The IP Law Book Review

IP Law Center, Golden Gate University School of Law

Vol. 1 No. 2 (February 2011) pp. 54-60

GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES, edited by Geertrui Van Overwalle.
Cambridge University Press, 2009, 455 pp. Hardcover $123.00.

Reviewed by J. Jonas Anderson, Microsoft Research Fellow,
Berkeley Center for Law & Technology.
janderson@law.berkeley.edu.

The typically esoteric world of patents has recently been thrust into the headlines as cases involving patented genes have received an unprecedented amount of press. For decades, academics, scientists, practicing attorneys, and legislators have vigorously debated the merits of granting patents on genes and medical diagnostic procedures. Only recently, however, have the courts entered the fray. For example, in March 2010, Judge Sweet of the U.S. District Court for the Southern District of New York handed down a ruling that invalidated a number of patents covering the BRCA genes that signal an increased likelihood of developing breast cancer.[1] Judge Sweet's ruling held that the patent claims on the BRCA genes were directed to unpatentable "product of nature." A few months later in a separate case, the U.S Court of Appeals for the Federal Circuit, following a grant-vacate-remand from the Supreme Court, upheld the validity of a patented method for determining a proper drug dosage level based on a patient's metabolite levels.[2] The courts' entrance into the debate surrounding patenting of human genetic material and medical diagnostics has elicited interest from the full spectrum of public news outlets: from the New York Times to Nature magazine.[3] It would seem that one, or perhaps both, of these cases will be heard at the Supreme Court. In any case, the contentiousness surrounding gene patenting and diagnostic patenting is unlikely to subside any time soon.

In light of the controversy surrounding patents on genetic material, Geertrui Van Overwalle has compiled a collection of writings on this topic by an outstanding group of academics and practicing attorneys in a book titled

GENE PATENTS AND COLLABORATIVE LICENSING MODELS. Van Overwalle and her fellow contributors ask whether collaborative licensing models can reduce public concerns that gene patents will lead to reduced access to research and health care choices. Van Overwalle's book examines the best methods of achieving innovation and maximizing access while assuming that "the problems created by patent law in genetic diagnostics are best served by contractual, collaborative measures" (p.454), and not by restricting patentability as some commentators have proposed. In light of the book's purpose and scope, this review will touch on the licensing ideas raised by the authors while critically examining Van Overwalle's summary of the various authors' contributions, which appears at the book's conclusion.

Before providing private solutions to the problems surrounding gene patenting, Van Overwalle first seeks to identify the precise problems that widespread patenting of genetic material and diagnostic procedures create. Two primary concerns are identified, both of which focus on transaction costs. First, the book examines the problem of increased transaction costs in upstream or basic research. Incentives to engage in initial upstream research can be reduced when an excessive number of property rights holders drive up the transaction costs associated with commercializing those property rights.[4] In the patent field, upstream research is thought to be harmed when, in order to commercialize a particular technology, it is necessary to obtain rights in a multitude of patents held by a multitude of owners (patent thickets), or when multiple patents covering the same technology are held by competing patent owners (blocking patents). Various contributors to GENE PATENTS AND COLLABORATIVE LICENSING MODELS note that empirical studies suggest that patent thickets are not currently a concern in the genetics field (pp.4, 387). Regardless, many observers predict that patent thickets may emerge in the field of medical diagnostics as diagnostic tools improve and personalized DNA arrays become more affordable. Indeed, patent clearance may prove to be the primary driver of diagnostic cost in the coming age of personalized medicine. Second, the book examines the risk of reduced downstream investment, or under-commercialization of patented genetic inventions. At least part of the "translational gap" between early-stage genetic research and therapeutic applications of that research may stem from the transaction costs associated with drug-related negotiations between academic and industry players.

