



IP Literature Watch

CRA Charles River
Associates

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This newsletter contains an overview of recent publications concerning intellectual property issues. The abstracts included below are as written by the author(s) and are unedited.

IP & Antitrust

Enjoining injunctions: the case against antitrust liability for standard essential patent holders who seek injunctions

Douglas H. Ginsburg (George Mason University School of Law)
Taylor M. Owings (U.S. Court of Appeals District of Columbia Circuit)
Joshua D. Wright (Federal Trade Commission)

The Antitrust Source, pp. 1-7, October 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2515949

A standard essential patent (SEP) may give the patent holder market power in the market for an input that technology manufacturers need in order to make their products compatible with each other. Several commentators have argued that, when a patent becomes part of a standard pursuant to an agreement among competitors given in exchange for the patent holder's promise to license the technology under fair, reasonable, and non-discriminatory (FRAND) terms, antitrust law should limit the holder's right to seek an injunction to stop an infringing manufacturer from selling its standardized product. We disagree for two reasons: First, antitrust sanctions are not necessary, given the law of contracts and of injunctions, to avoid harm to consumers and, second, the application of antitrust law in this situation could, by undermining the ability of courts to tailor appropriate remedies, diminish the incentives for companies to innovate and for industries to adopt standards.

FRAND royalties and injunctions for standard essential patents

Jay Pil Choi (Michigan State University – Department of Economics)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2512789

I develop a stylized model of court procedures that resolve disputes concerning FRAND-encumbered standard essential patents (SEPs). I analyze the effects of injunctions and potential court-imposed FRAND rates on negotiated royalty rates. The SEP-holders' ability to hold-up is constrained by the prospect of the court-imposed license terms in case of disputes, but is not completely eliminated. Possible mechanisms to address the residual hold-up power of the SEP-holders are discussed.

Sandoz v. Amgen: why the Biologics Price Competition and Innovation Act of 2009 allows biosimilar makers to pursue pre-application declaratory judgment actions and will enhance competition

Carl J. Minniti III (Rutgers, The State University of New Jersey)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2519393

The generic drug industry is shifting towards biosimilars. In the coming years, first-generation blockbuster biologic drugs will come off patent protection. However, unlike the small-molecule chemical drug market where exact generic copies can be produced, the complexity of large-molecule biologic drugs makes exact replicates impossible. As a result, biologic copies aim to be as similar as possible to their blockbuster counterparts – thus, the name: biosimilars. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) regulates biosimilar approval.

Submarine patents threaten the development of biosimilars. These types of patents are a product of manipulative continuation practices by the applicant, and can result in patent issuance more than a decade after the filing date. Submarine patents are meant to surprise an industry and preclude competition. While some believe submarine patents are a thing of the past, a pending case before the Federal Circuit shows they are not. In *Sandoz v. Amgen*, the Federal Circuit's interpretation of the BPCIA will determine what litigation strategies are available to biosimilar makers to combat submarine patents. This is the first case to arise in the biosimilar industry. The issue is one of pure statutory interpretation: does the BPCIA bar a biosimilar maker from filing a declaratory judgment (DJ) action before submitting an application for approval.

This article argues that the BPCIA does not preclude pre-application DJ actions. In addition, the article posits that pre-application DJ actions are an important tool in the fight against submarine patents and will enhance competition. The biosimilar industry is fast approaching and the legal community must take notice. This article seeks to further that conversation.

IP & Innovation

Intellectual property protection and financial markets: patenting vs. secrecy

Nishant Dass (Georgia Institute of Technology)

Vikram K. Nanda (Rutgers, The State University of New Jersey)

Steven Chong Xiao (Rutgers, The State University of New Jersey)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2517838

Firms can protect intellectual property (IP) by keeping their inventions secret or, alternatively, by seeking patent protection and disclosing the inventions. We expect the choice between secrecy and patenting to be affected by the degree of relative protection provided and to have distinct implications in terms of stock liquidity and equity financing. Our hypothesis is that stronger secrecy protection will encourage firms to adopt more secrecy, therefore increases information asymmetry and reduces stock liquidity. By contrast, better patent protection is hypothesized to cause firms to disclose more information by patenting their inventions, resulting in higher stock liquidity.

