coated with avidin.

80. See Kenneth Muhammad, Note, An Analysis of Patent Claim Construction for Newly Invented Monoclonal Anti-bodies, Johns Hopkins University v. CellPro, Inc., 152 F.3d 1342 (Fed. Cir. 1998), 18 TEMP. ENVT'L L & TECH. J. 95, 96 (1999). Antibodies have binding properties and monoclonal antibodies in particular have “antigen-specific binding sites.” This means that the reaction between antibodies and antigens is very specific: “one monoclonal antibody interacts with one antigen.” Johns Hopkins Univ., 931 F. Supp. at 308.

82. MURDOCK & FISHER, supra note 1, at 26.
83. Id. at 26–28.
84. See Irwin Bernstein, Therapy of Lymphoma/Leukemia with Monoclonal Antibodies (Project CA44991), National Cancer Institute, available at http://researchportfolio.cancer.gov/cgi-bin/abstract.pl?Term=27&CSO=5.5&ProjectID=37559 (last visited Apr. 8, 2002).
85. MURDOCK & FISHER, supra note 1, at 26.
86. Id.
87. Id.
88. Biotin is a vitamin and this binding ability allowed 12.8 to bind with primate cells, allowing the possibility of clinical trials with nonhuman primates. Johns Hopkins Univ. v. CellPro, 931 F. Supp. 303, 311 (D. Del. 1996).
89. MURDOCK & FISHER, supra note 1, at 26.
90. Id. at 27.
91. Id.
92. Id.
The stem cells would stick to the avidin and separate from the rest of the blood cells.93 The procedure ultimately worked and the "biotin stuck to the avidin as if it were flypaper, carrying with it the antibody and the stem cell."94 CellPro constructed their Ceprate stem cell separation system out of this process.95 The My-10 antibody would not work in the Ceprate system because the antibody lacked the ability to bind to biotin.96

On February 6, 1984, a patent was filed on behalf of Johns Hopkins University. This patent issued as U.S. Patent 4,714,680 (the '680 patent) and claimed a purified suspension of stem cells.97 The second patent issued as U.S. Patent 4,965,204 (the '204 patent) and claimed Civin's My-10 monoclonal antibody.98 The third patent, U.S. Patent 5,035,994 (the '994 patent) claimed a method of creating a purified suspension of stem cells.99 The final patent, U.S. Patent

93. Id.
94. Id. at 27–28.
96. MURDOCK & FISHER, supra note 1, at 51.

A suspension of human cells from marrow or blood comprising cells having a cell-surface antigen recognized by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-8493 and substantially free of cells that do not have a cell-surface antigen recognized by said antibody, said suspension having the ability to restore the production of lymphoid and hematopoietic cells to a human lacking said production.

Id. (emphasis added).
98. See U.S. Patent No. 4,965,204 (issued Oct. 23, 1990). The relevant portion of claim one recites:

A monoclonal antibody which specifically binds to an antigen on non-malignant, immature human marrow cells, wherein said antigen is stage specific and not lineage dependant, and said antigen is also specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-8483;

(a) which antigen is present on non-malignant, human blood or bone marrow;

(b) which antigen is present on a maximum of about 5% non-malignant, human marrow cells and a maximum of about 1% non-malignant, human peripheral blood cells; and

(c) which antigen is not present on non-malignant mature human myeloid and lymphoid cells.

Id. (emphasis added).

A method of isolating a population of human cells containing pluripotent lympho-hematopoietic stem cells comprising;
5,130,144 (the '144 patent) claimed the method for using the pure suspension in bone marrow transplants.\textsuperscript{100}

Johns Hopkins University was granted an assignment of these four patents and in turn licensed them to Becton Dickinson (Becton) and Baxter Healthcare (Baxter).\textsuperscript{101} The Hutchinson research center did not attempt to patent Bernstein's 12.8 antibody, but granted a license to use the antibody to CellPro.\textsuperscript{102} In December 1996, after extensive clinical trials, CellPro's Ceprate device received approval by the FDA.\textsuperscript{103} The comparable Baxter device, the Isolex system, met with poor success\textsuperscript{104} and a product launch was not expected until 1999.\textsuperscript{105}

