FEDERAL CIRCUIT PRACTICE SEMINAR (LAW 437)

The reading materials for the first class are attached. Please note that you only need to read pages R1-R18. You can skim the rest of the pages. We will provide the rest of the course materials during the first class.

We are looking forward to meeting everyone.



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History of the Federal Judiciary

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- Tenth Circuit Act

Landmark Judicial Legislation

Text of Document

The U.S. Court of Appeals for the Federal Circuit: "An Act To establish a United States Court of Appeals for the Federal Circuit, to establish a United States Claims Court, and for other purposes." 96 Stat. 25. April 2, 1982.

In an effort to promote greater uniformity in certain areas of federal jurisdiction and relieve the pressure on the dockets of the Supreme Court and the courts of appeals for the regional circuits, the Congress in 1982 established what is now the only U.S. court of appeals defined exclusively by its jurisdiction rather than geographical boundaries. The U.S. Court of Appeals for the Federal Circuit assumed the jurisdiction of the U.S. Court of Customs and Patent Appeals and the appellate jurisdiction of the U.S. Court of Claims. The new court was authorized to hear appeals from several federal administrative boards as well. Congress abolished the Court of Customs and Patent Appeals and the U.S. Claims or the Federal Circuit court. The act of 1982 also established a U.S. Claims Court (now the U.S. Court of Federal Claims).

The establishment of the Federal Circuit followed more than ten years of study and debate over reform of the appellate structure of the federal judiciary. A committee appointed by Chief Justice Warren Burger in 1971 recommended a National Court of Appeals that would decide cases and screen petitions for appeal to the Supreme Court. The 1975 report of the Commission on Revision of the Federal Court Appellate System proposed a like-named court that would determine national law and resolve inter-circuit conflicts by deciding certain categories of cases referred to it by the Supreme Court and the courts of appeals. Although Congress rejected both proposals for a national court of appeals, the studies drew attention to the problems associated with the lack of uniform rulings in specialized areas of jurisdiction. A proposal drafted by the Department of Justice led to President Carter's request in 1979 that Congress establish a court of appeals for a Federal Circuit, to be on the same jurisdictional level as the other U.S. courts of appeals. The proposed court would combine the functions of the Court of Customs and Patent Appeals with those of the U.S. Court of Claims, and the president also urged Congress to consider vesting the proposed court with the jurisdiction to promote uniformity and predictability in federal tax cases.

Although the House and Senate failed to complete consideration of the bill before the end of Carter's term, an endorsement by the Judicial Conference and support from business leaders resulted in the reintroduction of the legislation in 1981. In the approved act, Congress extended the jurisdiction of the Federal Circuit to the review of appeals from the U.S. Court of International Trade, the Merit Services Protection Board, the board of contract appeals, and certain administrative decisions of the secretaries of Agriculture and Commerce, as well as all appeals related to patents. Congress rejected the controversial proposals to grant the Federal Circuit court jurisdiction over appeals of tax and environmental cases. 7/25/13

Court Jurisdiction

The United States Court of Appeals for the Federal Circuit was established under Article III of the Constitution on October 1, 1982. The court was formed by the merger of the United States Court of Customs and Patent Appeals and the appellate division of the United States Court of Claims. The court is located in the Howard T. Markey National Courts Building on historic Lafayette Square in Washington, D.C.

The Federal Circuit is unique among the thirteen Circuit Courts of Appeals. It has nationwide jurisdiction in a variety of subject areas, including international trade, government contracts, patents, trademarks, certain money claims against the United States government, federal personnel, veterans' benefits, and public safety officers' benefits claims. Appeals to the court come from all federal district courts, the United States Court of Federal Claims, the United States Court of International Trade, and the United States Court of Appeals for Veterans Claims. The court also takes appeals of certain administrative agencies' decisions, including the United States Merit Systems Protection Board, the Boards of Contract Appeals, the Board of Patent Appeals and Interferences, and the Trademark Trial and Appeals Board. Decisions of the United States International Trade Commission, the Office of Compliance, an independent agency in the legislative branch, and the Government Accountability Office Personnel Appeals Board, and the Department of Justice Bureau of Justice Assistance also are reviewed by the court. The court's jurisdiction consists of administrative law cases (55%), intellectual property cases (31%), and cases involving money damages against the United States government (11%). The administrative law cases consist of personnel and veterans claims. Nearly all of the intellectual property cases involve patents. Suits for money damages against the United States government contract cases, tax refund appeals, unlawful takings, and civilian and military pay cases.

The judges of the court are appointed by the President, with the advice and consent of the Senate. Judges are appointed to the court for life under Article III of the Constitution of the United States. There are twelve judges in active service. When eligible, judges may elect to take senior status, which permits them to continue to serve on the court while handling fewer cases than a judge in active service. Each judge in active service employs a judicial assistant and up to four law clerks, while each judge in senior status employs a judicial assistant and one law clerk.

Title 28 of the United States Code, the Federal Rules of Appellate Procedure and the court's <u>Rules of Practice</u> and <u>Internal</u> <u>Operating Procedures</u> govern procedure in the Federal Circuit. Appeals are heard by panels comprised of three judges who are selected randomly for assignment to the panels. Losing parties may seek review of a decision of the Federal Circuit in the Supreme Court of the United States.

<u>Court sessions</u> generally are held during the first week of each month in Washington, D.C. The court also is authorized to hear cases in other cities throughout the United States to meet the needs of litigants in other parts of the country. The court has sat in <u>many other cities</u> during its existence.

The court's work begins when an appeal is docketed by the Clerk of the Court, and is assigned a docket number. The parties to the cases then prepare and file written briefs setting forth their arguments. Parties also may submit materials such as transcripts of testimony and other relevant parts of the record made in the lower tribunal from which the appeal originated. Once all the briefs have been received, the case may be scheduled for oral argument before the court. Each side usually is allotted between 15 and 30 minutes for argument, depending on the nature of the case. During oral argument, the lawyers for the parties present their arguments and answer questions of the judges concerning the issues presented. If the court determines that oral argument is unnecessary, the case is decided by a panel of judges based on the arguments presented in the briefs. In each appeal, the presiding judge of the panel assigns a member of the panel to prepare the <u>court's opinion</u>. The opinion sets out the decision of the court and the reasons for the decision. If the panel determines that its decision will add significantly to a body of law, it issues a precedential opinion. Decisions that do not add significantly to the body of law are issued as nonprecedential. All opinions are made available to the public, and may be obtained from the court's home page on the Internet, the Federal Reporter 3rd Series, Westlaw[®] and Lexis[®].

www.cafc.uscourts.gov/index.php?view=article&catid=2%3Athe-court&id=144%3Acourt-jurisdiction&tmpl=component&print=1&layout=default&page=&option=c... 1/2

7/25/13

Court Jurisdiction - cafc.uscourts.gov

The senior staff of the court consists of the Circuit Executive and Clerk of Court, the General Counsel, Senior Staff Attorney, Circuit Librarian, Administrative Services Officer, Director of Information Technology, and Chief Circuit Mediator.



A M E R I C A N C A S E B O O K S E R I E S

CASES AND MATERIALS ON PATENT LAW

Third Edition

Martin J. Adelman, Randall R. Rader, John R. Thomas



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The Paris Convention also calls for the independence of different national patents. Paris Convention, Art. Jois. Prior to the Paris Convention, many national laws applied a principle of patent dependence against foreign inventors. As a result, homestic patents would expire at the same time any foreign patent covering the same invention lapsed, regardless of the term the patentee vas ordinarily due. These provisions sometimes worked a hardship against inventors who had obtained patent protection in many countries, only to discover that marketing the invention was feasible only in some subset of them. Such an inventor would prefer to let some patent rights lapse rather than incur expensive maintenance fees. In a world where patent rights depended on one another, however, allowing one patent to lapse would amount to a global forfeiture of patent rights.

The independence principle established by the Paris Convention put an end to this situation. One significant consequence of the independence of national patents is that they must be enforced individually. Even different national patent instruments with identically drafted descriptions, drawings and claims do not stand or fall together. A competitor who succeeds in invalidating one national patent may face the prospect of repeating the effort within another set of national borders. Similarly, the successful enforcement of a patent in one forum may simply signal the start of patent litigation elsewhere.

The international priority system allows an inventor to file a patent application in one Paris Convention signatory state, which is usually the inventor's home country. Paris Convention, Art. 4. If the inventor subsequently files patent applications in any other Paris Convention signatory state within the next 12 months, overseas patent-granting authorities fill treat the application as if it were filed on the first filing date. Critically, information that enters the public domain between the priority date and subsequent filing dates does not prejudice the later applications. Paris Convention priority allows inventors to preserve their original filing dates as they make arrangements to file patent applications overseas. See generally G.H.C. BODENHAUSEN, GUIDE TO THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY (United International Bureau for the Protection of Intellectual Property, Geneva, Switzer and 1968).

§ 1.3[d] PATENTS IN THE TWENTIETH CENTURY

§ 1.3[d][1] U.S. DEVELOPMENTS

The Depression era, with all its sentiments against monopoly, brought with it a vigorous distrust of patents. Although the United States had a statutory patent system more than a century before a

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statutory antitrust policy, see, Sherman Act, 15 U.S.C.A. § 2, 26 Stat. 209 (July 2, 1890), courts often treated patent licensing and enforcement as antitrust violations. See, e.g., Hensley Equip. Co. v. Esco Corp., 383 F.2d 252 (5th Cir.1967) (license restricting licensee to use of only patented product violated Sherman Act). Additionally, federal courts including the Supreme Court created stricter and stricter tests for sufficient "inventiveness" to qualify for a patent. For example, in 1941, the Supreme Court opined: "[T]he new device [a cordless, pop-out cigarette lighter for cars], however useful it may be, must reveal the flash of creative genius." Cuno Eng. Corp. v. Automatic Devices Corp., 314 U.S. 84 (1941); see also Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147 (1950). As a workable rule of law, this standard creates more questions than answers: How much "flash" and how much "genius" suffices to show invention? How does the federal judiciary detect either the flash or the genius? The venerable Judge Learned Hand gave his pithy assessment of this legal test: "[The inventiveness test is] as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts." Harries v. Air King Prod. Co., 183 F.2d 158, 162 (2d Cir.1950).

