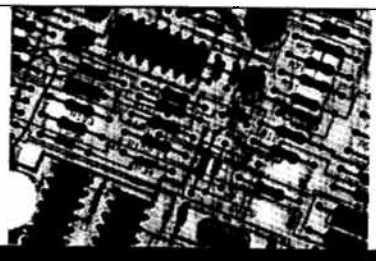
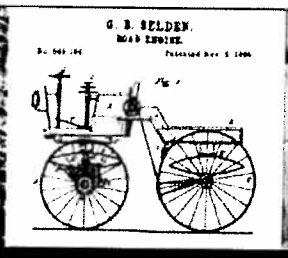
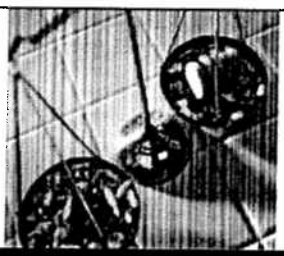
FEDERAL TRADE COMMISSION

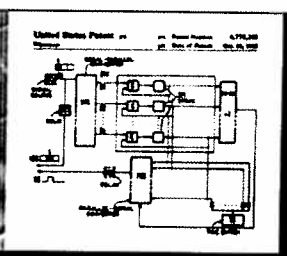
To Promote Innovation:
The Proper Balance of Competition and Patent Law and Policy

A Report by the Federal Trade Commission
October 2003









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I. SUMMARY

Over six days of Hearings, business representatives from four high-tech industries discussed the drivers of innovation in their industries. Representatives from the pharmaceutical, biotechnology, Internet, and computer hardware and software industries described their real-world experience with how patents and competition affect incentives to innovate. Their discussions confirmed many of the principles summarized in Chapter 2 and sometimes shed additional light and offered new perspectives on the topics. They highlighted both the benefits and costs of current patent and antitrust policies applied in their industries. This chapter discusses the diverse views presented by the panelists, and also incorporates the results of business surveys and other industry-specific scholarship.

The panelists identified various attributes that characterized innovation in the different industries. Panelists discussed whether innovation in their industries tends to be discrete or cumulative, building incrementally on prior discoveries. Panelists also addressed sources and amounts of capital required for entry, barriers to entry, the extent to which industries are vertically integrated, and difficulties in commercializing new products. They raised issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation, adding business insights and practical experience to the analysis of Chapter 2. According to both panelists and academics, factors such as these shape the role of competition and patents in spurring or discouraging innovation in their industries.

Pharmaceutical and biotechnology representatives testified that strong patent protection is essential to innovation in their industries. Business representatives characterized innovation in these industries as costly and unpredictable, requiring significant amounts of pioneering research to discover and test new drug products. By preventing rival firms from free riding on discoveries, patents allow pharmaceutical firms to recoup the substantial capital investments made to discover, test, and obtain regulatory approval of new drug products. Biotech representatives emphasized that patent protection is critical to attract the capital necessary to fund this high-risk investment. Indeed, firms believed that the biotech industry would not exist but for patents. One concern involved patents on the research tools used to assist in the discovery of new drug products. Biotech representatives expressed concern that such patents could obstruct the commercialization of new products, thereby hindering follow-on innovation. To date, however, evidence suggests that such problems have not emerged.

Pharmaceutical and biotech representatives testified that they use patent information disclosures required by the patent statutes to direct their research and development (R&D) into areas not claimed by the patents. Representatives from generic pharmaceutical firms discussed how patent disclosures guide their efforts to "design-around" patents, so that they can develop

non-infringing generic versions of brand-name drug products.

By contrast, computer hardware and software industry representatives generally emphasized competition to develop more advanced technologies as a driver of innovation in these rapidly changing industries. These representatives, particularly those from the software industry, described an innovation process that is generally significantly less costly than in the pharmaceutical and biotech industries, and they spoke of a product life cycle that is generally much shorter. Some software representatives observed that copyrights or open source code policies facilitate the incremental and dynamic nature of software innovation. They discounted the value of patent disclosures, because they do not require the disclosure of a software product's underlying source code.

Computer hardware manufacturers noted that they often use trade secrets, rather than patents, to protect their inventions, because it is difficult to discover whether a rival firm has infringed a patented manufacturing invention. Computer hardware manufacturers generally would rather keep the invention secret than publicly disclose it and risk third party misappropriation of patent rights that they will be unable to discover. By contrast, computer hardware firms that specialize solely in hardware design and have no manufacturing responsibilities valued patent protection as a way to raise venture capital.

Representatives from both the computer hardware and software industries observed that firms in their industries are obtaining patents for defensive purposes at rapidly increasing rates. They explained that the increased likelihood of firms holding overlapping intellectual property rights creates a "patent thicket" that they must clear away to commercialize new technology. They discussed how patent thickets divert funds away from R&D, make it difficult to commercialize new products, and raise uncertainty and investment risks. Some computer hardware and software representatives highlighted their growing concern that companies operating in a patent thicket are increasingly vulnerable to threats to enjoin their production from non-practicing entities that hold patents necessary to make the manufacturer's product.

A global concern that representatives from each of the four industries described was that poor patent quality (*e.g.*, a patent for which there is invalidating prior art, or a patent broader than was enabled) can blunt incentives to innovate. They described the costly nature of litigation to invalidate these patents, both in terms of dollars and resources diverted from R&D. They also discussed how a timely, less costly mechanism to review poor quality patents would enhance innovation in their industries.

These representatives also described how each industry has developed licensing practices to extract value from their patents or, in some cases, to obviate some of the problems raised by patent thickets. They raised concerns that uncertainty about the parameters of antitrust enforcement may be hindering the use of certain methods to extract patent value. For example, biotech

representatives noted that antitrust concerns have contributed to uncertainty about the propriety of using reach-through royalty provisions in research tool licenses.

Firms in the computer hardware and software industries indicated that antitrust concerns may be inhibiting joint discussions of licensing terms during the standard-setting process. They noted that antitrust has traditionally been suspicious of joint discussions of licensing terms arising prior to the adoption of a standard. Some panelists suggested, however, that such conduct is necessary for the efficient establishment of new standards because some companies are using patents strategically.

Box 3-1. ***Independent Inventors and the FTC's Invention Promotion Cases***

One cross-industry concern raised by a specific sub-group was the vulnerability of independent inventors to fraudulent practices as they seek patents and offer licenses on those patents. This problem has been, and continues to be, a matter of FTC concern. Two panelists representing the independent invention community mentioned the defrauding of inventors by invention promotion firms. *See* Udell 2/28 at 568-69 ("the FTC has done a magnificent job of not only educating inventors, but also getting the scam organizations that have been bleeding inventors for decades out of the pockets of the poor inventors in America."); Hayes-Rines 3/19 at 61-62 (urging enhanced FTC enforcement efforts).

In 1997, the FTC launched a consumer education program and a law-enforcement sweep entitled "Project Mousetrap" because a "number of firms in the invention promotion industry are perpetrating a massive fraud" against independent inventors. As a result of this sweep and other enforcement actions, the Commission brought eight cases against invention promoters during the 1990s. The complaints have named 41 defendants, consisting of 21 companies and 20 individuals. In some cases, the Commission alleged that the defendants represented that they would obtain patents for their customers' inventions without clarifying that these would be design patents, which typically have less commercial value than utility patents. The Commission generally alleged that the defendants represented that their research and marketing services were likely to secure profitable licenses for their customers' inventions. The Commission further alleged that, in fact, the defendants were rarely successful at securing licensing agreements, and that the few licenses that the defendants did secure seldom resulted in appreciable income for the inventors.

In six cases, the Commission obtained consent orders that required the defendants to pay consumer redress and to make affirmative disclosures to prospective customers about the promoters' past success rates. One case is still in litigation and the eighth case was dismissed after the U.S. Attorney's office filed criminal charges. More recently, the Commission has expanded its consumer education program, in cooperation with the PTO, to include rights available to inventors under the American Inventors Protection Act of 1999. Further details on the Commission's consumer education efforts and enforcement actions are *available at* http://www.ftc.gov/bcp/conline/edcams/invention/ and http://www.ftc.gov/opa/1997/07/mouse.htm.

II. THE PHARMACEUTICAL INDUSTRY

A. Introduction

Representatives from the pharmaceutical industry stated that patent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities. The sunk cost of engaging in research projects aimed toward the development of these drugs is extremely high. By preventing rival firms from free riding on the innovating firms' discoveries, patents can enable pharmaceutical firms to cover their fixed costs and regain the capital they invest in R&D efforts. Moreover, the patenting process requires disclosure of the underlying invention covered by the patent, potentially encouraging further innovation. Generic drug companies report they use disclosed patents as a basis on which to "invent-around" patented, brand-name products in order to develop generic variations.

The panelists who represented pharmaceutical firms or organizations at the Hearings were Robert A. Armitage, representing Eli Lilly and Company; Monte R. Browder, representing Ivax Corporation; David Coffin-Beach, representing Torpharm, Inc.; Gregory J. Glover, Counsel to Pharmaceutical Research and Manufacturers of America; Nancy J. Linck, representing Guilford Pharmaceuticals; and Ross Oehler, representing Aventis Pharmaceuticals Inc. One scholar, Edward A. Snyder, from the University of Chicago, and one attorney, Rochelle K. Seide, from Baker Botts, LLP, also participated in a business perspective panel on the pharmaceutical industry.

B. Industry Description

R&D in the pharmaceutical industry generally produces two main types of innovation: (1) discrete innovation, which means, in general terms, that the invention might be improved, but does not point the way to wide-ranging, subsequent discoveries of new chemical entities (NCEs);[1] and (2) incremental innovation, which describes the development of improvements to existing drug products, often referred to as product line-extensions.[2] Obviously, innovation can occur at many points along the continuum, from discrete to incremental, but these categories are useful in identifying certain characteristics associated with innovation in the pharmaceutical industry.

1. Discrete Research and Development for NCEs

Discrete R&D in the pharmaceutical industry focuses on the discovery and development of new chemical or molecular

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[1] *See* Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 880 (1990) (discussing types of innovation); *FTC/DOJ Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Mark Lemley Testimony Feb. 25, 2002*, at page 37 (hereinafter, citations to transcripts of these Hearings state the speaker's last name, the date of testimony, and relevant page(s)); Richard C. Levin, *Testimony of Richard C. Levin, President, Yale University* (2/6/02), at http://www.ftc.gov/os/comments/intelpropertycomments/levinrichardc.htm (hereinafter R. Levin (stmt)). *But cf.* Browder 3/19 at 174 (noting the potential need for progression from generic compound to specific compound to unique formulation).

[2] For an overview of the different types of pharmaceutical patents, *see* Box 3-2.

entities to make small molecule drug products.[3] The discovery of a chemical molecule that is both efficacious and safe for human usage can result in a totally new drug product. Such discoveries typically require significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high. Brand-name companies spend a substantial amount in development costs over the course of 10 to 15 years to bring a product involving an NCE to market from the initial research stage.[4] The brand-name companies' trade association reports that most newly marketed drugs do not cover their average development costs.[5] Brand-name companies typically rely on a small number of "blockbuster" drugs to recoup their overall investment in innovation, including R&D costs for failed products.[6]

Box 3-2. *Pharmaceutical Patents*

Pharmaceutical patents are issued for four different categories: drug substance, method of use, formulation, and process. Drug substance patents cover the compound or active ingredient in the drug product, such as fluoxetine hydrochloride, which is the active ingredient in Prozac. Method of use patents cover the use of the product to treat certain health problems, such as depression or asthma. Formulation patents cover the physical composition or delivery mechanism of the drug product, such as an extended release tablet or capsule. Process patents generally cover the procedure used to make the active ingredient. For further details on pharmaceutical patents, *see* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002) (hereinafter, FTC, *Generic Drug Study*), *at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

Relatively few patents are required to protect a product with an NCE.[7] One panelist noted that an actual drug product can be based on between four and 15 patents.[8] The low number of patents contained in a pharmaceutical product

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[3] This contrasts with the biotechnology industry, which focuses instead on cells and large biological molecules (such as DNA and proteins). *See* Beier 2/26 at 248.

[4] *See* Gregory J. Glover, *Competition in the Pharmaceutical Marketplace* (3/19/02) 3 (stating that the average cost to develop a new drug is $802 million), *at* http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf (hereinafter Glover (stmt)); Armitage 3/19 at 127-28; *see also* Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999) (discussing development risk), *available at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf (hereinafter BE Staff Report, *The Pharmaceutical Industry*); Arthur D. Little, *Examining the Relationship Between Market-Based Pricing and Bio-Pharmaceutical Innovation* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/littlearthurd2.pdf).

[5] *See* Pharmaceutical Research and Manufacturers of America, *Delivering on the Promise of Pharmaceutical Innovation: The Need to Maintain Strong and Predictable Intellectual Property Rights* (Public Comment) 9, *at* http://www.ftc.gov/os/comments/intelpropertycomments/phrma020422.pdf (hereinafter PhRMA (stmt)); *see also* Glover (stmt) 4; Armitage 3/19 at 129; BE Staff Report, *The Pharmaceutical Industry* (discussing market risk).

[6] *See* The National Institute for Health Care Management, *Changing Patterns Of Pharmaceutical Innovation* 4 (2002), *at* http://www.nihcm.org/innovations.pdf (hereinafter *NIHCM Innovation Report*); IMS Health, *IMS HEALTH Data Reveal Dramatic Growth in Megabrands*, *at* http://secure.imshealth.com/public/structure/dispcontent/1,2779,1362-1362-143992,00.html; PhRMA (stmt) 11.

[7] One panelist defined discrete product industries as those that require relatively few patents to protect a product, and complex product industries as those that require a relatively large number. *See* Cohen 2/20 at 30 and Wesley M. Cohen, *Patents: Their Effectiveness and Role* (2/20/02) (slides) at 13, *at* http://www.ftc.gov/opp/intellect/cohen.pdf.

[8] *See* Browder 3/19 at 174.

means that, as panelists noted, the development of patent thickets is generally not a concern.[9] Although brand-name companies may compete with each other in the same therapeutic class, such as anti-depressants or blood-pressure-lowering drugs, and may seek to obtain a number of patents in a particular area to ensure freedom to operate, such behavior has not given rise to so many overlapping sets of patent rights as to hinder the commercialization of new technologies.[10] From 1989 to 2000, the Food and Drug Administration (FDA) approved 1,035 New Drug Applications (NDAs), 361 of which were for NCEs.[11] The remaining 674 NDAs that FDA approved during this period were incrementally modified drugs (IMDs).[12]

2. The Demanding Nature of the NCE Development Process

Panelists provided an overview of the two-stage process to determine whether an NCE is safe and efficacious to market – a process that is time-consuming, uncertain, and expensive.[13] The first stage involves the identification of chemical compounds that might treat an indication or disease.[14] In general, the brand-name companies' trade association reported, "only 20 in 5,000 compounds that are screened enter preclinical testing," which involves laboratory and animal testing.[15]

The second stage begins when the company sponsoring the drug submits an NDA to the FDA. Three phases of clinical testing then follow, which the drug-sponsoring company undertakes and the FDA's Center for Drug Evaluation and Research oversees. Brand-name companies conduct Phase I clinical studies on healthy human beings to determine side effects and gather preliminary evidence of effectiveness. Phase II studies "are designed to obtain data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition."[16] Phase III studies are expanded controlled and uncontrolled trials and can involve thousands of patients. These clinical trials are often very resource and time-intensive.[17]

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[9] *See* Glover (stmt) 8.

A patent thicket is a "dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology." Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting, in* 1 INNOVATION POLICY AND THE ECONOMY 119, 120 (Adam Jaffe et al. eds., 2001) (hereinafter *Navigating the Patent Thicket*).

[10] *See* Glover (stmt) 6, 8; Armitage 3/19 at 230.

[11] *See NIHCM Innovation Report* at 3.

[12] *See NIHCM Innovation Report* at 3. IMDs are drugs which rely on an active ingredient present in a drug already approved for the U.S. market, or a closely related chemical derivative of such an ingredient, that has been modified by the manufacturer. *Id.* at 5.

[13] *See* Armitage 3/19 at 127-28.

[14] *See id.* "Indication" means disease, illness, or disorder.

[15] *See* Glover (stmt) 3; Armitage 3/19 at 127.

[16] Tufts Center for the Study of Drug Development, *How New Drugs Move through the Development and Approval Process* (2001), *at* http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=4.

[17] *See* Glover (stmt) 3.

3. The Implications of Clinical Trials for Effective Patent Term of NCEs

The time-consuming nature of clinical trials to evaluate a drug product's safety and efficacy may limit the length of effective patent term that brand-name companies can realize. Panelists testified that brand-name companies seek to obtain patents early in the R&D process – usually before clinical trials have commenced.[18] One panelist stated that the initial patent(s) to be issued for a totally new drug product are on the drug substance (*i.e.*, the NCE or molecule).[19] This panelist contended that drug substance patents are typically the most valuable for the brand-name company, because they are much more difficult for potential competitors (including generic companies) to design around than formulation or method of use patents.[20]

In the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, Congress provided for restoration of a portion of the patent term that elapses while clinical trials and FDA review are under way.[21] The Hatch-Waxman Amendments can restore patent term up to a maximum of five years, depending on how long clinical trials and FDA review take. Total effective patent term may not exceed more than 14 years from the date of FDA approval.[22] Pharmaceutical companies report, however, that by the time clinical trials are complete and a drug product is ready to market, the effective patent life for a drug patent – even with patent term restoration – is typically about 11 years,[23] substantially shorter than the 20-year statutory patent term.[24] Congress also has provided other market exclusivity periods for brand-name

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[18] *See* Glover 3/19 at 172-74; Armitage 3/19 at 176-77.

[19] *See* Armitage 3/19 at 178.

[20] *See id.*; McCurdy 3/20 at 36-37.

[21] Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

[22] 35 U.S.C. § 156 (c)(3). Another approach to restoring the patent term that elapses during FDA review would be to reduce FDA approval time. One study has found that reductions in regulatory approval times are somewhat more effective in increasing cash flow for a brand-name company, because such reductions add years to the less heavily discounted beginning of the product life cycle, rather than the end. *See* James W. Hughes et al., *"Napsterizing" Pharmaceuticals: Access, Innovation, and Consumer Welfare* (Public Comment) 8-9, *at* http://www.ftc.gov/os/comments/intelpropertycomments/snydermoorehughes.pdf.

[23] *See* PhRMA (stmt) 9-10 (stating that "the [average] effective patent life for drugs introduced from 1984-1995 that received patent term restoration, including such restoration, was only about 11 years" and *citing* Sheila R. Shulman et al., *Patent Term Restoration The Impact of the Waxman-Hatch Act on New Drugs and Biologics Approved 1984-1995*, 2 J. BIOLAW AND BUS. 63, 66 (1999)); *see also* Linck 4/9 at 97; Browder 3/19 at 174-75; Seide 3/19 at 176; Armitage 3/19 at 176-77. *But see* NIHCM Foundation Issue Brief, *Prescription Drugs and Intellectual Property Protection: Finding the Right Balance Between Access and Innovation* 1, 3 (Aug. 2000) (arguing that the effective patent term has increased by at least 50% since the passage of the Hatch-Waxman Amendments), *at* http://www.nihcm.org/prescription.pdf.

