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BIOTECHNOLOGY AND THE FEDERAL CIRCUIT

By Kenneth J. Burchfiel.[1]
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Congress established the U.S. Court of Appeals for the Federal Circuit on October 1, 1982,[2] granting the court broad jurisdiction, including jurisdiction over appeals from district court cases arising under the patent laws of the United States, and appeals from decisions of the Patent and Trademark Office ("PTO"). Prior to the creation of the Federal Circuit, Congress recognized a lack of uniformity among federal courts in their treatment of patent law matters. Because patent issues appeared infrequently on their dockets, existing federal courts were poorly positioned to render sound patent decisions and effectuate doctrinal stability. Tremendous growth in technology, particularly in the area of biotechnology, further complicated patent law matters, resulting in an increased number of conflicting and potentially destabilizing judgments. These problems helped trigger the creation of a specialized court aimed at addressing nuanced patent issues more efficiently and consistently.

In his new book, *Biotechnology and the Federal Circuit*, Kenneth Burchfiel chronicles the Federal Circuit's first decade of existence and critiques its decisions in the emerging field of biotechnology. He undertakes an exhaustive study of the court's opinions, based on his review of nearly one thousand published cases, in order "to determine whether the Federal Circuit has fulfilled its broad mandate and has made significant progress toward achieving the goals foreseen by Congress of harmonizing and rationalizing patent law" (p. 5). Burchfiel begins his book by placing the Federal Circuit in the appropriate context of the evolution of American patent law. Through the use of selected examples, he traces the Supreme Court's treatment of patent law over the course of the last two centuries. He notes the Supreme Court's historical antipathy for the issuance of patents, quoting Justice Jackson who acknowledged a "'strong passion in this Court for striking [patents] down, so that the only patent that is valid is one which this court has not been able to get its hands on'" (p. 7). Against this backdrop, Burchfiel outlines the mandate for a specialized Federal Circuit equipped to

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2. Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.

address the increasing complexity of patent law matters and clarify this confusing and important area of law.

In Chapter 2, Burchfiel includes a succinct technical introduction to basic cellular biology and recombinant DNA processes. Readers with a general familiarity with biology or chemistry should be able to understand his survey of the general technology, but may find the details and technical nuances of later chapters beyond their scope if they are not well-versed in biological terminology. The chapter also contains illustrative examples of typical biotechnology product claims that provide practical assistance to newcomers to the biotechnology field.

A significant portion of *Biotechnology and the Federal Circuit*, beginning in Chapter 3, is devoted to outlining specific patentability requirements. Burchfiel explains that "obtaining a patent under the statutory provisions has been compared to having 'separate keys to open in succession the three doors of sections 101, 102 and 103'" (p. 37). He first addresses the requirement that the technology must constitute patentable subject matter pursuant to 35 U.S.C. § 101 and fall into one of the "useful" categories of "invention." Chapters 3 and 4 cover issues concerning judicial interpretations of § 101. Burchfiel observes that since the Supreme Court decision in *Diamond v. Chakrabarty*,[3] patentable subject matter theoretically includes "anything under the sun that is made by man" (p. 40), but shows how the advent of patent applications for multicellular animals and the enactment of the Plant Variety Protection Act have clouded judicial decisionmaking based on this standard.

In Chapter 5, Burchfiel reviews the statutory requirement of novelty[4] over prior art as it applies to biotechnology inventions. He outlines several limitations on the power of prior art to defeat novelty. He explains that a product claim will not be defeated unless "each element of the claimed invention is disclosed in a single, effective prior art reference," "every element [is] literally present," and "the prior art [is] enabling, and a method for making the claimed product [is] disclosed by the prior art" (p. 65). Burchfiel follows up with a recitation of how each of these elements has factored significantly in a number of important biotechnology cases.[5] The chapter on novelty concludes with a detailed

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3. 447 U.S. 303 (1980) (holding that a living human-made microorganism is patentable subject matter under 35 U.S.C. § 101).