Thus, following the depression and the world wars, these twin foes of intellectual property—misplaced antitrust priorities and subjective inventiveness tests—eroded the incentives of the patent system. The Supreme Court's propensity to strike down patents in this era reached such proportions that Justice Jackson felt compelled to lament in dissent: "[T]he only patent that is valid is one which this Court has not been able to get its hands on." Jungersen v. Ostby & Barton Co., 335 U.S. 560, 571 (1949). Throughout this era, from the advent of its jurisdiction over appeals from the United States Patent Office in 1929, the Court of Customs and Patent Appeals strove to enunciate a more consistent patent policy. Because it had no jurisdiction to hear appeals from infringement actions in the district courts, however, this court could not influence the regional circuits which marched only to the unsteady drumbeat of the Supreme Court.

World War II forced the United States to innovate and experiment. When the war came to a close, the United State found itself in a position of world economic leadership that called for continued incentives for research and development. Market demands for innovation clashed with the confusion in the courts over enforcement of patent policies. This clash produced the first general reform of the patent system since 1870. The centerpiece of the Patent Act of 1952 replaced the subjective invention test with an objective test for nonobviousness. Drawing on the language from an early Supreme Court case, *see Hotchkiss v. Greenwood*, considered here at Chapter 7, the 1952 Act directed courts to determine patentability by an objective comparison of the claimed invention and the prior art at the time of invention. 35 U.S.C.A. § 103. To preclude subjectivity and hindsight analysis, the Act required this comparison to take place from the vantage point of one of ordinary skill in the art. *Id*.

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Over a decade later, the Supreme Court finally construed the pivotal language of the 1952 Act. In a trilogy of 1966 cases, reprinted here in Chapter 7, the Supreme Court applied the § 103 obviousness test as the correct test for patentability. These landmark cases should have closed the book on the amorphous invention test. Unfortunately, another Supreme Court opinion (without the careful reasoning of the 1966 trilogy) revived vestiges of the invention test: "A combination of elements may result in an effect greater than the sum of the several effects taken separately. No such synergistic result is argued here." Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 61 (1969); see also Sakraida v. Ag Pro, Inc., 425 U.S. 273 (1976). Synergism? The Supreme Court's dicta reawakened the ghosts of the invention test and haunted the regional circuits for years.

Two cases in the United States Court of Appeals for the Ninth Circuit present a microcosm of more than a decade of patent law confusion. These two cases, decided within a week of each other in the same circuit, applied vastly different law and reached vastly different results on patentability. In *Reeves Instr. Corp. v. Beckman Instr., Inc.*, the Ninth Circuit applied § 103 as directed by the Supreme Court's 1966 trilogy. The result was a valid patent for an electronic test circuit for analog computers. 444 F.2d 263 (9th Cir.1971). In *Regimbal v. Scymansky*, the same court applied a vague inventiveness test. The result was an invalid patent on a new hops-picking machine. 444 F.2d 333 (9th Cir.1971). This illustration of confusion within a single circuit magnifies as the lens turns to confusion amongst the circuits in this era.

In 1972, Congress created a Commission on Revision of the Federal Court Appellate System, known as the Hruska Commission after its Chairman, Senator Roman L. Hruska (R. Neb.). The Hruska Commission studied primarily the federal judiciary's difficulty in resolving conflicts amongst regional circuit courts. This subject led the Commission to examine patent law. The Commission's patent law consultants concluded:

Patentees now scramble to get into the 5th, 6th, and 7th circuits since the courts there are not inhospitable to patents whereas infringers scramble to get anywhere but in these circuits.... [Forum shopping of this magnitude] not only increases litigation costs inordinately and decreases one's ability to advise clients, it demeans the entire judicial process and the patent system as well.

Commission on Revision of the Federal Court Appellate System, Structure, and Internal Procedures: Recommendations for Change, 67 F.R.D. 195 (1975) (Conclusions of Commission's consultants, Professor James B. Gambrell and Donald R. Dunner). Despite this condemnation of patent law chaos, the Hruska Commission advised against the central recommendation for reform—a specialized appeals court for patent cases.

As more years passed without resolution of the central patent law conflicts, economic pressure encouraged reconsideration of appellate

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On March 15, 1979, the Chairman of the Senate Judiciary Committee, Edward M. Kennedy, introduced the OIAJ bill. The bill, S. 1477, passed the Senate before the close of the 96th Congress, but—due to the addition of a controversial amendment unrelated to the court reform proposal—did not pass the House. In the 97th Congress, the legislative process began anew. A few lawmakers expressed concerns that a specialized court might foster legal doctrines out of the mainstream of American jurisprudence or might fall captive to a narrow segment of the bar. This resistance gained little momentum for reasons mentioned in the House Judiciary Committee Report:

[T]he bill creates a new intermediate appellate court markedly less specialized than either of its predecessors and provides the judges of the new court with a breadth of jurisdiction that rivals in its variety that of the regional circuits.

H.R. Rep. No. 312, 97th Cong., 1st Sess. 19 (1981). Indeed the final version of the organic act for the Federal Circuit provided jurisdiction over more than ten categories of appeals, ranging from patents to customs to taxes to government contracts and more. 28 U.S.C.A. § 1295. Finally, on April 2, 1982, President Ronald Reagan signed into law the Federal Courts Improvements Act of 1982.

Immediately after formation, the Court of Appeals for the Federal Circuit adopted the law of its predecessor courts as binding precedent for its cases as well. South Corp. v. United States, 690 F.2d 1368 (Fed.Cir. 1982). Thus the decisions of the Court of Customs and Patent Appeals continued to bind the Federal Circuit. In other respects, however, the advent of the Federal Circuit changed significantly the decisional process for patent policy. For instance, the old Court of Customs and Patent Appeals-a five-judge body-always sat en banc. Thus later decisions always controlled any contrary earlier pronouncements. In re Gosteli, 872 F.2d 1008, 1011 (Fed.Cir.1989). The Federal Circuit, with up to 12 judges, rarely sits en banc. When it does sit en banc, of course, it has authority to overrule any prior ruling of the Federal Circuit or its predecessor courts. When sitting, as it customarily does, in three-judge panels, however, the Federal Circuit lacks authority to depart from decisions of earlier panels. The court in Newell Companies, Inc. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed.Cir.1988), explained: "This court has adopted the rule that prior decisions of a panel of the court are binding

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SEC. 1.3 ORIGINS OF THE PATENT SYSTEM

precedent on subsequent panels unless and until overturned in banc. Where there is direct conflict, the precedential decision is the first."

The creation of the Federal Circuit was the first major structural change in the federal appellate system since creation of the regional circuits in 1891. The confusion in patent law reached such proportions in the late 1960s and 1970s that only a structural change of this magnitude would correct the problem. Since its creation, the Federal Circuit has sought to bring uniformity and predictability to patent law. Much of this text tests the success of that venture.

More recently, Congress enacted significant substantive and procedural changes to U.S. patent law via the American Inventors Protection Act of 1999. Pub. L. No. 106–113, 113 Stat. 1501 (Nov. 29, 1999). Among the innovations of the AIPA were the creation of an infringement defense to first inventors of business methods later patented by another; the extension of patent term in the event of processing delays at the PTO; the mandate for publication of certain pending patent applications; and the provision of optional *inter partes* reexamination procedures.

As this book goes to press, discussion of even more dramatic reform continues in the 110th Congress. The proposed Patent Reform Act of 2007 arguably would work the most sweeping reforms to the U.S. patent system since the nineteenth century. Among the more notable of these proposed changes are a shift to a first-inventor-to-file priority system; a requirement that most inventors conduct a prior art search prior to filing a patent application, substantive and procedural modifications to the patent law doctrines of inequitable conduct and willful infringement; amendment of the best mode, venue, and damages statutes; and adoption of post-grant review proceedings. These legislative reform efforts appear likely to continue into the 111th Congress. For more on the ongoing patent reform effort, see John R. Thomas & Wendy H. Schacht, *Patent Reform in the 110th Congress: Innovation Issues*, CRS Report for Congress (Jan. 10, 2008).

§ 1.3[d][2] WORLD PATENT HARMONIZATION

Following World War II, global changes to the international patent system have proceeded at an accelerated pree. Numerous new treaties followed the Paris Convention now provide inventors with a network of global rights. Among the most significant of these treaties resulted from discussion of a uniform patent system for the then-emerging European Economic Community. Following adoption of a uniform patent classification system, European states agreed to the 1963 Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions. This so-called "Strasbourg Convention" set forth certain common substantive patent law principles, and formed the cornerstone of the European Patent Convention (EPC) to follow a decade later.

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Patents and the Mederal Circuit

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Preface to the First Edition

The Court of Appeals for the Federal Circuit was created October 1, 1982, and was given exclusive jurisdiction over, among other things, appeals from final decisions of district courts in those cases where the district court's jurisdiction was based in whole or part on the patent provisions of 28 U.S.C. §1338. In simpler terms, practically speaking, the court was to have exclusive appellate jurisdiction in patent cases, and its job was to increase doctrinal stability in the field of patent law. *Chemical Eng'g Corp. v. Marlo Inc.*, 754 F.2d 331, 222 USPQ 738 (Fed. Cir. 1984).

It would be chauvinistic in the extreme for this author to suggest that the court has in any way failed to do that job. Indeed, as the only appellate court dealing with the substantive law of patents, it could hardly fail. No, the only complaint on that score—if it may be called a complaint—is that the court may have attacked its job with perhaps a touch too much evangelical fervor. The result has been not opinions that are wrong, but language that goes too far, that is overbroad for the purpose.

