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Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law Practice and Strategy

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PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY

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THE COMMODITY OF INTELLECTUAL PROPERTY IN THE RISKY BUSINESS OF LIFE SCIENCE

"To make a small fortune, invest a large fortune."[1]

Years before investors flocked to e-commerce start-up companies, investors were drawn to biotechnology.[2] The modern biotechnology industry, much of which dates to the late 1980s,[3] was launched with an impassioned belief that small

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1. Bruce Cohn, *quoted in* THE 2,548 BEST THINGS ANYBODY EVER SAID no. 283 (Robert Byrne ed., 1996).

2. CYNTHIA ROBBINS-ROTH, FROM ALCHEMY TO IPO: THE BUSINESS OF BIOTECHNOLOGY 183–97 (2000).

3. *See id.* at 7–9; Michael J. Malinowski & Maureen A. O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163 (1996); ARTHUR KORNBERG: THE GOLDEN HELIX, INSIDE BIOTECH VENTURES 195–230 (1995). The beginning of the modern biotechnology industry often is traced to the founding of Genentech, Inc., in 1976. *See* KORNBERG, *supra*, at 195–202; ROBBINS-ROTH, *supra* note 2, at 13–30.

start-up companies could make breakthrough drugs in a fraction of the traditional time and at a fraction of the cost, shaming the multinational pharmaceutical behemoths and revolutionizing drug development and health care.[4]

The biotech industry has accomplished far more than sustaining itself.[5] Expectations for biotech are being realized, albeit a decade or so later than many early investors projected.[6] There now are approximately 100 biotech drugs on the market[7] and hundreds of other applications, ranging from medical devices to biomaterials that are revolutionizing industrial processes.[8] With a flow of products entering commerce,[9] maps of the human genome,[10] and innovative tools such as microarrays, biochips, and other information technologies to accelerate making genotype-phenotype connections,[11] the biotech industry is entering a new cycle of "thinking big"—this time with the pharmaceutical industry by its side.[12]

Given the pace of the development and commercialization of biotechnology, it is easy to be swept away by trends. In contrast, *Patents for Chemicals, Pharmaceuticals and Biotechnology*,[13] published nearly two decades after the original edition,[14] embodies the grounded perspective of a seasoned European patent attorney. *Patents* is foremost a crisp, precise primer on patent criteria and procedure in the European Union (E.U.) and United States (U.S.) that is geared to practice. The book presents pragmatic information on several levels, including the myriad considerations involved in developing effective global patent

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4. *Cf.* Malinowski & O'Rourke, *supra* note 3, at 178 & n.77 (assumption that FDA would be quicker to approve technology based on "'natural' biologically derived molecules").

5. *See* Aris Persidis, *Biotechnology in a Snapshot*, 18 NATURE BIOTECHNOLOGY IT2 (2000) (Industry Trends Supplement).

6. *See generally* ROBBINS-ROTH, *supra* note 2, at ix–xi; Juan Enriquez & Ray A. Goldberg, *Transforming Life, Transforming Business: The Life-Science Revolution*, HARV. BUS. REV., Mar.-Apr. 2000, at 96.

7. *See* MICHAEL J. MALINOWSKI, BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION Fig. 3-2 (1999 & Supp. 2000) (identifying biotech drugs approved through 1999). These include breakthrough drugs such as Avonex (beta interferon) to treat multiple sclerosis (*see* ROBBINS-ROTH, *supra* note 2, at 227 tbl. B.1) and Herceptin to treat breast cancer. *See generally* ROBERT BAZELL, HER-2: THE MAKING OF HERCEPTIN, A REVOLUTIONARY TREATMENT FOR BREAST CANCER (1998); Kenneth N. Gilpin, *How Biotech Has Held On, and Its Prospects*, N.Y. TIMES, Nov. 26, 2000, at 7.

8. *See generally* Enriquez & Goldberg, *supra* note 6; RICHARD W. OLIVER, THE COMING BIOTECH AGE: THE BUSINESS OF BIOMATERIALS (2000); *www.BIO.org* (web site of the major biotechnology trade organization, the Biotechnology Industry Organization, which includes identification of product applications and approvals).

9. *See generally* Enriquez & Goldberg, *supra* note 6; ROBBINS-ROTH, *supra* note 2; OLIVER, *supra* note 8.

10. *See* WALL ST. J. EUROPE, 2000 WL-WSJE 21064884, June 27, 2000; Frederick Golden & Michael D. Lemonick, *The Race Is Over*, TIME, July 3, 2000, at 18–23.