4. 35 U.S.C. § 102 (1994) (a valid patent may not be issued for any product that is the same as a known product).

5. For instance, in Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991), the Federal Circuit held a prior researcher's unique probing strategy to be nonenabling and hence not fatal to a later researcher's claim to isolation of the erythropoietin gene, because the earlier researcher did not have knowledge of the specific amino acid sequence which, in concert with the probing techniques, allowed the later researcher to

look at the implications and problems of filing foreign biotechnology applications.

Chapter 6 addresses the requirement of obviousness[6] and provides a thorough overview of sub-doctrines and critical case law. After reviewing the principal statutory considerations of obviousness, the author examines the PTO's general posture toward biotechnology patents. On a general level, Burchfiel criticizes the PTO's adherence to "a rule of per se obviousness of biotechnology invention" (p. 88). More specifically, he contends that on several occasions the PTO has confused the reference standards for prima facie obviousness with those involved in the issue of enablement. He further notes that in one instance, the PTO found a disclosure to be enabling even where "the owner of the patent application acknowledged that the disclosed method was unsuccessful and that the reference application was abandoned for this reason" (p. 90). To bolster his criticisms of the PTO, Burchfiel includes a synopsis of five Federal Circuit cases[7] that significantly impact the issue of obviousness in biotechnology patents. From these cases, Burchfiel develops a three-part test[8] that he believes should be employed in determining which claims should be rejected for prima facie obviousness. Burchfiel concludes his chapter with a review of the doctrine of structural obviousness and an extensive survey of how the obviousness requirement affects process claims.

The next section of the book, Chapters 7 through 10, describes the more procedural aspects of claim filing and contains explanations of the various requirements. Specifically, these chapters address the issues of written description and deposit, enablement, best mode, and claim definiteness. Burchfiel's thorough analysis of relevant case law and statutory considerations provides an insightful commentary on areas of critical importance to the biotechnology practitioner. For example, in

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obtain the isolated erythropoietin DNA sequence.

6. 35 U.S.C. § 103 (1994). An invention will not receive a patent if the difference between the subject matter sought to be patented and the prior art would have been obvious at the time the invention was made to a person with ordinary skill in the art. *Id.*

7. *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991); *In re* O'Farrell, 853 F.2d 894 (Fed. Cir. 1988); Hybritech v. Monoclonal Antibodies, 802 F.2d 1367 (Fed. Cir. 1986).

8. The three-part test requires that:

> 1. The prior art must disclose or suggest the modification in the prior art process that is required for the invention, without reference to the applicant's specification.
> 2. The reference must convey to one skilled in the art that there is a reasonable expectation of success if the modification is made.
> 3. The reference must provide detailed enabling methodology for practicing the claimed invention (p. 107).

Chapter 8, Burchfiel answers important questions about enablement, such as: Who is 'any person skilled in the art'? What experimentation is undue? What is the relevant date for enablement? By analyzing the decisions in pivotal biotechnology cases and wading through their dicta,[9] Burchfiel provides helpful guidance to practicing researchers and patent attorneys.

Chapters 11 through 14 of *Biotechnology and the Federal Circuit* detail the topic of infringement. Chapter 11 deals with the scope of patent rights, claim construction, and basic infringement analysis. In Chapter 12, Burchfiel presents a sweeping examination of the doctrine of equivalents. He surveys the doctrine's early development in the Supreme Court and explains that the doctrine of equivalents "extends the scope of patent claims beyond their literal boundaries in order to 'temper unsparing logic and prevent an infringer from stealing the benefit of the invention'"[10] (p. 260). Burchfiel then delineates the analytical steps the Federal Circuit employs in applying the doctrine[11] and chronicles the doctrine's influence both in and out of the biotechnology realm. Before delving into the subtleties of some celebrated biotechnology cases,[12] he includes a number of examples from the manufacturing industry as a useful introduction. Finally, Burchfiel criticizes the Federal Circuit's failure to develop a uniform standard for the doctrine of equivalents with regard to biochemical and mechanical claims and points out potential negative implications of the doctrine for the biotechnology industry. Chapters 13 and 14 discuss product and process patent infringement