When CellPro learned of Civin's patents, its attorneys evaluated the patents and believed that two of the four patents were invalid and therefore unenforceable.\textsuperscript{106} According to the court, when CellPro was formed, its investors, officers, and directors knew of the '680

(a) providing a cell suspension from human tissue, said tissue selected from the group consisting of marrow and blood;
(b) contacting said cell suspension with a monoclonal antibody to immature human marrow cells that is stage-specific and not lineage dependent so that said antibody binds to said stem cells, wherein said antibody specifically binds an antigen on human pluripotent lymphohematopoietic stem cells said stem cells expressing an antigen that is specifically bound by the monoclonal antibody produced by the hybridomas deposited under ATCC Accession No. HB-8433 and does not specifically bind an antigen on mature, human myeloid and lymphoid cells; and
(c) separating and recovering from said cell suspension the cells bound by said antibody, said bound cells being substantially free of mature lymphoid and myeloid cells.

\textit{Id.} (emphasis added).

\textsuperscript{100}See U.S. Patent No. 5,130,144 (issued July 14, 1992). Claim one recites:

A method of transplanting stem cells comprising:

(a) providing a suspension of human cells comprising pluripotent lymphohematopoietic stem cells substantially free of mature lymphoid and myeloid cells, having the ability to restore the production of lymphoid and hematopoietic cells in a patient where such production is lacking; and
(b) administering said cell suspension to a human patient in an amount effective to effect such restoration.

\textit{Id.} (emphasis added).

\textsuperscript{101}Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1349 (Fed. Cir. 1998).
\textsuperscript{102}MURDOCK & FISHER, supra note 1, at 44.
\textsuperscript{103}Id. at 240.
\textsuperscript{104}Id. at 270.
\textsuperscript{105}Id. at 292. The Isolex system was actually produced by a subsidiary of Baxter Healthcare, Nexell. Nexell announced its product launch date after acquiring CellPro technology after the end of the lawsuit.
CellPro’s in-house counsel reviewed the ’680 patent and “concluded the patent was invalid.” Based on review of the file wrapper and two abstracts of Civin’s work, the attorneys concluded the patent was “invalid for obviousness.” Civin had published his research over a year before the patent application had been filed; thus, Civin’s own research acted as prior art against the ’680 patent.

After writing an opinion on the validity of the ’680 patent, CellPro’s in-house counsel also provided CellPro with an opinion on the ’204 patent. Again, the conclusion was that the ’204 patent was invalid and unenforceable. Its in-house counsel reported to CellPro that the patent was “obvious in light of prior art publications” and that “CellPro does not infringe claims 2, 3, 5 and 6 of the ’204 patent.”

Neither attorney gave an opinion regarding claims 1 or 4 of the ’204 patent. Apparently concerned only with the ’680 and ’204 patents, no other legal opinions were given regarding the ’114 or the ’994 patents. Yet in preparation for its initial product launch and initial public offering, CellPro announced in its prospectus: “Based on the advice of Lyon & Lyon, special patent counsel to the company, CellPro believes the . . . patents are invalid and unenforceable.”

B. The Patent Infringement Litigation History

Even though CellPro thought the Civin patents were invalid, it entered into license negotiations with Baxter Healthcare in an attempt to avoid a lawsuit. Negotiations failed and the licensing deal fell through. CellPro then initiated a lawsuit hoping to “gain the home court advantage” as well as a declaratory judgment that the patents

107. Id. at 187. Although Murdock claims he never knew “exactly when CellPro’s original management became aware of the existence of these patents. What is certain is that management believed completely that these patents presented no serious legal problems.” MURDOCK & FISHER, supra note 1, at 44.