[24] A patent's term is 20 years from the date of *filing* the application. Due to the time-consuming nature of the patent examination process, *most* patents are unlikely to have an effective patent term of 19 or 20 years. *See* 35 U.S.C. § 154(a)(2), *as amended* by the Uruguay Round Agreements Act of 1994, Pub. L. No. 103-465, which changed patent term from 17 years measured from date of a patent's issuance to 20 years measured from date of filing the patent application.

companies.[25]

Box 3-3. ***Generic Drug Entry Prior to Patent Expiration: An FTC Study***

In light of the questions its various generic drug investigations raised, the Commission began an industry-wide study of generic drug competition in October 2000. The Generic Drug Study focused solely on the procedures used to facilitate generic drug entry *prior to* expiration of the patent(s) that protect the brand-name drug product. The Commission issued nearly 80 special orders - pursuant to Section 6(b) of the FTC Act - to brand-name companies and to generic drug manufacturers, seeking information about certain practices. The Commission staff compiled the information received to provide a factual description of how the 180-day marketing exclusivity and 30-month stay provisions affect the timing of generic entry prior to patent expiration. Based on this data, the Commission made two primary recommendations concerning the 30-month stay provision and the 180-day exclusivity to mitigate the possibility of abuse that deters more generic drugs from becoming available. The Generic Drug Study is *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

4. Incremental Innovation for the Development of IMDs

The other main type of innovation in the pharmaceutical industry consists of enhancing known chemical entities by formulating new dosage forms or additional methods of use for existing chemical entities. This type of innovation is generally described as "incremental," which, in general terms, means that "today's advances build on and interact with many other features of existing technology."[26] In the pharmaceutical industry, incremental innovation generally falls into one of three categories. The modified product may use a new formulation, such as a transdermal patch instead of a pill, may combine two previously approved active ingredients, or may use a new salt or esther, which is a more purified form of the original chemical entity.[27] Several panelists suggested that brand-name companies have responded to effective patent term reduction and the increasing cost of discovering and developing NCEs by implementing product life-cycle management, including the use of IMDs.[28] Some have noted that IMDs "provide a high return on investment."[29]

Participants in the Hearings expressed differing views about the benefits of these modified drugs. Some testified that IMDs benefit consumers by providing more convenient dosing or "superior therapeutic

[25] For example, the safety and efficacy data for a product may not be relied upon by another company for five years if the product contains an NCE and for three years if the product involves a new use of an existing compound. 21 U.S.C. § 355(c)(3)(D)(ii). A drug product also can obtain an additional six months of market exclusivity if it conducts studies showing the product is safe and effective for children. 21 U.S.C. § 355a.

[26] *See* Merges & Nelson, 90 COLUM. L. REV. at 881.

[27] *See NIHCM Innovation Report* at 5; Armitage 3/19 at 217.

[28] *See* Linck 4/9 at 97-98; Aventis Pharmaceuticals Inc., *Comments of Dr. Nahed Ahmed, Vice President, Productivity, Portfolio & Project Management Drug Innovation & Approval Aventis Pharmaceuticals Inc.* (Public Comment) 3-4 (contending that there are strong economic incentives for brand-name companies to implement IMDs, because they are "safer, faster, and more cost effective for the development as an incremental improvement rather than an original product."), *at* http://www.ftc.gov/os/comments/intelpropertycomments/aventis.pdf (hereinafter Aventis (stmt)); Armitage 3/19 at 216-218; Snyder 3/19 at 224; *NIHCM Innovation Report* at 3.

[29] *NIHCM Innovation Report* at 4; *see also* Aventis (stmt) 4.

properties than the original formulation,"[30] or by serving certain patient populations better than the original product.[31] The brand-name companies' trade association stated that if physicians and consumers choose IMDs in preference to generic alternatives of the original brand-name product, the modified drug is warranted.[32] In contrast, a generic drug manufacturer suggested that IMDs might be a tactic employed by brand-name companies "to extend patent monopolies beyond the patent expiry of the new chemical entity . . . by a matter of years, not days or weeks or months."[33] This panelist also argued that the PTO issues too many questionable patents, which create a gridlock of patent litigation in the district court system and thereby delay generic entry.[34] The FTC's Generic Drug Study found that over time, for blockbuster products, brand name companies are suing for infringement on more patents, and those suits take longer on average than suits involving a single patent.[35] Others have reported that "the FDA view[s] the vast majority of IMDs as providing no significant clinical improvement."[36]

C. The Role of Patents In Spurring Pharmaceutical Innovation

Panelists reported that patent protection promotes innovation in the pharmaceutical industry by creating incentives for brand-name companies to innovate, and by disclosing inventions, thereby encouraging generic companies to innovate by designing around brand-name company patents.

Participants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments in research and development of NCEs.[37] One panelist noted that patents are particularly important in the pharmaceutical industry, because the Hatch-Waxman Amendments permit generic applicants to rely on the brand-name company's proprietary data demonstrating the safety and efficacy of the brand-name drug product.[38]

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[30] Glover (stmt) 7.

[31] *See* Snyder 3/19 at 224.

[32] *See* PhRMA (stmt) 29-30; *see also* Glover (stmt) 7.

[33] Coffin-Beach 3/19 at 201-05, 212-213 (suggesting that brand-name companies time their incremental modifications to maximize their product's franchise, for example, by waiting 10 years to develop a sustained-release version of an NCE).

[34] Coffin-Beach 3/19 at 204-205.

[35] *See* FTC, *Generic Drug Study* at 47-48.

[36] *NIHCM Innovation Report* at 7; *see also* Coffin-Beach 3/19 at 201-05 (stating that IMDs may have "questionable therapeutic merit.").

[37] *See* PhRMA (stmt) 10-13; Glover (stmt) 2, 4 (describing the cost of new drug development and generic entry); Linck 4/9 at 48-49; Armitage 3/19 at 165; *see supra* Ch. 2(B)(1)(b) (discussing economic studies on the role of patents in protecting against free riding in different industries).

[38] *See* Armitage 3/19 at 133, 165. The FDA considered retesting of generic drugs to be wasteful if the underlying drug is safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be

Patent law requires applicants to disclose the inventions for which they seek patents. The purpose of the disclosure obligation is to foster further innovation by enabling a person skilled in the particular art to learn from another's invention.[39] This disclosure obligation is a trade-off for obtaining the right to exclude others from making, using, offering for sale or selling an invention.[40] Several panelists observed that the disclosure requirement fosters innovation in the pharmaceutical industry by enabling both brand-name and generic companies to discern the development plans and scientific development of rival companies.[41] One panelist reported that patent literature is an important source of information on technological advances for the pharmaceutical industry, whereas scientific literature, much of which is enabled by patents, is more important in the biotechnology industry.[42]

One way in which a generic company can compete with a particular brand-name product prior to the expiration of the patents that cover the drug product is to design around those patents.[43] Representatives of generic companies observed that the process of designing around brand-name patents can give rise to innovation.[44] In some circumstances a generic company may obtain a patent for its design-around innovations.[45]

D. The Role of Competition in Spurring Pharmaceutical Innovation

Panelists described competition among brand-name companies and the role of the Hatch-Waxman Amendments in fostering competition and innovation in the pharmaceutical industry. One panelist observed that the granting of a pharmaceutical patent does not necessarily confer a "monopoly on the treatment of any specific disease;" brand-name companies may compete with each other in the same therapeutic class, such as drugs that reduce cholesterol.[46] Moreover, according to the brand-name companies' trade association, competition among brand-name companies is increasing, because the period of market exclusivity between the introduction of breakthrough medicine and competing innovators has been consistently shrinking

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effective. *See* H.R. REP. No. 98-857, Part I at 16 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2649. The ability of other companies to rely on that data and develop bioequivalent generic versions of NCEs at much lower costs significantly reduces the profits for the branded product. One panelist stated that once a certain drug has a generic counterpart, the result is a "more rapid decline in the pioneer share of the market" because pharmacy benefit managers and formulary managers require that physicians and patients use generic drugs, as opposed to the more expensive branded drugs. *See* Glover 3/19 at 171.

[39] *See supra* Ch. 2(I)(A)(3).

[40] Rogan 2/6 at 21.

[41] *See* Coffin-Beach 3/19 at 212; Glover 3/19 at 224-25; Seide 3/19 at 226; Browder 3/19 at 238; Oehler 2/26 at 319.

[42] *See* Blackburn 2/26 at 319-20.

[43] For further details, *see* FTC, *Generic Drug Study*. For discussion of design-around innovation by brand-name companies, *see* Armitage 3/19 at 230.

[44] *See, e.g.*, Browder 3/19 at 228.

[45] *See* Coffin-Beach 3/19 at 225.

[46] *See* Glover (stmt) 6. *But see NIHCM Innovation Report* at 3 (suggesting that price competition among several new drugs products in a therapeutic class is limited.).

since 1965.[47] None of the panelists believed, however, that competition alone could generate sufficient innovation in the pharmaceutical industry.[48]

One of the unique aspects of the pharmaceutical industry is how the regulatory structure governing the approval of new brand-name and generic drug products has spurred additional competition and innovation. In this case, the Hatch-Waxman Amendments sought to balance incentives for continued innovation by research-based pharmaceutical companies and opportunities for market entry by generic drug manufacturers. The streamlined approval process gives generic drug applicants the opportunity to obtain FDA approval of their generic drug products prior to patent expiration.[49] By removing obstacles to generic competition, the Hatch-Waxman Amendments "stimulated the development of a generic pharmaceutical industry in the United States. Since the law's passage, the generic industry's share of the prescription drug market has jumped from less than 20 percent to almost 50 percent today."[50] The Hatch-Waxman Amendments have fostered significant price competition in those markets with generic entry.[51] The generic competition spurred by Hatch-Waxman has forced brand-name firms to come up with new products to replenish their revenue streams.[52] Brand-name companies often have introduced IMDs for which they can seek patent protection to lessen the impact of this generic competition.[53]

Congress also encouraged generic

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[47] *See* Glover (stmt) 7; PhRMA (stmt) 28. *But see* Sal Ricciardi, *Comments Re: Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy Public Hearings, Spring and Summer, 2002* (Public Comment) 10 (discussing restraints on secondary market competition), *at* http://www.ftc.gov/os/comments/intelpropertycomments/pda.pdf.

[48] Panelists disagreed on the extent to which innovation would occur in the pharmaceutical industry absent patent protection, although all believed that it would decline markedly. Professor Snyder, who has conducted research into this particular issue, cited findings indicating that in the absence of patent protection for pharmaceuticals, innovation would decrease by approximately 60%. Armitage disagreed with Snyder, asserting that the absence of patents would eliminate innovation in the pharmaceutical industry. *Compare* Snyder 3/19 at 170 *with* Armitage 3/19 at 180.

[49] Brand-name companies must provide the FDA with information regarding patents that cover their drug products, which the FDA then lists in a publication commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A) and FTC, *Generic Drug Study* at Ch. 3. Generic drug companies who seek FDA approval prior to patent expiration must give notice to brand-name companies stating that the listed patents are invalid or not infringed by the generic product.

[50] *See* Glover (stmt) 7; *see also* Ashoke Bhattacharjya, *FTC Health Care Workshop: Panel on Branded and Generic Pharmaceuticals* 5 (stmt presented at the FTC's Healthcare Workshop Sept. 10, 2002), *at* http://www.ftc.gov/ogc/healthcare/bhatta.pdf; FTC, *Generic Drug Study* at (i) (identifying these figures as shares of prescriptions filled).

[51] Studies indicate that the first generic typically enters the market at 70 to 80 percent of the price of the corresponding brand and rapidly secures as much as a two-thirds market share. *See, e.g.*, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 28 (July 1998), *at* http://www.cbo.gov/showdoc.cfm?index=655&sequence=0; DAVID REIFFEN & MICHAEL R. WARD, GENERIC DRUG INDUSTRY DYNAMICS (Federal Trade Commission Bureau of Econ. Working Paper No. 248, 2002), *at* http://www.ftc.gov/be/econwork.htm; *see also* BE Staff Report, *The Pharmaceutical Industry*.

[52] *See, e.g.*, Glover 3/19 at 146 (noting that "even major companies must develop a blockbuster every two to three years or face massive financial contraction").

[53] Browder 3/9 at 227-28.

entry by granting 180 days of marketing exclusivity to the first generic applicant to file an application for a generic drug product that does not infringe the brand-name product or that challenges the validity of the brand-name company's patents.[54] The 180-day exclusivity period increases the economic incentives for a generic company to be the first to file, because the generic applicant has the potential to reap the reward of marketing the only generic product (and, thus, to charge a higher price until more generic products enter). Through this 180-day provision, the Amendments provide an increased incentive for companies to challenge patents and develop alternatives to patented drugs.[55] Indeed, one generic panelist reported that competition among generic companies for the 180 days of exclusivity has become "acute."[56]

Once a brand-name company is notified of the filing of such a generic application, it has a 45-day window in which to sue the generic applicant for patent infringement. The initiation of the patent infringement suit triggers a 30-month stay of FDA approval of the generic drug application. According to the legislative history, the stay allows for the commencement of a lawsuit and takes into account the patent owner's rights while still encouraging generic entry.[57]

[54] For a fuller discussion of the effect of the 180-day marketing exclusivity provision on competition, *see* FTC, *Generic Drug Study* at Ch. 3.

[55] *See Granutec, Inc. v. Shalala*, 139 F.3d 889, 891 (4th Cir. 1998).

[56] Coffin-Beach 3/19 at 239.

[57] H. REP. NO. 98-857, at 27 (1984).

E. The FTC's Pharmaceutical Industry Enforcement Actions and Generic Drug Study

The Commission has pursued numerous antitrust enforcement actions affecting both brand-name and generic drug manufacturers when it had reason to believe that a company abused its patent rights in violation of the antitrust laws. The Commission has addressed conduct that it alleged would have the effect of delaying generic entry, including certain patent settlement agreements between brand-name companies and generic applicants,[58] a brand-name company's acquisition of an exclusive license to a particular patent,[59] the purported

[58] *Abbott Laboratories,* No. C-3945 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. *Geneva Pharmaceuticals,* No. C-3946 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3946.do.htm. *Hoechst/Andrx,* No. 9293 (FTC May 8, 2001) (consent order), *available at* http://www.ftc.gov/os/2001/05/hoechstdo.htm. In another matter, *Schering-Plough,* the Commission resolved all claims against one of three respondents, American Home Products (AHP), by issuing a final consent order. *Schering-Plough Corp.*, No. 9297 (FTC Apr. 2, 2002) (consent order as to AHP), *available at* http://www.ftc.gov/os/2002/04/scheringplough_do.htm.

The case against the other two respondents is in litigation before the Commission. *See Schering-Plough Corp.*, No. 9297 (FTC July 2, 2002) (Initial Decision), *available at* http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf.

[59] *Biovail Corp.*, No. C-4060 (FTC Oct. 2, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf.

use of sham litigation,[60] and an agreement between generic drug manufacturers.[61] It also has addressed conduct that the Commission contended would eliminate a potential competitor for an NCE in the merger context.[62]

Over the past few years the Commission also has observed through its investigations, law enforcement actions, and Generic Drug Study that some brand-name and generic drug manufacturers may have "gamed" the 180-day marketing exclusivity and the 30-month stay provisions, attempting to restrict competition beyond what the Hatch-Waxman Amendments intended.[63] The Commission has undertaken two main types of enforcement activities in this area. It has addressed patent settlement agreements between brand-name companies and generic applicants that the Commission alleged had delayed the entry of one or more generic applicants through manipulation of the 180-day exclusivity period.[64] It also has addressed allegations that individual brand-name manufacturers have delayed generic competition through the use of improper Orange Book listings[65] that trigger the Hatch-Waxman provision prohibiting the FDA from approving a generic applicant for 30 months.[66]

Brand-name companies previously could obtain additional 30-month stays by obtaining additional patents that claimed their brand-name products. There were opportunities for "gaming" the 30-month stay because the FDA does not oversee whether these additional patents meet the requirements for listing with the FDA, and there is no private right of action for a court to make such a determination. Not surprisingly, given the amount of revenue at stake, the FTC found in its Generic Drug Study that some brand-name companies have "gamed" the 30-month stay provision, and that it had the potential to be "gamed" in the future, absent reform.[67] The FDA changed its rule to prevent brand-name companies from obtaining additional 30-month stays. This rule change was based

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[60] *Bristol-Myers Squibb*, No. C-4076 (FTC Mar. 7, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[61] *Biovail Corp. and Elan Corp. PLC*, No. C-4057 (FTC Aug. 20, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/06/biovailelando.pdf.

[62] *In the Matter of Glaxo Wellcome plc, and SmtihKline Beecham PLC*, No. C-3990 (FTC Jan. 31, 2001) (consent order) (requiring divestiture of certain intellectual property rights on NCEs), *available at* http://www.ftc.gov/os/2001/01/glaxosmithklinedo.pdf.

[63] For further details on the Generic Drug Study *see* Box 3-3.

[64] *Abbott Laboratories*, No. C-3945 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3945.do.htm. *Geneva Pharmaceuticals*, No. C-3946 (FTC May 22, 2000) (consent order), *available at* http://www.ftc.gov/os/2000/05/c3946.do.htm.

[65] The Commission first raised concerns about the potential anticompetitive impact of improper Orange Book listings in *American Bioscience, Inc. v. Bristol-Myers Squibb Co.*, No. CV-00-08577 (C.D. Cal. Sept. 7, 2000). *See* Brief of Amicus Curiae Federal Trade Commission, *Am. Bioscience, Inc. v. Bristol Myers Squibb Co.*, 2000 U.S. Dist. LEXIS 21067 (No. CV-00-08577), *available at* http://www.ftc.gov/os/2000/09/amicusbrief.pdf.

[66] *Biovail Corp.*, No. C-4060 (FTC Oct. 2, 2002) (consent order), *available at* http://www.ftc.gov/os/2002/10/biovaildo.pdf; *Bristol-Myers Squibb*, No. C-4076 (FTC Mar. 7, 2003) (consent order), *available at* http://www.ftc.gov/os/2003/03/bristolmyersconsent.pdf.

[67] *See* FTC, *Generic Drug Study at* (ii)-(iv) and Ch. 3.

largely on the FTC's recommendation.[68]

F. Conclusion

Representatives from the pharmaceutical industry emphasized that patents are critical for promoting pharmaceutical innovation of NCEs. Brand-name companies depend on patents to recoup their substantial investment in the discrete innovation that leads to the development of new drug products. Also, brand-name companies make and patent incremental improvements to their products to manage them on a life-cycle basis. Panelists differed as to the extent to which such IMDs benefit consumers.

Competition in the pharmaceutical industry occurs in two primary ways: between brand-name companies that have products in the same therapeutic class and between brand-name and generic companies. Competition between and among brand-name companies and generics can foster innovation, as well as other benefits of competition. Patent disclosure requirements can enable brand-name and generic competitors to design around some patents covering brand-name drug products in order to bring competing products to market. The Commission has brought enforcement actions in the pharmaceutical industry to protect competition, including incentives to innovate.

