Preface

Preface to the Seventh Edition

Twenty-five years after the inception of this text, patent law remains a fascinating and challenging field of study. One of its sometimes maddening features is an almost constant and rapid rate of change. Patent law is never stagnant. Its evolution is driven by many factors: scientific and technological progress (can an AI chatbot be an inventor?), global trade and borderless innovation, public policy debate over the role of patents in the U.S. free market economy, the marketplace for patents as capital assets, patent litigation instituted by non-practicing entities (pejoratively, "patent trolls"), the 2011 America Invents Act ("AIA") implementation of the most significant changes to the U.S. Patent Act since its 1952 codification, a steady stream of decisions from the U.S. Court of Appeals for the Federal Circuit (having nationwide jurisdiction over patent-related appeals), and infrequent but often dramatic course corrections imposed by the U.S. Supreme Court. The new matter in the seventh edition of *Patent Law* reflects this dynamic milieu.

In the four years following publication of the sixth edition, the rapidity of change in patent law has not lessened. The considerable modifications worked by the AIA have radically altered U.S. patent practice. The AIA changed our historic method for determining priority of invention to a more streamlined first-to-file system, moving closer to international norms. The AIA also modified what qualifies as "prior art" to defeat patentability, and expanded the universe thereof by removing geographic limitations. The Federal Circuit continues to confront the ambiguities inherent in the AIA's provisions, such as the effective date for prior art in the form of patents and published applications.

Critically, the AIA first-to-file changes were prospective only; over two million patents already in force at its enactment were not impacted. The validity of patents issued from applications filed before March 16, 2013 is still assessed (in the USPTO, district courts, and the Federal Circuit) under pre-AIA rules for the remainder of the patents' lives and beyond. Accordingly, students of U.S. patent law need to understand not one but two sets of rules. This text explains both.

Although the change to a first-inventor-to-file system upended 200 years of U.S. patent practice, the AIA-implemented adjudicatory procedures for challenging the validity of issued patents are even more significant. Post-issuance review has transformed the landscape of U.S. patent litigation. These USPTO adjudications now far outnumber patent lawsuits filed in the federal courts. Moreover, the Federal Circuit's docket now comprises many more AIA review appeals than district court appeals. The Supreme Court continues to take cases involving the AIA procedures. In *Thryv* (2020), the Court boosted the USPTO's independence by affirming that the Federal Circuit cannot review the agency's decisions on whether parties are time-barred when filing AIA patent challenges. In *Arthrex* (2021), the Court determined that a Constitutional violation in the appointment of the Administrative Patent Judges who decide AIA reviews was remediable by implementing USPTO Director review.

The quandary of patent eligibility under Section 101 of the Patent Act persists, with the Supreme Court refusing to revisit the issue and Congress stymied over legislative reforms. The Court's regrettable 2012 decision in *Mayo*, which announced wide-ranging exceptions to patent-eligibility, has generated the greatest fallout. A mounting number of Federal Circuit decisions have applied *Mayo* and its progeny to strike down as patent-ineligible "laws of nature" a wide variety of inventions in the life sciences. Generally speaking, medical diagnostics inventions are no longer patentable.

Likewise, the rules for discerning the "abstract idea" category of exclusion from patentability, often encountered in software-implemented inventions, remain amorphous. The federal courts struggle with the vague boundaries of "abstract" and "inventive," and the USPTO faces similar challenges as post-grant review of AIA patents comes fully on line. Distinguished Federal Circuit judges have publicly called for Congressional clarification of Section 101, to no avail. Without straightforward standards or metrics, the Circuit decides patent-eligibility cases by simply analogizing to the factually closest cases it can identify. Policy concerns are not part of the calculus.

Although the AIA implemented myriad changes, its passage did not meaningfully impact patent eligibility and many other fundamental patent law principles. Since the last edition, the Supreme Court has revisited two bedrock patent law doctrines. In *Minerva* (2021), the Court affirmed that the equitable doctrine of assignor estoppel remains viable but has important limits. In *Amgen* (2023), the Court applied long-standing enablement rules to invalidate 21st century biotechnology patents. No matter how sophisticated or complex, the full scope of a claimed invention must be enabled; this is the fundamental patent bargain.

As this edition goes to print, U.S. patent lawyers are closely following revolutionary changes in patent procurement and enforcement in Europe. Taking effect in 2023 after years of negotiation and debate, the European Union's new Unitary Patent and Unified Patent Court will fundamentally

alter how U.S. entities obtain and enforce patent rights in the EU. This edition examines the new framework.

I am indebted to the many patent law students, academics, and practitioners whose feedback and suggestions for this text have proved invaluable during the revision process. Darren Kelly and Aiden Blasi provided essential editorial assistance. Any errors are my own. Comments or questions are welcome and should be e-mailed to the author at Janice@chisum.com.

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May 2024