108. Johns Hopkins Univ., 978 F. Supp. at 187. Kiley was not only CellPro’s legal counsel but also a former partner at the law firm Lyon & Lyon with experience in both patent prosecution and patent litigation. Id. Kiley was also counsel for Genentech and wrote the winning brief in Diamond v. Chakrabarty. CellPro also hired a current Lyon & Lyon partner, Coe Bloomberg, to provide an opinion on the ’680 patent. MURDOCK & FISHER, supra note 1, at 57.


110. Id.

111. Id. at 188.

112. Id.


115. MURDOCK & FISHER, supra note 1, at 48–52.

116. Id. at 52–54.
were invalid. On April 28, 1992, CellPro filed suit against licensees Baxter Healthcare and Becton Dickinson in federal district court in Seattle, Washington. The court then determined Johns Hopkins to be an indispensable party and the lawsuit was consolidated and reorganized in Delaware.

In the first trial in Delaware, there was immediate concern the technology would be too confusing for a jury, since “the language of science does not translate easily into terms comprehensible to the layperson.” However, even with a complex set of instructions and questions, the jury found Civin’s patents invalid. On August 4, 1995, it found the Civin patents invalid “as obvious in light of the prior art” and invalid “as not enabled.”

After the jury verdict, Johns Hopkins filed, and was granted, a motion for JMOL. The jury verdict was overturned. The district court judge granted the motion on June 28, 1996 for the following issues: 1) infringement and induced infringement of the '680 patent; 2) induced infringement of the '144 patent; and 3) enablement of the '680 patent. Judge McKelvie explained that the decision to grant a JMOL after a jury verdict involves the determination of “whether substantial evidence exists in the record to support the jury’s verdict when the correct legal standard is applied.” Although Judge McKelvie cautioned that “the court should not substitute its view of the facts for that of the jurors,” the prevailing ruling was derived from Markman:

The construction of patent claims is a matter for the court. In construing the words and phrases in a claim, the court should give those words and phrases their ordinary meaning, unless the specification clearly indicates that the inventor intended a different meaning. The court may also consider other words in the claim,

117. Id. at 55.
118. Id. at 58.
119. Id. at 70–71.
120. Id. at 83.
125. Johns Hopkins Univ., 931 F. Supp. at 313 (citing Wagner v. Fair Acres Geriatric Ctr., 49 F.3d 1002, 1017 (3d Cir. 1995)).
other claims in the patent, the specification, the prosecution history, and expert testimony and other extrinsic evidence.\textsuperscript{126}

*Markman v. Westview Instruments, Inc.* was a patent infringement case in which the term “inventory” in the patent for a dry cleaning device was at issue.\textsuperscript{127} The Federal Circuit held that district court judgments are reviewed de novo to determine whether the lower courts’ standards were “correct as a matter of law.”\textsuperscript{128} Specifically, in the case of JMOL, “the court retains the power and duty to say what the correct law is, and then to examine the factual issues submitted to the jury and determine whether findings thereon are supported by substantial evidence and support the verdict under the law.”\textsuperscript{129} The Federal Circuit identified a conflict—whether patent claim construction is a matter of law or fact\textsuperscript{130}—and concluded that claim construction is a matter of law to be decided by the court.\textsuperscript{131} Viewing what it thought were inconsistencies,\textsuperscript{132} the Federal Circuit definitively established that “the interpretation and construction of patent claims, which define the scope of the patentee’s rights under the patent, is a matter of law exclusively for the court.”\textsuperscript{133}

Rationalizing the patent as a written instrument, the Federal Circuit further explained that as a “fundamental principle of American law,” patent construction is a matter for the court to determine.\textsuperscript{134} As a “fully integrated written instrument,” a patent is “uniquely suited for having its meaning and scope determined entirely by a court as a matter of law.”\textsuperscript{135} Using a jury to decide patent construction as a matter of fact “would at once deprive the inventor of the opportunity to obtain a permanent and universal definition of his rights under the patent, and in each case of infringement it would subject him to the danger of false interpretation, from the consequences of which he could not escape.”\textsuperscript{136}