The innovation that the patent system spurs for the discovery and commercialization of NCEs in the pharmaceutical industry in many ways showcases the patent system's benefits. Such innovation entails the high fixed research costs, relative ease of imitation, and free riding problems that patent protection effectively manages. Fewer patent thicket issues arise in the pharmaceutical context than in industries where innovation is less discrete and individual products are covered by many patents. Subsequent sections examine how the roles of patents and competition vary in industries that exhibit different characteristics.

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[68] *See* Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 68 Fed. Reg. 36,675 (2003) (to be codified at 21 C.F.R. § 314).

III. THE BIOTECHNOLOGY INDUSTRY

A. Introduction

The biotechnology industry also relies primarily on patents to provide incentives to invest in innovation. Biotechnology companies seek patent protection to appropriate the value of their inventions, to attract investment from capital markets, which funds their costly research, and to facilitate inter-firm relationships necessary for commercial development of their inventions. Patent disclosures can assist biotechnology firms in focusing their R&D efforts on areas not covered by patents. Competition also encourages innovation, for example, as firms race to develop new technologies.

Although panelists generally agreed on the benefits of patents in the biotechnology industry, many panelists also stated that the issuance of questionable patents is harming innovation in the industry, and that the mechanisms for challenging such patents, including litigation, are inadequate. Some also expressed concern that the need for multiple, patented research tools has the potential to create difficulties for follow-on innovation. Others discussed how licensing practices, such as reach-through license agreements and patent pools, can be used to surmount some of these difficulties by facilitating access to research tools that promote further innovation.

The panelists who represented biotechnology firms or organizations at the Hearings were David W. Beier, Counsel to the Biotechnology Industry Organization; Lee Bendekgey, representing Incyte Genomics; Robert Blackburn, representing Chiron Corp.; Monte R. Browder, representing Ivax Corporation; Barbara Caulfield, representing Affymetrix, Inc.; David Coffin-Beach, representing Torpharm, Inc.; David J. Earp, representing Geron Corp.; Michael K. Kirschner, representing Immunex Corp.; and Ross Oehler representing Aventis Corp. Rochelle K. Seide, from Baker Botts, LLP, also participated in a business perspective panel on the biotechnology industry.

B. Industry Description

The biotechnology industry uses cellular and molecular (*i.e.*, biological) processes to address problems or make products. R&D in the biotechnology industry focuses on cells and large biological molecules (such as DNA and proteins) rather than the chemical compounds that the pharmaceutical industry uses to make small molecule drug products.[69]

Cells are the basic building blocks of all living things. Plants, animals, and humans are incredibly diverse, yet there are remarkable similarities among the species that are invisible to the naked eye. All living things use essentially the same cellular processes and speak the same genetic language.[70] This unity at the cell level of different species provides the foundation for biotechnology research.

Participants asserted that R&D

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[69] *See* Beier 2/26 at 248.

[70] *See* Biotechnology Industry Organization, *Biotechnology: A Collection of Technologies*, *at* http://www.bio.org/er/technology_collection.asp.

spending in the biotechnology industry "is more than double the average of the pharmaceutical industry (both on a per employee basis and as a percentage of sales), and the pharmaceutical industry is several times more R&D intensive than any other industry."[71] R&D is particularly lengthy for biotechnology firms, because biotechnology innovation is more uncertain than innovation in other industries.[72] Panelists also noted that the commercialization of biotechnology research is particularly difficult, due to three factors. First, as discussed above in relation to the pharmaceutical industry, the drug development process is time-consuming, uncertain, and expensive. One panelist noted that his company took 10 years to bring its first product to market, and another 6 years before it brought its second product to market.[73] Second, much biotechnology research is basic, at least a step removed from the more applied research that is directly susceptible to commercialization.[74] Biotechnology thus highlights the issues that lie at the core of the prospect theory regarding incentives for, and efficiencies in, bridging the gap between basic research and ultimate commercial sales.[75] Third, most biotechnology industry participants are small, particularly relative to the pharmaceutical industry, and lack internal financial resources sufficient for undertaking extensive drug development.[76]

Although innovation in the biotech industry has many facets, it generally results in two classes of inventions.[77] One class relates to newly discovered and isolated genes or proteins or to pharmaceutical inventions based on those genes or proteins. Although one cannot patent a naturally-occurring gene or protein as it exists in a plant, animal, or human, one can patent a gene or protein that has been isolated from the body and is useful in that form as a pharmaceutical drug or other application.[78] The other class of biotechnology inventions relates to methods of treating patients with a given disease through the use of a particular gene or protein. Even if someone has a patent on a gene or protein, a researcher who discovers a new method of use for that gene or protein can patent the new method of use.[79]

The biotechnology industry is closely related to the pharmaceutical industry. One panelist observed that both industries try to

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[71] Biotechnology Industry Organization, *Testimony* (2/26/02) 2, *at* http://www.ftc.gov/opp/intellect/020226davidwbeier.pdf (hereinafter BIO (stmt)); Kirschner 2/26 at 240.

[72] *See* Beier 2/26 at 248-49; Kirschner 2/26 at 240.

[73] *See* Kirschner 2/26 at 239.

[74] *See* Earp 2/26 at 252; Seide 3/19 at 167.

[75] *See* Rai 4/10 at 21 (citing bio-pharmaceuticals as a context in which "patents serve not only the traditional incentive function but also serve the function of incentivizing further commercialization and development"); *see generally supra* Ch. 2(III)(A)(1) (discussing Professor Kitch's prospect theory).

[76] *See* Earp 2/26 at 252.

[77] *See generally* Biotechnology Industry Organization, *Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine, at* http://www.bio.org/genomics/primer.html (hereinafter BIO, *Primer*).

[78] *See* United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 2105 (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep.htm (hereinafter MPEP); Seide 3/19 at 167-68.

[79] *See* BIO, *Primer* at 6.

discover end-use products.[80] Indeed, small molecule-type research, the aim of which is to produce a traditional pharmaceutical drug product, has become much more efficient through the use of biotechnology tools such as proteins and genomic sequences.[81] Also, many biotechnology companies conduct basic research to identify promising products, and then partner with a pharmaceutical company to test and commercialize the product.[82] Patents facilitate this process; there is a tremendous amount of licensing, as well as acquisition activity, between the two industries searching for synergies to bring products to market.[83]

C. The Role of Competition in Spurring Biotechnology Innovation

Several panelists discussed the role of competition in spurring biotechnology innovation.[84] One panelist commented that "one thing that competition does is, it sure makes you hurry up."[85] Drawing on his experience in the biotech industry, he observed that companies typically found their initial success by introducing a product with no comparable or rival product.[86] After this success, much bigger and better funded competitors entered the market, thus adding competitive pressure to keep innovating.[87] In general, however, although panelists found competitive forces important, they placed emphasis on the role of patents as drivers of innovation in the biotech industry.

D. The Implications of Patent Protection for Innovation

1. The Role of Patents in Spurring Innovation in the Biotechnology Industry

a. Patentability Encourages Investment in R&D

In 1980, the Supreme Court in *Diamond v. Chakrabarty*[88] decided that living organisms produced by human intervention are patentable. Participants stated that the biotechnology industry would not have emerged "but for the existence of predictable patents,"[89] and that *Chakrabarty* spurred significant growth in the biotechnology industry.[90] Their discussion describes the role of patents in an industry with a very costly, high-risk R&D process and a structure consisting significantly of

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[80] *See* Blackburn 2/26 at 250-51.

[81] *See* Seide 3/19 at 188-89, 244-45 (discussing "rational drug design"); Blackburn 2/26 at 250, 261-62.

[82] *See, e.g.*, Blackburn 2/26 at 251; Earp 2/26 at 252.

[83] *See* Bendekgey 2/26 at 257-59; Oehler 2/26 at 254.

[84] *See, e.g.*, Caulfield 3/19 at 242-43.

[85] *See* Bendekgey 2/26 at 286. Patent races may lead to excessive R&D in a particular area, although distinguishing beneficial from wasteful overlapping efforts may prove difficult. *See supra* Ch. 2(III).

[86] *See* Bendekgey 2/26 at 285-86.

[87] *See id.*

[88] *Diamond v. Chakrabarty*, 447 US 303 (1980).

[89] *See* Kirschner 2/26 at 240-41, 328.

[90] BIO (stmt) 4.

small, not-yet-profitable firms.[91]

A biotechnology trade association highlighted one particular role of patents in this setting: patentability of biotech inventions enables the biotechnology industry "to attract venture capital."[92] Biotechnology companies overwhelmingly underscored the importance of patents for attracting venture capital.[93] As one of these panelists stated, "patents are indeed the key asset for us. They enable us to have access to the capital markets and to continue our innovation and development."[94] The venture capital accessed through patents thus enables not-yet-profitable companies to "sustain . . . innovation through massive investments in research and development."[95]

b. *The Role of Patent Disclosures in Fostering Biotechnology Innovation*

The panelists differed on the extent to which required patent disclosures encourage the dissemination of information and, therefore, foster follow-on innovation in biotech.[96] One panelist stated that the patent literature "has not been a significant source of ideas" for the company's research.[97] By contrast, a panelist from a pharmaceutical firm with a biotechnology affiliate noted that "there is value to be found in patents as literature."[98] Another panelist noted that "the information transfer happens in the scientific literature [rather than] the patent literature," but added that "quite a bit of the scientific literature is enabled by the fact that there's been a patent filed on it."[99] This panelist observed that patent literature is a more important source of information in the pharmaceutical industry than the biotechnology industry.[100]

c. *Patenting of Biotechnology Research Tools*

A research tool is a technology that is used by pharmaceutical and biotechnology companies to find, refine, or otherwise design and identify a potential product or properties of a potential drug product.[101] As such, it serves as a springboard for follow-on innovation. Examples of these types of enabling tools include high-throughput screening technologies, micro-array-type technologies, genomic databases, and

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[91] *See id.* at 2, 4; Beier 2/26 at 265-66; Blackburn 2/26 at 275-76.

[92] BIO (stmt) 4.

[93] *See* Earp 2/26 at 237; Bendekgey 2/26 at 256; Blackburn 2/26 at 263.

[94] *See* Earp 2/26 at 326.

[95] BIO (stmt) 4.

[96] *See* Kirschner 2/26 at 318; Blackburn 2/26 at 319; Oehler 2/26 at 319.

[97] Kirschner 2/26 at 318.

[98] Oehler 2/26 at 319.

[99] *See* Blackburn 2/26 at 319.

[100] *See id.* at 320.

[101] *See* Blackburn 2/26 at 250, 260 (noting that there are likely to be slightly varying definitions of research tools); Bendekgey 2/26 at 267-68, Cohen 10/30 at 150, McGarey 11/6 at 160.

Box 3-4. ***Effects of Research Tool Patents and Licensing on Biomedical Innovation***
John P. Walsh, Ashish Arora & Wesley M. Cohen *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://books.nap.edu/books/0309086361/html/285.html#pagetop.

John P. Walsh, Ashish Arora, and Wesley M. Cohen conducted an empirical study of the implications for innovation of patenting and licensing practices in the pharmaceutical and biotech industries. The authors conducted "70 interviews with IP attorneys, business managers and scientists from 10 pharmaceutical firms and 15 biotech firms, as well as university researchers and technology transfer officers from 6 universities, patent lawyers and government and trade association personnel."

The authors found that patents on research tools have increased, but have not significantly hindered drug discovery. The increased complexity of the patent landscape, they concluded, has not resulted in a tragedy of the anticommons. (*See* Box 3-5 for further explanation of this theory.) They noted that some university research has been delayed by restrictions on the use of patented genetic diagnostics, and that there have been some delays or access restrictions to research tools or other foundational discoveries. In some instances, research was re-directed to areas where there were fewer patents. Overall, however, the researchers found that no valuable research projects were halted as a result of limited access to a research tool. The authors cautioned, however, that the potential exists and ongoing scrutiny is warranted. *See infra* Ch. 3(III)(D)(4).

The authors also concluded that firms and universities use a range of strategies to avoid breakdown and restricted access to research tools, including taking licenses, inventing around patents, infringement (often informally invoking a research exemption), developing and using public tools and challenging patents in court. New PTO guidelines, active intervention by the NIH, and overall shifts in the courts' attitudes towards research tool patents also have lessened these potential threats, they found. A new Federal Circuit case that stated a narrow scope of the research exemption available to universities led the authors to question the extent to which some of these findings will remain applicable. The relevant Federal Circuit case, *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert denied*, 123 S. Ct. 2639 (2003), is discussed *infra* Ch. 4(II)(D).

modeling programs. Research tools are generally patentable. Researchers require a license to use patented research tools to identify and develop inventions, but typically do not require a license from the research tool patent holder to practice the ensuing inventions.[102]

Several commentators discussed the benefits to innovation derived from using and patenting research tools.[103] For example, one panelist explained that with gene chip array technology "what used to take a post-doc[toral student] in the laboratory approximately six months with proper front-end research can now be done in 20 minutes."[104] Another panelist suggested that research tools have led to a considerable reduction in the cost and time required for the targeting of therapeutic antibodies during the initial stages of new drug research. He mentioned "a very small pre-IPO firm that has moved into a phase two product in three years based on research tool technology" and went on to state that this would have been "inconceivable to have

[102] *See* Blackburn 2/26 at 260.

[103] *See id.* at 262; Bendekgey 2/26 at 258-59 and 267-68; Seide 3/19 at 167. For discussion of issues raised by research tool patents, *see* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://books.nap.edu/books/0309086361/html/285.html#pagetop (hereinafter *Research Tool*) and Box 3-4.

[104] *See* Caulfield 3/19 at 135.

happened 20 years ago, before the invention of research tools."[105]

Two panelists stressed the importance of patenting research tools.[106] One of them asserted, for example, that "if there's anything you want to protect and incent with patents, it's the research tool technology."[107] He argued that patent protection will be critical in encouraging investment in the next generation of research tools, which might reduce the costs and time required for the clinical trial phases, which are the most "expensive part" of the drug development process.[108]

2. The Quality of Biotechnology Patents

Panelists discussed concerns with the quality of biotechnology patents. Many of the panelists observed that poor quality patents can hinder innovation and competition.[109] A number of panelists stated that poor quality patents can harm innovation and competition by deterring a rival firm from entering or continuing with a particular area of research.[110] Two panelists observed that questionable patents create a "significant drag" on competition, and another panelist stated that questionable patents have a "chilling effect on both public and private sector research."[111]

One panelist stated his personal view that "the PTO's ability to provide a meaningful examination of biotechnology patents right now is in a cris[i]s."[112] Acknowledging the dedication and quality of the PTO's examiners, this panelist noted that the examiners are under such time constraints that they may be unable to conduct a meaningful patent examination.[113] According to this panelist, the PTO should

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[105] Blackburn 2/26 at 261, 262 (discussing the screening of small molecules); Oehler 2/26 at 277-78 (noting that research tools offer "great promise," but as yet have only reduced the time required for the early phases of research).

[106] *See* Blackburn 2/26 at 262; Bendekgey 2/26 at 258-59, 267-68.

[107] *See* Blackburn 2/26 at 262.

[108] *See id.* at 262-63. *See supra* Ch. 3(II)(B) (discussing the phases of pharmaceutical drug development).

[109] *See* Bendekgey 2/26 at 230; Earp 2/26 at 238; Kirschner 2/26 at 241; Oehler 2/26 at 292; Blackburn 2/26 at 294.

[110] *See* Earp 2/26 at 238, 290-91; Caulfield 3/19 at 159; Blackburn 2/26 at 296.

[111] Caulfield 3/19 at 159; Barbara A. Caulfield, *Business Perspectives on Patents: Biotech and Pharmaceuticals, Federal Trade Commission/Department of Justice Hearings* (3/19/02) (slides) at 6, *at* http://www.ftc.gov/opp/intellect/020319barbaracaufield.pdf (hereinafter Caulfield Presentation); Blackburn 2/26 at 296, Kirschner 2/26 at 328.

[112] *See* Kirschner 2/26 at 242. Mr. Kirschner voiced concerns with patents issued to wrong parties or to multiple parties on the same invention; patents that "contain overly-broad claims in view of the prior art or the scope of what was enabled or the scope of what was described" *id* at 242; and patents for which "the best prior art was not cited to the patent office, was not discovered by the patent office, or was cited to the patent office and clearly the examiner did not appreciate it." *Id.* at 241-42, 289.

[113] *See* Kirschner 2/26 at 241-44, 288-90. Similarly, a panelist commented that "examiners have an incentive to move cases along and dispose of them." *See* Bendekgey 2/26 at 231 ("I've certainly had comments repeated to me to the effect that . . . examiners have an incentive to move cases along and dispose of them, and sometimes they think there's something novel here, they're not sure what, and so they're just going to allow it and let things get sorted out in litigation. And I can tell you, when you're at the receiving end of litigation like that it has a decidedly chilling effect on competition.").

"focus on improving quality, at least within [the biotechnology patent examination group]," because patent quality is more important than pendency in the biotechnology industry.[114] Another panelist observed, "of the issues that people raise . . . in many cases [it] just come[s] down to the quality of the examination."[115]

Although panelists agreed that poor patent quality can adversely affect innovation, disagreement existed whether patent quality in the biotechnology area was any different from that in other industries. One panelist reported that patent quality is not a field-specific problem.[116] In fact, he observed that biotechnology patents may be of a higher quality than those in other industries, because of "the concentration of the Patent Office on guidelines and resources in the biotech field" in the last 10 years.[117] The representative of a biotechnology trade association similarly noted that the PTO has responded affirmatively to public controversies in relation to biotechnology patents as they have arisen and thus has headed off any lasting adverse impacts of questionable biotechnology patents.[118]

[114] *See* Kirschner 2/26 at 243, 329. *But cf.* Armitage 3/19 at 134 (raising concerns with pendency periods for biotechnology patent applications).

[115] *See* Bendekgey 2/26 at 230.

[116] *See* Oehler 2/26 at 292.

[117] *See id.*

[118] *See* Beier 2/26 at 296 (noting that "the patent system has been remarkably self-correcting."); *see also* Kirschner 2/26 at 329 (noting the PTO's responsiveness to concerns raised by the industry).

3. The Mechanisms Available for Challenging Questionable Patents

Firms in the biotechnology industry reported that they avoid infringing even questionable patents and therefore refrain from entering or continuing with a particular field of research.[119] Most panelists observed that the two existing mechanisms for challenging a questionable patent are generally inadequate.[120]

a. Challenging Questionable Patents Through Litigation

Panelists considered litigation to be an inadequate means of challenging a patent for three main reasons. First, the pace of innovation in the biotechnology industry is so rapid that by the time a court determines the question of patent validity, the research or product opportunity has passed. As one panelist observed, "six months can be a tremendous amount of time" in biotechnology research, while a biotechnology patent case "takes two to three years" to litigate.[121] Moreover, other

[119] *See, e.g.*, Earp 2/26 at 290-91, 238; Blackburn 2/26 at 296; Caulfield 3/19 at 161; *see also* Alik Widge, *Comments Regarding Competition and Intellectual Property* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/widgealik.htm.

[120] *See* Bendekgey 2/26 at 231; Earp 2/26 at 238, 291, 327; Kirschner 2/26 at 244, 328; Blackburn 2/26 at 294; Caulfield 3/19 at 160. One panelist noted that a third option exists that permits the public to submit comments to the PTO about patent applications published because they have been pending before the PTO for longer than 18 months. He also acknowledged this approach was not as "perfect and as targeted as an opposition proceeding, as in Europe." Oehler 2/26 at 294.

