ABSTRACT

Before the establishment of the Federal Circuit, the system of patent enforcement was deeply flawed, with the circuit courts then responsible for reviewing district court patent decisions harboring widely varying attitudinal views in the interpretation of the patent law. Suggestions for solving the problem through a single specialized appellate patent court were consistently rejected due to general hostility to specialized courts.

The formation of the Federal Circuit in 1982 initially appeared to solve the problem in providing uniform and predictable rules governing the enforcement of patents, an essential aspect of the court’s mission. The Supreme Court did not provide any obstacles to this early problem-solving but, in about 2001, the Court’s interest in the Federal Circuit’s holdings increased exponentially.

The end result has been significantly detrimental to the implementation of the Federal Circuit’s mission, creating uncertainty and a lack of predictability in the enforcement of patents, undermining the very reason the Federal Circuit was established. Among the main culprits are the Supreme Court’s aversion to bright line rules and its interest in bringing the Federal Circuit into conformity with the general law, an aversion and interest which are misguided and inimical to the public interest in a sound patent system.
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THE SUPREME COURT: A HELP OR A HINDRANCE TO THE FEDERAL CIRCUIT'S MISSION?

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Before the establishment of the Federal Circuit in 1982, the system of patent enforcement was deeply flawed. Specifically, the circuit courts then responsible for reviewing district court decisions in patent cases harbored widely varying attitudinal views in the interpretation of the patent law, ranging from one extreme in the 8th Circuit -- which was totally hostile to patents -- to the other extreme in the 5th and 7th Circuits -- which were totally hospitable to patents. The end result of this disparity in views was a patent jurisprudence lacking in uniformity and predictability, resulting in rampant forum shopping between friendly and hostile circuits by patent owners and accused infringers. That, in turn, had a direct impact on the willingness of innovators to invest the large sums required to bring new technologies to market.

While the problem could have been solved by having a single, specialized appellate court, the issue of specialized courts had been raised many times before but consistently rejected due to general hostility to specialized courts. That hostility is best summed up by a statement made by Judge Simon Rifkind, Co-Chairman of President Johnson’s Commission on the Patent System, delivered to the House of Representatives on April 26, 1967:

In my view, when you are dealing with a matter that concerns the general welfare of the United States, it is not wise to create a small group of men who become, like the Egyptian Priests, the sole custodians of a body of knowledge and who sooner or later begin to talk a language that nobody else understands but which is common only to them and the practitioners that appear before them and who drift away from those general principles of equity and morality, which pervade the entire judicial system.

In the mid-1970’s (1974-1975), however, the first of several events took place that paved the way to solving the problem. That first event was the convening of the Hruska Commission on Revision of the Federal Court Appellate System, on which I was

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privileged to serve as a patent consultant -- along with one of my patent law colleagues -- Professor James B. Gambrell.

The Hruska Commission was formed not principally to examine the patent law but to focus on possible modifications of the Federal Court Appellate system to provide an additional layer of review of circuit court opinions to supplement the limited review provided by the Supreme Court. As an adjunct to its efforts, the Commission asked Professor Gambrell and me to examine whether the patent system was functioning adequately, and whether it was desirable to modify the appellate review of patent decisions by the formation of a specialized appellate patent court. While Professor Gambrell and I recommended against such a court, as the result of a survey we took of patent trial lawyers, we also concluded that the patent system was not functioning properly given the aforenoted widely varying attitudinal views of the circuit courts in their interpretation of the patent law.

Given the Hruska Commission’s recommendation against the formation of a specialized patent appeals court and the general hostility towards such courts as reflected in the Rifkind quote, nothing happened on the subject until the late 1970’s, when a confluence of events took place which had a dramatic effect on the dialogue regarding a specialized appellate patent court.

One of those events was the formation by then President Carter of the Advisory Committee on Industrial Innovation, on which I, Federal Circuit Judge Polly Newman, and others were privileged to serve. The Carter Committee was charged with formulating options to deal with a then-perceived innovation crisis. At or about the same time, Professor Daniel Meador, on leave from the University of Virginia Law School and serving as an Assistant Attorney General in the Office for Improvements in the Administration of Justice, came up with the brilliant idea of merging two existing courts -- the Court of Customs and Patent Appeals and the Court of Claims -- which, at the time, occupied different parts of the same courthouse. The key to his proposal was including in the jurisdiction of the proposed court not only review of PTO decisions and almost all district court patent appeals but review of such non-patent issues as international trade and customs cases, Merit Systems Protection cases, tax cases, government contracts, veterans’ appeals, and the like. The end result would be a non-specialized appellate court with exclusive patent jurisdiction designed to avoid the Rifkind concerns while minimizing forum shopping and providing the desperately needed uniformity and predictability of patent jurisprudence. And the icing on the cake was that no new courthouse, no new judges or law clerks, or other court personnel would be required for this new court.