In order to overcome obstacles to the upstream research problem, Van Overwalle's book examines three primary collaborative arrangements:

patent pools, clearinghouses, and open source models. Patent pools, such as the DVD and MPEG-2 pools, have been successfully employed for some time by the electronics industry (pp.33-41). However, the translation of a licensing arrangement from the electronics industry to the diagnostic industry is not without pitfalls. First, most successful patent pools to date (particularly in the electronics industry) have been established in order to create industry standards; the genetics industry, by contrast, does not have such standards with which to comply (pp.38, 48). Whereas the electronics industry is able to increase the value of its products via mutually agreed-upon standards, the genetics industry does not enjoy such interoperability benefits. The lack of standards-driven economics in the genetic industry leads Birgit Verbeure to conclude that patent pools will not provide great benefits to the genetics industry (p.29). Second, and perhaps most troubling from a diagnostic perspective is the problem of holdouts. In the electronics industry, interdependency increases value; the establishment of standards (e.g., the standard diameter of compact discs) increases interoperability and reduces or eliminates switch-over costs. In essence, consumer electronics manufacturers rely on their competitors to create a market for electronic products. Value in the biotech industry, on the other hand, is driven by exclusivity, not interoperability (pp.55-56). Thus, biotech patentees risk much less and stand to gain much more than electronics patentees by refraining from joining a patent pool. Some authors, such as Jorge Goldstein, envision a standards-based regime emerging in the biotech industry via respected health organizations such as the WHO or NIH (p.56). Others, including Dan Burk and Verbeure, suggest that reducing the property-like rights of the patent holder (either through liability regimes or compulsory licenses) may ameliorate some of the holdout issues (pp.28, 306). While promising, both governmentally-set standards and compulsory licenses involve non-contractual solutions to the holdout problem, which, as I discuss below, is not optimal.

The second licensing arrangement discussed in Van Overwalle's book is the clearinghouse model. Clearinghouses come in many shapes and sizes, some dealing primarily with efficient knowledge transfer while others are concerned with rights management and royalty collection. While the idea of facilitating access and knowledge through clearinghouses enjoys universal authorial support, the various authors acknowledge that the analogy between existing copyright clearinghouses and potential patent clearinghouses is inexact at best and undesirable at worst. For example, Esther Van Zimmeren concludes that the time is not ripe for patent royalty collection clearinghouses (pp.111-12). She reads the literature on copyright clearinghouses as demonstrating that while "collectivization" of rights and

enforcement may indeed increase the value of IP rights, it is unclear whether access is increased by such clearinghouses (pp.111-12). Michael Spence cautions that any analogy between established copyright clearinghouses and potential patent clearinghouses is inexact (pp.166-67). Spence concludes that patent royalty clearinghouses could lower transaction costs for genetic innovators, but may also increase royalty stacking and cost of access for consumers (p.167). For Spence, establishment of patent clearinghouses will not overcome the potential anticommons problems in the genetics industry and may exacerbate rather than remedy the access problem in diagnostics (pp.166-68).

The book suggests that open source models are a third licensing scheme that could be employed to improve access to diagnostics while maintaining incentives to innovate in the industry. Janet Hope proposes employing the open-source model that has transformed the software industry (p.192). However, other authors cast doubt on the applicability of software norms into the genetics industry conclusion. Arti Rai notes that the set of participants and economic realities in biotechnology is wholly different than that of software (p.217). Whereas the software industry involves numerous manufacturers and millions of users, the biotech industry has a smaller set of players and a targeted group of potential consumers. More importantly, there is little evidence that IP rights are strong drivers of creation in the software industry, whereas IP serves as the principal incentive to biotech companies (p.215). Thus, software designers are likely to be much more willing than their biotech counterparts to contribute to a public commons. Echoing Rai's suggestion that the high value of IP in the biotech industry may severely reduce the applicability of an open source model, Andrzej Kilian states that the only opportunity for using open-source in genetics will be "in an area of limited financial opportunity, where competition with mainstream companies would be less intense" (p.211). Wholly new business models would have to arise in order for biotech to embrace open-source, Van Overwalle concludes (p.431).

Van Overwalle concludes that licensing schemes meant to solve the patent thicket problem in upstream research (namely patent pools, clearinghouses, and open source models) are capable of achieving the goal of increasing access to diagnostic procedures (p.454). She is optimistic that pools, clearinghouses and open source can enable access despite widespread genetic patenting. Her conclusion, however, does not enjoy universal agreement from her contributors. The controversy surrounding the applicability of such regimes stems from their ability to attract actors interested in maximizing the value of their intellectual property. While