11. Michael Malinowski, *Separating Predictive Genetic Testing from Snake Oil: Regulation, Liabilities, and Lost Opportunities*, 41 JURIMETRICS J. 23 (2000); ROBBINS-ROTH, *supra* note 2, at 73–81.

12. *See* Michael D. Lemonick, *The Genome Is Mapped. Now What?*, TIME, JULY 3, 2000, at 24–29; Enriquez & Goldberg, *supra* note 6.

13. *See* PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY (1999) [hereinafter GRUBB].

14. PHILIP W. GRUBB, PATENTS FOR CHEMISTS (Oxford 1982); *see also* PHILIP W. GRUBB, PATENTS IN CHEMISTRY AND BIOTECHNOLOGY (1986).

prosecution strategies.[15] It begins with an introduction to the modern patent system, followed by sections on patent law and procedure, the patentability of inventions in specific technical fields, patenting in practice, and the commercial exploitation of patents.

But *Patents* transcends the functional aspects of patenting in life science. The author shares many thoughts, insights, and even some convictions on fundamental issues in patent law and policy. Given the visionary nature of invention, a scholarly, thoughtful treatment of intellectual property must do nothing less—it *must* look forward. In the life sciences, today's intellectual property protection is the foundation for the next decade's product R&D.[16] *Patents* embodies recognition that trends in science will affect the course of R&D and changes in industry and markets in life science.[17] The author appreciates the extent to which modern biotechnology is revolutionizing commercial life science,[18] and he emphasizes that patent protection is essential to investment in the costly endeavor of life science R&D.[19]

A theme running throughout *Patents* is that it is difficult to overestimate the impact of intellectual property on the existence of today's commercial life science industries. Arguably, the biotech industry has been as creative and resourceful in finance as it has been in research.[20] The industry has sustained and distinguished itself by approaching intellectual property as an investment commodity, permitting investors to absorb extraordinary R&D risks.[21] By embracing the patentability of inventions in life science and making these inventions available

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15. GRUBB, *supra* note 13, at 70–86.

16. Drug development spans 10–12 years and costs hundreds of millions of dollars. *See* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, 1998 INDUSTRY PROFILE 20, 24–25 (1998).

17. As stated by the author,

> In certain fields, however, development of a product necessarily takes very much longer than this [two to five years], because the approval of regulatory authorities has to be obtained before marketing is allowed. This is particularly the case for the pharmaceutical industry, since no new drug can be approved without extensive clinical testing to prove that it is safe and efficacious, and this process may easily take eight to 12 years or even more from the filing date of the original patent application, leaving an effective patient term of only eight to 12 years instead of approximately 17 for most other products . . . .

GRUBB, *supra* note 13, at 146.

18. *See id.* at 225 ("Biotechnology has based a whole new industry, and patent protection for biotechnological inventions is of immense commercial importance.").

19. *See id.* at 225, 364. On the importance of intellectual property to the financial viability of the biotechnology industry, see James Donahue, Comment, *Patenting of Human DNA Sequences—Implications for Prenatal Genetic Testing*, 36 BRANDEIS J. FAM. L. 267, 282 (1997-1998) ("Patent protection for DNA sequences is essential to secure continued private investment in biotechnology research."); Cliff D. Weston, *Chilling of the Corn: Agricultural Technology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 385 (2000) (observing that "biotechnology has been characterized as an industry whose wealth exists in its patents more than its products" and citing KENNETH J. BURCHFIEL, BIOTECHNOLOGY AND THE FEDERAL CIRCUIT § 18.5 (1995)).

20. *See* ROBBINS-ROTH, *supra* note 2, at 131–79; Stelios Papadopoulos, *Business Models in Biotech*, 18 NATURE BIOTECH. IT3–T4 (2000) (Industry Trends Supplement).