We test our hypothesis by exploiting exogenous law changes, such as state trade secret statute and the implementation of TRIPS, that improves the protection of either form of IP. We find that exogenous, staggered passage of state-level statutes that strengthened trade-secret protection increase opaqueness, reduce stock liquidity and worsen the market's reaction to announcement of seasoned equity offerings (SEOs). By contrast, implementation of Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS), that strengthened patent protection, enhanced transparency and stock liquidity of patenting firms and reduced the stock market reaction to SEOs.

Our findings provide policy makers and academic researchers with a new perspective for the discussion and future development of IP protection law. In particular, our findings show that IP protection plays a more important role in the financing of small firms, that are typically in a more vulnerable position in product market and encounter more frictions in raising capital. Therefore, our study has important implication to policies that aim to facilitate growth of small innovative firms.

Patent antecedents and Tobin's q ratio

Kathryn Rudie Harrigan (Columbia Business School)

Maria Chiara DiGuardo (University of Cagliari)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2509359

High backward-citation patent scores indicated that inventive firms had positive prospects for future returns (as evidenced by their Tobin's q ratios) because patents incorporating substantial external knowledge were also broadly-cited. Results suggested a three-year lag in the market's positive assessment of radical inventions after positive evidence first appeared. (Post-acquisition backward-citation patent-score patterns reached positive inflection points after four years.) Therefore we concluded that the market's assessment of inventions that were created through organizational exploration and learning activities was not instantaneous.

Evidence of innovation synergies

Kathryn Rudie Harrigan (Columbia Business School)

Maria Chiara DiGuardo (University of Cagliari)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2509337

Patterns of patents' backward citations were used to find evidence of organizational learning by identifying improvements in firms' patent scores. Innovation synergies were indicated where firms' post-acquisition patent scores showed that more non-core knowledge had been synthesized by working together than had occurred when each respective firm was earning patents alone. Negative results were found for diversification, which suggested that highly-diversified firms did not necessarily enjoy the post-acquisition innovation synergies that were found in this study; less-diversified firms enjoyed greater innovation synergies (as they were defined herein).

Dispersion measures and out-of-the-box innovation

Kathryn Rudie Harrigan (Columbia Business School)

Maria Chiara DiGuardo (University of Cagliari)

Brian Nicholas Velez (Columbia University)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2509301

Using a scoring methodology that is a refinement over the Trajtenberg, et al (1997) indices, we found that the financial performance measures of communications services firms having patents which synthesized highly-diverse technological knowledge streams had positively correlated patterns with scores for backward-cited antecedents. Alarming, tests of the relationship of Tobin's q measures with the backward-dispersion citation scores indicated that a negative relationship exists -- a result which may indicate that investors are not as eager to bet on the rewards of out-of-the box inventions as management is.

Venture capital and intellectual property rights effects on innovation in different industries and socioeconomic environments: a systematic review and exploration of various contradictive studies

Arsalan Safari (Massachusetts Institute of Technology)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2516661

Academic literature has well discussed the effects of Venture Capital (VC) investment, Intellectual Property Rights (IPR) and other socioeconomic parameters on business innovation. While many scholars emphasize this positive effects, others argue that there is no strong association between VC, IPR and business innovation. Therefore, these scholars do not appraise the efforts of regulators and policymakers who are trying to establish stronger intellectual property protection regime for promoting innovation and patenting. This study systematically reviews the literature and explores the effects of VC investment and IPR on innovation on a detailed level in all industries worldwide, considering other socioeconomic parameters. We discuss the level of effects and the contrary perspectives as well. This review provides a configurative framework from the current research streams which is useful for researchers, regulators, policymakers and entrepreneurs.