Near the end of its second full year of existence, the court was taken to task gently by Senior Circuit Judge Nichols in a concurring opinion. What Judge Nichols had to say eloquently summarizes the present thoughts of the author of this book; three years later still:

So I am taking issue about what we say, not what we do, and my position here is contrary to my more usual view that talk is cheap and the mere words chosen by an intermediate appellate judge are of little consequence. I think we are painting ourselves into corners by our eagerness to pronounce legal doctrines not immediately necessary to make our decisions, and the more important our words are, the more confining will be the corners into which we have painted ourselves. I further think that our exclusive jurisdiction, over certain areas of law, is not to be construed as a legislative direction to ignore the efforts of other courts to deal with the same problems, efforts exerted when over many years they shared the responsibility that is now ours. Not only are such efforts not to be ignored, but sporadic notice of them, when it occurs, is not to take the form of selecting decisions that happen to agree with our thinking, without regard to their place in the development of the case law in that jurisdiction. "The life of the law is not logic but experience," and judicial experience is having to confront not just one case, but a series. As of right now, many other courts have had more continuous experience with patent validity issues than we have, at least as one body. Congress decreed that their conclusions should not bind us, but surely it did not require us to ignore them. Every court except, apparently, this one, knows the difference between being *bound* by the decision of another court, and being *aided* by study of the efforts of that other court to solve problems we must solve, if the aid is given only by providing examples to avoid.

Weiner v. Rollform, Inc., 744 F.2d 797, 223 USPQ 369 (Fed. Cir. 1984).

The very concept for this book grew from an early recognition that the Court of Appeals for the Federal Circuit would very likely be disinclined to pay much attention to the patent law precedents of any other court save its predecessors. This has proved to be so, and it is for that reason that the book concentrates, virtually exclusively, on Federal Circuit decisions. What other courts have to say about patent law these days is of little concern to the pragmatic practitioner. This is regrettable. Any time we reduce the number of educated, intelligent people of the caliber of federal appellate judges who are thinking and writing about a particular area of law, we are bound to lose some of the literature of that law.

As a lawyer with a large Chicago intellectual property firm, my time had been largely devoted, for some 20 years, to patent infringement litigation. I therefore greeted the creation of the Federal Circuit with mixed feelings, to say the least. I welcomed the prospect of doctrinal stability, but I dreaded the loss of healthy cross-fertilization of ideas that would no longer be forthcoming from the regional courts of appeals. Like it or not, however, it was clear that my partners and associates and I in our day-to-day practice simply had to be able to know, quickly and accurately, whether the Federal Circuit had confronted a given issue and, if so, what its views were.

Fortunately, the firm at that time was just in the beginning stages of a massive computerization—one that has resulted in virtually every lawyer having a personal computer in his or her office, and most with one at home as well. My own involvement in that project led me to the idea of creating my own Federal Circuit "database"—a sort of personalized digest of Federal Circuit decisions that could be accessed by computer. Thus I began, religiously, to read each opinion of the Federal Circuit as it was published in the weekly advance sheets and to create my own headnotes.

This database quickly became a useful research resource for the lawyers in my firm. In particular, it could, if used properly, ease the life of an associate, for whom the most frequently encountered work assignment, then and now, began with the words "see what the Federal Circuit has said about" such and such a subject. Just as quickly, however, I began to notice a somewhat unexpected phenomenon. The Federal Circuit appeared to be developing a significant and important body of case law much more rapidly than I had thought possible. When I was a law clerk for Judge Arthur Smith at the predecessor Court of Customs and Patent Appeals, in the early 1960s, we heard

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Preface to the First Edition

200 cases a year, but these produced no more than a dozen or so rulings that were of interest to anyone but the immediate parties. Now I was seeing a successor court producing only perhaps 80 or 100 published patent opinions a year, but fully a third or more of these were noteworthy in some respect.

In retrospect, two factors unique to this new court should have prepared me for this performance. First, it *was* a new court and naturally determined to make its mark. Second, and probably much more significant, the Federal Circuit, unlike the CCPA before it, was now looking at patent issues in the context of infringement litigation, resulting in a richer variety of questions and problems than even its other predecessor, the Court of Claims, had ever been exposed to.

Whatever the cause, the effect was clear: this court was developing precedent at a rate that was nothing short of amazing. The Federal Circuit database was accumulating week after week, kilobyte upon kilobyte—indeed, it was reaching *book-like* proportions. It dawned upon me, before the court was three years old, that perhaps this rate would produce sufficient material for a book in record time. And such has proved to be the case: this book reflects the work of a scant four and one-half years of judicial decision—barely 500 cited cases.

The next step was, in the words of a familiar patent statute, obvious: I had only to turn this computerized legal database into a book. You will, mercifully, be spared the details of this conversion process. Suffice it to say that this book may be one of the first in the legal field that was, almost entirely, written by a computer. The database was searched and sorted by computer. The outline was generated by computer. The data were retrieved and organized by computer and inserted into a textual format by a computerized word processor. The footnotes were generated, compiled, tabulated, and checked by computer. The index and case table were constructed by computer. The entire conglomeration was then rewritten, spell-checked, and edited, again using the ubiquitous computer. Finally, when the procreative acts reached term, the computer gave birth to a series of small diskettes, which were rushed to the publisher's own larger and perhaps more motherly computer, there to be incubated and transformed into the book you now have before you.

Looking back, I sometimes wonder where I, the putative author, fit into this creative scheme. I have concluded that it must have been, like any father, at the very beginning, when I read the cases and made the notes that reflected my own perception of what the Federal Circuit was doing about, and to, my beloved patent law. The rest was just busy work, organizing those perceptions into some coherent patterns that might possibly be useful to other practitioners. I hope that you will find them so.

The bulk of the book is devoted to substantive patent law, with emphasis on how those issues arise in infringement litigation. The final two chapters, however, consider in some detail the jurisdiction

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and judicial method of the Federal Circuit and, to a lesser extent, its general jurisprudence.

The Appendix comprises a statistical analysis of the court's validity and infringement holdings during its first five years of work.

Special thanks go to Cathy Scarriot, who supervised the preparation of the appendices, and to my secretaries, Sharon Stewart and Mary Morgan, who did everything they could to insulate me from the real world of clients and courts during the busy days of this project.

The dedication page is a reflection of how I came to the patent practice. The fact that this book exists at all is a reflection of the constant support and encouragement of my wife, Sue.

Chicago, 1987

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Robert L. Harmon

United States Code Annotated

Title 28. Judiciary and Judicial Procedure (Refs & Annos) Part IV. Jurisdiction and Venue (Refs & Annos) Chapter 83. Courts of Appeals (Refs & Annos)

28 U.S.C.A. § 1295

§ 1295. Jurisdiction of the United States Court of Appeals for the Federal Circuit

Effective: September 16, 2011

Currentness

(a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction--

(1) of an appeal from a final decision of a district court of the United States, the District Court of Guam, the District Court of the Virgin Islands, or the District Court of the Northern Mariana Islands, in any civil action arising under, or in any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents or plant variety protection;

(2) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1346 of this title, except that jurisdiction of an appeal in a case brought in a district court under section 1346(a)(1), 1346(b), 1346(c), or 1346(f) of this title or under section 1346(a)(2) when the claim is founded upon an Act of Congress or a regulation of an executive department providing for internal revenue shall be governed by sections 1291, 1292, and 1294 of this title;

(3) of an appeal from a final decision of the United States Court of Federal Claims;

(4) of an appeal from a decision of-

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(A) the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences, at the instance of an applicant for a patent or any party to a patent interference, and any such appeal shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;

(B) the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office or the Trademark Trial and Appeal Board with respect to applications for registration of marks and other proceedings as provided in section 21 of the Trademark Act of 1946 (15 U.S.C. 1071); or

(C) a district court to which a case was directed pursuant to section 145, 146, or 154(b) of title 35;

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§ 1295. Jurisdiction of the United States Court of Appeals for the..., 28 USCA § 1295

(5) of an appeal from a final decision of the United States Court of International Trade;

(6) to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337);

(7) to review, by appeal on questions of law only, findings of the Secretary of Commerce under U.S. note 6 to subchapter X of chapter 98 of the Harmonized Tariff Schedule of the United States (relating to importation of instruments or apparatus);

(8) of an appeal under section 71 of the Plant Variety Protection Act (7 U.S.C. 2461);

(9) of an appeal from a final order or final decision of the Merit Systems Protection Board, pursuant to sections 7703(b)(1) and 7703(d) of title 5;

(10) of an appeal from a final decision of an agency board of contract appeals pursuant to section 7107(a)(1) of title 41;

(11) of an appeal under section 211 of the Economic Stabilization Act of 1970;

(12) of an appeal under section 5 of the Emergency Petroleum Allocation Act of 1973;

(13) of an appeal under section 506(c) of the Natural Gas Policy Act of 1978; and

(14) of an appeal under section 523 of the Energy Policy and Conservation Act.

(b) The head of any executive department or agency may, with the approval of the Attorney General, refer to the Court of Appeals for the Federal Circuit for judicial review any final decision rendered by a board of contract appeals pursuant to the terms of any contract with the United States awarded by that department or agency which the head of such department or agency has concluded is not entitled to finality pursuant to the review standards specified in section 7107(b) of title 41. The head of each executive department or agency shall make any referral under this section within one hundred and twenty days after the receipt of a copy of the final appeal decision.

(c) The Court of Appeals for the Federal Circuit shall review the matter referred in accordance with the standards specified in section 7107(b) of title 41. The court shall proceed with judicial review on the administrative record made before the board of contract appeals on matters so referred as in other cases pending in such court, shall determine the issue of finality of the appeal decision, and shall, if appropriate, render judgment thereon, or remand the matter to any administrative or executive body or official with such direction as it may deem proper and just.

Credits

(Added Pub.L. 97-164, Title I, § 127(a), Apr. 2, 1982, 96 Stat. 37; amended Pub.L. 98-622, Title II, § 205(a), Nov. 8, 1984, 98 Stat. 3388; Pub.L. 100-418, Title I, § 1214(a)(3), Aug. 23, 1988, 102 Stat. 1156; Pub.L.