[121] Caulfield 3/19 at 160; *see also* Barton 2/26 at 220-21.

panelists suggested that just because a patent is not challenged through litigation does not mean that the patent is not problematic.[122]

Second, the cost of litigation is prohibitively expensive for many firms in the biotechnology industry. One panelist reported that a biotechnology patent case costs between five and seven million dollars to litigate.[123] Such expenditure, this panelist observed, on an area that may not end up producing revenue is beyond the means of most firms in the biotechnology industry.[124] According to panelists, most firms tend to be small and generally have to obtain funding from the capital markets or venture capitalists because of the difficulties in commercializing products.[125]

Finally, current standing requirements prevent a potentially infringing party from determining in advance the merits of a questionable patent.[126] A potentially infringing party can seek a declaratory judgment to invalidate a patent only after that party has been threatened with litigation by the patent owner. Patent owners in the biotechnology industry are careful to avoid such a situation.[127] This means the potentially infringing party has to choose whether to forge ahead with the research, and risk being sued after significant costs have been sunk, or avoid the area of research.[128] Panelists stated their companies usually will choose to avoid the area of research altogether rather than risk possible infringement later in the R&D process.[129] One panelist observed that the inability of a company to challenge the validity of a patent unless that company itself has been threatened with litigation by the patent owner results in harm to competition, because "bad patents [are able to] . . . sit out there . . . [where] you can't touch them."[130]

b. Challenging Questionable Patents Through Reexamination Procedures

Any person at any time may file a request for reexamination, and if the request raises a substantial new question of patentability affecting any claim of the patent, reexamination is commenced. Reexamination is available on an *ex parte* and *inter partes* basis.[131] The panelists unanimously considered the reexamination procedures as they existed at the time of the hearing inadequate for a third party to challenge the validity of another party's patent.[132] Participants articulated three

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[122] *See* Blackburn 2/26 at 309; Kirschner 2/26 at 308.

[123] *See* Caulfield 3/19 at 160.

[124] *See id.*

[125] *See* Kirschner 2/26 at 239; Earp 2/26 at 252; Armitage 3/19 at 166; Seide 3/19 at 167.

[126] *See* Blackburn 2/26 at 294.

[127] *See id.*

[128] *See id.* at 295.

[129] *See* Earp 2/26 at 238, 290-291; Caulfield 3/19 at 159; Caulfield Presentation at 6; Blackburn 2/26 at 296.

[130] Blackburn 2/26 at 294-6.

[131] For further discussion of reexamination, opposition, and review, *see infra* Ch. 5(III).

[132] *See, e.g.*, Earp 2/26 at 301, Bendekgey 2/26 at 303, Beier 2/26 at 301, Blackburn 2/26 at 294-96. One panelist wryly observed that as of the time of the hearing the *inter partes* reexamination procedures had been invoked in only four out of 160,000 cases. *See* Beier 2/26

problems with the reexamination system, two of which Congress has addressed by legislation since the Hearings.[133] The remaining problem panelists cited was that participation in an *inter partes* reexamination proceeding estops a third party participant from raising a broad spectrum of issues in subsequent court litigation.[134]

c. *Challenging Questionable Patents Through a New Opposition System*

Three of the panelists suggested that the United States should implement an opposition system for challenging questionable patents.[135] These panelists recommended that such an opposition system draw on the best features of other patent opposition proceedings, particularly the European system.[136] One panelist suggested that the best features of the existing United States reexamination system should also be incorporated into any opposition system.[137]

Another panelist stated that an opposition system should be implemented regardless of whether the problems discussed above in relation to reexamination proceedings were addressed by statute.[138] In fact, he noted that even if the reexamination proceedings were improved, it "probably wouldn't convince a whole lot more people to go forward with it."[139] This view was not challenged among the panelists.

4. The Potential for Patents to Impede Innovation in the Biotechnology Industry

Unlike the pharmaceuticals industry, in which major aspects of the innovation process are relatively discrete, biotechnology innovations typically form the basis of, or provide the tools for, independent follow-on R&D. Commentators discuss two ways in which patents have the potential to harm follow-on innovation in biotechnology: (1) through the development of an anticommons;[140] and (2) through the withholding of access to technologies

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at 301.

[133] These two problems were: a third-party who invoked the reexamination procedures was precluded from appealing the PTO's decision to the federal courts (*see* BIO (stmt) 24; Beier 2/26 at 301; Earp 2/26 at 301; Bendekgey 2/26 at 303); and prior art of record during the patent application process could not be the basis for a reexamination (*see* Earp 2/26 at 302). Amendments to the patent statute enacted in November 2002 conferred appeal rights on third party requesters in *inter partes* patent reexamination proceedings, overruled the decision in *In re Portola Packaging Inc.*, 110 F.3d 786 (Fed. Cir. 1997) (holding that reexamination could not be used if the basis is the same prior art references that the examiner considered, since such references do not raise a substantial new question of patentability), and clarified that patent reexamination on the basis of previously cited prior art "is not precluded." Patent and Trademark Office Authorization Act of 2002 § 5-6, 35 U.S.C. § 303(a), 312 (a) 134, and 141-44.

[134] *See, e.g.*, Beier 2/26 at 301.

[135] *See* Bendekgey 2/26 at 231; Earp 2/26 at 238, 291, 327; Kirschner 2/26 at 244, 329.

[136] *See* Earp 2/26 at 238, 291, 327; Bendekgey 2/26 at 231.

[137] *See* Kirschner 2/26 at 244.

[138] *See* Earp 2/26 at 327.

[139] *See id.*

[140] For further explanation of this theory, *see* Box 3-5.

needed for follow-on innovation.[141]

a. The Development of an Anticommons

Scholars have argued that innovation can be harmed by the development of an anticommons, which can arise when multiple property right owners have claims to separate inputs needed for some product or line of research.[142] Some panelists believe that an anticommons threatens innovation in the biotechnology industry.[143] One panelist stated, for example, that the need "to have access to a wide range of technologies to discover, create, manufacture and market a human therapeutic product" means the biotechnology industry is "highly vulnerable to . . . the tragedy of the anticommons";[144] he found "the risk of" an anticommons problem.[145] He cited the example of Enbrel, which at one time was subject to royalties paid to seven companies.[146] The panelist later noted that the royalty stacking that took place in relation to Enbrel was prior to the advent of research tool patents and reach-through royalties, which, he indicated, have increased the likelihood of anticommons problems.[147]

In their business survey of the biotechnology industry, Professors Walsh, Arora, and Cohen examined whether the existence of multiple research tool patents associated with a new product or process poses anticommons concerns.[148] They concluded that such concerns have "not been especially problematic," because mechanisms are being used, such as relying on a research exemption, obtaining a license, or inventing around patents, to prevent harm

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[141] One potential limit on such harm may spring from an experimental use defense. Although there is some debate about its scope, the industry panelists generally accepted that an experimental use defense exists at common law offering some shelter from infringement litigation to non-commercial research. *See* Armitage 3/19 at 186-87; Polk 3/19 at 190; *cf.* Thomas 2/8 (Patent Session) at 30; Sung 2/8 (Patent Session) at 136-38; Caulfied 3/19 at 163. For further discussion of the research exemption, *see infra* Ch. 4(II)(D). In their study of the biotechnology industry, Walsh, Arora, and Cohen noted that informal reliance on this defense by members of the research community has helped to prevent an anticommons or lack of access to existing patents from stifling follow-on innovation. *See* Walsh et al., *Research Tool* at 333-34.

The Federal Circuit has stated a narrow scope of this exemption in an opinion in October 2002: *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), *cert denied*, 123 S. Ct. 2639 (2003). Some believe that this decision will chill university research, because researchers will no longer be able to rely on the exemption to overcome anticommons or access issues. *See* Cohen 10/30 at 149-52, 161-62.

[142] *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE MAG., May 1, 1998, *available at* http://www.sciencemag.org/cgi/content/full/280/5364/698 and Box 3-5. For further discussion of anticommons and related issues deriving from the presence of multiple patents, *see supra* Ch. 2(III)(C).

[143] *See* Kirschner 2/26 at 241, 310-11; Caulfield 3/19 at 163-64; McGarey 11/6 at 153-54. *See also* Tom Horton, *Patenting Our Lives and Our Genes: Where Does Congress Stand in the Coming Clash?* 7-8 (noting the development of practical problems from the proliferation of biotechnology patents but finding the effect on research "uncertain"), *at* http://www.ftc.gov/os/comments/intelpropertycomments/hortonthomasjarticle.pdf.

[144] *See* Kirschner 2/26 at 241.

[145] *See id.* at 310-11.

[146] *See id.* at 241. He went on to note that one of those companies no longer receives royalties because its patent expired.

[147] *See id.* at 310. Reach-through royalties are discussed below.

[148] *See* Walsh et al., *Research Tool* at 286-89.

Box 3-5. ***Can Patents Deter Innovation? The Anticommons in Biomedical Research***
Michael A. Heller and Rebecca S. Eisenberg, Science 1998 May 1; 280: 698-701.

The tragedy of the anticommons refers to a problem that might arise when multiple owners each have a right to exclude others from a scarce resource, and no one has an effective privilege of use. There are two mechanisms by which a government might inadvertently create an anticommons:
(1) by creating too many concurrent fragments of intellectual property rights in potential future products;
(2) by permitting too many existing patent owners to stack licenses on top of the future discoveries of users.

The authors theorize that patenting of gene fragments and of receptors useful for screening potential pharmaceutical products are two situations in which too many concurrent fragments may result in an anticommons. If a tragedy of the anticommons were to emerge, it might endure because of the transaction costs of rearranging entitlements, heterogeneous interests of owners, and cognitive biases among researchers, the authors suggest.

The authors suggest that policy-makers should seek to ensure coherent boundaries of existing patents and to minimize restrictive licensing practices that interfere with product development. Otherwise, they conclude that more patent rights may lead paradoxically to fewer useful products for improving human health.

to innovation from occurring.[149] Another factor that mitigated anticommons concerns, the authors noted, is the very high number of technological opportunities in the biotechnology industry, which enables firms to redirect their research efforts to areas less encumbered by patent claims to avoid possible infringement issues.[150]

Some panelists expressed views similar to these findings.[151] One panelist commented, for example, that licensors tend to be "fairly sensitive" to the implications of royalty-stacking for product commercialization.[152] "If the licensor . . . is about to propose a royalty that's going to kill the product, [the licensor] is not going to make any money. And most of the players in this field are sophisticated enough to understand that," he argued.[153]

b. Access to Existing Technologies Needed for Follow-On Innovation

There is a debate among scholars as to the optimal balance of incentives to innovate between parties engaged in initial research and parties engaged in follow-on research. Some contend that broad patents maximize innovation by enabling the initial inventor to coordinate future follow-on R&D.[154] Others contend that restricted access to patents - especially broad patents - on discoveries such as research tools can

[149] *See id.* at 331, 333-34 (Although these mechanisms may prevent projects from being stopped, these scholars cautioned that they impose social costs, such as time delays and distraction from research.).

[150] *Id.* at 304, 331-32.

[151] *See* Blackburn 2/26 at 314-15; Beier 2/26 at 312-13; Seide 3/19 at 189; Dreyfuss 7/10 at 62

[152] *See* Blackburn 2/26 at 315.

[153] *Id.* But *cf.* Janice M. Mueller, *No "Dilettante Affair:" Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 7, 57 (2001) (arguing that "[t]he royalty stacking problem in biotechnology . . . has escalated in severity").

[154] *See, e.g.*, Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 265 (1977).

harm follow-on innovation.[155]

In their business survey of the biotechnology industry, Professors Walsh, Arora, and Cohen evaluated whether the later possibility has arisen. They concluded that there is no evidence that biotechnology research has been significantly impeded. Nevertheless, "the prospect exists and ongoing scrutiny is warranted."[156] They noted that access restrictions that harm innovation are most likely to occur when a research tool will be used primarily to develop innovations that will compete with one another in the marketplace, and the research tool is potentially key to progress in one or more therapeutic areas.[157] In such circumstances, the patent holder may seek either to develop the technology itself or exclusively license it to another.[158] Given that multiple technologies may require the use of such a research tool to foster further innovation, the authors saw such a development as likely to retard innovation.[159] These scholars also observed that mechanisms to mitigate such harm to innovation exist, such as "invoking a 'research exemption' that is broader than the existing legal exemption," inventing around patents, using the technology offshore, or seeking to invalidate the patent, but cautioned that many of these mechanisms can impose social costs.[160]

E. Licensing Practices for Biotechnology Research Tools

The panelists discussed two licensing arrangements that have been used in the biotechnology industry to provide firms with access to research tools: reach-through license agreements and patent pools. They also offered some observations on the merits of exclusive licensing of research tools.

1. Reach-Through License Agreements

Reach-through license agreements (RTLAs) are a form of licensing agreement used by patent owners that hold rights on a biotechnology research tool, or other upstream areas of research, to share in the value of the discoveries by licensees. Typically, RTLAs establish royalty obligations measured as a percentage of sales of the licensee's product. Usually, however, the licensee of the research tool does not need access to the research tool to make or sell its product. Rather, the licensee uses the research tool only to identify and develop the product.[161] By letting eventual market results determine the amount of royalties paid, RTLAs potentially are a means to overcome some of the uncertainties and valuation disputes that may

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[155] *See, e.g.,* Merges & Nelson, 90 COLUM. L. REV. 839; Frederick M. Scherer, *The Economics of Human Gene Patents*, 77 ACADEMIC MEDICINE 1348 (2002). For further discussion of these issues, *see supra* Ch. 2(III).

[156] Walsh et al., *Research Tool* at 331.

[157] *Id.* at 333. The authors cite stem cell technology as an example of a technology to which a patent holder might prefer to restrict access. *Id. See also* Cohen 10/30 at 94-95 (discussing Geron's incentives to limit access to embryonic stem cell technology).

[158] Walsh et al., *Research Tool* at 333.

[159] *Id.* at 290-91, 333 (arguing that "no one firm can even conceive of all the different ways that the discovery might be exploited. . . .").

[160] *Id.* at 324, 334-35.

[161] *See supra* Ch. 3(III)(D)(1)(c).

impede efficient licensing, as discussed *supra* in Chapter 2. [162]

One panelist identified two ways in which reach-through license agreements for research tools can promote competition and innovation. First, they can facilitate access to a wide range of research tools by reducing the up-front licensing costs.[163] This access is particularly important in the context of the biotechnology industry, which includes many small and yet-to-be-profitable firms.[164] Second, RTLAs may facilitate risk-sharing between the tool owner and the licensee.[165] One panelist suggested that RTLAs might place too much risk on the licensor, because the research tool may prove useful in the initial stages of R&D, but the potential product ultimately might fail in the clinical trial phase, thereby denying the tool owner licensing fees.[166] Such risk-allocation issues, however, might be resolved through adjustments to the pricing levels in RTLAs.[167]

Other panelists identified potential ways in which RTLAs might harm competition and innovation, and noted uncertainty surrounding the antitrust analysis of these agreements. One panelist contended that RTLAs present a "severe risk" of creating an anticommons by fostering royalty stacking.[168] Another panelist expressed concern that, by "demanding royalties on the sale of a product that is not covered by their patent," a licensing company could be violating the patent misuse and antitrust laws.[169] This panelist stated that it is unclear how antitrust would weigh the competitive effects of these types of arrangements and suggested that additional guidance by the Agencies may be necessary to provide certainty surrounding the use of RTLAs.[170]

2. Patent Pools

Patent pools involve "patents [from multiple patentees being] licensed in a package, either by one of the patent holders or by a new entity established for this purpose, usually to anyone willing to pay the associated royalties."[171] A biotechnology trade association stated that voluntary patent pools are "one of the important potential solutions to concerns regarding overlapping patents."[172] Indeed, this participant noted approvingly the paper released by the PTO entitled "Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?," which discusses the use of patent pools as a means of fostering access to

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[162] According to one panelist, RTLAs tend to be used "in more unique tool technology" rather than "fungible research tools." *See* Blackburn 2/26 at 315.

[163] *See id.* at 275.

[164] *See* Beier 2/26 at 265; Blackburn 2/26 at 275-76; BIO (stmt) 2.

[165] *See* Blackburn 2/26 at 275.

[166] *See* Oehler 2/26 at 278.

[167] *See* Blackburn 2/26 at 279.

[168] *See* Kirschner 2/26 at 311.

[169] Earp 2/26 at 270.

[170] *See id.* at 272-73, 327-28. For further discussion of RTLAs under the antitrust laws, *see* Second Report (forthcoming).

[171] Shapiro, *Navigating the Patent Thicket* at 127. For antitrust treatment of patent pools, *see* Second Report (forthcoming).

[172] BIO (stmt) 12.

patented research tools.[173]

The OECD, however, has questioned whether industry participants can solve the transaction cost problems that arise in markets for genetic inventions by forming patent pools.[174] It noted that these technologies are fundamentally different from the electronics sector, in which patent pools are used more frequently because of the importance of standards and interoperability.

3. Non-Exclusive Licensing of Patented Research Tools

Two of the panelists observed that owners of patented research tools generally have the incentive to grant non-exclusive, rather than exclusive, licenses. One panelist explained that firms prefer to grant non-exclusive licenses on their research tools, because it is impossible to know in advance whether any particular licensee will succeed in bringing a product to market.[175] He suggested that when the patentee can profit from the exploitation of a research tool, the incentives exist to drive the broad dissemination of the particular tool.[176] He did, however, note that there "are probably examples of tools that maybe are appropriately exclusively licensed" and suggested that the market for potential genomic cancer targets might be such a market.[177]

Another panelist cited an example to demonstrate the potentially adverse implications for a business of exclusive licensing: in a market with two competitors over the provision of genomic database information, one of the companies gave an exclusive license to its database to a large pharmaceutical company. The direct consequence of this exclusive license was to force the other large pharmaceutical companies to seek nonexclusive access to the rival firm's database.[178] This panelist noted that the economics of licensing databases or research tools dictate that companies license on a nonexclusive basis, because it is not possible to build a business

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[173] United States Patent and Trademark Office, *Patent Pools: A Solution to the Problem of Access in Biotechnology Patents?* 3 (2000), *at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

[174] Organisation for Economic Co-operation and Development, *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies* 67 (2002) ("It is true that there is a growing interdependence among patents, that the claims of many patents are narrower, and that patents are held by multiple owners. Licensing transaction costs are burdensome and freedom of operation is restricted, thus increasing the potential for conflict among researchers. However, the pharmaceutical biotechnology industry may be fundamentally different from the electronics sector. It is not an industry in which defining standards is important, and assuring interoperability of technologies is not very important, especially not in the development of therapeutics. A company's worth is tightly tied to its intellectual property and fosters a 'bunker mentality.' There are likely to be disagreements among partners over the value of the different patents in a pool, and dominant players may not have a strong incentive to join the pool. If a limited field of application and essential patents can be defined, the patent pool model is worthy of consideration in biotechnology (Marks et al., 2001). The suitability of the patent pool for biotechnology patents certainly requires further study, as does the role of government in promoting them."), *at* http://www.oecd.org/dataoecd/42/21/2491084.pdf.