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9. *See* Genentech, Inc. v. Wellcome Found., 29 F.3d 1555 (Fed. Cir. 1994); *In re* Vaeck, 947 F.2d 488 (Fed. Cir. 1991); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991); *In re* Fisher, 427 F.2d 833 (C.C.P.A. 1970); *Ex Parte* Humphreys, 24 U.S.P.Q.2d (BNA) 1255 (Pat. Off. Bd. App. 1992).

10. *Quoting* Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 608 (1950).

11. The five-step analysis for applying the enablement doctrine is:

> 1. Construction of the claim language to determine its meaning;
> 2. Determining whether literal infringement of properly construed claims is present;
> 3. If no literal infringement is present, determining whether the allegedly infringing device, composition, or process is equivalent to the claimed technology;
> 4. If the accused device is equivalent, determining whether expansion of the literal language of the claim is prohibited by prosecution history estoppel; or
> 5. If the accused device is equivalent, determining whether the expansion of the literal language of the claim is restricted by the prior art (p. 262).

12. *See Genentech*, 29 F.3d 1555; *Scripps*, 927 F.2d 1565; Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558 (Fed. Cir. 1990); American Hosp. Supply Corp. v. Travenol Lab., 745 F.2d 1 (Fed. Cir. 1984).

issues. In addition to a thorough review of doctrinal issues in chapter 13, Burchfiel also relates a "gloves-off debate" among members of the Federal Circuit over its treatment of claim precedents (p. 295), thus providing a more lively perspective on the dynamics of the Federal Circuit.

The next four chapters address special topics relating specifically to the biotechnology industry. Chapter 15 discusses experimental and exempt uses of biotechnology, including a detailed overview of the Food and Drug Administration ("FDA") clinical trial exemption guidelines. Chapter 16 analyzes aspects of patent term extension, and Chapter 17 focuses on plant inventions. Each of these chapters provides practical, valuable guidance to biotechnology practitioners. Burchfiel concludes the book with a critique of the Federal Circuit and its treatment of biotechnology issues as well as its efforts to achieve doctrinal stability. Burchfiel discusses the court's treatment of precedent and the structural consequences of exclusive jurisdiction, laments the court's tendency to insert unneeded and confusing dicta, and criticizes the court's reliance on policy considerations in its disposition of cases.

Biotechnology and the Federal Circuit is an ambitious work, and Burchfiel succeeds in producing an encyclopedic practitioner's handbook that skillfully intertwines history, doctrinal analysis, and policy considerations. Through crisp writing and focused criticism, he furnishes an overview of an entire discipline of law while concurrently providing substantive analysis of many important court decisions. The book is well-organized and its overall structure is easy to follow. Logical chapter subdivisions, which correspond to a detailed table of contents, and comprehensive indices of cases, statutes, and textual subject matter aid the reader in finding particular areas of interest. Accurate and explanatory footnotes also provide substantive foundation. But the book's greatest strength is Burchfiel's critical analysis of the PTO's and the Federal Circuit's treatment of biotechnology issues. For example, in his discussion of the obviousness requirement, Burchfiel notes that "[b]ecause a majority of Federal Circuit judges have no technical background, it is predictable that their decisions . . . will gravitate to nontechnical factors, such as commercial success and long-felt need of others" (pp. 82-83).[13] Burchfiel supports this observation with a review of cases that have turned on such issues. Furthermore, Burchfiel ably identifies important policy implications surrounding the doctrinal issues he reviews. For example, Burchfiel notes that the Supreme Court's focus on "commercial usefulness" in deciding the issue of utility — which he believes "has no foundation in the statutory language or its legislative

13. As of 1995, only three of the seventeen active and senior Federal Circuit court judges had the technical qualifications to prosecute patents before the PTO (p. 13).

history" (p. 51) — may hinder the useful art of chemical research, where small incremental inventions may be without commercial utility but may still be vital to the development of the field as a whole.