How do open standards influence inventive activity? Evidence from the IETF

Wen Wen (The University of Texas at Austin)

Chris Forman (Georgia Institute of Technology – Scheller College of Business)

Sirkka Jarvenpaa (University of Texas at Austin – Red McCombs School of Business)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2507478

We examine how standardization in the information and communication technologies affects the inventive activities of firms that do not contribute standards but potentially produce to the standards. In the context of the Internet Engineering Task Force, we find that as a technological area releases 100 more open standards contributed by commercial firms, non-contributing firms have 18%-20% less inventive output in the same technological area. This negative effect of standardization in a technological area is stronger when the standards-contributing firms hold a large fraction of complementary intellectual property rights (IPR) in the area, but is somewhat lessened when the ownership of complementary IPR is highly concentrated among these contributing firms. These effects are also stronger (more negative) on the inventive activity of small firms. In contrast, we find that increases in the number of standards developed solely by academics and others associated with noncommercial entities are positively associated with inventive activity.

IP & Litigation

Invalid but infringed? An analysis of Germany's bifurcated patent litigation system

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Fabian Gaessler (Max Planck Institute for Innovation and Competition)

Dietmar Harhoff (Max Planck Institute for Innovation and Competition)

Christian Helmets (Santa Clara University – Leavey School of Business)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2504507

We analyze the impact of the probabilistic nature of patents on the functioning of Germany's bifurcated patent litigation system where infringement and validity of a patent are decided independently by different courts. We show that bifurcation creates situations in which a patent is held infringed that is subsequently invalidated. Our conservative estimates indicate that 12% of infringement cases in which the patent's

validity is challenged produce such ‘invalid but infringed’ decisions. We also show that having to challenge a patent’s validity in separate court proceedings means that more resource-constrained alleged infringers are less likely to do so. We find evidence that ‘invalid but infringed’ decisions create uncertainty which firms that were found to infringe an invalid patent attempt to reduce by filing more oppositions against newly granted patents immediately afterwards.

Are patent trolls ‘opportunistic’?

Ted M. Sichelman (University of San Diego School of Law)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2520125

A recent and widely received study by Lauren Cohen, Umit G. Gurun, and Scott Duke Kominers finds that non-practicing entities (NPEs) — pejoratively known as “patent trolls” — are “opportunistic” because they target defendants that (1) are cash-rich (particularly compared to practicing entity patentees), (2) operate in industries that “have nothing to do with the patent” in suit, (3) are staffed by small legal teams, and (4) are busy with numerous non-IP cases. Additionally, the authors conclude that defendants that lose in patent litigation with NPEs on average have marked declines in subsequent R & D expenditures, on the order of \$200 million per year. On this basis, the authors suggest “the marginal policy response should be to more carefully limit the power of NPEs.” Here, I critique in detail the most recent, publicly available version of this study. I conclude that although the authors’ project is admirable in attempting to comprehensively examine the litigation behavior of NPEs, their dataset is incomplete and unrepresentative, their theoretical model is flawed, and their empirical models are unsound. As such, neither their findings nor policy prescriptions are justified.

IP Law & Policy

Inter partes review: an early look at the numbers

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Shawn Ambwani (Unified Patents, Inc.)

University of Chicago Law Review Dialogue, Vol. 81, p. 93, 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2512519

In the roughly two years since inter partes review replaced inter partes reexamination, petitioners have filed almost two-thousand requests for the Patent Trial and Appeal Board to review the validity of issued U.S. patents. As partial data on inter partes review (IPR) has trickled out via the blogosphere, interest from patent practitioners and judges has grown to a fever (and sometimes fevered) pitch. To date, however, no commentator has collected a comprehensive set of statistics on IPR. Moreover, what little data currently exists focuses on overall institution and invalidation rates — data that, alone, gives us little idea whether IPR is thus far accomplishing its original goal of serving as a quick, efficient alternative to defending patent suits filed in federal court, particularly those initiated by non-practicing entities (NPEs).