\textsuperscript{126} Johns Hopkins Univ., 931 F. Supp. at 313 (citations omitted) (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 979–81 (Fed. Cir. 1995)).
\textsuperscript{127} Markman v. Westview Instruments, Inc., 52 F.3d 967, 973–74 (Fed. Cir. 1995).
\textsuperscript{128} Id. at 975.
\textsuperscript{129} Id.
\textsuperscript{130} Id. at 976–77.
\textsuperscript{131} Id. at 977–79.
\textsuperscript{132} Id. at 979.
\textsuperscript{133} Id. at 977–79.
\textsuperscript{134} Id. at 970–71.
\textsuperscript{135} Id. at 978.
\textsuperscript{136} Id. at 979.
While the CellPro case was being decided, the Supreme Court reviewed *Markman*. The Court affirmed the Federal Circuit's right to review patent claim construction de novo. Looking back to jury practices in the 18th century, the Court found no historical standard requiring juries to interpret patent claims. In fact, the Supreme Court held that a judge was inherently better positioned than a jury to construe patent claims. The Court saw patent construction as a special occupation, requiring like all others, special training and practice. The judge, from his training and discipline, is more likely to give a proper interpretation to such instruments than a jury; and he is, therefore, more likely to be right, in performing such a duty, than a jury can be expected to be.

Using this clarification from the Supreme Court, Judge McKelvie established the "proper construction of the Civin patent claims." Focusing on the phrases "specifically binds," "wherein," and "substantially free," Judge McKelvie found that "[n]o reasonable jury could conclude that CellPro did not infringe and induce infringement of claims 1-5 of the '680 patent and induce infringement of claims 1-4 of the '144 patent" and ordered new trials for the '994 and '204 patents. Judge McKelvie also determined that "no reasonable jury could conclude that claims 1-5 of the '680 patent are invalid for lack of enablement." New trials were allowed for the remaining issues of obviousness and lack of enablement for the '994 and '204 patents. Johns Hopkins University then withdrew its claims for the '994 and '144 patents and the district court moved forward with a trial on damages and willful infringement.

On remand, the second jury found CellPro willfully infringed the Civin patents and granted Johns Hopkins' motion for treble damages.

138. *Id.*
139. *Id.* at 379–84.
140. *Id.* at 388.
141. *Id.* at 388–89 (citing Parker v. Hulme, 18 F. Cas. 1138, 1140 (CC ED Pa. 1849) (No. 10,740)).
143. *Id.* at 313–14.
144. *Id.* at 313.
145. *Id.* at 318.
146. *Id.* at 319.
147. *Id.* at 325.
150. *Id.* at 184.
Critical in this decision was McKelvie’s view of the legal opinions by CellPro’s in-house counsel. McKelvie called CellPro’s argument of reliance on advice from counsel a “weak and disingenuous defense of alleged good-faith reliance on the advice of counsel.” He called their testimony insincere and said it lacked credibility. Overall McKelvie criticized the opinions as so obviously deficient, one might expect a juror to conclude the only value they had to CellPro in the world outside the courtroom would have been to file them in a drawer until they could be used in a cynical effort to try to confuse or mislead what CellPro, its Board, and counsel must have expected would be an unsophisticated jury.

He also considered the opinions to be a “weak pass at the quality of work one might expect from independent counsel.”

CellPro appealed both the JMOL and the finding of willfulness; yet each decision, as well as the Markman standard of de novo review, was upheld. The court of appeals explained a factual determination of willful infringement would not be reversed “unless it was unsupported by substantial evidence.” An award of treble damages is reviewed only for “an abuse of discretion.” The only abuse of discretion by Judge McKelvie was an order for repatriation and destruction of some CellPro technology. The decisions that the legal opinions were incompetent and that both the district court and court of appeals could review claim construction de novo were upheld.

IV. WAS MURDOCK RIGHT?

Is the patent infringement court process “about as real as pro wrestling,” as Murdock claims it is? Although questionable in light of the judge’s personal remarks regarding the case, the judgment as a matter of law was not improperly decided. Yet the Federal Circuit

151. Id. at 196.
152. Id. at 193.
153. Id.
154. Id.
156. Id. at 194.
158. Id.
159. Id. at 1366.
160. Id. at 1364.
161. Id. at 1353.
reaffirmed its power to perform de novo review. This system of review has the potential to improperly shift the balance of judicial power and should be carefully scrutinized until Congress develops a more specialized patent review system.