[175] *See* Blackburn 2/26 at 264.

[176] *See id.* at 265.

[177] *See id.* at 264 (noting that his company has identified so many potential genomic cancer targets that supply exceeds demand, and licensees can insist on exclusive licenses).

[178] *See* Bendekgey 2/26 at 268-69.

around a single customer.[179]

F. Conclusion

Biotechnology innovation is heavily dependent on the patent rights that have been available for biotechnology inventions since 1980. Patents help firms to recover high, fixed R&D costs and are particularly useful in enabling biotechnology companies, which are generally small in size, to attract capital investment and to contract with other firms for commercial development of their inventions. This capital is critical for ongoing R&D, because product commercialization in the biotechnology industry is particularly time-consuming and expensive. Patent disclosures assist the innovation process by encouraging information dissemination and enabling the publication of discoveries in the scientific literature. Competition also encourages innovation, although panelists typically gave greater stress to the role of patents.

Poor quality biotechnology patents also have the potential to harm innovation by causing companies to avoid the field of inquiry covered by such patents, rather than to seek to invalidate them. Panelists stated that litigation is too expensive and time-consuming for small biotechnology companies. Views varied on whether patent quality in the biotechnology field differed from that in other industries.

Biotechnology, with its heavy investment in basic research and research tools, poses more issues of cumulative innovation than pharmaceutical drugs, for which much of the innovation process was discrete. Biotechnology patents might harm follow-on innovation through the creation of an anticommons and by restricting access to inventions. A few panelists suggested that these problems can be mitigated by mechanisms such as reach-through royalty agreements, cross-licensing, and patent pools. It is also possible that recent uncertainty about the scope of the research exemption may hinder non-commercial research.

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[179] *See id.* at 269.

IV. THE COMPUTER HARDWARE INDUSTRIES, INCLUDING SEMICONDUCTORS

A. Introduction

In the computer hardware industries, panelists reported that firms' attitudes toward the role of competition and patent protection in furthering innovation depends on the nature of the firm. Panelists stressed the importance of competition and trade secrecy as drivers of innovation for integrated design and manufacturing firms and foundries; for specialized design firms, panelists gave greater emphasis to patents. Discussion frequently highlighted the special issues that arise in industries characterized by incremental, cumulative innovation and by products requiring a great many, separately held patents. Commentators, for example, extensively discussed the problems that patent thickets pose for innovation and the licensing arrangements that firms use to maneuver through such thickets to achieve product commercialization. Commentators also expressed concern that patents may deter innovation in the computer hardware industries as a result of hold-up strategies by firms unconstrained by litigation concerns.

The panelists who represented computer hardware firms at the Hearings were Robert Barr representing Cisco Systems, Inc; George B. Brunt representing Alcatel USA; Peter N. Detkin representing Intel Corporation; Stephen P. Fox representing Hewlett-Packard Company; Les Hart representing Harris Corporation; Julie Mar-Spinola representing Atmel Corporation; Daniel McCurdy representing ThinkFire; Joel Poppen representing Micron Technology, Inc; Desi Rhoden representing Advanced Memory International, Inc.; Frederick J. Telecky, Jr. representing Texas Instruments; Richard L. Thurston representing Taiwan Semiconductor Manufacturing Company, Ltd.; Harry Wolin representing Advanced Micro Devices, Inc.; and Gary Zanfagna representing Honeywell International. Two scholars, Bronwyn H. Hall, from the University of California, Berkeley, and Rosemarie Ham Ziedonis, from the University of Pennsylvania, also participated in business perspective panels on the computer hardware industry.

B. Industry Description

In general terms, the computer hardware industries produce the physical components for computers, telecommunications, and other information technology devices, such as the computer itself, monitors, servers, routers, and scanners.[180] The semiconductor industry produces one particular type of hardware: the integrated circuits and discrete devices that process binary data through the control of electrical signals. Integrated circuits are more commonly referred to as 'chips' or 'processors.'

The panelists discussed various types of firms that drive innovation in these industries: specialized design firms, integrated firms, and semiconductor foundries.[181] Both specialized design firms and integrated firms engage in R&D, but

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[180] "Hardware" is a general term that distinguishes the physical aspects of computers and related devices from "software," which is the intangible aspect that controls hardware through programs.

[181] *See* Ziedonis 3/20 at 11, 16.

they differ in terms of the ownership of manufacturing facilities. Specialized design firms, which emerged in the 1980s,[182] contract with semiconductor foundries[183] to have their products manufactured; integrated firms own their manufacturing facilities.[184] One panelist observed that the emergence of independent semiconductor foundries (or "contract manufacturers") "enabled the creation and proliferation of a new generation of semiconductor companies - the fabless semiconductor company."[185] Panelists reported that manufacturing facilities cost at least two billion dollars to construct, and the construction of the most advanced facilities can cost in excess of four billion dollars. They also stated that more advanced manufacturing facilities can become obsolete in less than five years, and that less advanced facilities become obsolete even more quickly.[186]

C. The Role of Competition in Spurring Computer Hardware Innovation

Panelists representing integrated firms, foundries, and hardware companies observed that competition drives innovation.[187] Similarly, the business survey of Cohen, Nelson, and Walsh shows that obtaining lead-time over rivals, which is a function of the competitive process, is one of the two key mechanisms for ensuring appropriability of returns on R&D investments in the semiconductor industry. The other mechanism is trade secret protection.[188]

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[182] *See* Jeffrey T. Macher et al., *Semiconductors, in* U.S. INDUSTRY IN 2000: STUDIES IN COMPETITIVE PERFORMANCE 247 (1999), *at* http://www.nap.edu/books/0309061792/html/245.html. Hall and Ziedonis, in their business survey of the effects of strengthening patent rights on firms in the semiconductor industry, attribute the emergence of specialized design firms to the strengthening of patent rights in the 1980s. Bronwyn H. Hall & Rosemarie Ham Ziedonis, *The Patent Paradox Revisited: An Empirical Study of Patenting in the U.S. Semiconductor Industry, 1979-1995*, 32 RAND J. ECON. 101,104 (2001) and Box 3-6. A similar version of this study is available in draft under the name *The Effects of Strengthening Patent Rights on Firms Engaged in Cumulative Innovation: Insights from the Semiconductor Industry*, June 2001, *at* http://emlab.berkeley.edu/users/bhhall/papers/HallZiedonis01%20libecap.pdf.

[183] Foundries are referred to as wafer fabrication facilities, or "fabs" for short, in the semiconductor industry.

[184] *See* Ziedonis 3/20 at 17.

[185] Richard L. Thurston, *Opening Statement of Dr. Richard L. Thurston, Vice President and General Counsel, Taiwan Semiconductor Manufacturing Company* (3/20/02) 3, *at* http://www.ftc.gov/opp/intellect/020320richardthurstonstatement.pdf (hereinafter Thurston (stmt)); *see also* Thurston 3/20 at 10 (noting that Taiwan Semiconductor Manufacturing Company has contracted with over 175 fabless companies).

[186] *See* Poppen 2/28 at 683; Thurston 3/20 at 29; Ziedonis 3/20 at 16, 83; Hall & Ziedonis, 32 RAND J. ECON. at 110.

[187] *See* Detkin 2/28 at 751 (stating that "the clear driving force behind innovation is competition"); Poppen 2/28 at 750; Fox 2/28 at 757; Barr 2/28 at 674-77; Brunt 3/20 at 91; Thurston (stmt) 9. For discussion of the changing nature of competition in the semiconductor industry, *see* Peter C. Grindley & David J. Teece, *Managing Intellectual Capital: Licensing and Cross-Licensing in Semiconductors and Electronics*, 39 CAL. MGMT. REV. 8, 27-29 (1997).

[188] *See* W. M. COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS: APPROPRIABILITY CONDITIONS AND WHY U.S. MANUFACTURING FIRMS PATENT (OR NOT) (National Bureau of Econ. Research Working Paper No. 7552, 2000), *at* http://papersdev.nber.org/papers/w7552 (hereinafter COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS); Rosemarie Ziedonis, *The Role of Patents in Semiconductors: Insights from Two Recent Studies* (3/20/02) (slides) at 2, *at* http://www.ftc.gov/opp/intellect/020320rosemarieziedonis.pdf. Trade secrecy is discussed below. Patents were considered relatively unimportant for securing returns to innovation in the hardware industry.

The representative of one hardware company stated that between 1984 and 1993, the first 10 years of the company's existence, it filed only one patent, which issued in 1992.[189] Yet by 1994, "the company had grown to over a billion dollars in annual revenue. This growth was obviously not fueled by patents, it was fueled by competition and by open, nonproprietary interfaces."[190] Another panelist stated that "competition is what drives . . . innovation; patents have almost nothing to do with innovation."[191] Similarly, a third panelist noted that "innovation is driven by competition in all of our markets."[192]

D. Alternative Means of Fostering Innovation

The panelists representing integrated firms and foundries identified trade secrecy as an important mechanism for protecting a company's investment in innovation.[193] Some panelists expressed the view that trade secret protection is a supplement to patent protection in the sense that the two are used in different factual contexts, rather than as substitutes to be used in the same contexts.[194] One panelist suggested, for example, that trade secrecy is useful in the early stages of innovation.[195]

Other panelists discussed how they choose between the use of trade secret protection and patents as means to protect their inventions. They stated that firms consider whether they could detect patent infringement.[196] Disclosure of an invention due to patent requirements may simply enable rival firms to copy the invention without the patentee being able to detect and sue for patent infringement.[197] Because manufacturing processes cannot easily be observed by rivals, trade secrecy is particularly important for foundries and the manufacturing facilities of integrated firms.[198] Panelists observed that holders of trade secrets risk losing access to their technologies, however. Should a rival company obtain a patent on an invention for which a company had used trade secret protection, the patentee could successfully sue the company that used trade secret protection for patent infringement, despite its having discovered the invention earlier.[199]

One panelist noted that reliance on trade secrecy could harm competition and innovation by stifling the flow of

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[189] This panelist represented Cisco Systems.

[190] Barr 2/28 at 673-74.

[191] Rhoden 2/28 at 754.

[192] Zanfagna 3/20 at 90.

[193] *See* Thurston 3/20 at 29-30, 47-8; Wolin 3/20 at 51; Ziedonis 3/20 at 52; McCurdy 3/20 at 53; Brunt 3/20 at 26, 46-47; Detkin 2/28 at 666; Barr 2/28 at 756 and 10/30 at 79-80.

[194] *See* Ziedonis 3/20 at 52; McCurdy 3/20 at 53; Brunt 3/20 at 47.

[195] *See* Brunt 3/20 at 47.

[196] *See, e.g.*, McCurdy 3/20 at 49-50, 53; Thurston 3/20 at 30, 47-48; Detkin 2/28 at 665.

[197] *See* McCurdy 3/20 at 49-50.

[198] *See* Thurston 3/20 at 30, 47-48.

[199] *See id.* at 47; McCurdy 3/20 at 49; MERGES & DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS at 463 (explaining that trade secrets do not serve as prior art).

information to the public domain.[200] Another panelist, however, questioned whether patents yield significantly better results, asserting that the disclosure of information through patents is seldom sufficient for a rival to replicate the innovation.[201] That panelist viewed the frequent inclusion of trade secret information in modern patent licenses to facilitate the licensee's harnessing of the technology as evidence of the uninformative nature of patent disclosures.[202]

E. The Implications of Patent Protection for Innovation

The panelists differed on how patents affect innovation; differences depended on whether patents fulfilled offensive or defensive purposes.[203] Although the terms do not have a precise definition, "offensive patenting" generally means obtaining patents to appropriate returns in R&D; it can require the patent to be enforced through litigation.[204] In this sense, the term is synonymous with the traditional economic justification for the patent system. "Defensive patenting" is primarily motivated by a desire to ensure freedom to operate and includes the use of patents as bargaining chips in cross-licensing negotiations.[205] It thereby reflects the strategy identified by economic analysts of using the prospect of mutually assured destruction to achieve detente, as discussed *supra* in Chapter 2.

1. The Role of Patents in Spurring Innovation

A number of representatives of integrated firms, foundries, and hardware companies testified that patents are necessary for innovation, and thus they obtain patents for offensive reasons.[206] One panelist stated, for example, that the prevention of free riding is their primary motivation for obtaining patents; three other reasons are to negotiate cross-licenses, to obtain freedom to operate, and to generate revenue through licensing.[207] Another panelist contended that, although patents are necessary to prevent free riding, the number of patents in the semiconductor industry far exceeds any requirement for that purpose.[208] He pointed to the pharmaceutical industry as an example of one in which only a few patents cover each product, yet he considered free riding to be successfully

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[200] *See* Brunt 3/20 at 46.

[201] *See* McCurdy 3/20 at 53; *see also* Barr 2/28 at 755-56 ("it's been my experience in my practice, not just with Cisco, that I've actually never met an engineer that learned anything from a patent"). *But see* Telecky 2/28 at 754 (finding patent disclosures "a source of ideas").

[202] *See* McCurdy 3/20 at 38, 53.

[203] *See e.g.* Detkin 2/28 at 751.

[204] *See* Teece 2/27 at 507; David J. Teece, *IP, Competition Policy, and Enforcement Issues* (2/27/02) (slides) at 8, *at* http://www.ftc.gov/opp/intellect/020227davidjteece.pdf.

[205] Cross-licensing is discussed below in the context of patent thickets. Obtaining freedom to operate and patent mining are discussed below in the context of hold-up.

[206] *See* Thurston (stmt) 5; Fox 2/28 at 753; Barr 2/28 at 678, 755; Brunt 3/20 at 23-24.

[207] *See* Fox 2/28 at 753.

[208] *See* Barr 2/28 at 678 (stating that, in an ideal world, to prevent copying in the semiconductor industry "we'd need probably one or two or three for each product on the key features, and that's what I think you'll find in [the pharmaceutical and medical devices] industries.").

prevented.[209]

Specialized design firms typically obtain patents for offensive purposes. According to Professor Ziedonis, patents are critical business assets for design firms, and are used in a manner consistent with how the patent system was intended to operate.[210] Such firms seek "very strong, solid patent protection" for two reasons: to raise venture capital and to stake out proprietary positions primarily against other niche market rivals, but also against integrated firms.[211]

Professor Ziedonis noted two differences about the patenting behavior of specialized design firms when compared to that of integrated firms, foundries, and hardware companies. First, the rate at which specialized design firms are enforcing their patent rights is high. Four out of every hundred patents issued to specialized design firms are enforced through a court action, which is a "very, very high number relative to other industries and within the semiconductor industry."[212] Second, as the revenue of specialized design firms increases and the companies mature, attitudes toward patenting shift, so that such firms begin to patent more defensively and to increase their patent portfolio size, she noted.[213]

[209] *See* Barr 2/28 at 678.

[210] *See* Ziedonis 3/20 at 19.

[211] *Id.* at 17-18.

[212] *Id.* at 18 (observing, however, that specialized biotechnology firms exhibit a similar high rate of patent enforcement).

[213] *See id.*

2. The Potential for Patents to Impede Innovation

a. Patent Thickets in the Computer Hardware Industries

None of the panelists disputed the existence of densely overlapping patent rights (*i.e.*, a patent thicket) in the computer hardware industries. One panelist stated that more than "90,000 patents generally related to microprocessors are held by more than 10,000 parties."[214] Likewise, he reported, there are approximately 420,000 semiconductor and systems patents held by more than 40,000 parties.[215] This panelist observed that the number of patents on semiconductor-related inventions has increased to the point where there is an "unavoidable overlap" of intellectual property.[216]

Panelists discussed three reasons for the emergence of patent thickets in the computer hardware industries: (1) incremental innovation due to the nature of

[214] Detkin 2/28 at 667-68 and Peter N. Detkin, *A Semiconductor Patent Survey* (2/28/02) (slides) at 5, *at* http://www.ftc.gov/opp/intellect/020228peterndetkin.pdf (hereinafter Detkin Presentation).

[215] Detkin 2/28 at 667-68 and Detkin Presentation at 5.

[216] Detkin 2/28 at 668 ("there's an unavoidable overlap of IP. . . people are tripping over each other's patents right and left"); *see also* Barr 2/28 at 677; Macher et al., *Semiconductors* at 281. Commentators have described the computer hardware industries as prime examples of "complex product industries," in which relatively numerous patents protect individual commercializable products. *See, e.g.*, Cohen 2/20 at 30.

Box 3-6. ***The Patent Paradox Revisited: An Empirical Study of Patenting in the US Semiconductor Industry, 1979-1995***
Bronwyn H. Hall and Rosemarie Ham Ziedonis, RAND Journal of Economics, Vol. 32, No. 1, Spring 2001, pp 101-128.

Bronwyn H. Hall and Rosemarie Ham Ziedonis conducted an empirical study of patenting practices in the semiconductor industry in order to explain a paradox in the economic literature: the patenting rate per R&D dollar doubled in the semiconductor industry since the mid-1980s, while other economic studies indicated that industry participants did not regard patents as an important means for recouping investments in innovation.

The study was based on a combination of qualitative and quantitative research methods. The qualitative analysis involved the authors conducting interviews with intellectual property managers and executives from several U.S. semiconductor firms. The quantitative analysis involved the authors compiling a database of the patent portfolios of 100 publicly traded U.S. semiconductor firms whose R&D expenditures were primarily focused on semiconductor-related areas from 1975 to 1998. They matched these data with financial and other variables to formulate estimates of the patent propensities of individual firms during the period of the study.

The authors concluded that the significant increase in patenting per R&D dollar was attributable to the strengthening of patent rights in the United States, which spurred "patent portfolio races" among capital-intensive firms. Firms were engaged in these races to reduce concerns about "being held up by external patent owners and at negotiating access to external technologies on more favorable terms."

the underlying technology; (2) the rise of defensive patenting; and (3) the ease of obtaining patents at the PTO.

(i). Incremental Innovation and the Nature of Hardware and Semiconductor Technology

Four industry representatives testified that the technology developed by the hardware and semiconductor industries is susceptible to the creation of patent thickets, because hardware and semiconductors contain an incredibly large number of incremental innovations.[217] The complex nature of computer hardware technology is one factor that contributes to the existence of a technology thicket over which a patent thicket has developed.[218]

(ii). The Rise of Defensive Patenting

As discussed above, firms in the computer hardware industries have been obtaining patents at rapidly increasing rates largely for defensive purposes. The likelihood of firms holding overlapping intellectual property increases as more patents issue over semiconductor and hardware innovations. In this way, the problem is self-perpetuating. As one panelist acknowledged, "the only practical response to this problem of unintentional and sometimes unavoidable patent infringement is to file hundreds of patents each year ourselves."[219]

In their research, Professors Hall and

[217] *See* Detkin 2/28 at 669-70, 710-11; Poppen 2/28 at 684, 712; Barr 2/28 at 713-14; Fox 2/28 at 714. Their testimony offered confirmation of similar observations by academic panelists. *See, e.g.*, R. Levin (stmt); Lemley 2/25 at 37 (noting the cumulative nature of semiconductor innovation).

[218] *See* Teece 2/27 at 500.

[219] Barr 2/28 at 677; *see also* Hart 4/9 at 42-42.