This Essay aims to fill both gaps by reporting the findings of an empirical study tracking the outcome of IPRs and their impact on co-pending litigation. As described in greater detail below, we find that: Petitions for IPR are instituted for at least one challenged claim 84 percent of the time; Among instituted IPRs, all challenged claims are instituted 74 percent of the time; Among IPRs that reach a final decision on the merits, all instituted claims are invalidated or disclaimed more than 77 percent of the time; IPRs challenging NPE-owned patents are more likely to be instituted and, on average, are instituted for a larger share of challenged claims, but have their claims invalidated at a lower rate; Litigation proceeding in parallel with an instituted IPR is stayed about 82 percent of the time.

Though it is too early to draw sweeping conclusions from these statistics, they suggest that inter partes review promises to be considerably more potent than inter partes reexamination and, moreover, to have a substantial impact on co-pending patent litigation, particularly suits filed by NPEs.

One hundred nos: an empirical analysis of the first 100 denials of institution for inter partes and covered business method patent reviews

Jarrad Lucian Wood (American University Intellectual Property Brief)

Jonathan R. K. Stroud (Finnegan, Henderson, Farabow, Garrett & Dunner LLP)

14 John Marshall Review of Intellectual Property Law, 2014, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2510475

Tasked in 2011 with creating three powerful new patent review trial regimes, the U.S. Patent and Trademark Office — through the efforts of their freshly empowered quasi-judicial body, the Patent Trial and Appeal Board — set to creating a fast-paced trial with minimal discovery and maximum efficiency. In the first two years of existence, the proceedings have proved potent, holding unpatentable many of the claims that reach decisions on the merits. Yet a small subsection of petitions never make it past the starting gate, resulting in wasted time and effort on the parts of petitioners — and likely sighs of relief from the rights-holders. Parties on both sides of a petition can learn volumes by looking to the first 100 denials of institution. In a regime where so many petitions have been granted, knowing the ones that haven't could be the key to success. This paper reviews the orders denying review of patent validity under two AIA post-grant review procedures: Covered Business Method review, and Inter-Partes Review. The paper is written with practitioners in mind. Indeed, the paper tracks the spirit of the AIA in that it aspires to “improve patent quality and limit unnecessary and counterproductive litigation costs.”

Patent infringement, litigation, and settlement

Haejun Jeon (Osaka University)

Working Paper

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2509066

We propose a model that integrates a series of events regarding patent rights based on real option framework. After the incumbent has acquired a patent, it can be infringed by the challenger, and the conflict between them can be resolved via litigation or settlement with endogenously determined triggers and royalties. The model explains why litigation is so unusual in the real world and why most of the lawsuits over patent rights cease before the court's judgment is made. It also clarifies why roughly a half of litigated patents are found to be invalid in court and in what circumstances the introduction of new technology or the infringement of patent is delayed. From the perspective of implications on patent system, the model shows that neither tightening the patent examination nor widening the patent scope guarantees the acceleration of R&D investment, and rather delays it in some cases.

Patent conflicts

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Georgetown Law Journal, Vol. 103, July 2015, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2520698

Patent policy is typically thought to be the product of the Patent and Trademark Office, the Court of Appeals for the Federal Circuit, and in certain instances, the Supreme Court. This simple topography, however, understates the extent to which outsiders shape the patent regime. Indeed, a wide range of administrative actors influence a variety of questions ranging from the standards of patentability to the remedies for infringement through the exercise of their regulatory authority and administrative power.

Although such interventions into patent policy by nonpatent agencies predate the First World War, the PTO and the Federal Circuit have often resisted attempts at regulation by outsiders, and the authority for

these agencies to take patent-related action has rarely been clearly articulated. As a result, outside agencies will sometimes avoid such regulation. In other cases, the nonpatent agency's policymaking process can be costly and inefficient, requiring Supreme Court or congressional intervention. This is true even where patent-related regulation is critical to achieving an agency's objective. This dynamic has the striking effect of shifting authority away from the nonpatent agency and to patent policymakers, thereby replacing a specific regulatory design with a patent's generic innovation-inducing incentive.