A. JMOL and Appeals

Both rights of appeal and JMOL are established by statute. However, the intersection of these procedures with the power of review and claim construction from *Markman* grants too much power to a single judge. In CellPro’s case, McKelvie first determined the patent claim construction for the jury, essentially telling them what the patent meant. Yet even after the jury entered the verdict, the judge again intervened. If the court of appeals can review the facts as if for the first time, why have a jury at all?

Rule 50 of the Federal Rules of Civil Procedure establishes judgment as a matter of law. Essentially, if a judge finds

there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue, the court may determine the issue against that party and may grant a motion for judgment as a matter of law against that party with respect to a claim or defense that cannot under the controlling law be maintained or defeated without a favorable finding on that issue.

These motions may be made before the case is submitted to the jury and, if the court agrees, the judge then will direct the verdict. Motions may also be made after the trial, but a grant of such a motion is improper “unless there is ‘such a complete absence of evidence supporting the verdict that the jury’s findings could only have been the result of sheer surmise and conjecture’.” Therefore, the trial judge should only grant a motion for a JMOL if “convinced

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165. Id. (outlining the jury instructions).
167. FED. R. CIV. P. 50.
168. Id. 50(a)(1).
169. Id. 50(a)(2).
170. Id. 50(b).
that the jury has reached a seriously erroneous result” and not based on “disagreement with the jury’s verdict.”  

The Constitution stipulates: “[T]he Supreme Court shall have appellate jurisdiction, both as to law and fact, with such exceptions, and under such regulations as the Congress shall make.” Congress has regulated the right to appeal. The United States Code established that “the courts of appeals . . . shall have jurisdiction of appeals from all final decisions of the district courts of the United States.” However, appeals are limited at law to two situations. First, the appeals court can consider substantial errors of law, such as errors granting a judgment as a matter of law, or error by lawyers. Notwithstanding that fact, an appellate court cannot re-decide the facts. The Constitution further limits appellate review by stating “no fact tried by a jury, shall be otherwise re-examined in any court of the United States, than according to the rules of common law.” Secondly, an appellate court can review judicial abuse of discretion from the lower court. However, Markman extends this right to appeal, allowing review to be de novo, as if for the first time; or more simply, as if there had been no trial.

Judge McKelvie used harsh language when describing CellPro’s actions during the trial and he appears to have granted the judgment as a matter of law merely for personal reasons. McKelvie construed the claim for the original jury and they still decided in favor of CellPro. It is possible McKelvie was aggravated with the jurors for disagreeing with his view of the meaning and scope of the claims. It may be difficult to understand, at first glance, how a unanimous jury verdict can be considered unreasonable and without sufficient evidence. His personal contempt for CellPro (and CellPro’s counsel) is quite clear from his language. He explains that the “five years of effort to bring this matter to a resolution have left the plaintiffs with too many examples of conduct by and on behalf of CellPro that demonstrate contempt . . . for the law; and for our system of civil

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175. U.S. CONST. amend. VII.
176. Id.
180. Id. at 193.
In the same opinion in which he severely criticizes CellPro's opinion of counsel, Judge McKelvie describes their legal arguments as having "no real basis in fact," and the whole process as "miss[ing] the mark in working to bring this matter to a just, speedy and inexpensive determination." Judge McKelvie's remarks, although harsh, were not necessarily biased, because his independent analysis of the Civin patents does support his overall finding. The descriptive requirements of the '204 patent, although broad, were not overly broad, since a proper description of a monoclonal antibody is its binding properties. Further, CellPro did not provide sufficient evidence in support of its claims regarding the phrase "substantially free" in the '680 patent and lack of enablement of the '204 patent. Additionally, CellPro erred during the trial by allowing inconsistencies that hampered their overall legal arguments. CellPro erred during the pleadings and attempted during trial to raise issues not identified before trial. Its in-house counsel's testimony at trial proved inconsistent with CellPro's main defense, which was switched during the trial. Accordingly, the grant of the motion for judgment as a matter of law was properly granted. Even so, the new role of the Federal Circuit in de novo review is too strong without stricter congressional guidance.

