

Preface to the Second Edition

Patent law brings the spark of imagination to the gasoline of greed. It is dynamic, an explosive force driving innovation in industry as in law, which is inherently unstable. It is also by far the most complex and arcane field of U.S. legal practice, with copious precedent extending to the earliest years of the republic. Principles codified in the patent statutes were devised and elaborated by the most astute jurists of the 19th century, including Supreme Court justices who tried patent cases while riding circuit, when federal questions consisted chiefly of patent and admiralty law. The subtlety and richness of U.S. patent law is a product of evolution, experimentation, reflection, and refinement, not just by generations of judges, including the patent specialist judges of the CCPA, but also by 150 years of published Patent Office precedent.

At its inception in 1982, when the Federal Circuit was entrusted with sole appellate jurisdiction in patent cases, the new court was not writing on a clean slate. Viewed as an experimental court of specialized jurisdiction, the Federal Circuit was founded for the purposes of enhancing predictability and consistency in patent law, and increasing its doctrinal stability. Uniformity, stability and predictability of patent law are thus the touchstones of the court's success. In its first 25 years, the court has not attained these goals.

Core tenets of patent law have been destabilized by the Federal Circuit's disregard of precedent, and its preference for reinventing the patent law wheel. Too often, when the court has been most uniform, it has been most wrong. Its *Festo* decisions demolished the venerable doctrine of equivalents and rejected 150 years of Supreme Court precedent, based on a policy preference for notice over equity in patent litigation. In *Bilski* the court adopted a wooden machine-or-transformation test that turned back the clock to the late 19th century in determining patent eligible subject matter, and now threatens to destroy thousands of basic biotechnology patents claiming DNA and protein inventions. In *KSR*, the Supreme Court rejected the Federal Circuit's similarly inflexible teaching-suggestion-motivation test, which had governed obviousness determinations for 20 years, with an admonition to heed Supreme Court precedent that had been universally disregarded by the Federal Circuit.

Under the Federal Circuit, patent law has also been splintered by a proliferation of new doctrines, and abrupt and unexpected departures from previously settled principles. Noteworthy recent examples include the super-enablement requirement grafted onto Section 112 by *Ariad*, and the flowering of the judge-made rule against obviousness-type double patenting to encompass anticipation-type double patenting, no longer confined to consideration of patent claims. Life is full of surprises, particularly for biotechnology and pharmaceutical companies who find their core patent assets threatened or eliminated by unforeseeable swerves, such as the expansion of “inherent” anticipation to prior art that does not describe any part of the claimed subject matter, as in *Schering*. These may all be very clever positions, and advances over established law, but they have eroded the stability and predictability of patent law.

Divisions between panels of the Federal Circuit on fundamental questions of patent law have been as pronounced as any between the regional circuits, as illustrated by the 17-year impasse over the scope of product-by-process claims, which was finally resolved in *Abbott v. Sandoz*. The proliferation of inconsistent decisions, and the court’s historic unwillingness to resolve disagreements en banc, have produced a wealth of conflicting precedent that consists largely of dicta and can be cited to support almost any position. This is evident in panels’ divergent applications of the doctrine of inequitable conduct, which deviate widely from fairly clear principles established in the en banc *Kingsdown* decision, and the court’s adherence in *Digital Control* to the subjective “reasonable” examiner standard, which rests on the strange principle that a reasonable examiner is not required to follow the PTO rules of procedure. Uncertainty concerning inducement of infringement, resulting from panels’ failure to follow the en banc *DSU* decision and *Grokster*, have again led to Supreme Court review of conflicting Federal Circuit panel pronouncements.

This lack of adherence to Federal Circuit precedent has led to a consensus that the court’s decisions are often panel dependent. In too many cases, even with knowledge of undisputed facts and exhaustive legal research, it is not possible to advise a client as to the likely outcome of a dispute, without being able to foresee the panel that will decide the case.

The predictability of the outcome in patent litigation has also been seriously undermined by the Federal Circuit’s disastrous *Cybor* doctrine, under which all issues relating to claim construction are reviewed de novo, with no deference whatsoever required to the legal and factual findings of the district court. *Cybor* as a practical matter has led to a rate of appellate reversal in patent cases—at times approaching 50%—which almost entirely eliminates predictability. The predictable result of the *Cybor* doctrine is that patent litigation is extended and its cost is multiplied, with the expectation of a trial *de novo* in the court of appeals on the ephemeral issue of claim scope, armed with the panoply of *Phillips*.

Confidence in the patent system by industry depends to a large extent on the ability of businesses to apply established and stable legal prin-

ciples to contracts, investments, and the evaluation of risks, and to foresee the outcome of patent litigation. As Congress realized in 1982, uniformity, stability and predictability of patent law are essential attributes of industrial policy, which are critical to the competitiveness and advancement of biotechnology. These goals are less likely to be advanced by brilliant innovations in patent law, than by adherence to precedent and deference to the findings of the district courts and the reasoning of the Supreme Court, which has now revived its dormant interest in patent law. It is encouraging that the Federal Circuit has recently changed course, and has actively undertaken en banc review to resolve long-standing conflicts in its precedent.

Patent law is an area of policy in which disagreement on specific issues, as well as deeper philosophical differences, is inherent. I often disagree with particular decisions of the court, and hope that my criticism will be constructive in focusing further discussion on the practical and economic impact of the court's decisions on the biotechnology industry and the dangers it faces, both from international competition and from gradual disintegration of patent law's consistency.

The views expressed are my own, and not those of my firm or any of its clients. As in any treatise, the focus is necessarily general, and my analysis cannot be applied to the specific facts of any future case without careful consideration. I have attempted to fairly consider the content of every important Federal Circuit biotechnology case, rather than express my own views, but I do not necessarily endorse the court's reasoning.

Thanks go, first, to my partners, who have generously provided me with the time to rewrite and expand this edition, and have refined my understanding in hours of dialog and debate. I am indebted to the editorial staff of BNA Books, who painstakingly corrected the text through several revisions, leaving only errors that are my own responsibility, and to Jim Fattibene for his boundless patience as my progress on the manuscript languished. Ned Burchfiel deserves praise for tackling the footnotes of Chapters 6 to 16 in an hour of need. I also owe a lasting debt to the dissents of Judge Pauline Newman, for their clarity, precision, and insight. However, the second edition, like its author, remains dedicated to my wife, Linda.

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