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100-702, Title X, § 1020(a)(3), Nov. 19, 1988, 102 Stat. 4671; Pub.L. 102-572, Title I, § 102(c), Title IX, § 902(b)(1), Oct. 29, 1992, 106 Stat. 4507, 4516; Pub.L. 106-113, Div. B, § 1000(a)(9) [Title IV, §§ 4402(b)(2), 4732(b)(14)], Nov. 29, 1999, 113 Stat. 1536, 1501A-560, 1501A-584; Pub.L. 111-350, § 5(g)(5), Jan. 4, 2011, 124 Stat. 3848; Pub.L. 112-29, § 19(b), Sept. 16, 2011, 125 Stat. 332.)

Editors' Notes

AMENDMENT OF SUBSEC. (A)(4)(A)

<Pub.L. 112-29, § 7(c)(2), (e), Sept. 16, 2011, 125 Stat. 314, 315, provided that effective upon expiration of the 1-year period beginning on Sept. 16, 2011, and except as otherwise provided, applicable to proceedings commenced on or after such effective date, subsec. (a)(4)(A) is amended to read:>

<(A) the Patent Trial and Appeal Board of the United States Patent and Trademark Office with respect to a patent application, derivation proceeding, reexamination, post-grant review, or inter partes review under title 35, at the instance of a party who exercised that party's right to participate in the applicable proceeding before or appeal to the Board, except that an applicant or a party to a derivation proceeding may also have remedy by civil action pursuant to section 145 or 146 of title 35; an appeal under this subparagraph of a decision of the Board with respect to an application or derivation proceeding shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35; >

Notes of Decisions (191)

28 U.S.C.A. § 1295, 28 USCA § 1295

Current through P.L. 112-139 approved 6-27-12End of Document

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Federal Circuit Rules That Gene Patents Are Eligible Subject Matter, but Some Related Method Claims Covered Unpatentable Abstract Ideas...

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ss'n for Molecular Pathology v. USPTO, No. 10-01406, 2011 BL 197401 (Fed. Cir. July 29, 2011)		NLOAD	
three-judge panel of the U.S. Court of Appeals for the Federal Circuit reversed-in-part and affirmed-in-part a istrict court ruling that patents related to the human BRCA1 and BRCA1 genes, which are associated with an increased risk of breast and ovarian cancer, were not eligible subject matter under 35 U.S.C. § 101. The Federal Circuit ruled that claims directed to Isolated DNA sequences and complementary DNA ("CDNA") corresponding to the BRCA1/2 genes were patentable subject matter because the molecules were chemically different from native NA in the human body. The court, however, ruled that several claims directed to methods for detecting inomalies in a patient's genes using the DNA sequences were invalid because the claims only recited mental rocesses that were unpatentable abstract ideas.	VIDEO	HURE >>> ed Programs Shoul Lawyer Says	
The plaintiffs, represented by the American Civil Liberties Foundation Legal Foundation ("ACLU"), are genetic testing laboratories, physicians, researchers, and patients who are unable to afford BRAC1/2 testing provided by Myriad. In May 2009, the plaintiffs filed suit against the U.S. Patent and Trademark Office in the U.S. District	ARTICL		
ourt for the Southern District of New York, alleging that 12 broad claims in the Myriad patents are invalid under ection 101 and that the USPTO Issued the patents in violation of Article I, Section 8 of the U.S. Constitution and e First and Fourteenth Amendments to the Constitution.	House Rep Corzine	ublicans Urge Perjury	Probe or
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itially the district court denied the USPTO's motion to dismiss the action, ruling that the plaintiffs had standing to			MORE >
aintain their challenge, and the district court had jurisdiction over the defendants. Then, in a detailed 156 page ecision, the district court granted the plaintiffs' motion for summary judgment, finding that the disputed claims ere invalid as ineligible subject matter under Section 101. See Myriad BRAC 1/2 Gene Patents Held Not Eligible ubject Matter Under 35 USC § 101, Bloomberg Law Reports – Intellectual Property, Vol. 4, No. 15 (Apr. 12, 010) for a discussion of the district court's decision.	Preemption Warn Case	T PRACTITION RIBUTIONS	allure to e' That
he patents' claims fall into three groups. First, several claims are directed to isolated DNA that codes for the RCA1/2 genes. Second, a limited number of claims cover cDNA corresponding to the same genes. Third, the	Change is	Demonstrated	
patents claim processes covering (1) the use of the DNA sequences and/or cDNA to detect mutations in a patient by comparing the patient's native DNA with the isolated sequences or known mutations and (2) the screening of potential cancer drugs by analyzing changes in affected cell growth rates.		of Defining a Patent T	roll MORE >
y comparing the patient's native DivX with the isolated sequences of known inductions and (2) are concerning the			

http://about.bloomberglaw.com/law-reports/federal-circuit-rules-gene-patents-are-eligible-subject-matter/

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The district court ruled that the Myriad patents were not eligible for patenting. Among other things, the district court ruled that the DNA sequences claimed in the Myriad patents were not eligible for patenting because they were merely purified compounds that existed in nature, without any substantial change. Moreover, the district court noted that the purified DNA contained exactly the same coding information as native DNA, and that Myriad's entire test technology rested on that equality. The district court also ruled that the Myriad method claims were not eligible under the "Machine-or-Transformation Test," which was the applicable standard at the time under the Federal Circuit's decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008), affirmed on other grounds by Bilski v. Kappos, 130 S. Ct. 3218 (2010). Myriad appealed to the Federal Circuit.

FEDERAL CIRCUIT RULES THAT ONE PLAINTIFF HAS STANDING TO MAINTAIN DECLARATORY JUDGMENT ACTION

In a decision spanning three separate opinions, the Federal Circuit reversed the district court ruling in part and affirmed-in-part. Circuit Judge Alan Lourie wrote the majority opinion of the panel. As a threshold issue, the Federal Circuit ruled that at least one plaintiff, Dr. Harry Ostrer, had standing to maintain a declaratory judgment action challenging the validity of the Myrlad patents. Applying the "all of the circumstances" test established in MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007), the appeals court held that Ostrer established a sufficiently real and imminent injury to confer standing under the Declaratory Judgment Act. 28 U.S.C. § 2201. Ostrer alleged that he desired to engage in genetic testing for BRCA1/2 gene mutations, but Myriad's actions in enforcing its patents, including sending him cease and desist letters and filing infringement suits against other health professionals, caused him to avoid that activity. The court noted that the mere risk of infringement alone does not create an actual controversy, without "some affirmative act of the patentee." Myriad at 28 (citing SanDisk Corp. v. STMicroelectonics, Inc., 480 F.3d 1372, 1380 (Fed. Cir. 2007)). Because Myrlad had demanded a royalty from Ostrer and had sued or threatened to sue other health practitioners, however, Ostrer was compelled to cease his work and send to Myriad all patient samples that he planned to use for genetic testing, despite his belief that the Myriad patents were invalid. Accordingly, the court found that Myriad and Ostrer had taken adverse legal positions on Ostrer's right to conduct genetic testing of the BRCA1/2 genes. Ostrer also established a real and immediate controversy, since he had the experience and resources to conduct the testing and stated unequivocally that he would immediately commence testing in the event the threat of infringement was removed.

The Federal Circuit rejected Myriad's argument that Ostrer's injury was "stale," because Myriad's threats occurred 10 years before the commencement of the litigation. The court noted that:

In many cases a controversy made manifest by a patentee's affirmative assertion of its patent rights will dissipate as market players and products change. In this case, however, the relevant circumstances surrounding Myriad's assertion of its patent rights have not changed despite the passage of time.

Id. at 31. Among other things, despite the 10-year gap between Myriad's threats and the filing of the lawsuit, Myriad continued to maintain that Ostrer's proposed tests infringed its patents, and Ostrer maintained his belief that his inability to conduct genetic testing was due to Myriad's invalid patents. As a result, the Federal Circuit reversed the district court's broad recognition of the plaintiffs' standing, and affirmed the district court only with respect to Ostrer's individual standing. As to the other plaintiffs, the court noted, "[s]imply disagreeing with the existence of a patent or even suffering an attenuated, non-proximate, effect from the existence of a patent does not meet the Supreme Court's requirement for an adverse legal controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. at 35.

FEDERAL CIRCUIT FINDS DNA AND CDNA CLAIMS RECITE PATENT-ELIGIBLE SUBJECT MATTER

Turning to the merits of the dispute, the Federal Circuit ruled that claims in the Myriad patents directed to Isolated DNA sequences and cDNA were eligible subject matter under Section 101. The court noted that the statute is to be construed broadly, but not without limits. The Supreme Court has identified three general categories of ineligible subject matter: laws of nature, physical phenomena, and abstract Ideas. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). The Federal Circuit ruled, however, that the isolated DNA and cDNA were distinctive chemical molecules that differed from molecules present in the human body. According to the court, native (or naturally-occurring) DNA exists in the human body in chromosomes surrounded by proteins, chromatin, and other compounds. Isolated DNA, on the other hand:

[I]s a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (i.e., had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. For example, the BRCA1 gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Similarly, BRCA2 in its native state is located on chromosome 13, a DNA of approximately 114 million nucleotides. In contrast, isolated BRCA1 and BRCA2, with introns, each consists of just 80,000 or so nucleotides. And without introns, BRCA2 shrinks to just 10,200 or so nucleotides and BRCA1 to just around 5,500 nucleotides.... Accordingly, BRCA1 and BRCA2 in their isolated state are not the same molecules as DNA as it exists in the body; human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA.

Myriad at 42. In addition, the court ruled that cDNA molecules, which are created by reassembling a DNA-like molecule using transcription based on the "blueprint" of a messenger RNA molecule, are eligible subject matter because they are engineered by man and, with rare exceptions, are not present in nature.