21. *See* ROBBINS-ROTH, *supra* note 2, at 131–79.

for commercial applications via federal technology transfer policy, the U.S. has assumed a position of world leadership.[22]

Beyond recognizing the connection between intellectual property and investment, however, *Patents* is cautious. It touches on fundamental issues in patent policy and offers an invaluable, reflective, historical perspective, but it does not reach fully into the pressing policy issues encasing intellectual property protection in life science.[23]

In light of the connection between intellectual property and investment, a pragmatic treatment of life science patenting necessitates rigorous analysis of ongoing policy challenges to the patent regime. The stakes never have been higher. The intellectual property regime that is the basis for billions of dollars of investment in a number of industries is being challenged. The author's summary discussion of controversy over basic patent policy and practice in the U.S. does not fully capture the present state of affairs. Most notably, the maps of the human genome (near completion at the time *Patents* went into print) have rekindled challenges to patenting "products of nature" and accusations of over-patenting.[24] Critics charge that the U.S. permits overly broad claims that do not reflect meaningful knowledge of the sequences being patented.[25] Arguably, this

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22. *See generally* Michael J. Malinowski, *Biotechnology in the USA: Responsive Regulation in the Life Science Industry*, 2 INT'L J. BIOTECH. 16 (2000). Any allegations that the industry has grossly overstated the nexus between recognition of intellectual property in life science invention and investment in life science R&D were put to rest on March 14, 2000. On that day, President Clinton and British Prime Minister Tony Blair issued a joint statement in support of public availability of all information about gene sequencing and the human genome. *See* Peter G. Gosselin & Paul Jacobs, *Clinton, Blair to Back Access to Genetic Code*, L.A. TIMES, Mar. 14, 2000, at C1. Pharmaceutical and biotech stocks plunged 21% over the next 48 hours. President Clinton quickly retreated from his position. *See BIO Wins Clinton Clarification on Gene Patents, Market Recovery*, 62 PINK SHEET, Apr. 10, 2000, 2000 WL 8634334; Alex Berenson & Nicholas Wade, *A Call for Sharing of Research Causes Gene Stocks to Plunge*, N.Y. TIMES, Mar. 15, 2000, at A1, C16; E.S. Browning, *NASDAQ Plunge Puts Index Down 6.77% in 2 Days; Biotech Spur 200-Point Fall; Traders Shaken*, WALL ST. J., Mar. 15, 2000, at C1; Andrew Pollack, *Protecting a Favorable Image: Biotechnology Concerns in Quandary Over Drug Giants*, N.Y. TIMES, Apr. 4, 2000, at C1 ("Remarks by President Clinton and Prime Minister Tony Blair of Britain in March that seemed to question patents on genes knocked $100 billion in market value from the biotechnology industry in a day.").

23. *See, e.g.*, GRUBB, *supra* note 13, at 245–69 ("patenting of genes, plants, and animals"), 248–49 (patenting of ESTs), 249–51 (transgenic animals and plants), 256–60 (morality issues), 256 (analysis of article 53(a), which "prohibits the grant of European patents for inventions the publication or exploitation of which would be contrary to (a) 'ordre public' or (b) morality, irrespective of whether or not the invention is patentable under Article 52"). For timely discussion of some of the most controversial issues in life science patenting, see Donna M. Gitter, *Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law*, 19 BERKELEY J. INT'L L. 1 (2001); *see also* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47 (2001).

24. *See* GRUBB, *supra* note 13; Donahue, *supra* note 19, at 270–71.

25. *See* Naomi Aoki, *Patent Applications Booming in Biotech Strides in Human Genetic Code, Drive to Accrue Intellectual Capital Cited*, BOSTON GLOBE, Aug. 30, 2000, at D1. Controversy centers on patent inventions premised on DNA sequences known as expressed sequence tags (ESTs) and single nucleotides polymorphisms (SNPs), small fragments of genes that identify genetic variations associated with susceptibility to disease and responsiveness to drugs. *See* Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for*

controversy is augmenting the influence of the Federal Circuit over claim drafting and interpretation,[26] toughening patent application requirements, narrowing the view of infringement, and generally weakening patent protection for biotech inventions.[27]

In addition to claim interpretation, maturation of the biotechnology industry is spurring a proliferation of patent infringement litigation, forcing the courts to further scrutinize patent fundamentals in life science.[28] The patent infringement suits by Amgen and Genzyme against Transkaryotic[29] are likely to mark the

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Expressed Sequence Tags, 85 IOWA L. REV. 735 (2000). Some companies, such as Human Genome Sciences and Celera Genomics, have been attempting to patent thousands of gene sequences. Because these companies know little about the function of the sequences, the practice raises questions under the utility standard. *See* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

26. According to Weston, *supra* note 19, at 395 (footnotes omitted):

> Courts have treated biotechnology as an unpredictable art. While the industry and technology advances, the court's estimation of predictability must naturally lag behind. Courts are reluctant to read claims and specifications broadly in fields of technology in which uncertainty inheres. The Federal Circuit has consistently placed biotechnology in the same unpredictable caste as chemistry and physiology. This practice alters the patent examiner's view of the inventor's application. Because the technology is unpredictable, greater particularity is required in invention disclosures. Frequently, examiners (or defendants in litigation) challenge the specification, claiming that it failed to describe the invention or to fully enable one skilled in the art to practice the invention. Enablement varies inversely with the unpredictability of the art. The inventor's assertions—that disputed steps in the specification are easily carried out by those skilled in the art—tend to be less willingly accepted by courts when assessing an unpredictable art.