The genius of this idea was quickly recognized by my colleagues and me in the Carter Committee, which adopted it as one of its key recommendations. In the face of some meaningful opposition, the new Federal Circuit court was signed into law by President Reagan and opened its doors in October 1982.

For many years, the Federal Circuit succeeded beyond the wildest dreams of its proponents. Its decisions in the patent area brought patent law into the mainstream of the legal profession. The value of patents increased exponentially. Patent litigation -- previously the focal point of patent boutiques -- became a staple of many generalist firms, which clamored to develop their own or acquired patent practices.

For much of this early period, the Supreme Court was content to leave the Federal Circuit alone, permitting it relatively free reign in eliminating the pre-1982 chaos that existed and providing the ultimate in developing uniform and predictable rules
governing the enforcement of patents. Thus, for the period 1982 - 2000, the total of Federal Circuit patent cases reviewed by the Supreme Court was 11. Beginning in about 2001, however, the Supreme Court’s review of Federal Circuit patent cases increased meaningfully, for a total of 47 cases for the period 2001 - 2017, with two Federal Circuit patent cases currently being on the Court’s docket for hearing.

The reasons given by commentators for this significant increase in interest by the Supreme Court in Federal Circuit patent cases varies. Included in the list of culprits are (1) the Court misunderstands the patent law; (2) the Court misunderstands innovation policy; (3) the Court misunderstands the patent system; (4) the Court misunderstands the technical facts of patent cases; (5) the Court wants to bring the Federal Circuit into conformity with the general law; and (6) the Court has an aversion to the bright line rules that the Federal Circuit has often employed; and there are still others.

I strongly doubt the accuracy of the first four explanations. Explanations (5) and (6), however, are on the mark. And to the Supreme Court’s credit, its increased interest in reviewing Federal Circuit patent holdings has resulted in a number of salutary decisions, such as *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 124 (2014) (clarifying the law of indefiniteness as requiring definition of the scope of the invention with “reasonable certainty”); *Microsoft Corp. v. i4i, Ltd. P’ship*, 564 U.S. 91 (2011) (patent invalidity proved by clear and convincing evidence, even where evidence relied on to prove invalidity was not considered by the PTO).

But whatever the reason, it is abundantly clear that the Supreme Court’s increased interest in the Federal Circuit’s patent holdings has also been significantly detrimental to the implementation of the Federal Circuit’s mission. It has created uncertainty and a lack of predictability in the enforcement of patents, undermining the very reason the Federal Circuit was established in 1982.

Examples abound, perhaps the best of which is the Supreme Court’s Section 101 jurisprudence, notably *Bilski v. Kappos*, 561 U.S. 593 (2010); *Mayo Collaborative Servs. v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012); *Ass’n for Molecular Pathologies v. Myriad Genetics*, 569 U.S. 576 (2013); and *Alice Corp. v. CLS Bank Int’l*, 134 S.Ct. 2347 (2014). Setting aside whether there is any legal justification for the two-part patent eligibility test of these cases, the courts, the patent bar and the Patent

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1 In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375-76 (Fed. Cir. 2015), *en banc* denied, 809 F.3d 1282 (2015), cert. denied, 136 S. Ct. 2511 (2016), the Federal Circuit stated the following:

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289 (2012), the Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent-ineligible concept. *Id.* at 1297. If the answer is yes, then we next consider the elements of each claim both individually and “as an ordered combination” to determine whether additional elements “transform the nature of the claim” into a patent-eligible application. *Id.* at 1298. The Supreme Court has described the second step of this analysis as a search for an “inventive concept” -- i.e., an element or combination of elements that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” *Id.* at 1297; see also *Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (“Without additional limitations, a process that employs mathematical algorithms
and Trademark Office are completely lost on how to apply it. Indeed, even the Supreme Court seems to be at sea in applying the test given the significant inconsistencies between its § 101 opinions on the subject.

For example, in *Parker v. Flook*, 437 U.S. 584, 588 (1978), the Court held that the novelty of the ineligibility concept is not a determining factor at all, but must be treated as though it were a familiar part of the prior art. In *Diamond v. Diehr*, 450 U.S. 175, 188-89 (1981), on the other hand, the Court found patent-eligible a process for molding raw, uncured synthetic rubber into cured precision products involving the use of a known equation in combination with conventional steps; the equation was not considered as part of the prior art.

In *Mayo*, the Court held that it’s not enough to add conventional steps to the ineligible concept. 566 U.S. at 79. In *Diehr*, on the other hand, the Court held that: “It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.” 450 U.S. at 188.