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The court rejected the district court's reliance on cases holding that purified forms of naturally-occurring chemical compounds are not patentable unless the purified form exhibits markedly different or distinctive characteristics. See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948). The court noted that, "[I]solated DNA is not purified DNA." Id. at 42. Unlike a purified compound, isolated DNA has been chemically altered by removing it from its native chemical environment. As a result, when isolated, the DNA molecule is cleaved from the chemical bonds and becomes a distinct chemical entity, not simply a purified form of the same compound.

In a concurring opinion, Circuit Judge Kimberly Moore agreed with the court's ruling that isolated DNA and cDNA were patent-eligible, but elaborated on the reasons for her conclusion. As to cDNA, Judge Moore noted that the molecules have a "unique sequence of DNA bases (A, C, G, T) which Is not actually present in nature." Myriad, Moore, J., concurring at 12. Thus, Judge Moore concluded that cDNA are not naturally-occurring compounds and are eligible under § 101. She also observed that small DNA fragments are patentable because they have a different chemical structure from native DNA "which is the product of the intervention by man, [and] leads to a different and beneficial utility" in diagnostic and other testing. Id. at 16. Finally, Judge Moore observed that larger DNA strands pose a "closer question," but that the strands were patent-eligible largely because of the long-established practice of granting patents to such inventions:

This case, however, comes to us with a substantial historical background. Congress has, for centuries, authorized an expansive scope of patentable subject matter. Likewise, the United States Patent Office has allowed patents on isolated DNA sequences for decades, and, more generally, has allowed patents on purified natural products for centuries. There are now thousands of patents with claims to isolated DNA, and some unknown (but certainly large) number of patents to purified natural products or fragments thereof....[] believe we must be particularly wary of expanding the judicial exception to patentable subject matter where both settled expectations and extensive property rights are involved. Combined with my belief that we should defer to Congress, these settled expectations tip the scale in favor of patentability.

ld_ at 18-19.

Circuit Judge William Bryson submitted a separate opinion concurring in the court's conclusion that the cDNA claims were patent eligible, but dissenting from the decision relating to Isolated DNA fragments. Judge Bryson argued that the isolated DNA were essentially the same as native DNA, and the only chemical changes were those incidental to the necessity of removing the DNA from human cells. He likened the isolation of DNA to removing a leaf physically connected to a tree. "[P]rematurely plucking the leaf would not turn it into a humanmade invention. That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf, unless those differences imparted 'markedly different characteristics' to the plucked leaf." Myriad, Bryson, J., concurring-in-part and dissenting-in-part at 10 (citations omitted).

Federal Circuit Rules Some Myriad Method Claims Are Unpatentable as Abstract Ideas

All three judges joined the majority opinion on the Issue of patentability of the Myrlad process claims. Applying the Supreme Court's Bilski analysis, the court held that claims reciting the steps of "comparing" and "analyzing" patient DNA samples and isolated DNA or cDNA sequences were only abstract mental processes. The claims did not recite a particular machine, or result in a transformation, two important clues to patent eligibility identified in Bilski. Further, the court noted:

Although the application of a formula or abstract idea in a process may describe patentable subject matter, Myriad's claims do not apply the step of comparing two nucleotide sequences in a process. Rather, the step of comparing two DNA sequences is the entire process claimed.

Myriad at 50-51 (emphasis In original).

The court distinguished the "comparing" and "analyzing" claims in the Myriad patents from the claims at issue in Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010), cerl. granted, 2011 BL 161646 (June 20, 2011). The Prometheus claims, directed to a method of adjusting the dosage of a drug used to treat gastrointestinal disorders, recited the administration of a drug which resulted in a chemical transformation in the patient's system. A metabolite of the drug was then used to assess whether to adjust the dosage. Thus, although the claims recited the steps of "administering" and "determining," the claimed method required the transformative step. The Myriad claims, in contrast, recited that "comparison between the two sequences can be accomplished by mere inspection alone." Id. at 52. Thus, the methods were merely mental processes that are ineliable abstract ideas.

Finally, the Federal Circuit held that other Myriad process claims directed to screening potential cancer drugs by evaluating cell growth rates were eligible under Section 101. Among other things, the claims recited the step of "growing" cells, a step that is clearly transformative. Thus, under the Bilski standard, the court ruled that those method claims recited eligible subject matter.

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SCOTUS in Myriad: Federal Circuit doesn't know what's patent-eligible

June 13, 2013 @ 10:34 pm

By Alison Frankel

Justice **Clarence Thomas** of the U.S. Supreme Court doesn't come out and say so in his straightforward, rhetoric-free, 19-page opinion for a unanimous court in <u>Association for</u> <u>Molecular Pathology v. Myriad Genetics</u>^[1], but the takeaway from the ruling is not only that human genes are not patentable in and of themselves but that the Federal Circuit Court of Appeals isn't very good at interpreting patent-eligibility under Section 101 of the Patent Act. As the Supreme Court decision notes, the Federal Circuit panel that ruled Myriad has the right to composition patents on genes associated with breast cancer disagreed on the rationale. One judge said that isolated genes are chemically distinct from the molecules found in nature. Another cited longstanding Patent and Trademark Office policy on gene patentability. The third disagreed with both explanations. So too did the entire Supreme Court, which said the dispositive question is whether the purported invention is created or found in nature. Genes are found in nature, the court said, and thus not patent-eligible.

Myriad's share price actually bumped up after the court's ruling because the justices also held that synthetic composite DNA is eligible for patenting, and that biotech companies may still seek patents on applications for human genes. In that regard, the Supreme Court decision is good news for both researchers, who argued that patents should not be used to restrict their use of identified genes, and the biotech industry, which quite understandably wants to profit from its investment in gene isolation.

But if you're an IP lawyer trying to advise clients on the patent-eligibility of their research and development projects, the Myriad ruling is yet another exasperating sign that you can't rely on the Federal Circuit to decide issues that are supposed to be at the heart of its mission. The United States has a centralized court for patent appeals because Congress wanted a single set of experienced judges to offer definitive interpretations of IP law, which often involves highly technical but economically critical decisions. As former Federal Circuit Judge**Arthur Gajarsa**, now senior counsel at **Wilmer Cutler Pickering Hale and Dorr**, said in <u>a speech in March</u>^[2], the court's statutory mandate is "to normalize patent law ... by establishing rules which district courts can follow."

That structure presumes, of course, that the Federal Circuit's rules pass Supreme Court muster. Alas, that hasn't been true in recent years. Instead, what we've seen repeatedly is that on threshold questions of patent-eligibility, Federal Circuit rulings don't hold up. The Supreme Court struck down the Federal Circuit's test for business method patents in <u>Bilski v.Kappos</u> ^[3] in 2009. It raised the bar for method patents based on naturally occurring phenomena in <u>Mayo v.</u> <u>Prometheus Laboratories</u> ^[4] in 2011, and then <u>remanded cases involving software patents</u> ^[5] to the Federal Circuit in light of Mayo. You know the mess that ensued: last month'stortured and <u>tormented en banc decision</u> ^[6] in CLS Bank International v. Alice Corporation, in which the appeals court spun out 135 pages of concurrences, partial concurrences and dissents by various groups of judges yet offered essentially no clarity on the standard of patent eligibility for software that permits the implementation of otherwise unpatentable abstract ideas. Undoubtedly, that question too will be resolved only when the Supreme Court gets involved.

I understand the tension Gajarsa outlined in his speech in March. The Federal Circuit wants to be an effective rulemaker for the USPTO and for patent developers, establishing standards that are "clear, concise and in some cases rigid," the former judge said. The Supreme Court isn't as

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interested in rigid rules as in interpreting the law. Gajarsa said that as a result, the high court has "muddled" straightforward patent-eligibility tests.

But that worldview, in which Gajarsa is not alone, seems to me to misunderstand the Federal Circuit's place in the judicial hierarchy. Yes, the appeals court must set the law that guides the operation of the patent system. But it also has to assimilate the Supreme Court's directives in executing that mission. The Federal Circuit has to look up as well as down.

And most importantly, the appeals court has to do a better job of reaching internal consensus, starting with a unified recognition that unless it pays more than mere lip service to the Supreme Court, it is not serving the patent system. Too often Federal Circuit judges have resisted the justices. Both the Mayo and Myriad cases, for instance, were remanded by the Supreme Court for reconsideration by the Federal Circuit. In both, the appeals court stuck to its guns, and in both the Federal Circuit was overruled by the Supreme Court.

That's not an efficient process, especially considering that the Federal Circuit was supposed to streamline patent litigation. The patent system deserves – and demands – better.

(Reporting by Alison Frankel)

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[1] Association for Molecular Pathology v. Myriad Genetics:

http://www.supremecourt.gov/opinions/12pdf/12-398_8njq.pdf

[2] a speech in March:

http://newsandinsight.thomsonreuters.com/Legal/News/2013/03_-_March/Ex-Federal_Circuit_judge_sees_patent_tensions_with_Supreme_Court/

[3] Bilski v.Kappos: http://www.supremecourt.gov/opinions/09pdf/08-964.pdf

[4] Mayo v. Prometheus Laboratories: http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf

[5] remanded cases involving software patents:

http://newsandinsight.thomsonreuters.com/Legal/News/2012/05_-_May/SCOTUS_to_Federal_Circuit__Think_harder_about_what_s_patentable/

[6] tortured and tormented en banc decision:

http://newsandinsight.thomsonreuters.com/Legal/News/2013/05_-

May/Splintered_Federal_Circuit_fails_in_its_essential_mission/

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Owners? Should companies be allowed to patent genes?

Have

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useful gene, but separating that gene from its surrounding genetic material is not an act of invention."

The course of scientific research and medical testing in other fields will also be shaped by the court's ruling, which drew a sharp distinction between DNA that appears in

8. Seeing Narcissists Everywhere

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nature and synthetic DNA created in the laboratory. That distinction may alter the sort of research and development conducted by the businesses that invest in the expensive work of understanding genetic material.