27. *See id.* at 377. *See, e.g.*, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558 (Fed. Cir. 2000) (sharply limiting patent owner's access to the doctrine of equivalents); Utility Examination Guidelines, 66 Fed. Reg. 1092 (2001) (setting forth specific standards for the utility requirement); Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, P1, "Written Description" Requirement, 66 Fed. Reg. 1099 (2001).

28. *See, e.g.*, *Festo Corp.*, 234 F.3d 558. Many industry insiders emphasize uncertainty:

> "The patent landscape is a minefield." Litigation can be expected to increase in the wake of the written description, doctrine of equivalents, and the patent caselaw. Many researchers have filed patent applications without a full understanding of the products of the genes isolated. The flurry of patent activity surrounding gene and DNA fragments prompted one industry analyst to remark that "812 percent of the genome is covered" by patent applications.

Weston, *supra* note 19, at 408 (quoting Tom Abate, *Worms and Germs Bait Biotech's Hooks*, S.F. CHRON., Jan. 12, 2000, at D1 (quoting Robert Levy, senior vice president for American Home Products, and Robert Olan, Chase H & Q analyst)) (footnotes omitted).

29. The litigation is described in Ronald Rosenberg, *TKT Tests Patent Law Limits*, BOSTON GLOBE, Dec. 20, 2000, at C6; Ronald Rosenberg, *Genzyme Sues TKT Over Drug*, BOSTON GLOBE, July 26, 2000, at C1; *Transkaryotic, Aventis Resume Defense Against Amgen in Trial*, BOSTON GLOBE, July 6, 2000, at C7 (from Dow Jones); Jennifer Heldt Powell, *Firm Hopes to Sell Despite Drug Lawsuit*, BOSTON HERALD, Aug. 4, 2000. Amgen filed suit against TKT and its partner Aventis SA in federal district court in Boston to stop them from selling Dynepo, an anemia treatment. According to Amgen, TKT is infringing on three key Amgen patents for Epogen (erythropoietin), the best-selling biotech drug ($4 billion in U.S. sales in 1999), which is used to stimulate red blood cell production. TKT claims that Amgen's patents are overly broad, invalid, and fraudulently obtained. It contends that its approach to making Dynepo is distinguishable because it makes EPO using human cells rather than animal cells. (TKT uses a "gene activation" technology which turns on a switch inside human cells that activates the dormant gene responsible for making EPO, while Amgen makes the drug by cloning a human gene and splicing it into Chinese hamster ovary cells.)

Similarly, Genzyme and TKT are competing to be the first to introduce a drug to treat Fabry's disease, a rare metabolic disorder that causes kidney failure and affects 2,000 to 4,000 men worldwide.

commencement of a phase of costly litigation resolving the scope of patent claims.[30]

Such questions about the patentability of sequence data are being raised when reliance on the patent regime is at an all-time high. Historically, the pharmaceutical industry has invested 15 to 20% of total sales revenue on R&D compared with less than 4% for industry overall.[31] In recent years, the investment in life science R&D has increased to well over 20%.[32] The United States Patent and Trademark Office (PTO) is deluged with patent filings,[33] particularly in genetics.[34]

Even respecting the author's express decision to not predict how the patent system may change in the next decade,[35] one cannot overlook that *Patents* does not fully address several trends already well underway. Perhaps reflecting major differences in intellectual property between the United States and European Union, *Patents* does not consider the complexity and intensity of technology transfer and licensing that has distinguished U.S. life science in recent years.[36] Although *Patents* includes a section on licensing and technology transfer,[37] this discussion simply is not rigorous enough given the ongoing proliferation of academic-industry research alliances, the extent to which contemporary life science represents collaborations including licensing among competitors,[38] and

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Both companies have designed an enzyme replacement, alpha-galactosidase. Genzyme's preexisting patent is directed at methods of making the enzyme, and Genzyme's methodology, like Amgen's, is to use mammalian Chinese hamster ovaries. TKT has not revealed how it makes the enzyme. Genzyme filed its action against TKT in federal district court in Wilmington, Delaware.