Ziedonis identified a "pro-patent" shift in the US legal environment in the 1980s as the stimulus for the rise of defensive patenting.[220] The authors believe that this shift resulted from a series of congressional reforms in the early 1980s, including the creation of the Court of Appeals for the Federal Circuit, which "put in place a number of procedural and substantive rules that collectively strengthened the rights of US patent owners."[221]

Professors Hall and Ziedonis also identified two events that arose out of the "pro-patent" shift and signaled the importance of the new patent regime to firms in the semiconductor industry. First, Polaroid's successful patent infringement suits against Kodak resulted in Polaroid being "awarded almost $1 billion in damages and Kodak . . . [being] barred from competing in the instant-film camera business."[222] This case created a fear among firms that owned manufacturing facilities that the "courts were willing to take an aggressive stance against infringement by halting – either temporarily or permanently – production utilizing infringed technologies."[223] Second, the revenue obtained by Texas Instruments from mining its patents – that is, seeking patent royalties from firms that operate outside the range of Texas Instruments' business – prompted other firms also to commence patent mining programs.[224]

(iii). Ease of Obtaining Patents

Professor Ziedonis contended that the ease of obtaining patents at the PTO, although not the sole cause of the thicket, is a contributing factor.[225] She cited interviews conducted with participants in the semiconductor industry in which the participants stated that the standard for obviousness should be increased so as to prevent "very trivial inventions" being patented by the PTO.[226]

b. The Potential for Patent Thickets to Harm Innovation

The panelists discussed several ways in which patent thickets can harm innovation.[227] First, the need of integrated firms and hardware companies to develop extensive patent portfolios for defensive purposes diverts funding from R&D into the obtaining of patents. As one panelist

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[220] Hall & Ziedonis, 32 RAND J. ECON. at 105.

[221] Hall & Ziedonis, *The Effects of Strengthening Patent Rights on Firms Engaged in Cumulative Innovation: Insights from the Semiconductor Industry* at 12.

[222] Hall & Ziedonis, 32 RAND J. ECON. at 109.

[223] *Id.* A number of panelists discussed the threat of an injunction. *See, e.g.*, Poppen 2/28 at 686, 691, 725; Detkin 2/28 at 722-23; Barr 2/28 at 723.

[224] Hall & Ziedonis, 32 RAND J. ECON. at 109. Panelists reported that some companies have sought to license their patents to companies that operate outside the market of the patent holder, because a higher royalty can be extracted due to an imbalance in bargaining positions. *See* Brunt 3/20 at 25; Poppen 2/28 at 684; Thurston 3/20 at 34. In this situation, one panelist contended, the management of a company treats patents as an asset that must generate a return, instead of as a means to exclude parties from a particular invention. *See* Wolin 3/20 at 81. *See also infra* Ch. 3(IV)(E)(2)(c)(i).

[225] *See* Ziedonis 3/20 at 15-16.

[226] *Id.*

[227] Another potential harm, resulting from the strategic use of patents in licensing negotiations, is addressed in the next section.

observed, "the time and money we spend on patent filings, prosecution, maintenance, litigation and licensing could . . . be much better spent on product development and research leading to more innovation."[228]

Patent thickets can reduce follow-on innovation by requiring an innovator to seek licenses from multiple patentees.[229] In these industries, one panelist reported, "hundreds, thousands of patents cover a single product."[230] As discussed *supra* in Chapter 2, the transaction costs and potential for royalty stacking involved in obtaining multiple licenses from numerous patent holders may pose obstacles to the development of follow-on technologies.[231]

Patent thickets also can harm innovation by creating uncertainty, which affects investment decisions. One panelist stated that the proliferation of patents and patent-related litigation has created "pervasive uncertainty about legal rights . . . [that] heightens risks surrounding innovation investment decisions . . . [and] is without doubt a serious drag on the technological and scientific progress that the patent system was designed to promote."[232]

[228] Barr 2/28 at 677-78. Similarly, another panelist contended that "patents are assets that suck money out of the system." Brunt 3/20 at 25.

[229] *See* Shapiro, *Navigating the Patent Thicket* at 120-121.

[230] Poppen 2/28 at 684.

[231] *See* Detkin 2/28 at 764 (noting the presence of "half a million patents owned by 40,000 parties . . . and we have to worry about how we're going to negotiate with them"); Poppen 2/28 at 690 (raising royalty stacking concerns).

[232] Fox 2/28 at 696; *see also* Barr 2/28 at 675-76.

c. *The Strategic Use of Patents in Licensing Negotiations*

Panelists discussed the strategic use of patents in licensing negotiations, and in particular one type of strategic use, generally known as "hold-up."[233] They discussed hold-up as enabled by sunk costs that a firm already has invested in product development or manufacturing, before learning of the patent, which in turn enable the patentee to demand royalties higher than it could have sought before the firm sunk its costs; with so very many patents at issue, panelists suggested, infringing *someone's* patent may be inevitable, but there may be no economically feasible way, prior to making sunk investments, to identify and obtain rights to all the relevant patented technologies.[234] Some commentators argue that hold-up in this sense harms competition and innovation.[235] Others suggest that such behavior constitutes a legitimate exercise of a patentee's right to exclude.[236]

[233] For discussion of hold-up for antitrust enforcement purposes, *see* Timothy J. Muris, *The FTC and the Law of Monopolization*, 67 ANTITRUST L.J. 693, 704 (2000); Benjamin Klein, *Market Power in Franchise Cases in the Wake of Kodak: Applying Post-Contract Hold-Up Analysis to Vertical Relationships*, 67 ANTITRUST L.J. 283 (1999).

[234] *See, e.g.*, Barr 2/28 at 677; Detkin 2/28 at 764.

[235] *See* Shapiro, *Navigating the Patent Thicket* at 124-26; *see also supra* Ch. 2(III)(C)(2) and *infra* Ch. 3(IV)(E)(2)(c)(iii).

[236] *See generally* Frederick J. Telecky, *Statement of Frederick J. Telecky, Jr., Senior Vice President and General Patent Counsel, Texas Instruments: FTC/DOJ Hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy"* (2/28/02) 5 ("refusal to license is at the heart of the patent system"), at http://www.ftc.gov/opp/intellect/020228telecky.pdf (hereinafter Telecky (stmt)).

In their business survey, Professors Hall and Ziedonis concluded that semiconductor firms with large sunk costs in complex manufacturing facilities started to patent defensively in the 1980s to reduce, among other things, "concerns about being held up by external patent owners."[237] These concerns stemmed in part from Polaroid's successful patent infringement suit against Kodak.[238] One industry participant interviewed by Professors Ziedonis and Hall stated, "a preliminary injunction would be detrimental to a firm if it means shutting down a high-volume manufacturing facility; loss of one week's production alone can cost millions of dollars."[239] Firms in the computer hardware industries responded to the possibility of having their production enjoined by accumulating large patent portfolios. If a rival company sought to employ a hold-up strategy against them, they would draw on their portfolio to assert patent infringement counterclaims against that rival, resulting in what panelists described as "mutually assured destruction" or "MAD."[240]

(i). The Rise of Non-Practicing Entities

The potential for hold-up to result in mutually assured destruction means firms actively participating in the industry – patent practicing entities (PPEs) – are unlikely to employ this strategy against each other.[241] Panelists, however, identified firms referred to as non-practicing entities (NPEs) that can successfully employ a hold-up strategy without fear of retaliation.[242] NPEs obtain and enforce patents against other firms, but either have no product or do not create or sell a product that is vulnerable to infringement countersuit by the company against which the patent is being enforced. As discussed *supra* in Chapter 2, MAD strategies to mitigate hold-up will not work against NPEs, who are not susceptible to the threat of a countersuit shutting down their production.[243] In contrast, NPEs can threaten PPEs with patent infringement and an injunction, which, if granted, could inflict substantial losses.[244]

Panelists identified three types of NPEs in the computer hardware industry: (1) non-practicing design firms, which patent their inventions but do not make or sell patented products to consumers; (2)

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[237] Hall & Ziedonis, 32 RAND J. ECON. at 104; *see also* Box 3-6; Rosemarie Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* 4 (July 2002) *in draft at* http://www.isnie.org/ISNIE02/Papers02/ziedonis.pdf.

[238] *See* Hall & Ziedonis, 32 RAND J. ECON. at 109.

[239] *Id.*; *see generally* John R. Boyce & Aidan Hollis, *Innovation, Imitation & Preliminary Injunctions in Patents* (Public Comment), at http://www.ftc.gov/os/comments/intelpropertycomments/0205xxhollis.pdf.

[240] *See* Hall 2/28 at 662; Detkin 2/28 at 669; Poppen 2/28 at 684-85; Barr 2/28 at 713; *see also* Hall & Ziedonis, 32 RAND J. ECON. at 109.

[241] *See* Poppen 2/28 at 684-86.

[242] *See* Rhoden 2/28 at 723-24; Carl Shapiro, *Technology Cross-Licensing Practices: FTC v. Intel (1999), in* 4 THE ANTITRUST REVOLUTION: ECONOMICS, COMPETITION AND POLICY 350, 356 (John E Kwoka, Jr. & Lawrence J. White eds. 2004).

[243] *See* Poppen 2/28 at 685-89; Detkin 2/28 at 671-72.

[244] *See* Poppen 2/28 at 685-89; Detkin 2/28 at 671-72; Hall & Ziedonis, 32 RAND J. ECON. at 109. For additional discussion of issues raised by NPE conduct, *see supra* Ch. 2(III)(C)(2) and Second Report (forthcoming).

"professional" patent assertion companies that buy patents from other companies, particularly those that are bankrupt, and then assert them against practicing entities; and (3) "patent miners," which are companies that assert their patent portfolios against firms outside of their business.[245]

Professor Ziedonis noted that the number of cases filed by NPEs has increased since the mid-1980s, and that the sale of patents by failing companies has increased since the 1990s.[246] One third of the patent lawsuits filed by a group of 136 companies, for example, involved patents not invented by the company.[247] Two panelists confirmed that an increasing number of companies are seeking to buy and sell the patent portfolios of failing companies to assert against other firms.[248] In their business analysis of licensing practices in the semiconductor and electronics industry, Professors Grindley and Teece observe that "occasionally, firms can purchase a portfolio of patents with which to establish cross-licensing relationships; but quality patents often are not available in this fashion."[249]

(ii). Hold-Up and Patent Thickets

In industries such as the computer hardware industries, where innovation is cumulative, panelists noted that hold-up is more likely to occur, because the presence of a patent thicket makes patent infringement very difficult to avoid.[250] As Professor Shapiro observed, participants in the semiconductor industry receive "thousands of patents . . . each year and manufacturers can potentially infringe on hundreds of patents with a single product."[251] Another panelist stated that "the large number of

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[245] *See* Poppen 2/28 at 685-88; Detkin 2/28 at 672.

The panelists discussed two reasons for the emergence of "patent mining" by companies. First, the need to patent defensively has forced many firms to develop extensive patent portfolios, at considerable cost. One business representative stated that it costs about $200,000 to maintain a patent worldwide over a period of 20 years. *See* Brunt 3/20 at 25. Panelists reported that some companies have sought to offset these costs by seeking to license their patents to other companies, particularly companies that operate outside the market of the patent holder, because a higher royalty can be extracted due to an imbalance in bargaining positions. *See id.*; Poppen 2/28 at 684; Thurston 3/20 at 34.

Second, panelists contended that business attitudes towards patents have changed since the 1980s. The management of some companies, some asserted, have begun to treat patents as an asset that must generate a return, instead of as a means to exclude parties from a particular invention. *See* Wolin 3/20 at 81. Panelists cited two examples to support this change in attitude. First, a number of panelists mentioned Texas Instruments, which successfully instigated a patent mining program in the late 1980s to save the company from bankruptcy, and thereby became an example to other companies of how to mine their patents. *See* Thurston 3/20 at 28-29; Wolin 3/20 at 81; Ziedonis 3/20 at 83; Telecky 2/28 at 653; Macher et al., *Semiconductors* at 281; Grindley & Teece, 39 CAL. MGMT. REV. at 20. Second, a widely read book in business circles entitled *Rembrandts in the Attic* encourages managers to generate revenue from their patents by mining them. *See* Hughes 2/28 at 614; KEVIN G. RIVETTE & DAVID KLINE, REMBRANDTS IN THE ATTIC: UNLOCKING THE HIDDEN VALUE OF PATENTS (Harvard Business School Press 1999).

[246] *See* Ziedonis 3/20 at 71, 73-74.

[247] *See* Ziedonis 3/20 at 73-74.

[248] *See* Thurston 3/20 at 75; Wolin 3/20 at 76.

[249] Grindley and Teece, 39 CAL. MGMT. REV. at 31; *see also* Shapiro 11/6 at 176 (observing that "I've even seen a situation where a portfolio was split up and some patents split off to a third party who had no other commercial interests, so they could assert it most aggressively against other industry players.").

[250] *See* Barr 2/28 at 676; Hall & Ziedonis, 32 RAND J. ECON. at 110.

[251] *See* Shapiro, *Navigating the Patent Thicket* at 125.

issued patents in our field makes it virtually impossible to search all potentially relevant patents, review the claims, and evaluate the possibility of an infringement claim or the need for a license."[252] This problem of unavoidable patent infringement is heightened, commentators stated, by the risk of patent applications still pending and unpublished by the PTO after a company has sunk significant costs in a new product.[253]

Commentators have also observed that companies seeking to hold up rivals can set the licensing fees below the cost of litigation, including the managerial distraction, so as to make the taking of a license the only economically sensible alternative, regardless of the strength of the patent.[254] Professor Shapiro contends that the lack of effective mechanisms to challenge questionable patents, the presumption of validity, and "a patent office that is generous to patent applicants" also facilitate the use of hold-up strategies by NPEs.[255] Several panelists asserted that companies can use a continuation on their own patent application deliberately to delay patent issuance by the PTO.[256] This enables such companies, one panelist asserted, to tailor their patent claims to cover a rival's product using insights gained from reverse-engineering that product.[257]

(iii). The Potential for Hold-Up to Harm Consumers

Commentators identified four ways that hold-up can harm competition and innovation. First, obtaining a license after costs have been sunk will result in a higher royalty to the NPE than if a license were negotiated prior to the sinking of costs.[258] One reason for this higher royalty is that PPEs obtaining a license under threat of hold-up typically do not have the option of designing around the patent the NPE asserted, because redesigning a product after significant costs have been sunk is usually not economically viable.[259] According to Professor Shapiro, the higher royalty paid by companies subject to a hold-up strategy may result in higher prices to consumers, inefficiently low use of the affected

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[252] Robert Barr, *Statement* (2/28/02) 1, *at* http://www.ftc.gov/opp/intellect/barrrobert.doc (hereinafter Barr (stmt)).

[253] *See* Barr 2/28 at 676; Shapiro, *Navigating the Patent Thicket* at 125-26. *See supra* Ch. 2(III)(C) and *infra* Chs. 4(II)(C)(1) and 5(II)(C)(4).

[254] *See* Ziedonis 3/20 at 71-72; Barr 2/28 at 680 and (stmt) 2; Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. L.REV. 1495, 1517 (2001) (noting that "patent owners might try to game the system by seeking to license even clearly bad patents for royalty payments small enough that licensees decide that it is not worth going to court").

[255] Shapiro, *Technology Cross-Licensing Practices: FTC v. Intel (1999)* at 355.

[256] *See* Poppen 2/28 at 687-88; McCurdy 3/20 at 37; Mar-Spinola 2/28 at 715-16; Barr 10/30 at 146-47; *see also infra* Ch. 4(II)(C)(1).

[257] *See* Poppen 2/28 at 688.

[258] *See* Shapiro, *Navigating the Patent Thicket* at 125.

[259] *See* Shapiro, *Navigating the Patent Thicket* at 125; Barr (stmt) 2-3; Rosemarie Ziedonis, *When the Giants' Shoulders are Crowded: Fragmented Rights and Patent Strategies in Semiconductors* at 8. Just as an NPE may wish to set the royalty fee it seeks at just below what it would cost the "held up" firm to litigate the validity or infringement of the NPE's patent, so an NPE may wish to set its requested royalty fee at just below what it would cost the firm to redesign around the patent.

products, and deadweight loss.[260] The cumulative effect of many such licenses may exacerbate these effects.[261] Second, innovation may suffer because some companies will "refrain from introducing certain products for fear of hold-up."[262]

Third, by seeking royalties below the cost of challenging a patent's validity, NPEs can obtain royalties on improperly granted patents. Royalties on improperly granted patents cause an inefficient allocation of society's resources and a transfer that "encourages patenting and discourages competition to a greater extent than is socially optimal."[263] One panelist observed that NPEs can use this same strategy to induce PPEs to obtain licenses for patents that are likely not infringed by the PPE's product.[264] Finally, a number of panelists representing manufacturing firms contended that hold-up causes a wealth transfer from firms engaged in innovation that results in benefits to firms that are simply exploiting the patent system without benefitting consumers.[265] One panelist, however, responded that "we're not sure that in every instance where there's a patentee with no product, that they haven't legitimately contributed something to the fund of human knowledge."[266]

F. Tools to Navigate the Patent Thicket

The panelists discussed three licensing strategies that firms can use to navigate patent thickets: (1) cross-licensing; (2) patent pooling; and (3) standard setting. The panelists generally agreed that each strategy, despite involving certain transaction costs, has been effective in clearing the patent thicket.[267]

1. Cross-Licensing

Cross-licensing is one of the mechanisms used by integrated firms and hardware companies in particular to obtain design freedom when a patent thicket exists.[268] The main variables are: (1) the number of patents at issue; and (2) the use of balancing payments (*i.e.*, monetary payments to even out the value of the portfolios being cross-licensed).[269] The

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[260] *See* Shapiro, *Navigating the Patent Thicket* at 125; Poppen 2/28 at 690.

[261] *See* Shapiro, *Navigating the Patent Thicket* at 126.

[262] *Id.*; *see also* Grindley & Teece, 39 CAL. MGMT. REV. at 20.

[263] Lemley, 95 NW. L. REV. at 1517.

[264] Barr (stmt) 2-3.

[265] *See* Poppen 2/28 at 689-90; Barr 2/28 at 679 and (stmt) 1-3 (the exploitation of the patent system as a revenue-generating tool in its own right has hindered true innovation and outweighed the benefits); Detkin 2/28 at 673 and 728-30. Another concern expressed was that hold-up may force innovative firms to move their manufacturing and sales operations offshore to minimize their exposure to such strategies.

[266] Telecky 2/28 at 703.

[267] *See* Grindley & Teece, 39 CAL. MGMT. REV. at 16; Detkin 2/28 at 711 (stating that hold-up is the problem, not thickets).

[268] *See* McCurdy 3/20 at 67 (noting the greater prevalence of cross-licensing in semiconductors and information technology industries than in pharmaceuticals). For a discussion of the antitrust treatment of cross-licensing, *see* Second Report (forthcoming). For an historical overview of licensing practices at Texas Instruments, *see* E. Thompson 11/6 at 9-11.