Burchfiel also displays a knack for including quotes from judges that lend credence to his arguments and add flavor to the text. For example, in his discussion of the deficiencies inherent in the federal court system with respect to patent issues before the creation of the Federal Circuit, Burchfiel cites an aphorism from Judge Gee — "patent cases are the only cases argued by professionals and decided by amateurs" (p. 12). Burchfiel also relies on illustrative anecdotes for support. In order to convey the sense of confusion that pervades modern patent law, Burchfiel recounts the testimony of the author of an eleven-volume patent law treatise who admitted that at the time of drafting an original patent application for a method of preparing a particular product, he was unaware that the product itself was patentable.[14]

Throughout *Biotechnology and the Federal Circuit*, Burchfiel maintains his pro-patent bias and explains the urgent need for uniformity and clarity in the patent law regime in order to provide a more hospitable environment for biotechnology practitioners. His strident support of the biotechnology industry gives the book direction, but it is also the book's only weakness. Burchfiel frequently describes the dynamic interactions of the Federal Circuit and the PTO, but in zealously advancing the interests of biotechnologists, Burchfiel downplays or ignores the criticisms of judges and examiners who are reluctant to treat biotechnological inventions, particularly multicellular animals, as being indistinguishable from other inventions. Burchfiel doggedly criticizes the PTO for "impos[ing] a moratorium on patents for higher vertebrates, without action by Congress and without statutory authority" and then states: "It simply does not seem rational to speculate that the patenting of five mice, one rabbit, and a worm will reduce science or civilization as we know it to slavery or doom" (pp. 42-43). While his criticism of the PTO's operating beyond its proper authority may be accurate, his sarcastic dismissal of any conceivable ethical objections[15] pertaining to

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14. *See* Scripps Clinic & Research Found. v. Genentech, Inc., 707 F. Supp. 1547, 1558-59 (N.D. Cal. 1989).

15. Opposition to the issuing of patents for higher animals has come from many segments of the population, including religious leaders, animal rights advocates, and scientists. Many believe that patenting life forms tends to depreciate the sanctity of life by making it a marketable commodity, while others believe that it will lead to heightened exploitation of lesser beings by humans. Some scientists also argue that encouraging further transgenic combinations may result in the loss of genetic diversity. *See, e.g.*, Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267 (1995); Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science?*, 16 HASTINGS CONST. L.Q. 221 (1989).

the patenting of multicellular animals detracts from his overall presentation. Burchfiel balances his views at other points in the book, such as in his introduction to the Federal Circuit, where he includes a section entitled "Theoretical Objections to Specialized Courts," yet he neglects to discuss countervailing viewpoints with regard to issuing patents for multicellular animals. Burchfiel's claim that "[t]he biotechnology industry has a right to an explanation of why it is easier to patent a mousetrap in Group 320 than a mouse in Group 180" (p. 143) reveals that potential ethical considerations do not factor into his equation. Burchfiel's work would have been more convincing and thorough had he addressed the ethical dimension in the current debate over patenting animals and then offered his arguments in rebuttal. Instead, his summary dismissal of moral considerations on this issue deprives his analysis of the comprehensiveness that characterizes the rest of the book.

Despite this minor shortcoming, *Biotechnology and the Federal Circuit* remains an excellent work that cogently reviews a critical and rapidly expanding area of law. It provides a foundation for new biotechnology practitioners by affording valuable insight into the history and complexities of how the Federal Circuit addresses biotechnology issues. For experienced practitioners, the book furnishes an astute overview and catalog of the court's first decade of existence, and should serve as a significant reference tool.

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