30. "Patent applications take their cue from caselaw, with claim scope expanding and contracting to follow the prevailing regime. Under the current legal environment, inventors must submit narrower claims for their biotechnology inventions." Weston, *supra* note 19, at 409. More costly disputes are likely as competition increases. *See* Angela Cullen, *Biotech Firms Expect an Increase in Patent Suits*, WALL ST. J., Aug. 21, 2000. For example, Germany's MorphoSys AG incurred costs of $2.7 million to fight a high-profile patent dispute with the United Kingdom's Cambridge Antibody Technology Group. As a result, MorphoSys was forced to license the underlying technology from Genentech, Inc.

31. GRUBB, *supra* note 13, at 367.

32. PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS OF AMERICA, ANNUAL REPORT 22 (2000-2001), *available at* www.phrma.org.

33. The PTO now issues 70% more patents—approximately 170,000 in 1999—than it did a decade ago. Peter Coy, *The 21st Century Corporation*, BUS. WEEK , Aug. 28, 2000, at 76; *see also* Aoki, *supra* note 25, at D1 ("The rise in patents can be explained, in part, by the unprecedented growth in the understanding of human biology and, more specifically, of the human genetic code. Scientists are making discoveries in record numbers. And more discoveries obviously mean more patents.").

34. "Gene patent filings are growing even faster than patent applications for the biotech industry as a whole, said John Doll, who heads the patent office's biotechnology division. He estimates the number of gene applications will grow by one-third this year and expects the rate to accelerate in coming years." *Id.*

35. GRUBB, *supra* note 13, at v.

36. The author commits less than 20 of the 448 pages in *Patents* to the patent aspects of licensing. *See id.* at 370–77, 395–407.

37. *Id.* at 395–407.

38. *See generally* MALINOWSKI, *supra* note 7, at ch. 8; Malinowski & O'Rourke, *supra* note 3. Arguably, patents encourage licensing and collaboration among competitors and offer an alternative to secrecy. *See, e.g.*, Aoki, *supra* note 25, at D1 (quoting Gregory Williams, General Counsel for Biolabs Inc.).

the resulting complexities and implications. For example, *Patents* does not provide sufficient detail about U.S. federal technology transfer policy, the relevant legislation and regulations, and its aggressive implementation by both the public and private sectors.[39] Minimal attention is paid to the fact that academic-industry research alliances have made the life science industry and its partners susceptible to a multitude of challenges from members of the academic community concerned about academic freedom.[40] Related issues that are addressed in passing if at all include: a dramatic shift in university policies to include equity interests in commercial endeavors;[41] institutional and researcher conflicts of interest;[42] the emergence of disputes between industry and academia arising out of these relationships;[43] the fact that so many tools for doing cutting-edge research have been developed by the private sector and are proprietary;[44] and the role of organizations such as the Association of University Technology Managers and the Licensing Executives Society that facilitate information sharing among universities.[45]

The author also does not probe the relationship between intellectual property and health care. Recent controversy over drug pricing in the United States has popularized challenges to the patent regime and its federal technology transfer counterpart.[46] A public without national health care and exasperated by the cost

39. For full identification and discussion of the related pieces of legislation and university application, see GENERAL ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL COMMITTEES: TECHNOLOGY TRANSFER—ADMINISTRATION OF THE BAYH-DOLE ACT BY RESEARCH UNIVERSITIES GAO/RCED 98–126, 1998 WL 403207 (May 7, 1998).

40. *See generally* Rai, *supra* note 25; Eyal Press & Jennifer Washburn, *The Kept University*, 285 ATLANTIC MONTHLY, Mar. 2000, at 39–54. *But see* David Blumenthal et al., *Participation of Life-Science Faculty in Research Relationships with Industry*, 335 NEW ENG. J. MED. 1734 (1996) (data suggesting that industry providing up to two-thirds of overall funding may increase desired faculty behaviors without negatively affecting teaching and other obligations); Michael J. Malinowski & Nick Littlefield, *Transformation of a Research Platform into Commercial Products: The Impact of United States Federal Policy on Biotechnology*, *in* THE COMMERCIALIZATION OF GENETIC RESEARCH: ETHICAL, LEGAL, AND POLICY ISSUES (Timothy A. Caulfield & Bryn Williams-Jones eds., 1999).