This article offers a novel description of the ways in which agencies have sought to intervene into questions of patent policy. In particular, the article examines forms of direct and indirect agency intervention, and finds indirect intervention to be more costly yet prevalent. The article thus considers two related paths forward. First, it recommends borrowing from an often overlooked theory of agency authority in order to enable nonpatent agencies to issue patent-related orders that are directly related to their regulatory objectives. Second, where such agency authority may be insufficient, the article suggests that nonpatent agencies should appeal to authorities within the Executive Branch, including the PTO, to give effect to their policy aims before turning to the legislature or judiciary. Such intervention and regulation by nonpatent agencies can be more efficient, and may give rise to a context-sensitive patent regime that is more harmonious with other regulatory goals.

The failed promise of user fees: empirical evidence from the U.S. Patent and Trademark Office

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Melissa F. Wasserman (University of Illinois College of Law)

Journal of Empirical Legal Studies, Vol. 11, Issue 4, pp. 602-636, 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2516107

In an attempt to shed light on the impact of user-fee financing structures on the behavior of administrative agencies, we explore the relationship between the funding structure of the Patent and Trademark Office (PTO) and its examination practices. We suggest that the PTO's reliance on prior grantees to subsidize current applicants exposes the PTO to a risk that its obligatory costs will surpass incoming fee collections. When such risks materialize, we hypothesize, and thereafter document, that the PTO will restore financial balance by extending preferential examination treatment - that is, higher granting propensities and/or shorter wait times - to some technologies over others.

Copyright Law

Garcia v. Google and a 'related rights' alternative to copyright in acting performances

Jacob M. Victor (Yale University)

Yale Law Journal Forum, Vol. 24, 80, 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2511641

A recent Ninth Circuit case, *Garcia v. Google*, held that an actor can maintain a copyright interest in her acting performance in a film — independent of the copyright held by the filmmaker — and that this copyright can sometimes be sufficiently powerful to allow the actor to prevent public dissemination of the film. The decision has been widely criticized for its interpretation of the Copyright Act, its First Amendment implications, and its potential economic impact on the film and television industries. But few have considered the point that “related rights” — an alternative form of intellectual property distinct from copyright and designed to protect performances and recordings — could provide a more effective way of balancing the many interests at stake in cases like *Garcia*. Related rights protection for acting performances is not currently available in the United States, although it is widely recognized under international law and in the laws of many European countries. This means that, under American law, acting performances must either be governed by conventional copyright law or receive no IP protection at

all. By adding related rights protection to American law, Congress could stake out a middle ground between these two extremes and thus prevent quagmires like Garcia from emerging in the future.

How copyright keeps works disappeared

Paul J. Heald (University of Illinois College of Law)

Journal of Empirical Legal Studies, Vol. 11, Issue 4, pp. 829-866, 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2516113

A random sample of new books for sale on Amazon.com shows more books for sale from the 1880s than the 1980s. Why? This article presents new data on how copyright stifles the reappearance of works. First, a random sample of more than 2,000 new books for sale on Amazon.com is analyzed along with a random sample of almost 2,000 songs available on new DVDs. Copyright status correlates highly with absence from the Amazon shelf. Together with publishing business models, copyright law seems to deter distribution and diminish access. Further analysis of eBook markets, used books on Abebooks.com, and the Chicago Public Library collection suggests that no alternative marketplace for out-of-print books has yet developed. Data from iTunes and YouTube, however, tell a different story for older hit songs. The much wider availability of old music in digital form may be explained by the differing holdings in two important cases, *Boosey & Hawkes v. Disney* (music) and *Random House v. Rosetta Stone* (books).

The interstices of copyright law and contract law II: finding the terms of an implied nonexclusive license in the absence of joint authorship

Scott J. Burnham (Gonzaga University School of Law)

Journal of the Copyright Society of the USA, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2517631

In a 1999 article, I explored the problem that arises when one party -- whom I called the hiring party -- commissions a work from another party -- whom I called the hired party. The hired party is generally found to be the sole author of the work. The question then becomes: If the hired party is the copyright owner, what rights does the hiring party have to use the work?