open-source models have been employed to increase access to intellectual property-protected goods in the software industry, the translation of open-source models to diagnostic testing appears to be limited to the small subset of cases in which profit motive is not the driving force behind research and development. Van Overwalle notes that numerous commentators are skeptical of open-source's feasibility in a for-profit genetics setting: "[I]t is questionable whether [the open source] model can stand the test in market segments aiming at the largest potential profit margins, such as the biomedicine sector" (pp.452). Obviously, this is a rather large problem. If open source is not an attractive alternative for profit-maximizing organizations, the ability of open source to overcome access problems in the medical diagnostics industry will be quite limited. Van Overwalle's optimism regarding the ability of licensing schemes to overcome research access problems also must be tempered by the reality that few authors can offer a licensing solution to the holdout problem. If valuable genetic patents are withheld from pooling or clearinghouse schemes, the effectiveness of those schemes in reducing transaction costs is likely to be greatly limited. Van Overwalle acknowledges this problem (pp.448) and suggests that "compulsory license schemes and informal norms of fair licensing" can be helpful in eliminating blocking patents. Of course, if reducing the access problems associated with genetic patents requires some form of compulsory licensing scheme or relies on the establishment of informal norms, then licensing models such as clearinghouses and patent pools are either unnecessary or inadequate to solve the problems associated with upstream research of diagnostic innovations.

To address the translational gap, the book deftly moves from the problem of patent thickets and blocking patents, to the problem of downstream commercialization. Oftentimes patents can stymie the translation of early-stage genetic inventions into medical applications because patents increase the transaction costs between upstream researchers (often-times academics or publically funded institutions) and downstream developers (typically private entities) (pp.392-93). This so-called "translational gap" is well-known in the pharmaceutical industry, but seems to be less prominent in the field of diagnostics (pp.246-57, 392-93), primarily because finding a link between a particular nucleic acid sequence and the ability to diagnose a disease does not involve the same enormous investment that creating marketable drugs entails.

In order to bridge the translational gap, the book examines various liability regimes. The most robust proposed solution to the translation gap comes from Arti Rai. Rai proposes a two-tiered public-private partnership in

which participants enter into contractual agreements to treat their discoveries under a liability regime rather than as property (p.247). Initial research would be conducted behind a "veil of ignorance" which would be breached only when promising collaborators had been identified. The attractiveness of Rai's proposal is that it increases knowledge sharing (assuming buy-in by a large number of players) and reduces transaction costs. Dan Burk builds on Rai's proposal, likening the regime to one of option trading (pp.294-306). Van Overwalle concludes that liability regimes are "rather limited in this area [diagnostics]" (p.454). She bases this conclusion on the practical difficulties that implementing any liability regime is bound to face. Her concern with the hurdles faced by a liability regime is, of course, correct. The implementation of a large-scale liability regime to encourage development of medical technology is destined to encounter practical problems: the devil is always in the details. However, as Rai's elaborate proposal demonstrates, there is common ground upon which profit-maximizing corporations and academic researchers can collaborate and which can result in increased diagnostic tools at reduced prices to consumers. Because Rai's liability regime is modeled on a world in which players are profit-maximizing, it would seem that such a regime would offer the best potential to create real-world change. Van Overwalle's practical objections aside, liability regimes provide a theoretical licensing solution to reduced commercialization of genetic discoveries.

At the end of the book, Van Overwalle writes a final piece to summarize and crystallize the various contributions of the authors. Her synthesis of the literature and the contributions is very nicely done and gives the book—which is truly an exploration of the future landscape—a feeling of finality. The book offers an important survey of different perspectives on what is certain to be a central issue in patent law going forward. Van Overwalle has done an excellent job in creating a compilation that offers diverse perspectives on the feasibility and desirability of translating successful licensing schemes from other industries (electronics, software, entertainment) to biotechnology. Anyone interested in the future of diagnostic and genetic patents—and the manner in which the social drawbacks of such patents might be mitigated—would be well-advised to examine the book.

ENDNOTES

[1] Ass'n for Molecular Pathology v. U.S.P.T.O, 702 F. Supp. 2d 181 (S.D.N.Y. 2010).

[2] Prometheus Labs., Inc. v. Mayo Collaborative Services, 2010 WL 5175124 (Fed. Cir. Dec. 17, 2010).

[3] New York Times, March 29, 2010, available at http://www.nytimes.com/2010/03/30/business/30gene.html; Jeffrey L. Furman, et. al, 468 Nature 757-78 (Dec. 9, 2010).

[4] See, e.g., Michael A. Heller, The Tragedy of the Anticommons: Property in the Transition from Marx to Markets, 111 Harvard L. R. 668 (1998).

Suggested Citation: 1 *The IP Law Book Review* 54 (2011).