41. *See, e.g.*, Guide to the Ownership, Distribution and Commercial Development of M.I.T. Technology (May 7, 2001), *available at* web.mit.edu/afs/athena.mit.edu/org/t/tlo/www/guide.toc.html.

42. *See* Conference Materials, Conference on Human Subject Protection and Financial Conflict of Interest, Sponsored by HHS, NIH, CDC, ASPE, and FDA, Aug. 13–16, 2000, Bethesda, Maryland, *available at* orhp.osophs.dhhs.gov/coi/index.htm.

43. For example, on May 30, 2000, Abbott Laboratories filed a lawsuit against Dr. Judah Folkman and Boston's Children's Hospital over inventorship, and Dr. Folkman filed counterclaims involving a substance that could starve cancerous tumors, which create their own blood vessels via angiogenesis. *See* Raja Mishra, *Children's Countersues in Cancer Study Battle*, BOSTON GLOBE, July 19, 2000, at A1. In summer 2000, U.S. Senator Judd Gregg attempted to insert a 350-word amendment into an unrelated federal spending bill to enable Columbia University to obtain a patent extension estimated to generate $150 million. *See* Ronald Rosenberg, *Gregg Draws Ire Over Columbia Patent Move*, BOSTON GLOBE, July 13, 2000, at A1. The patent at issue had been licensed by 33 companies, including biotech leaders Amgen, Biogen, and Genzyme. *Id.*

44. *See generally* Malinowski, *supra* note 22.

45. *See, e.g.*, www.autm.net; www.les.org.

46. *See Campaign 2000 Third Party Candidates: Site Compiles Health Care Views, American Political Network*, American Health Line, Sept. 26, 2000 (challenges of Ralph Nader and Green Party).

of health insurance and drug prices is demanding price controls on the ground that pharmaceutical companies have benefitted from the billions of dollars of government investment in basic research.[47]

Although *Patents* shies away from predicting how the patent system will look in ten or twelve years, it does predict that the book will be outdated by that time.[48] In fact, several aspects of *Patents* already invite change. First, the pragmatic treatment of patenting in Europe and the U.S. in Parts I and II is accompanied by separate individual chapters addressing chemical inventions, pharmaceutical inventions, biotechnological inventions, patenting of genes, plants, and animals, and software-related inventions. These classifications already are somewhat forced. These technical fields are being integrated and influenced by fields such as combinatorial chemistry that are vital to both the pharmaceutical and biotechnology industries.[49] With the R&D distinction between the pharmaceutical and biotechnology industries becoming increasingly forced, "Patents in Life Science" will be a suitable title for the author's next edition.

Change also is warranted in the treatment of information technology. In *Patents*, the author includes a somewhat gratuitous discussion of software.[50] In fact, there already are an abundance of natural bridges between information technology and life science, including bioinformatics, biochips, microassays, data mining, proteomics, pharmacogenomics, and pharmacogenetics, some of which are mentioned by the author in passing.[51] The explosive potential of informatics is a driving force in life science R&D,[52] and the full impact of this collection of technologies on life science R&D by the next edition of *Patents* truly is beyond prediction.

These reservations aside, *Patents* is exactly what it proposes to be—a pragmatic primer on life science patenting in Europe and the United States that encompasses a critical mass of clear and thoughtfully presented information on the topic. Like the editions that came before, *Patents* is an invaluable resource for reference as well as strategy and study. Given the increased globalization of life science in recent years, the European perspective and sensitivity to global issues embodied in *Patents* are particularly valuable for U.S. patent attorneys and scholars. The author should be congratulated on making yet another ambitious contribution to this rapidly evolving and increasingly international field of law, science, and business.

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47. *See id.* Moreover, prices are exceeding expectations. *See* Robert Pear, *Health Costs Underestimated, Experts Say Cost of Medical Care Is Underestimated*, N.Y. TIMES, Nov. 30, 2000, at A1.

48. GRUBB, *supra* note 13, at v.

49. *See generally* Persidis, *supra* note 5; Enriquez & Goldberg, *supra* note 6.

50. *See* GRUBB, *supra* note 13, at 261 ("A chapter on software-related inventions may appear to be a digression in a book primarily concerned with the technical fields of chemistry, pharmaceuticals, and biotechnology.").

51. For discussion of these and other innovative technologies, see Persidis, *supra* note 5, at IT31–T47; ROBBINS-ROTH, *supra* note 2, at 73–81 (discussing biochips and microarrays).

52. *See* Malinowski, *supra* note 11, at 26, 32–33.