In *Mayo*, the Court held that it’s proper to include §§ 102, 103 and 112 inquiries as part of the § 101 inquiry. 566 U.S. at 91. In *Diehr*, on the other hand, the Court held that § 101 is a general statement of the type of subject matter that is eligible for patent protection “subject to the conditions and requirements of this title”; the question of whether a particular invention is novel is wholly apart from whether the invention falls into a category of statutory subject matter. 450 U.S. at 189-90.

Unfortunately, the uncertainty in the application of the Supreme Court’s § 101 jurisprudence has resulted in the invalidation of significant inventive contributions, a prime example of which was the pioneering medical invention involved in *Ariosa*, leading to a multitude of opinions by Federal Circuit judges obviously frustrated by their inability to avoid the handcuffs of the Supreme Court’s § 101 jurisprudence. What Judges Lourie and Moore said in their opinion in *Ariosa* denying en banc review sums up that frustration:

But focusing on the claims we have rather than those we might have had, the claims here are directed to an actual use of the natural material of cffDNA. They recite innovative and practical uses for it, particularly for diagnostic testing: blood typing, sex typing, and screening for genetic abnormalities. And it is undisputed that before this invention, the amplification and detection of cffDNA from maternal blood, and use of these methods for prenatal diagnoses, were not routine and conventional. But applying *Mayo*, we are unfortunately obliged to divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.

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2 *Ariosa*, 788 F.3d at 1375-76.
3 Id. at 1376.
Moreover, the claims here are not abstract. There is nothing abstract about performing actual physical steps on a physical material. And if the concern is preemption of a natural phenomenon, this is, apparently, a novel process and that is what patents are intended to incentivize and be awarded for. The panel here also noted that there were other uses for cfDNA and other methods of prenatal diagnostic testing using cfDNA that do not involve the steps recited in the various claims. That fact should sufficiently address the concern of improperly tying up future use of natural phenomena and laws.

In sum, it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts. But I agree that the panel did not err in its conclusion that under Supreme Court precedent it had no option other than to affirm the district court.

It is true that a number of the patent-hostile § 101 cases contain positive statements indicating that the door is not completely closed to patent-friendly holdings:

- “In choosing such expansive terms ... modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope.'... Congress took this permissive approach to patent eligibility to ensure that ‘ingenuity should receive liberal encouragement.’”

- Reliance on Diehr to support the notion that “an application of a law of nature or mathematical formulas to a known structure or process may well be deserving of patent protection.”

- “The rule against patents on naturally occurring things is not without limits, ... for 'all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,’ and 'too broad an interpretation of this exclusionary principle could eviscerate patent law.'

- Recognition of the need to consider the invention as a whole, rather than dissecting the claims into old and new elements and then ignoring the presence of the old elements in the analysis.

- § 101 “precludes the broad contention that the term ‘process’ categorically excludes business methods. The term ‘method’ ... may include at least some methods of doing business.”

- “It is said that the decision precludes a patent for any program servicing a computer. We do not so hold.”

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5 Id. at 611.
6 Assn for Molecular Pathology v. Myriad Genetics, 133 S. Ct. 2107, 2116 (2013).
7 Bilski, 561 U.S. at 611.
8 Id. at 606-07.
But given the actual holdings in the bulk of the Supreme Court cases, one cannot be too encouraged by these positive tidbits, and the Supreme Court seems disinclined to fix the problem given its denial of cert in Ariosa and other § 101 cases, probably requiring legislation to clear up the mess.

Nor is the problem restricted to § 101 issues. Over a period of more than forty-five years, the CCPA and then the Federal Circuit had developed the teaching, suggestion, or motivation (TSM) test for obviousness. This was a highly useful test for resolving a critical patent validity issue, one that was relatively easy to apply and which contributed meaningfully to the Federal Circuit’s goal of uniformity and predictability. Yet, consistent with its aversion to bright-line rules, the Supreme Court in KSR\textsuperscript{10} held that the TSM test provides “a helpful insight” but that it should “not become [a] rigid mandatory formula[.]”\textsuperscript{11}

And still other examples could be given.

The bottom line is that, whatever the Supreme Court’s motivation in subjecting the Federal Circuit to review of its patent holdings, most of which have resulted in reversals, and notwithstanding the fact that a number of its decisions have resulted in useful guides to the patent laws, the Supreme Court has significantly undermined the Federal Circuit in achieving its goal of providing uniformity and predictability to the implementation and enforcement of the patent laws. If, as I believe, the main culprits are the Supreme Court’s aversion to bright-line rules and its interest in bringing the Federal Circuit into conformity with the general law, that aversion and interest applied sweepingly to the Federal Circuit are misguided and inimical to the public interest in a sound patent system.


\textsuperscript{11} Id. at 419.