The article argued that in the absence of a written agreement addressing the issue, under contract law principles, the hired party as copyright owner has granted the hiring party an implied nonexclusive license to use the work. The scope of that license can be deduced from the facts and circumstances using principles of contract law. The article suggested that courts apply a use test, under which the hiring party will be granted an implied nonexclusive license when the facts and circumstances indicate that the hiring party intended to use the work. The scope of that license is limited to the use reasonably contemplated.

This article explores a similar problem that arises when one party -- whom we will call the secondary party -- contributes to the work of another party -- whom we will call the primary party -- and claims that a joint work has been created. In the problematic cases, the contribution of the secondary party is likely made temporally after the primary party has largely completed the work, and spatially usually consists of a small part of the completed work. This article argues that principles of contract law should be used to determine whether the work is a joint work.

If the work is determined not to be a joint work, and the primary party has incorporated into the work material in which the secondary party is entitled to copyright protection, this article argues that the situation is analogous to the relationship between the hiring party and the hired party under a failed work for hire agreement. The secondary party has granted the primary party an implied nonexclusive license to use the work and principles of contract law will again be used to determine the scope of that license.

Private copying and downloading from unlawful sources

João Pedro Quintais (University of Amsterdam)

Forthcoming International Review of Intellectual Property and Competition Law (IIC), 2015

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2513794

Private copying is one of the most contested areas of EU copyright law. This paper surveys that nebulous area and examines the issue of copies made from unlawful sources in light of the ECJ's ACI Adam decision. After describing the legal background of copyright levies and the facts of the litigation, the paper scrutinizes the Advocate General's Opinion and the Court's decision. The latter is analyzed against the history of copyright levies, the ECJ's extensive case-law on the private copying limitation and Member States' regulation of unlawful sources. This paper further reflects on the decision's implications for end-users, rights holders, collective management organizations and manufacturers/importers of levied goods. It concludes that, from a legal and economic standpoint, the decision not only fails to be properly justified, but its consequences will likely diverge from those anticipated by the Court. Most worrisome is the Court's stance on the three-step test, which it views as a restrictive, rather than enabling, clause. In its interpretation of the test, the decision fails to strike the necessary balance between competing rights and interests. This is due to multiple factors: overreliance on the principle of strict interpretation; failure to consider the fundamental right of privacy; lack of justification of the normative and empirical elements of the test's second condition; and a disregard for the remuneration element in connection with the test's third condition. To the contrary, it is argued that a flexible construction of the three-step test is more suited to the Infosoc Directive's balancing aims.

IP & Biotechnology

The new genomic semicommons

Anna B. Laakmann (Lewis & Clark Law School)

UC Irvine Law Review, 2015, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2509571

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court held that isolated genomic DNA constitutes patent-ineligible subject matter, but that laboratory created complementary DNA (cDNA) is patent-eligible. This result makes sense as a matter of innovation policy, since it places genomic DNA into the research commons while maintaining patent eligibility for cDNA used to discover new drug targets and to produce therapeutic biologics. However, the decision's flawed reasoning based on misconceptions of products and laws of nature could have wide-ranging negative effects on the nascent field of personalized medicine. Although Myriad ostensibly averts an anticommons tragedy associated with gene patenting, the decision may in fact worsen a growing commons problem in medical research. Heightened uncertainty surrounding the patentability of complex, data-driven discoveries could undermine socially productive sharing regimes by altering the private payoffs associated with cooperation. Rising patent eligibility hurdles coincide with intensifying regulatory scrutiny of medical diagnostics. The obvious concern is that the combination of an inability to patent genomic inventions and higher regulatory barriers to market entry could decimate the fledgling industry supporting personalized medicine. However, perhaps counter-intuitively, a carefully crafted regulatory scheme actually could promote innovation by acting as a "visible hand" to coordinate the generation and dissemination of patent-ineligible genomic information.