[269] *See* McCurdy 3/20 at 67-69.

number of patents that are cross-licensed can vary from two to a complete patent portfolio, which might include thousands of patents. Balancing payments are often negotiated by the parties and are used to address a relative imbalance in patent portfolio size or quality.[270]

One panelist outlined three factors his company considers when deciding whether to license: (1) potential patent infringement claims the prospective licensee might have against his company; (2) potential patent infringement claims his company has against the prospective licensee; and (3) the relative interest of the parties in reaching a cross-licensing arrangement.[271] According to another panelist, integrated firms and hardware companies usually settle cross-licensing negotiations without filing lawsuits.[272]

2. Patent Pools

The centralized management that patent pools entail may help in avoiding the royalty stacking/complements problems that economists have suggested may develop when multiple patents are needed for follow-on activities, and each patentee independently determines its own royalty rates.[273] One panelist stated that "patent pools have become critically important mechanisms for enabling widespread use of new technologies that require access to a multitude of patents dispersed among a multitude of parties."[274]

That panelist expressed two concerns, however, about the use of patent pools. First, he stated that some patent holders with critical patents avoid *ex ante* negotiations by asserting that the antitrust laws prevent them from negotiating royalties prior to selection of the specific patents in the pool.[275] He argued that the negotiation of the royalty in advance of the selection of specific patents in the pool was preferable.[276] Second, he contended that applicants should be able to choose which patents they license from a patent pool, rather than be forced to take a license for the totality of patents, which is the most commonly used approach.[277]

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[270] *See id.* at 69, 72.

[271] *See* Detkin 2/28 at 669-70 (stating that Intel considers three things when deciding whether to license: "What have they got on us, what do we have on them, and who cares?").

[272] *See* McCurdy 3/20 at 69. For a discussion of some of the antitrust issues raised by cross-licensing, *see* Second Report (forthcoming).

[273] *See* Barr 2/28 at 733 (finding patent pools useful for consolidating administration and limiting royalty stacking problems). *See generally supra* Ch. 2(III)(C)(3) (discussing royalty stacking and Cournot's complements problem).

[274] Fox 2/28 at 700.

[275] *See id.* at 732; *see also* Second Report (forthcoming).

[276] *See* Fox 2/28 at 737, 732 (suggesting that lower royalties or better terms might be negotiated in return for accepting the patent into the pool). For analysis of analogous issues raised by *ex ante* negotiations involving standard-setting bodies, *see* Second Report (forthcoming).

[277] *See* Fox 2/28 at 699. For analysis of the relevant antitrust considerations, *see* Second Report (forthcoming).

3. Standard-Setting

By establishing rules governing access to the intellectual property embodied in their standards, standard-settings organizations (SSOs) can clear patent thickets that otherwise might stand in the way of follow-on innovation. Professor Lemley, who recently conducted a study of SSOs, found them most active "in industries in which it looks like patent hold-up is the biggest problem [such as] in computers, in semiconductors . . . [but not in] pharmaceuticals, in biotechnology, and so forth."[278] Without a way to "clear[]" intellectual property rights held by "dozens or hundreds of different parties," he warned, "nobody's going to be able to make a product that works with a particular technical standard."[279] Professor Lemley found that 17 of the 21 SSOs studied in fact required "some form of licensing . . . [m]ost commonly . . . on 'reasonable and non-discriminatory terms.'"[280]

G. Conclusion

Panelists in the hardware and semiconductor industries emphasized competition as a driver of innovation. Trade secret protection also contributes to innovation in these industries. Testimony regarding the role of patents was mixed. The record generally corresponded with the results obtained by Professors Cohen, Nelson, and Walsh in their business survey of appropriability mechanisms for firms in the United States: the semiconductor industry was among the least reliant on patents to appropriate returns on investment in R&D.[281] Panelists, however, also identified an exception to these results: patents are a driver of innovation for design firms.

The hearing record highlighted many of the issues that economists suggested might arise in contexts that involve cumulative innovation and a multiplicity of patents. Specifically, the participants from these industries confirmed a trend toward defensive patenting and stated that patents can deter innovation: (1) by contributing to patent thickets, and (2) through their use by NPEs to hold up PPEs. Panelists also observed that various patent licensing arrangements – cross-licensing, patent pools, and the licensing requirements of standard setting organizations – have helped to mitigate the potential harm to innovation caused by patent thickets.

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[278] Lemley 4/18 at 35-37. Of course, other factors, such as considerations of achieving compatibility and network effects, also might explain this result.

[279] *Id.* at 20.

[280] *Id.* at 23. Certain of the antitrust issues raised by SSO activities are discussed in Second Report (forthcoming).

[281] *See* COHEN ET AL., PROTECTING THEIR INTELLECTUAL ASSETS.

V. THE SOFTWARE AND INTERNET INDUSTRIES

A. Introduction

In the software and Internet industries, innovation generally occurs on an incremental basis, with participation possible at the design level by individual programmers and small firms. Panelists consistently emphasized that competition is an important driver of innovation in these industries. Although some panelists stated that software and business method patents foster innovation, many disagreed, asserting that such patents are often questionable and are actually stifling innovation by increasing entry barriers and creating pervasive uncertainty. Some panelists questioned whether it was necessary to have patent protection on software, given the availability of copyrights. Others reported that defensive patenting has accelerated the development of a patent thicket, which, in turn, has increased the likelihood of patentees holding up their rivals. Panelists generally agreed that too many questionable patents are issued; they attributed this to the difficulty patent examiners can have in considering all the relevant prior art in the field and staying informed about the rapid advance of computer science.

The software and Internet industry panelists who participated in the Hearings were: Dean Alderucci, representing Walker Digital; Edward J. Black, representing the Computer & Communications Industry Association; Yar R. Chaikovsky, General Counsel, Zaplet, Inc.; Bradford L. Friedman, Director of Intellectual Property, Cadence Design Systems, Inc.; R. Jordan Greenhall, representing Divx Networks; Joshua Kaplan, representing Intouch Group, Inc.; Robert H. Kohn, Vice Chairman, Borland Software Corp.; Paul Misener, representing Amazon.com; Mary U. Musacchia, representing SAS Institute; Scott Sander, representing SightSound Technologies; Richard Stallman, representing Free Software Foundation; Mark Webbink, representing Red Hat, Inc.; and Robert Young, Chairman, Center for Public Domain and Chairman, Red Hat, Inc. Two scholars, Dan L. Burk, from the University of Minnesota Law School, and David C. Mowery, from the University of California, Berkeley, participated in business perspective panels on the software and Internet industries. Also, three attorneys, Timothy D. Casey, from Fried, Frank, Harris, Shriver & Jacobson, R. Lewis Gable, from Cowan, Liebowitz & Latman, P.C., and James Pooley, from Milbank, Tweed, Hadley & McCloy, participated in business perspective panels on the software and Internet industries, and Dan Crouse, Deputy General Counsel of Microsoft Corporation, submitted a statement.

B. Industry Description

The software and Internet industries create programs, sometimes consisting of millions of lines of code, that direct the functions of a computer, or a group of several computers, and provide a range of services through electronic commerce. Commentators identified five factors that characterize the software and Internet industries. First, innovation occurs cumulatively.[282] As one panelist noted in a

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[282] Microsoft, *Statement of Dan Crouse, Deputy General Counsel, Microsoft Corporation* (Public Comment) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/m

paper he co-authored, "[i]nnovation in software is a cumulative activity, and individual software products frequently build on components from other products."[283] Another participant similarly noted, "The path of innovation is often incremental, with new ideas added, and products developed and commercialized, using earlier work as the foundation and building blocks."[284]

Second, innovation in the software and Internet industries generally requires considerably less capital than innovation in other high-tech industries.[285] Companies or individuals can develop and distribute software without the high up-front research costs, clinical trials, or factories required in the pharmaceutical, biotechnology, hardware, and semiconductor industries. The growth of the Internet has further enhanced the market significance of programs developed with limited financial backing by creating "new channels for low-cost distribution and marketing."[286]

Third, the rate of technological change in the software and Internet industries is rapid.[287] Imitation may occur quickly,[288] and entire product life cycles sometimes pass before patents can be issued.[289] Fourth, alternative means of fostering innovation exist: software can be protected by copyright protection and can be developed using open source software strategies. Finally, the software and Internet industries have experienced a regime change in terms of the availability of patent protection.[290] The formal recognition of the

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sc.pdf (hereinafter Microsoft (stmt)); *see also* Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308, 2346 (1994).

[283] Stuart J. H. Graham & David C. Mowery, *Intellectual Property Protection in the U.S. Software Industry, in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 225 (Wesley M. Cohen & Stephen A. Merrill eds. 2003), *available at* http://faculty.haas.berkeley.edu/graham/unix/swconf.pdf.

[284] Microsoft (stmt) 2.

[285] *See* Young 4/11 at 31 ("we started [Red Hat] on our credit card balances"); Mowery 2/27 at 427 ("the cost of entry [in the software industry] . . . is relatively low"); Mark Webbink et al., *Red Hat's Comments to the Joint FTC/DOJ Hearing on Competition and Intellectual Property Law* (Public Comment) 3, *at* http://www.ftc.gov/opp/intellect/020320webbink.pdf (hereinafter Webbink (stmt)); *see also* League for Programming Freedom, *Against Software Patents* (Public Comment) 3-4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lpf.pdf (hereinafter League for Programming Freedom (stmt)). *But cf.* Microsoft (stmt) 2 (discussing large investments made by Microsoft in connection with some products).

[286] Graham & Mowery, *Intellectual Property Protection in the U.S. Software Industry* at 223.

[287] *See* Webbink (stmt) 3; Rusty Lee, *Comments regarding Competition & Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/lerusty.htm (hereinafter Lee (stmt)); Microsoft (stmt) 4; Samuelson et al., 94 COLUM. L. REV. at 2345, n. 134; Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 CAL. L. REV. 1, 46 (2001).

[288] *See* Brunt 3/20 at 26 (innovations "walk out the door far before the patent is available to help us"); Jeremiah T. Moree, *IP Law* (Public Comment), *at* http://www.ftc.gov/os/comments/intelpropertycomments/moreejeremiaht.htm.

[289] *See, e.g.*, Burk 3/20 at 140-41; Young 4/11 at 64 ("by the time we get a patent, we aren't using that piece of technology anymore").

[290] *See* Mowery 2/27 at 427. *Diamond v. Diehr*, 450 U.S. 175 (1981), held that a process claim that included use of a computer program was patentable subject matter. The Federal Circuit's ruling in *State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U. S. 1093 (1999), made it clear that business methods can be patented. For a discussion of the history of software patents, *see* Cohen &

patentability of software and Internet-related business methods has spurred increased patenting and has presented challenges in locating the relevant prior art, much of which exists outside of traditional prior art sources.[291]

C. The Role of Competition in Spurring Software and Internet Innovation

Several panelists asserted that competition to commercialize the most recent technological advance drives innovation in the software and Internet industries, and that the patent system does not encourage innovation.[292] One panelist stated, for example, that "innovation generally is promoted by competition."[293] Another panelist similarly commented that "a competitive marketplace between similar or only slightly different businesses is all that is truly necessary to spur improvements."[294]

D. Alternative Means of Fostering Innovation

Participants discussed the role of two additional means for spurring innovation in the software industry: copyright, which is an alternative form of intellectual property, and open source software, which is developed without reliance on intellectual property protection.

1. Copyright

A number of participants noted that copyright exists as an alternative means for fostering software innovation.[295] "Copyright protects only the *expression* contained within a work," not "the underlying ideas expressed in that work."[296] Some commentators questioned whether it was necessary to have patent protection on software given the availability of copyright.[297] As one participant noted, for example, "[i]ndividual software programs are also protected by copyright, so that even without any patent protection, software would be a lucrative enterprise."[298] Two scholars offered similar conclusions in an economic study of innovation in the software industry in which they stated that

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Lemley, 89 CAL. L. REV. at 7; Graham & Mowery, *Intellectual Property Protection in the U.S. Software Industry* at 226-31. *See also infra* Ch. 4(II)(E).

[291] *See* Mowery 2/27 at 427.

[292] *See* Chaikovsky 2/27 at 385; Kohn 2/27 at 350; Friedman 2/27 at 354, 357; Musacchia 4/9 at 44-45.

[293] Kohn 2/27 at 350.

[294] Mary U. Musacchia, *Prepared Remarks* (4/9/02) 2, *at* http://www.ftc.gov/os/comments/intelpropertycomments/musacchiamaryu.pdf (hereinafter Musacchia (stmt)); *see also* Musacchia 4/9 at 57-58. A panelist with expertise as a programmer stated that "it's clear to me that software patents are just an obstacle to the development of software. . . . Even patents covering ideas I would say are brilliant have caused tremendous obstruction in [the] progress of software." Stallman 4/9 at 17-18.

[295] *See* Kohn 2/27 at 350; Webbink (stmt) 3; Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform* (Public Comment) 7, *at* http://www.ftc.gov/os/comments/intelpropertycomments/nonobviousness.pdf; Lee (stmt) 1.

[296] ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS, AND TRADEMARKS § 3.3 at 31-32 (2003) (emphasis in original).

[297] *See* Webbink (stmt) 3; Kohn 2/27 at 350.

[298] Lee (stmt) 1.

"copyright protection for software programs . . . may have achieved a better balance [for promoting innovation] than patent protection."[299]

By contrast, one panelist observed that patents can be preferable to copyright for software, because patent protection also covers processes.[300] This perspective finds support in an analytical study that concluded that certain aspects of computer programs not protected by copyright law "are vulnerable to rapid imitation that, left unchecked, would undermine incentives to invest in software development."[301] The authors also noted that the extended period of protection available under copyright law has the potential to harm innovation and consumer welfare "by banning for seventy-five years functionally indistinguishable products, having independently created texts."[302] The scholars, however, expressed some concern that applying two intellectual property rights regimes to software may not always work smoothly: "No one knows just where the boundary line between these domains does or should lie."[303] The use of overlapping regimes has left "considerable uncertainty about the scope of protection available from each."[304]

2. Open Source Software

Commentators discussed the open source software movement and its role as an alternative means of fostering innovation. At the most basic level, open source software is software that is distributed with its source code so that the user may alter the program if she or he so chooses.[305] By contrast, most commercial software is distributed in compiled form that cannot be altered by the user.

The development of open source software occurs through the use of three key organizational principles.[306] These include: (1) the absence of most legal constraints on copying and use common to proprietary materials; (2) the accepting (and frequent public dissemination) of contributions from many developers; and (3) the confining of the right to modify the official version of the program to a smaller subset of individuals or a leader closely involved with the project.[307]

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[299] James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* (Public Comment) 20 (arguing that "software patents have been too broad and too obvious," and that copyright protections focus better on barring imitations while permitting development of "potentially valuable complementary contributions."), *at* http://www.researchoninnovation.org/patent.pdf (hereinafter Bessen & Maskin (stmt)).

[300] *See* Gable 3/20 at 136-37.

[301] Samuelson et al., 94 COLUM. L. REV. at 2310.

[302] *Id.* at 2430.

[303] *Id.* at 2347.

[304] *Id.* at 2346-47.

[305] *See* Zoe Konovalov, *The Economics of Open Source Software* (Public Comment) 5, *at* http://www.ftc.gov/os/comments/intelpropertycomments/konovalovzoe.pdf (hereinafter Konovalov (stmt)).

[306] *See* JOSH LERNER & JEAN TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE 6 (National Bureau of Econ. Research Working Paper No. 7600, 2000), *at* http://papers.nber.org/papers/w7600.pdf.

[307] *See* Webbink 3/20 at 98, 101; Konovalov (stmt) 15-16; Mark Ellis, *Comments regarding Competition and Intellectual Property* (Public Comment) 9-11, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ellismark.pdf; LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 6; Yochai Benkler, *Coase's Penguin, or, Linux and the Nature of the Firm*, 112 YALE L. J. 369, 374-75 (2002).

Open source software has received considerable attention in recent years due to: (1) its rapid adoption, particularly by expert users and corporations; (2) significant capital investments in open source projects by corporations such as Hewlett Packard, IBM, and Sun Microsystems; and (3) the hailing of its collaborative nature of development by business and trade press as an important organizational innovation.[308] Scholars have identified both disadvantages and advantages to open source methods. On one hand, "[c]ommercial projects have an edge on the current-compensation dimension because the proprietary nature of the code generates income."[309] On the other hand, open source may have certain cost advantages,[310] and may permit programmers to benefit from a range of delayed rewards.[311]

E. The Implications of Patent Protection for Innovation

1. The Role of Patents in Spurring Innovation in the Software and Internet Industries

Participants discussed various ways in which software and Internet patents can spur innovation: (1) by preventing free riding and encouraging investment in innovation; (2) by encouraging disclosure of inventions; and (3) by fostering design-around innovation. Commentators were generally skeptical about the benefits of the patent system in these industries.

a. The Role of Patents in Preventing Free Riding and Encouraging Investment in Innovation

Panelists expressed differing views about whether patents play significant roles in preventing free riding and encouraging investment in innovation in the software and Internet industries. Some panelists stated that patents provide incentives to invest in R&D by deterring free riding.[312] One participant stated that "dynamic growth and robust innovation in the software industry in the United States [has been] coincident with the provision of patent protection to software-related inventions."[313] Other panelists took a different view, contending that the availability of patents on software and Internet-based business methods does not significantly encourage investment in

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[308] *See* LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 6; Konovalov (stmt) 37-39. The emergence of open source software as an alternative means of fostering innovation has led one scholar to identify it as "an emerging third mode of production . . . in the digitally networked environment," which he titled "commons-based peer production," and distinguished from "the property- and contract-based modes of firms and markets." Benkler, 112 YALE L. J. at 374-75.

[309] LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 16.

[310] *See id.* (citing programmers' familiarity with open source software from university experience); Benkler, 112 YALE L. J. at 374-75, 377 (citing efficiencies in "large-scale collaborations in many information production fields" and increasing returns to "large- and medium-scale collaboration among individuals that are organized without markets . . . in the informational and cultural production system").

[311] *See* LERNER & TIROLE, THE SIMPLE ECONOMICS OF OPEN SOURCE at 17-18 (noting that open source methods permit outsiders to view an individual programmer's contribution to a project); Konovalov (stmt) 19-20.

[312] *See* Kaplan 2/27 at 399; Alderucci 4/9 at 39-41; Sander 3/20 at 106.

[313] Microsoft (stmt) 5.

innovation.[314] Many of the panelists who expressed this view emphasized that competition provides incentives to innovate in the software and Internet industries. "Compared to the effect of competition in this industry, the current patent system has relatively little effect on the motivation to innovate," according to one panelist.[315]

Three panelists, two of whom were entirely opposed to the issuance of business method patents, commented that the patent term for business methods should be reduced to between three and five years.[316] One of these panelists commented, "three years is more in line with the development time and cost that . . . business methods face."[317]

b. *The Role of Patents in Fostering Innovation Through Disclosure*

Panelists also expressed differing views about whether software and business method patents foster innovation by forcing patent applicants to disclose their inventions. Some panelists expressed the view that the patent system spurs innovation by allowing "anyone to review the public disclosures in issued patents or published patent applications."[318] A number of other panelists disagreed, however, noting that the Court of Appeals for the Federal Circuit does not interpret current patent law to require patent applicants to disclose underlying technology, such as source code.[319] One of these panelists argued that without disclosure of the underlying technology, business method patent disclosures "fail to augment public knowledge," because "in many instances, the business process, by its nature, is public."[320] Another panelist stated that "we have to require that the person applying for the software patent files the source code behind that patent, because the source code is the invention."[321]

Some of the panelists expressed concern that the possibility of exposing oneself to allegations of willful infringement by reading another firm's patents reduces the value of patent disclosures. One panelist stated that "the [patent] system discourages you from looking very hard [at patent disclosures] because . . . simply by virtue of poking around to find out what patents exist you expose yourself to willfulness claims which can triple the amount of damages and exposure to attorney's fees."[322] A second panelist confirmed that the potential for being accused of willful infringement had

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[314] *See* Chaikovsky 3/27 at 343 (stating that Yahoo reached $120 billion market capitalization with only three issued patents); Friedman 2/27 at 357; Musacchia 4/9 at 44-45, (stmt) 2; Black 3/20 at 138; Webbink (stmt) 2.