The decision tracked the position of the Obama administration, which had urged the justices to rule that isolated DNA could not be patented, but that synthetic DNA created in the laboratory — complementary DNA, or cDNA — should be protected under the patent laws. In accepting that second argument, the ruling on Thursday provided a partial victory to Myriad and other companies that invest in genetic research.

The particular genes at issue received public attention after the actress Angelina Jolie <u>revealed</u> in May that she had had a preventive double mastectomy after learning that she had inherited a faulty copy of a gene that put her at high risk for breast cancer.

The price of the test, often more than \$3,000, was partly a product of Myriad's patent, putting it out of reach for some women.

That price "should come down significantly," said Dr. Harry Ostrer, one of the plaintiffs in the case, as competitors start to offer their own tests. The ruling, he said, "will have an immediate impact on people's health."

Myriad's stock price was up about 10 percent in early trading, a sign that investors believed that parts of the decision were helpful to the company. But the stock later dropped, closing the day down by more than 5 percent.

In a statement, Myriad's president, Peter D. Meldrum, said the company still had "strong intellectual property protection" for its gene testing.

The central question for the justices in the case, Association for Molecular Pathology v. Myriad Genetics, No. 12-398, was whether isolated genes are "products of nature" that may not be patented or "human-made inventions" eligible for patent protection.

Myriad's discovery of the precise location and sequence of the genes at issue, BRCA1 and BRCA2, did not qualify, Justice Thomas wrote. "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," he said. "It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes."

"Groundbreaking, innovative or even brilliant discovery does not by itself satisfy the criteria" for patent eligibility, he said.

Mutations in the two genes significantly increase the risk of cancer. Knowing the location of the genes enabled Myriad to develop tests to detect the mutations. The company blocked others from conducting tests based on its discovery, filing patent infringement suits against some of them.

"Myriad thus solidified its position as the only entity providing BRCA testing," Justice Thomas wrote.

Even as the court ruled that merely isolating a gene is not enough, it said that manipulating a gene to create something not found in nature is an invention eligible for patent protection.

"The lab technician unquestionably creates something new when cDNA is made," Justice Thomas wrote.

He also left the door open for other ways for companies to profit from their research.

They may patent the methods of isolating genes, he said. "But the processes used by Myriad to isolate DNA were well understood by geneticists," Justice Thomas wrote. He



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added that companies may also obtain patents on new applications of knowledge gained from genetic research.

Last year, a divided three-judge panel of a federal appeals court in Washington <u>ruled for</u> <u>the company</u> on both aspects of the case. All of the judges agreed that synthesized DNA could be patented, but they split over whether isolated but unaltered genes were sufficiently different from ones in the body to allow them to be protected. The majority, in a part of its decision reversed by the Supreme Court, said that merely removing DNA from the human body is an invention worthy of protection.

"The isolated DNA molecules before us are not found in nature," Judge Alan D. Lourie wrote. "They are obtained in the laboratory and are man-made, the product of human ingenuity."

Long passages of Justice Thomas's opinion read like a science textbook, prompting Justice Antonin Scalia to issue a brief concurrence. He said the court had reached the right result but had gone astray in "going into fine details of molecular biology."

"I am unable to affirm those details on my own knowledge or even my own belief," Justice Scalia wrote.

The ruling on Thursday followed <u>a unanimous Supreme Court decision last year</u> that said medical tests relying on correlations between drug dosages and treatment were not eligible for patent protection.

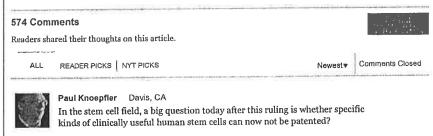
Natural laws, Justice Stephen G. Breyer wrote for the court, may not be patented standing alone or in connection with processes that involve "well-understood, routine, conventional activity."

A version of this article appeared in pnnt on June 14, 2013, on page A1 of the New York edition with the headline: Justices, 9-0, Bar Patenting Human Genes,

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Will existing patents for these stems cells be nullified?

There are a lot of parallels between stem cell patents and gene patents.

The stem cell clinics making millions today find themselves in a paradox because they do not want their products to be regulated by the FDA as drugs and they claim the stem cells should not be regulated as drugs because they are natural products that are minimally different than the stem cells in our bodies. BUT at the same time they also want to patent the same cells as unique, innovative products that are not just something any old bozo could get and use on patients. They cannot have their cake and eat it too. We'll see how it plays out.

I discuss the key issues here: http://www.ipscell.com/2013/06/the-myriadscotus-decision-stem-cell-pate...

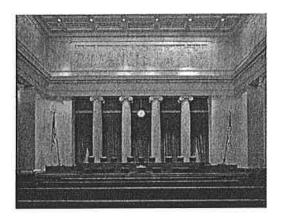
Paul Knoepfler, PhD Associate Professor UC Davis School of Medicine

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R-32

By Erik Sherman / MoneyWatch/ June 28, 2010, 5:00 PM

Supreme Court Says No to Bilski Decision, Yes to Software Patents



High tech firms and patent lawyers have closely watched the **Bilski** case, which had the potential to completely disrupt software patents as the U.S. has come to know them. The **Supreme Court** has finally issued its decision on Bilski, having agreed to hear it over a year ago. The bottom line: contrary to <u>some reports</u>, experts say that the 5-4 ruling offers little to no change in business method and software patents.

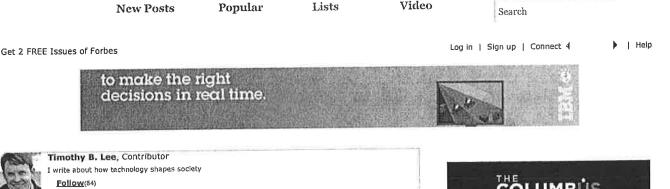
"It was a rather uneventful opinion and kind of what we asked for," said **Scott Bain**, litigation counsel of the **Software & Information Industry Association**, when I spoke to him earlier. "Things are pretty similar if not the same as before Bilski. The Supreme Court decided this single case on these facts, but didn't give much guidance on how other cases will come out." Bain says that patent lawyers will likely approach writing software patent applications as they did before, and that no change is good news for people and companies that currently hold software patents.

Raymond Van Dyke, an independent software patent attorney, told me that the Court "affirmed the judgment, but not necessarily the reasoning" of the lower courts. One issue in the case was the so-called machine-or-transformation test, under which a software patent application, to prove that it was not an abstract matter disallowed by under section 101 of the applicable patent law, would have to show either that the code was tied to a specific type of machine, rather than a general computer, or that it performed some sort of transformation on data. Here is the part of the decision that addresses the test:

The machine-or-transformation test is not the sole test for patent eligibility under ?101. The Court's precedents establish that although that test may be a useful and important clue or investigative tool, it is not the sole test for deciding whether an invention is a patent-eligible "process" under ?101. In holding to the contrary, the Federal Circuit violated two principles of statutory interpretation: Courts " 'should not read into the patent laws limitations and conditions

which the legislature has not expressed,' " Diamond v. Diehr, 450 U. S. 175, 182, and, "[u]nless otherwise defined, 'words will be interpreted as taking their ordinary, contemporary, common meaning,' " ibid. The Court is unaware of any ordinary, contemporary, common meaning of "process" that would require it to be tied to a machine or the transformation of an article. The Court was splintered on the decision, with one of the more complicated sets of alliances, as evidenced through who wrote what parts of the decision and other opinions: KENNEDY, J., delivered the opinion of the Court, except for Parts II?€"B?€"2 and II?€"C?€"2. ROBERTS, C. J., and THOMAS and ALITO, JJ., joined the opinion in full, and SCALIA, J., joined except for Parts II?€"B?€"2 and II?€"C?€"2. STEVENS, J., filed an opinion concurring in the judgment, in which GINSBURG, BREYER, and SOTOMAYOR, JJ., joined. BREYER, J., filed an opinion concurring in the judgment, in which SCALIA, J., joined as to Part II. The specifics of the Bilski case were about a patent for "how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes." **Bernard Bilski** and **Rand Warsaw** filed their patent application in 1997, and it took over 13 years to reach final resolution.

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The Federal Circuit, Not the Supreme Court, Legalized Software Patents

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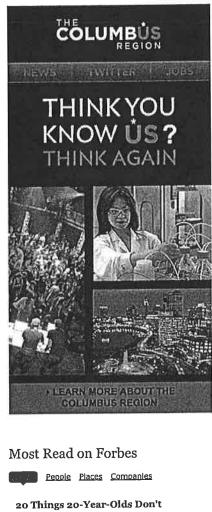
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Most of the time I ignore trolls in the hope they'll go away. But patent attorney Gene Quinn <u>outright accuses me of lying</u> in his response to my <u>recent piece</u> on how the Federal Circuit Court of Appeals wrecked the patent system. So I thought a quick response was in order. Here's Quinn, arguing that my claim that "software was generally considered to be ineligible for patent protection" under pre-1982 Supreme Court precedents is "completely false."

66 The United States Supreme Court first addressed the patentability of computer software in Gottschalk v. Benson. It is true that it was the widespread belief in the industry that the Supreme Court in Benson decided that software was not patentable, which is a fair reading of the decision. What Lee ignored, however, is that the Supreme Court later retracted the blanket prohibition against patenting software in Diamond v. Diehr. So it is simply factually inaccurate to say that Supreme Court precedent prohibits the patenting of software. Lee just didn't do his homework or didn't care to get it correct.

I've written about the patentability of software <u>in depth</u>. The view that the Supreme Court "retracted the blanket prohibition against patenting software" isn't a crazy interpretation of the *Diehr* decision, but I think it's incorrect. Here's the key paragraph from the Supreme Court's 1981 <u>ruling</u>:

66 A mathematical formula as such is not accorded the protection of our patent laws, and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment. Similarly, insignificant postsolution activity will not transform an unpatentable principle into a patentable process. To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection. On the other hand, when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e. g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101. Because we do not view respondents' claims as an



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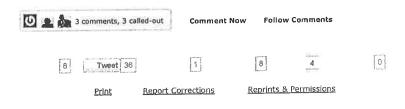
I read this as holding that the patent meets the requirements of the law precisely because it's not a software patent. Rather, the patent covers a physical machine whose purpose is "transforming or reducing an article to a different state or thing." The key principle is that the "post solution activity" in this case, opening the rubber mold at just the right time—has to be more than trivial.