The Hatch-Waxman Act's side effects: precautions for biosimilars

Anna B. Laakmann (Lewis & Clark Law School)

Loyola of Los Angeles Law Review, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2518666

The Drug Price Competition and Patent Term Restoration Act of 1984 (generally known as the Hatch-Waxman Act, or "Hatch-Waxman") was designed to expedite regulatory approval of generic drugs while

simultaneously preserving incentives for innovators to invest in the research and development of new drugs. While Hatch-Waxman has undoubtedly achieved its aim of creating a robust generic pharmaceuticals market, it has also produced several unanticipated consequences. Its changes to the federal regulatory scheme have yielded convoluted products liability rules, upsetting the conventional notion that the seller of a defective product is liable for harm caused by its intended use. In addition, its modifications to patent law have had the perverse effects of propagating patents of questionable value and encouraging potentially anti-competitive agreements between generic and brand name manufacturers.

Hatch-Waxman's emergent repercussions are particularly salient in light of the recent passage of the Biologics Price Competition and Innovation Act (BPCIA). The BPCIA, enacted as part of the Patient Protection and Affordable Care Act of 2010, crafted a compromise between pioneer and follow-on biologics manufacturers patterned after Hatch-Waxman's regulatory scheme for pharmaceuticals. This Article reviews Hatch-Waxman unintended effects, and suggests that they should serve as precautionary guideposts for implementation of the BPCIA. The FDA and lawmakers should heed these potential pitfalls and proactively confront unavoidable tradeoffs between safety, cost, and access to therapeutic biologics.

Other IP Topics

Do managers use meeting analyst forecasts to signal private information? Evidence from patent citations

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Tracey Chunqi Zhang (Singapore Management University)

Journal of Business Finance & Accounting, Vol. 41, Issue 7-8, pp. 950-973, 2014

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2511996

This study examines whether firms manage earnings to meet analyst forecasts to signal superior future performance. Prior research finds that firms use earnings management to just meet analyst forecasts and that these firms have a positive association with future performance (Bartov et al., 2002). There are two potential explanations for the positive association – signaling and attaining benefits that allow for better future performance (i.e., the real benefits explanation). Prior studies cannot provide evidence of signaling because they do not control for the real benefits explanation. Our research design enables us to control for the real benefits explanation because we can identify potential signaling firms within the sample of firms that just meet analyst forecasts. We use a unique database from the National Bureau of Economic Research to construct a proxy for the manager's belief about future firm value due to patents. We find that firms with more patent citations are more likely to just meet the analyst forecast and manage earnings to achieve this goal. We also find firms that just meet analyst forecasts with more patent citations have significantly better performance than firms with fewer patent citations, which is consistent with signaling and not the real benefits explanation.

The new cognitive property: human capital law and the reach of intellectual property

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Texas Law Review, 2015, Forthcoming

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2517604

Contemporary law has become grounded in the conviction that not only the outputs of innovation – artistic expressions, scientific methods, and technological advances – but also the inputs of innovation – skills, experience, know-how, professional relationships, creativity and entrepreneurial energies – are subject to control and propertization. In other words, we now face a reality of not only the expansion of intellectual property but also cognitive property. The new cognitive property has emerged under the radar, commodifying intellectual intangibles which have traditionally been kept outside of the scope of

intellectual property law. Regulatory and contractual controls on human capital – post-employment restrictions including non-competition contracts, non-solicitation, non-poaching, and anti-dealing agreements; collusive do-not-hire talent cartels; pre-invention assignment agreements of patents, copyright, as well as non-patentable and non-copyrightable ideas; and non-disclosure agreements, expansion of trade secret laws, and economic espionage prosecution against former insiders – are among the fastest growing frontiers of market battles. This article introduces the growing field of human capital law, at the intersections of IP, contract and employment law, and antitrust law, and cautions against the devastating effects of the growing enclosure of cognitive capacities in contemporary markets.

About the editor

Dr. Anne Layne-Farrar is a vice president in the Antitrust & Competition Economics Practice of CRA. She specializes in antitrust and intellectual property matters, especially where the two issues are combined. She advises clients on competition, intellectual property, regulation, and policy issues across a broad range of industries with a particular focus on high-tech and has worked with some of the largest information technology, communications, and pharmaceuticals companies in the world.

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