B. Criticism of Markman

As much as Markman has been criticized for focusing power on a single judge, it has been applauded for its attempt at standardization of the patent infringement court process. For example, "Markman clarified the role of a jury in a patent infringement case when deciding a mixed question of law and fact." Proper patent claim

181. Id. at 192-93.
182. Id. at 195.
183. Id. at 196.
184. Muhammad, supra note 80, at 107.
185. Id. at 105.
186. Id. at 107.
189. Id. at 194. Although not critical as a legal standard, there was additional evidence that CellPro's counsel "attempted to and did establish an inappropriate relationship with the court's deputy" which included "having Lyon and Lyon's litigation team take her out to dinner during the trial." Id. at 195.
190. See Dawson, supra note 19.
construction is the "logical first step in any patent infringement suit," since it determines "exactly what the patented invention is."192 Juries are not completely eliminated, since "Markman makes it very clear that a patent owner is entitled to a jury for infringement cases after the claims have been properly interpreted by the court."193 Overall, judges maintain control over the litigation proceedings194 and help standardize the process as the original court intended.195 One commentator cautions critics: "[W]e have to remember that these are patent cases, they are commercial cases, and not criminal cases. They are not situations where we are talking about constitutional liberties and things like that."196

In spite of some praise, Markman has been criticized for giving too much power to a single judge and limiting rights to a trial by jury as guaranteed by the Seventh Amendment.197 For example, one such commentary describes the decision as "plainly hasten[ing] the Federal Circuit’s move toward greater involvement as an appellate tribunal in the sorts of de novo review that have tempted the court to take on the role of advocate."198 Instead of standardizing patent cases like the court intended, "the Federal Circuit dramatically reduces certainty and predictability in patent appeals."199 Because of the high risk of claim construction’s being reversed on appeal, many patent infringement cases are tried essentially twice, with sometimes-imaginative results.200 Where "a genuine dispute about the meaning of a claim term exists, litigation will be required for resolution," regardless of whether the patent claim is interpreted by a judge or a jury.201 In one case, the Federal Circuit decided not to adopt either of the appealing party’s claims but “instead created an entirely new

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192. Dawson, supra note 19, at 1265.
193. Lee & Evans, supra note 193, at 7.
194. Id. at 19.
199. Id. at 751.
200. Dawson, supra note 19, at 1272.
201. King, supra note 197, at 1134.
Instead of remanding the case under the newly determined claim construction, the Federal Circuit "reversed the trial court's ruling and entered judgment for [defendant-appellant]" and effectively "deprived [plaintiff-appellee] of the right to litigate the merits of its case."\textsuperscript{203}

The rationale for the decision in \textit{Markman} is further criticized since the Supreme Court "failed to explain why judge-interpreted claims are more consistent than jury-interpreted ones."\textsuperscript{204} There is no guarantee individual judges will be consistent with one another when deciding patent cases, and there are no safety mechanisms to "prevent different district courts from reaching contrary conclusions as to the meaning of claim terms when construing a single patent in separate infringement lawsuits."\textsuperscript{205} Overall, \textit{Markman} undermines the nature of appellate review created by the Seventh Amendment: "Our civil litigation system is based on the premise that the trial is the most important phase of the process. Creating a scheme wherein the most important and often most detail-oriented issue is reviewed de novo by an appellate court undermines that premise."\textsuperscript{206}