Now compare this to the patent at issue in the Federal Circuit's infamous 1998 *State Street* decision. There, the court held that you could patent a strategy for managing a mutual fund with a computer. The "invention" used a generic computer to perform some mathematical calculations and issue orders to buy or sell assets. This seems like a textbook example of the kind of "insignificant postsolution activity" the Supreme Court said doesn't transform a mathematical formula into a patentable invention.

To be clear, plenty of people disagree with me about how *Diehr* should be interpreted. The Supreme Court's decisions on this question have not been models of clarity. But I think one indication that my claim was basically right is the way the software industry reacted, or more precisely didn't react, to the 1981 *Diehr* ruling. The legalization of software patents produced a backlash in the software industry. If the impetus for software patents came from the Supreme Court, we should have expected that backlash to start in the early 1980s. Instead, opposition started cropping up in the 1990s, shortly after the Federal Circuit <u>decided</u> a case called *In Re Iwahashi* in November 1989. Bill Gates's famous memo expressing concerns about software patents was penned in 1991. Oracle <u>testified at the Patent Office</u> opposing software patents in 1981, why did Oracle wait until 1994 to start complaining about it?

The obvious answer is that most people in the software industry believed that the Supreme Court had excluded most software from patent protection. They were thus blindsided when the Federal Circuit started upholding software patents in 1989.

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Timothy B. Lee Search Contributor Follow(84)

I write about how technology shapes society, and vice versa. In addition to blogging for Forbes, I <u>cover tech policy</u> for Ars Technica. I'm an adjunct scholar at the Cato Institute and have a master's degree in computer science from Princeton. I live in Philadelphia with my wife and our two cats. There's <u>more information</u> about me on my website, including a comprehensive disclosure statement. Please follow me on Twitter. You can email me at

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The "death of hundreds of thousands of patents?" How the CLS Bank decision could affect the future of software patents. | IP Spotlight

The "death of hundreds of thousands of patents?" How the CLS Bank decision could affect the future of software patents.

Posted on May 11, 2013 | 1 Comment

What does the Federal Circuit's recent decision in <u>CLS Bank Int'l v. Alice Corporation Pty Ltd.</u> mean for software patents? Is it the "death of hundreds of thousands of patents" as one judge stated, or just a bump in the road?

In a *per curiam* opinion published May 10, 2013, the Court ruled that the method and computer-readable medium claims of four patents were not directed to patent-eligible subject matter. The patents at issue were U.S. patents <u>5.970,479</u>; <u>6,912,510</u>; <u>7,149,720</u>; and <u>7,725,375</u>. In broad terms, the patents covered methods and systems for managing risk, such as the risk that may arise from one party failing to perform an obligation (such as pay a debt or honor a warranty) to another party.

The Court's five-judge panel opinion determined that the claims merely covered an "abstract idea." In support of this determination, the panel's opinion noted:

The concept of reducing settlement risk by facilitating a trade through third-party intermediation is an abstract idea because it is a "disembodied" concept . . . a basic building block of human ingenuity, untethered from any real-world application. Standing alone, that abstract idea is not patent-eligible subject matter.

Many of the claims required more than just facilitating a trade. Specifically, the claims also required discrete processing steps such as limitations requiring creating shadow records, using a computer to adjust and maintain those shadow records, and reconciling shadow records and corresponding exchange institution accounts through end-of-day transactions. Nonetheless, the panel's opinion stated:

None of those limitations adds anything of substance to the claim. . . With the term "shadow record," the claim uses extravagant language to recite a basic function required of any financial intermediary in an escrow arrangement — tracking each party's obligations and performance.

In dissent, Judge Moore noted:

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If all of these claims, including the system claims, are patent-ineligible, this case is the death of hundreds of thousands of patents, including all business method, financial system and software patents as well as many computer-implemented and telecommunications patents.

While the five-judge panel's opinion parsed the specific language of the claims at hand, it provided few bright-line rules to guide future decisions. The panel stated that "adding generic computer functions to facilitate performance provides no substantial limitation and therefore is not "enough" to satisfy § 101," but it did not generally state what types of functions should be considered "generic" and what functions would add enough technical substance to make a claim cover more than an abstract idea.

Many of the Court's judges disagreed with not only the result, but also with the reasoning of the fivejudge panel. Ten judges participated in a total of seven different opinions in the case. While seven judges agreed that the method and computer-readable medium claims were not patent-eligible, only five of them adopted the specific reasoning of the lead opinion. Half of the judges specifically found the system claims to be patent-eligible. In dissent, three of the judges asserted that *all* of the claims were patent-eligible.

Recognizing this fracture, Judge Newman noted that the Court's decision was supposed to remedy the Court's inconsistent precedent regarding Section 101, but that "[t]his remedial effort has failed."

It is difficult to find concrete guidance within the Court's fractured decision for patent applicants, patent holders, and defendants in future cases. However, the following observations may help patent applicants in future cases:

- In view of the court's split regarding system claims, software and business method patent applicants should consider ensuring that the application includes at least one system claim.
- When drafting claims for automated processes, applicants should include at least one claim element that is not inherent in any existing concept. For example, in a concurring-in-part opinion joined by two other judges, Judge Rader found that steps such as creating "shadow records," obtaining values of previously created accounts, adjusting balances and issuing credits were steps inherent in the concept of an escrow." To the extent that a claim merely automates previous manual processes, the Court may be more likely to find the claim not patent-eligible.

To be sure, the *CLS Bank* decision will be front and center in future court actions involving software and business method patents. It's also likely that the decision will be appealed to the Supreme Court. This blog will closely monitor future developments and court decisions that relating to the opinion.

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SOFTWARE (/CATEGORY/SOFTWARE)

apple (/tag/apple/), legal issues (/tag/legalissues/), patents (/tag/patents/) Appeals court ruling could be 'death' of software patents

Grant Gross, IDG News Service @GrantGross

May 10, 2013 1:13 PM

A U.S. appeals court has ruled that an abstract idea is not patentable simply because it is tied to a computer system, signaling what one judge described as the "death" of software and business method patents.

The U.S. Court of Appeals for the Federal Circuit ruled Friday

(http://www.cafc.uscourts.gov/images/stories/opinions-orders/11-1301.Opinion.5-8-2013.1.PDF) that four patents held by electronic marketplace Alice are too abstract for a patent, despite a long-standing legal assumption that software running on a computer is eligible for patents.

The implications of the case are huge, wrote Judge Kimberly Moore, dissenting in part with the majority decision.

The ruling in CLS Bank v. Alice gives "staggering breadth to what is meant to be a narrow judicial exception" on patent ineligibility, she wrote. "And let's be clear: if all of these claims, including the system claims, are not patent-eligible, this case is the death of hundreds of thousands of patents, including all business method, financial system, and software patents as well as many computer implemented and telecommunications patents."

Several recent U.S. Supreme Court rulings against patent eligibility are "causing a free fall in the patent system," Moore added. "Today, several of my colleagues would take that precedent significantly further, lumping together the asserted method, media, and system claims, and holding that they are all patent-ineligible."

Five judges in the 10-judge court sided with the majority opinion, while five other judges concurred in part and dissented in part. In addition to the majority ruling, judges filed five other comments on the case.But <u>Julie Samuels</u>

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(https://www.eff.org/deeplinks/2012/10/federal-circuit-take-on-software-patent), an intellectual property lawyer with the Electronic Frontier Foundation, said the ruling gives little guidance to courts on patent eligibility. While judges on the court agreed Alice's patents weren't valid, they agreed on little else, she said.

"We have not very much more direction as to what's patentable," said Samuels, who filed a brief asking the court to invalidate the Alice patents. "This ruling is all over the place."

The variety of opinions from the judges leaves the case open for Supreme Court review, she said. "The only thing the judges seem to agree on is that we need more clarity, but they can't even figure out what that looks like," Samuels added. "No one understands what the hell is or isn't patentable, including the ... federal circuit."

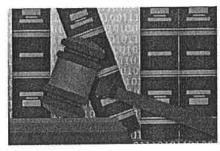
In the case, defendant CLS argued that Alice's four software patents

(http://www.ipwatchdog.com/2012/07/12/cls-bank-international-a-fractured-landscape-ofpatent-eligibility-for-business-methods-and-systems/id=26342/) covering a computerized trading platform for currencies were too abstract to be patentable. A district court agreed, but the appeals court reversed the decision.

The appeals court, however, heard arguments in February

(http://www.pcworld.com/article/2027756/appeals-court-considers-software-patents.html) to examine whether an abstract idea combined with a computer is patentable, and whether some software patent claims involving methods, systems or storage should be grounds for granting a patent.

"There is nothing in the asserted method claims that represents 'significantly more' than the underlying abstract idea," Judge Alan Lourie wrote for the majority. "As described, adding generic computer functions to facilitate performance" is not enough to make an abstract idea patentable.



Alice's lawyers had argued that the patents covered specific ways a computer is configured to run the company's trading platform, but Lourie rejected that argument. Adam Perlman, Alice's lawyer in the federal circuit hearing, declined to comment Friday.

The patented processes of "providing end -of-day instructions to the exchange institutions to reconcile the parties' realworld accounts with the day's accumulated adjustments to their shadow records is a similarly trivial limitation that does not distinguish the claimed method," Lourie wrote. "Whether the instructions are issued in real time, every two hours, or at the end of every day, there is no indication in the record that the precise moment chosen to execute those payments makes any significant difference in the ultimate application of the abstract idea."

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Moore agreed with the majority that an abstract idea is not patentable when it's tied to a computer, but she argued the Alice patents went beyond abstract ideas into "a practical application of the underlying idea, limited to the specific hardware recited and the algorithms disclosed to perform the recited functions."