[315] Friedman 2/27 at 354.

[316] *See* Misener 2/27 at 395-96; *see also* Musacchia (stmt) 4; Webbink (stmt) 4.

[317] Webbink (stmt) 4.

[318] Alderucci 4/9 at 40; *see also* Gable 3/20 at 118; Myrick 10/30 at 60.

[319] *See* Webbink 3/20 at 145; Burk 3/20 at 108; Musacchia (stmt) 2; Casey 4/9 at 32; Young 4/11 at 99-100; *see, e.g., Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941-43 (Fed. Cir. 1990); *Fonar Corp. v. General Electric Company*, 107 F.3d 1543, 1549 (Fed. Cir.), *cert denied*, 522 U.S. 908 (1997).

[320] Musacchia (stmt) 2.

[321] Young 4/11 at 99.

[322] Pooley 2/27 at 380.

deterred him from reading patents.[323] Another panelist reported that uncertainty in the patent system hinders the use of patent disclosures in a competitive manner.[324] The panelist summed up the problem with the statement "there's too much information and it is no longer meaningful."[325]

c. *The Role of Patents in Fostering Design-Around Innovation*

A number of panelists raised questions concerning the extent to which the patent system fosters useful design-around innovation in the software industry. Some complained that design-around efforts may prove costly, duplicative, wasteful, and sometimes technologically impossible.[326] One panelist stressed that entrenchment of a patented technology as a *de facto* standard might prevent design-around innovation from being adopted, even when it is technologically superior.[327] Others observed that programmers can only design around those patents that are published, and the absence of a publication requirement for *all* patent applications means "it may be years beyond the time that a particular piece of technology has hit the marketplace before it is evident that it, in fact, is covered by a form of patent protection."[328] The skepticism, however, was not universal. One panelist argued that forcing design-around efforts may be "the most significant way in which patents promote innovation," although he did not expressly tie his remark to the software industry.[329]

2. The Potential for Patents to Impede Innovation in the Software and Internet Industries

Panelists and participants discussed several ways in which patents might deter innovation: (1) by denying follow-on innovators access to necessary technologies; (2) by increasing entry barriers; (3) through business uncertainty and the expense required to avoid patent infringement; and (4) through the issuance of questionable patents.

a. *Patents May Impede Independent Follow-On Innovation*

Some participants cautioned that patents are likely to thwart beneficial follow-on R&D when innovation depends on incremental efforts, such as software and the Internet.[330] As one participant has

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[323] *See* Greenhall 2/27 at 420-21.

[324] *See* Friedman 2/27 at 411-12. Factors this panelist identified as causing uncertainty include the issuance of questionable patents and the process of judicial review of patents.

[325] *Id.*

[326] *See, e.g.*, Stallman 4/9 at 18-20, 38, and Richard Stallman, *The Danger of Software Patents, Speech by Richard Stallman at Cambridge University, March, 25 2002* (Public Comment) 4, *at* http://www.ftc.gov/os/comments/intelpropertycomments/stallmanrichard.pdf; Musacchia 4/9 at 91; *see also* Cohen & Lemley, 89 CAL. L. REV. at 56 (noting that the courts may "apply the doctrine of equivalents too broadly in software infringement disputes, and thus may stifle efforts by second-comers to design-around existing patents").

[327] *See* Stallman 4/9 at 88-90.

[328] Webbink 3/20 at 99-100; *see infra* Ch. 5(II)(C)(4) for a discussion of patent publication requirements.

[329] Casey 4/9 at 85.

[330] *See, e.g.*, Stallman 4/9 at 17-18; Kohn 2/27 at 348-49 (stressing effects on development of complementary products); Bessen & Maskin (stmt) 2-3; League for Programming Freedom (stmt).

explained, "[A]n early patent holder has a potential claim against subsequent innovators. Anticipating the expected cost of such claims, a second innovator may choose to perform a sub-optimal level of R&D or, perhaps, not to invest in the innovation at all."[331] This argument, of course, has limits; failure to reward initial innovators for the benefits that they confer upon follow-on activity could leave inadequate incentives for the initial innovators.[332] Another panelist contended that "the speed of innovation in [the software industry] is so fast that the long periods of protection granted by patents is stifling subsequent innovation."[333]

b. *Patents May Increase the Costs of Entry*

In the software and Internet industries, innovation by firms and individuals with limited working capital may often be viable. Some participants, however, warned that patents can raise the cost of market entry or ongoing market participation and thereby deter such innovation.[334] Some claimed that software patentability has introduced new costs, such as the cost of obtaining a patent, determining whether a patent is infringed, defending a patent infringement lawsuit, or obtaining a patent license,[335] which may disproportionally affect small firms and individual programmers[336] and the open source community.[337] According to one commentator, "[T]he problem in the United States [software industry] . . . [is] that rights might be too *strong* to permit a healthy, competitive rate of entry."[338]

c. *Avoiding Patent Infringement Is Costly and Uncertain*

Avoiding infringement raises its own

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[331] James Bessen, *Hold-Up and Patent Licensing of Cumulative Innovations with Private Information* 1 (2002), *at* http://www.researchoninnovation.org/holdup.pdf; *see also* Samuelson et al., 94 COLUM. L. REV. at 2346.

[332] *See supra* Ch. 2(I) and (III)(A).

[333] Webbink (stmt) 4.

[334] *See id.*; Gregory Casamento, *Comments, FTC Hearings on Competition and Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/johncasamentogregory.htm; Lee (stmt) 1-2; Eric Buddington, *Comments Regarding Competition and Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/buddingtoneric.pdf (hereinafter Buddington (stmt)); League for Programming Freedom (stmt) 3-5; Stallman 4/9 at 96.

[335] *See* Gable 3/20 at 136 (stating that the preparation, filing and prosecution of a routine patent in the software area costs between $30,000 and $40,000); Lee (stmt) 2.

[336] Lee (stmt) 2 (observing that "although a few thousand dollars may not be a major expense for a large company, it is far too expensive for many small businesses and independent software developers who cannot even afford an office."); *see generally* Place 2/27 at 477-478; Nickolaus E. Leggett, *Comments Regarding Competition & Intellectual Property* (Public Comment) 1, *at* http://www.ftc.gov/os/comments/intelpropertycomments/leggettnick.htm.

[337] *See* Stallman 4/9 at 96 (arguing that the open source movement, which often relies on volunteer programmers, is particularly vulnerable to cost increases resulting from the patenting of software). *See also* Robert M. Riches, *Comments regarding Competition and Intellectual Property* (Public Comment) 3, *at* http://www.ftc.gov/os/comments/intelpropertycomments/ipriches.pdf.

[338] Robert P. Merges, *A Comparative Look at Property Rights and the Software Industry, printed in* THE INTERNATIONAL COMPUTER SOFTWARE INDUSTRY: A COMPARATIVE STUDY OF INDUSTRY EVOLUTION AND STRUCTURE 285 (David Mowery ed., 1996).

set of concerns. In a setting with cumulative innovation and multiple surrounding patent rights, patent thickets may make avoiding infringement very difficult and give rise to defensive patenting and hold-up concerns.[339] Avoiding infringement can also be fraught with uncertainty, because the metes and bounds of software patent claims are often ambiguous.[340]

(i). Patent Thickets, Defensive Patenting and Hold-Up

A number of panelists confirmed the existence of a patent thicket in the software industry, which makes avoiding patent infringement very difficult.[341] A panelist who had studied patenting trends in the software industry stated that the industry poses unusual challenges, because there can be "potentially dozens or hundreds of patents covering individual components of a product."[342] Another panelist provided an anecdote to support the existence of a software patent thicket; he undertook a search to determine the patent landscape surrounding a particular patent relevant to his business and in the process identified 120 patents that appeared to overlap each other, as well as to be infringed by his own product.[343] Commentators noted that patent thickets are likely to arise in industries where innovation occurs on an incremental basis, such as the software industry.[344]

Defensive patenting has accelerated the development of a patent thicket in the software industry. Panelists explained that firms pursue defensive patenting: (1) to maintain detente with rivals; (2) to obtain portfolio cross-licenses from rivals; and (3) to raise a patent infringement counter-claim should a rival sue a firm for patent infringement.[345] One panelist commented that the process of obtaining defensive patents to obtain portfolio cross-licenses from rivals, and thereby maintain freedom to operate, is essentially an attempt "to solve the problem you're creating" by issuing patents on software in the first place.[346]

Another panelist observed that defensive patents have implications for innovation. Companies may have to divert resources from R&D to fund their defensive patent programs. The panelist issued a directive to his company requiring that they "reallocate roughly 20 to 35 percent of [their] developer's resources and sign on two separate law firms to increase [their] patent portfolio" for purely defensive reasons.[347] The engineers' time dedicated to assisting in the filing of defensive patents, which "have no . . . innovative value in and of

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[339] *See supra* Ch. 2(III)(C).

[340] *See, e.g.*, Greenhall 2/27 at 376; League for Programming Freedom (stmt) 5.

[341] *See* Shapiro, *Navigating the Patent Thicket* at 120-121 (observing that a patent thicket has formed in the software and Internet industries); Mowery 2/27 at 427; Stallman 4/9 at 20; Burk 3/20 at 149; Greenhall 2/27 at 375-76.

[342] Mowery 2/27 at 427; *see also* Kohn 2/27 at 349 (complex software can contain "potentially hundreds of thousands" of patentable inventions).

[343] *See* Greenhall 2/27 at 375-76.

[344] *See* Telecky (stmt) 3; Teece 2/27 at 500.

[345] *See* Kohn 2/27 at 350-51; Friedman 2/27 at 356; Greenhall 2/27 at 375-76.

[346] Stallman 4/9 at 88.

[347] Greenhall 2/27 at 376.

themselves," could have been spent on developing new technologies, this panelist asserted.[348]

The existence of a software patent thicket significantly increases the likelihood of companies being held-up due to the difficulty of avoiding patent infringement. Commentators reported that a software program with hundreds of thousands of patentable ideas can be held-up by a patent that claims a single routine in the program.[349] Building up a patent portfolio by engaging in defensive patenting cannot always protect against hold-up; when small companies or NPEs engage in hold-up, they generally are not susceptible to pressure from patent infringement counter-claims.[350]

(ii). The Metes and Bounds of Patent Claims Are Ambiguous

Some panelists expressed concern that the subjective and ambiguous process of construing patent claims makes avoiding patent infringement uncertain and deters innovation.[351] Others asserted that a lack of an effective disclosure requirement exacerbated the difficulty of construing patent claims in the context of software patents.[352]

Two commentators described the impact of this uncertainty on their businesses:

> "[O]ne of the biggest risks I face is uncertainty in the marketplace. I can minimize my risk by understanding my competitor's products . . ., my products . . ., [and] what the consumers and customers want. But I've found . . . that I really can't understand the patent landscape and that I'm sitting with a nuclear bomb on top of my products that could go off at any point and cause me to simply not have a business anymore."[353]

> "For some software projects that I have worked on, I have personally spent over 30% of my time trying to ensure that I was not accidentally infringing on a patent . . . This results in an incredibly large amount of wasted labor, harms our nation's economy and results in less time spent on actual software innovation."[354]

d. Questionable Patents Create Uncertainty and Hinder Innovation

Many participants stated that the PTO issues too many questionable software

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[348] *Id.* at 377 and 420; *see also* Kohn 2/27 at 350-51.

[349] *See* Kohn 2/27 at 351-52; Pooley 2/27 at 382.

[350] *See* Chaikovsky 2/27 at 390-91; League for Programming Freedom (stmt) 6. For further discussion of hold-up issues in the context of patent thickets, *see supra* Ch. 3(IV)(E)(2)(c) and Ch. 2(III)(C)(2).

[351] *See* Greenhall 2/27 at 375-76; Lee (stmt) 2; League for Programming Freedom (stmt) 5; *see generally* Black 3/20 at 161-62 (discussing uncertainty from a business perspective).

[352] *See* Webbink 3/20 at 145; Burk 3/20 at 149-150.

[353] Greenhall 2/27 at 375.

[354] Lee (stmt) 1.

and business method patents.[355] They identified two main reasons. First, some argued that the PTO fails to examine all the relevant prior art and consequently issues patents that are either overly broad or obvious.[356] Panelists identified factors to which this lack of adequate consideration of prior art is attributable, including: (1) the informal nature of software development, especially among the open source community; (2) the rapidly changing and complex nature of the software and Internet industries; (3) the absence of a legal requirement for patent applicants to disclose source code; (4) the use of trade secrecy for almost 20 years of commercial software development; and (5) the relatively recent recognition of the validity of business method patents by the courts.[357]

Questionable patents may have a disproportionally adverse impact on entry by small firms and individuals who lack the resources to challenge such patents. As one software programmer commented, "the ease with which the US Patent Office has been granting patents in the last few years has already dampened my plans to write software as a primary business."[358] In contrast, a panelist from a larger firm suggested that incentives to innovate are not undermined by questionable patents.[359] The panelist observed that it is "a fairly straightforward exercise for our research department to investigate the relevant prior art [for an overly broad patent] and therefore obviate any further discussion on the matter."[360]

The lack of effective mechanisms for third-party challenges to patents compounds the harm to innovation caused by questionable patents, according to some. Panelists contended that the court system is too uncertain, time-consuming, and costly to examine questionable patents effectively.[361] They argued that the reexamination process also has significant defects: the challenging party is at a significant disadvantage procedurally and is then estopped from raising key issues in the courts.[362] Panelists advocated that reforms be made to the reexamination procedures so as to increase their effectiveness for challenging questionable patents and that the possibilities for pre-grant comment also be more fully utilized.[363]

A number of commentators maintained that the PTO's issuance of

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[355] For further discussion of business method patents *see infra* Ch. 4(II)(E).

[356] *See, e.g.,* Webbink (stmt) 2-3; Friedman 2/27 at 355; Gable 3/20 at 114-5.

[357] *See* Kohn 2/27 at 428; Gable 3/20 at 116-17; Lee (stmt) 3; Webbink (stmt) 2-3; *see also* Cohen & Lemley, 89 CAL. L. REV. at 42-46. For further discussion of challenges posed by business method patents, *see infra* Ch. 4(II)(E).

[358] Buddington (stmt) 1.

[359] *See* Alderucci 4/9 at 58.

[360] *Id.*

[361] *See, e.g,* Pooley 2/27 at 379; Friedman 2/27 at 411-12; Gable 3/20 at 155; Sander 3/20 at 156.

[362] *See* Gable 3/20 at 163; Pooley 2/27 at 405; Edward J. Black, *Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy, Testimony of Edward J. Black, President & CEO* (3/20/02) 7, *at* http://www.ftc.gov/opp/intellect/020320black.pdf.

[363] *See* Gable 3/20 at 163; Pooley 2/27 at 405; Misener 2/27 at 396; Black 3/20 at 126. For a discussion of recent reforms to reexamination procedures, *see infra* Ch. 5(III)(A).

questionable patents results in part from a lack of funding that is attributable to the diversion of PTO user fees to non-patent related matters.[364] Several panelists argued that if the PTO had more examiners, made a greater effort to keep experienced examiners, and gave patent examiners more time to spend on their initial examination, the PTO would issue fewer questionable patents.[365] "Improving patent quality will increase confidence in the validity of patents, thus making it easier for patent owners to commercialize their inventions and decreasing the possibility that potential defendants will have to address infringement allegations that ultimately prove to be without merit," one commentator stressed.[366]

F. Licensing Strategies to Navigate the Patent Thicket

As in the panels devoted to the computer hardware industries, software and Internet panelists discussed three licensing strategies that firms can use to navigate patent thickets: (1) cross-licensing; (2) patent pooling; and (3) standard setting.[367] Two panelists suggested that the process by which royalties are determined for patent licensing – one patentee at a time, with potential for royalty stacking and hold-up by patents on small pieces of much larger programs – exacerbates the problem of hold-up and lessens the effectiveness of the licensing strategy.[368] One panelist argued that there should be a reasonableness element to determining royalties, which should be based on the value of the contribution of the particular patented feature to the total product.[369] Such determinations need to be made at an early stage, he urged, so that royalty negotiations are not conducted under the threat of litigation, preliminary injunctions, and damages.[370] Another panelist suggested a mechanism for permitting a legal action by which a company could implead all relevant intellectual property owners to settle all outstanding royalty claims in a single forum.[371] Such a mechanism might be a means for addressing royalty stacking problems that may arise when royalties are negotiated sequentially.[372]

G. Conclusion

The software and Internet industries generally are characterized by five factors: (1) innovation occurs on a cumulative basis; (2) capital costs are low, particularly relative to the pharmaceutical, biotechnology and hardware industries; (3) the rate of technological change is rapid, and product life cycles are short; (4) alternative means of fostering innovation exist, including copyright protection and open source

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[364] *See* Alderucci 4/9 at 12-16; Musacchia (stmt) 4; Webbink 3/20 at 171; Gable 3/20 at 121-22; Microsoft (stmt) 5-6.

[365] *See* Gable 3/20 at 121-22; Alderucci 4/9 at 12-16; Microsoft (stmt) 5-6.

[366] Microsoft (stmt) 6.

[367] *See, e.g.*, Friedman 2/27 at 355; Greenhall 2/27 at 377, 417; Stallman 4/9 at 38. For further discussion of each strategy, *see supra* Ch. 3(IV)(F).

[368] *See* Kohn 2/27 at 351-52, 415, 429; Pooley 2/27 at 381-83.

[369] *See* Kohn 2/27 at 351-52, 415, 429.

[370] *See id.* at 415, 429-30.

[371] *See* Pooley 2/27 at 415-16.

[372] *See supra* Ch. 2(III)(C)(3).

software; and (5) the industries have experienced a regime change in terms of the availability of patent protection.

Panelists consistently stated that competition drives innovation in these industries. Innovation is also fostered by some industry participants' use of copyright protection or open source software. Several panelists discounted the value of patent disclosures, because the disclosure of a software product's underlying source code is not required.

Many panelists and participants expressed the view that software and Internet patents are impeding innovation. They stated that such patents are impairing follow-on incentives, increasing entry barriers, creating uncertainty that harms incentives to invest in innovation, and producing patent thickets. Panelists discussed how defensive patenting increases the complexity of patent thickets and forces companies to divert resources from R&D into obtaining patents. Commentators noted that patent thickets make it more difficult to commercialize new products and raise uncertainty and investment risks. Some panelists also noted that hold-up has become a problem that can result in higher prices being passed along to consumers.