\textbf{C. Criticism of Juries}

Praise for \textit{Markman} is typically accompanied by criticism of modern juries.\textsuperscript{207} Still, there is no evidence that juries cannot be equally sufficient as judges in construing patent claims. As one comedian summarized the feeling of critics: "When you go into court you are putting your fate in the hands of twelve people who weren't smart enough to get out of jury duty."\textsuperscript{208} United States Patent Quarterly conducted a study from 1989 through 1996 and found that "juries are more likely than judges are to hold patents valid," giving credit to the theory that juries make their decisions by emotional response rather than logic.\textsuperscript{209} Critics assume not only that juries cannot understand complex technology, but also that they are
confused by “nuances of the legal standards for patent validity and infringement, and that they are swayed too easily by tangential issues.” In the United Kingdom, there is concern that there are still some cases that are “too complicated for a jury of laymen to rule upon.” Canada also has concerns “about whether juries should be allowed to decide relatively complex issues of Internet and intellectual property law.” However, a “survey found that in evaluating expert testimony, jurors use criteria as rational and practical as those suggested by the Court of the trial judge.” Even though jurors may not understand the intricacies of the technology at trial, the inherent logic of the law, combined with the jury instructions, is just as likely to lead the jury to the same result as a trained judge with a technical background and legal experience.

D. Judicial Activism and Alternatives to Markman

An overly powerful judiciary risks upsetting the balance of power and encourages judges to act as advocates or legislators instead of judges. Even though the Federal Circuit has exclusive jurisdiction over patent issues, it would be prudent to wait for explicit congressional authorization before taking on this powerful role. Marbury v. Madison established that “[i]t is emphatically the province and duty of the judicial department to say what the law is.” However, the court is also bound by a “paradigm of judicial restraint,” giving deference to Congressional legislation and abstaining from invalidating laws for social reasons. Too much overreaching by the court into the function of the other two governmental branches leads to judicial activism and could be construed as “going beyond the substantive statutory or common law to reach ideologically-motivated outcomes.” Additional overactivity by the court, or judicial hyperactivity, describes “what happens when the court from time to time loses track of the important
distinction between trial and appellate roles and engages in a form of decision-making at odds with traditional notions of appellate review. The limited deference to the trial court’s judgment moves the Federal Circuit close to overstepping the bounds of its appellate role.

As an alternative to a federal judge or a jury, Congress could create a specialized, exclusive patent court to hear patent cases. One proposal is a “blue-ribbon” jury consisting of “experts in the subject matter” for the particular issue before the court. Congress could also create a specialized patent court system, comparable to the bankruptcy court. Another alternative is having experts join the district court judge in construing patents, like the system in China where “two ‘highly specialized technicians’ are appointed ‘to sit together with the judge’ and hear patent cases.” Notwithstanding its potential benefits, such a specialized system also presents a risk of serious pitfalls. Ultimately, if Congress agrees that there is an unlawful or unconstitutional increase of judicial power, then it can amend the Seventh Amendment to include issues of law or fact on appellate review. For example, Louisiana stipulates in its constitution that appellate review is extended “to both matters of law and fact.” Regardless of the ultimate view, the Federal Circuit must balance its desire for standardization with the concept of separation of powers, and wait for proper constitutional authorization before it takes on additional power. Whatever action it takes, its goal must continue to be stability, since “the value of the court depends on the success with which it provides a stable and consistent law on which the technology community can rely” for a “stable and reliable framework for behavior.”

V. CONCLUSION

After losing the fight to retain his company’s technology in spite of patent infringement, Rick Murdock described the federal district court that heard his case as “a sham, a kangaroo court . . . about as

219. Id. at 725.
220. King, supra note 197, at 1153.
221. Leibold, supra note 206, at 648.
222. King, supra note 197, at 1154.
real as pro wrestling.\textsuperscript{226} Although research for the fight against cancer and other diseases is at odds with the rush to patent biological material and processes, the justice system that hears patent cases is not devoid of substance. The judgment as a matter of law that decided CellPro's case was proper for the circumstances, leaving an unfortunate result for CellPro and its technology. However, \textit{Markman} grants too much power to the federal judiciary at the expense of a jury. The courts should avoid this standard of review until Congress creates an alternate solution.

\textsuperscript{226} Murdock \& Fisher, \textit{supra} note 1, at 244.