The case generated briefs from Google, Facebook, Newegg and software trade group BSA, with some tech companies arguing the Alice patents should be invalid.

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Federal Circuit Giveth, and Taketh Away

May 14, 2010Bryan BeelLeave a commentGo to comments



In business, we often forget, the effect of an adverse (or favorable) court ruling can be drastic, and immediate. Today's shining example of this effect is the ruling of the <u>Court of Appeals for the Federal Circuit</u> that it will <u>reconsider</u>, <u>en banc</u>, its March 4, 2010 ruling (in favor of TiVo) in <u>Tivo Inc. v</u>. <u>Echostar Corp. et al.</u> In that earlier decision, the Federal Circuit held (roughly) that <u>Echostar's</u> attempts to design around <u>TiVo's</u> DVR patents (after an earlier loss at trial) were properly found invalid by the district court, and upheld a more-than-\$90 million award against Echostar. The decision and award have now been vacated, and the case will be decided anew.

TiVo's <u>stock</u> dropped approximately 35% in the minutes after the Federal Circuit's decision was announced today, wiping out grand amounts of bookmoney for TiVo's shareholders. Before, however, anyone cries great tears for TiVo and its owners, please recall that this effect essentially restores the *status quo*. After the Federal Circuit's March 4 ruling, TiVo's stock price leapt more than 60%; today's loss brings TiVo's shares back to within a dollar of their pre-March 4th selling price.

For you legal nerds, the Federal Circuit's order establishes that rehearing en banc will address the following issues:

- 1. Following a finding of infringement by an accused device at trial, under what circumstances is it proper for a district court to determine infringement by a newly accused device through contempt proceedings rather than through new infringement proceedings? What burden of proof is required to establish that a contempt proceeding is proper?
- 2. How does "fair ground of doubt as to the wrongfulness of the defendant's conduct" compare with the "more than colorable differences" or "substantial open issues of infringement" tests in evaluating the newly accused device against the adjudged infringing device? See Cal. Artificial Stone Paving Co. v. Molitor, 113 U.S. 609, 618 (1885); KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1532 (Fed. Cir. 1985).
- 3 Where a contempt proceeding is proper, (1) what burden of proof is on the patentee to show that the newly accused device infringes (see KSM, 776 F.2d at 1524) and (2) what weight should be given to the infringer's efforts to design around the patent and its reasonable and good faith belief of noninfringement by the new device, for a finding of contempt?
- 4. Is it proper for a district court to hold an enjoined party in contempt where there is a substantial question as to whether the injunction is ambiguous in scope?

Between this and the rehearing en banc order in Therasense, Inc. v. Becton, Dickinson and Co., there is a lot of amicus briefing fun to be had.

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Bloomberg

LogMeIn Must Face Revived Patent Suit by 01 Communique

By Susan Decker - Jul 31, 2012

LogMeIn Inc. must face a patent-infringement lawsuit filed by <u>01 Communique Laboratory Inc.,</u> (<u>ONE)</u> a U.S. appeals court ruled today. 01 Communique soared 44 percent, while LogMeIn shares fell to the lowest in more than two years.

The <u>U.S. Court of Appeals</u> for the Federal Circuit <u>said</u> a trial judge erred in his interpretation of a patent owned by 01 Communique and vacated a ruling that LogMeIn didn't infringe the patent. The case was sent back to the lower court for further proceedings.

The appeals court, which specializes in <u>patent law</u>, sided with 01 Communique on how the patented invention works. 01 Communique filed the lawsuit in 2010, claiming Woburn, Massachusetts-based LogMeIn infringed a patent related to a method of providing remote access to a desktop computer. 01 Communique, based in Mississauga, Ontario, runs the "I'm InTouch" remote access service.

The appeal turned on the question of whether the intermediary between a personal computer and a remote computer must be on a single server, as claimed by LogMeIn, or if it could be on multiple server computers. U.S. District Judge Claude Hilton in Alexandria, <u>Virginia</u>, had said the patent was limited to products on a single server, while LogMeIn's software uses multiple servers.

Multiple Computers

The Federal Circuit said the patent wasn't limited to a single server, and ruled instead it could comprise "one or more computers."

"We're feeling this is a step in the right direction,"Brian Stringer, 01 Communique's chief financial officer, said in a telephone interview.

The company spent more than \$30 million to develop its product, and serves mostly small and medium-sized companies, he said. A suit against <u>Citrix Systems Inc. (CTXS)</u> over the same patent has been on hold while the U.S. Patent and Trademark Office took a second look at it. Stringer said the examiner upheld the patent, and Citrix is challenging that decision.

In a statement, LogMeIn said it "continues to believe that it has strong defenses to the claims made by 01 Communique and intends to vigorously defend against these claims."

01 Communique rose 37 Canadian cents to C\$1.22 in Toronto. LogMeIn dropped \$5.44, or 22 percent, to \$18.95 in Nasdaq Stock market trading of 3.8 million shares, or more than 10 times the three-month daily average.

The case is 01 Communique Laboratory Inc. v. LogMeIn Inc., 2011-1403, U.S. Court of Appeals for the Federal Circuit (<u>Washington</u>). The lower court case is 01 Communique Laboratory Inc. v. <u>LogMeIn Inc. (LOGM)</u>, 10cv1007, U.S. District Court for the Eastern District of Virginia (Alexandria).

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To contact the editor responsible for this story: Bernard Kohn at <u>bkohn2@bloomberg.net</u>

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Eli Lilly stock plunges after court opens door to Prozac generics - Aug. 9, 2000



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Eli Lilly gets Prozac blues



NEW YORK (CNNfn) - A U.S. appeals court on Wednesday set a sooner-than-expected end to Eli Lilly and Co.'s reign as the sole marketer of Prozac, the popular antidepressant drug, a development that sent the pharmaceutical company's stock down by more than 30 percent.

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Shares of Indianapolis-based Eli Lilly plunged 32-17/32 a share to 76, after the U.S. Circuit Court of Appeals for the Federal Circuit in Washington, D.C. reversed a decision from an Indiana lower court that had given the company's antidepressant drug Prozac patent protection through 2003.



The decision opens the door to Barr Laboratories (BRL: Research, Estimates) and other drug makers who manufacturer generic versions of Prozac, which at more than 34.5 million prescriptions is the most widely prescribed antidepressant of its kind. Under the ruling, Barr can is in August 2001

put a generic version in pharmacies in August 2001.

The news propelled shares of Barr Laboratories to a closing price of 77, up 31-1/4, or about 68 percent.

Competition seen hurting Lilly results in 2001, 2002

Increased competition for Prozac is seen bruising Eli Lilly's results for the next two years, if the ruling is not overturned in appellate court. Lilly's Prozac revenue in 1999 stood at \$2.61 billion, more than one-quarter of its total sales of \$10 billion.

The company expects to post single digit earnings-per-share growth in the calendar years 2001 and 2002, accelerating to double-digit sales and earnings growth in 2003.

"We expect to continue our strong earnings growth in the first half of 2001 leading up to the generic entry in August," Charles Golden, the company's chief financial officer, said in a statement. "Then, we'll likely see earnings declines in the second half of 2001 and the first half of 2002.



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Earlier this year, the company predicted per-share earnings growth to be in the mid-teens over the next three years. Last year, Lilly earned \$2.5 billion, or \$2.46 a share.



The company anticipates that strong underlying growth of current products and others to be launched in 2001 and 2002 will lead to a return to doubledigit earnings growth in the second half of 2002.

In an interview on CNNfn's *Moneyline*, Eli Lilly Chief Executive Sidney Taurel said that despite the development, new drugs will provide the fuel to overcome any Prozac-related setbacks.

"(Looking forward) the strategy ... is to come up with new products," he said. "Currently we have eight products which are in phase three clinical trials and two more which will reach that stage by the end of the year."

"That means up to 10 products that will be launched between 2001 and 2004, which will help us weather the storm," Taurel added.

Pharmaceutical analyst Len Yaffe of Banc of America Securities said the early arrival of Prozac generics would trim about \$1 billion in Lilly's Prozac sales for the year of August 2001 to August 2002. Still, he told CNNfn's *Street Sweep* that the company's roster of planned products is strong, and that in time, new products will fill the revenue gap.



Sidney Taurel CEO, Eli Lilly (courtesy/ Eli Lilly.com)

"We think that their pipeline looks extremely robust and these recent drugs again are adding \$800 to \$900 million a year in revenues which is almost what they are going to lose to Prozac," he said.

Other drug stocks suffer

The news also infected the stocks of other pharmaceutical companies on Wednesday. Shares of Forest Laboratories (FRX: Research, Estimates), which makes a brand name antidepressant, fell 24-15/32, or 21.3 percent, to 90.

Shares of Sepracor also stumbled on the news, falling 18 percent to 106-1/8. Eli Lilly has a licensing agreement to develop and sell Sepracor's R-fluoxetine, a variation of Prozac that is undergoing clinical trials and is believed to have fewer side effects.

Analyst Yaffe labeled the slump a setback for drug company stocks, which had been outperforming major indices, and said his firm had been urging some clients to buy at the lower levels.

"The drug stocks have been phenomenal performers, since March," he said. "So I think it is appropriate to put it in its proper context in the fact that the drug stocks now maybe are taking a little bit of a breather." (283K WAV, 283K AIFF)

Signs of the potential erosion of Prozac sales amid a rise in competition are already evident in non-U.S. markets, the company revealed last month in its second-quarter earnings



report. Eli Lilly said Prozac sales dipped 31 percent in non-U.S. markets in the period, including the

United Kingdom, where its patent on Prozac has expired and competition has grown.

The company recently attempted to expand Prozac's uses, and in July won government approval for Sarafem, a form of Prozac. Sarafem is the first prescription drug for women suffering from the temporary depression and severe physical symptoms of premenstrual syndrome.

-- from staff and wire reports

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