



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 & Innovation

The innovation consequences of mandatory patent disclosures

Jinhwan Kim (Stanford Graduate School of Business)

Kristen Valentine (University of Georgia)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3469400

We investigate the effect of patent disclosures on corporate innovation. Using the American Inventor's Protection Act (AIPA) as a shock that increased patent disclosures, we find an increase in innovation for firms whose rivals reveal more information after the AIPA and a decrease in innovation for firms whose own disclosures are divulged to competitors as a result of the law. These findings suggest patent disclosures generate both spillover benefits and proprietary costs. Further, we find that firms use strategic disclosure choices allowed by patent law in an attempt to mitigate proprietary costs. Our findings provide justification for patent disclosure requirements by demonstrating positive externalities: rivals' disclosures facilitate a firm's innovation. However, we also highlight that mandatory patent disclosure can impose proprietary costs on firms that are not fully mitigated by strategic disclosure responses.

The biosimilar action plan: An effective mechanism for balancing biologic innovation and competition in the United States?

Simone A. Rose (Wake Forest University School of Law)

Tracea Rice (Fish & Richardson P.C.)

McGeorge Law Review, Forthcoming

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3489444

The strain between balancing pharmaceutical innovation and competition in the United States (U.S.) is centered around the need to ensure that the U.S. continues to encourage medical innovation while simultaneously providing patients with access to affordable and innovative drug treatments. This tension exists whether the drugs at issue are chemically-synthesized or complex large molecule drugs, such as biologics. In 2010, Congress passed the Biologic Price Competition and Innovation Act (BPCIA). The statute created a statutory approval pathway for biological products shown to be biologically similar

(biosimilar) to the originator or “brand” biologic, while retaining the same safety, purity, and potency as the brand. Unfortunately, the BPCIA’s provisions failed to accelerate biosimilar product development in the United States and we continue to lag behind Europe in providing patient access to affordable biosimilars.

To help stimulate the U.S. biosimilar market, the Food and Drug Administration (FDA) issued the Biosimilar Action Plan (BAP) in July 2018. BAP focuses on four key strategies: 1) streamlining the biosimilar approval and product development process; 2) increasing biosimilar informational resources; 3) maximizing scientific and regulatory clarity; and 4) “getting competitively priced biosimilars into the market by reducing the gaming of FDA requirements and other attempts to unfairly delay competition.”

An enhanced informational platform and streamlined approval process should increase the biosimilar approval rate and accelerate biosimilar product development. However, the FDA’s regulatory powers are insufficient to curb the gaming and other anticompetitive behaviors that most negatively impact access, such as: 1) rebating schemes; 2) pay-for-delay agreements; 3) leveraging innovator patent rights to impede biosimilar market entry and 4) other regulatory abuses. Partnerships with key stakeholders, such as Congress, the Federal Trade Commission, States, Non-Governmental Organizations, and Payors are therefore crucial to achieving the BAP’s overarching goal of “promoting competition and affordability [of biosimilars] across the market.” The recently proposed Biologic Patent Transparency Act provides an example of how Congress can work in tandem with the FDA and other stakeholders to foster innovation and build a competitive and sustainable biosimilar marketplace for patients in the U.S.

Corporate innovation and returns

Jan Bena (University of British Columbia – Sauder School of Business)

Lorenzo Garlappi (University of British Columbia (UBC) – Sauder School of Business)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3471692

Among U.S. public firms, technological innovation is concentrated in a small set of large players, with innovation “leaders” having considerably lower systematic risk than “laggards.” To understand this fact, we build a winner-takes-all patent-race model and show that a firm’s expected return decreases in its innovation output and increases in that of its rivals. Using a comprehensive firm-level panel of information on patenting activity by fields of technology in 1950-2010, we find strong support for the model’s predictions. Our results highlight that strategic interactions among firms competing in innovation are an important determinant of risk and expected returns.

Artificial intelligence in pharmaceuticals, biologics, and medical devices: Present and future regulatory models

David W. Opderbeck (Seton Hall University – School of Law)

Fordham Law Review, Vol. 88, 2019

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3478135

This Essay surveys the current legal and economic framework for drugs, biologics, and medical devices in the United States, and discusses some ways in which AI might disrupt that framework. It examines emerging policies at the FDA for in silico trials — trials conducted by computer models, often involving AI technologies — and AI-enabled medical devices. It also discusses how AI might stretch those policies over the next ten to twenty years and takes a speculative look at AI-enabled drugs and devices in the year 2050.

IP & Law Intersections

Spousal rights to inventions: A latent threat to corporate patent portfolios

Daniel H. Shulman (Vedder Price P.C.)

Angela Upchurch (Southern Illinois University at Carbondale – School of Law)

Seton Hall Law Review, Vol. 50, No. 1, 2020

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3476899

The intersection between patent law and family law principles has the potential to create an irreconcilable conflict in the area of patent ownership. These two legal worlds operate by virtue of different statutory provisions of automatic vesting of title that appear to be unable to coexist. Under U.S. patent law, ownership of a patent automatically vests, as personal property, in the individual inventor. Many, if not most, inventors are employees who, under some written obligation (such as a routine employment agreement), assign their ownership rights to the inventions created as part of their jobs to their employers. At the same time, however, property acquired by a married individual (in most, if not all states) is considered marital or community property of the married couple. In that case, then, when an employee invents something and acquires an interest in a patent (which the employee does automatically upon invention under U.S. law), that patent may become marital property of the couple before the employee assigns the employee's interest to the employer. In other words, an employer who receives an assignment from the employee alone of only the employee's interest may end up owning the patent jointly with the spouse who has his or her own undivided interest in the marital property.

This problem is particularly acute when, as is commonly the case, the assignment from the employee to the employer is a present assignment of an expectant interest which transfers legal title in the patent to the employer as soon as the patent arises. In that case, the two property regimes — patent law and marital property law — have competing, incompatible automatic vesting regimes. Patent law automatically vests ownership of patents in inventors and, by virtue of most common employment agreements, their employees; marital law, at least in community property states, automatically vests ownership of property in the spouse. The result, never previously explored, is that vast corporate patent portfolios may be subject to co-ownership with thousands of individual employee spouses (or ex-spouses).

Federal courts may not be able to resolve this conflict without wading into family law, an area traditionally left to the states. In addition, federal courts have long maintained that patent ownership is a matter of state property and contract law, making a judicial remedy on the basis of preemption unlikely. In *Spousal Rights to Inventions: A Latent Threat to Corporate Patent Portfolio*, we propose new federal legislation is necessary to create predictability in corporate patent ownership. Additionally, we provide some practical suggestions for employers confronted with this dilemma.

Explaining criminal sanctions in intellectual property law

Irina D. Manta (Hofstra University – Maurice A. Deane School of Law; St. John's University School of Law)

1 Journal of Law & Innovation 16 (2019)

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3464725

This symposium piece first seeks to unpack the relationship between intellectual property infringement and property offenses, and then to understand how the connection between the two has informed when the former is criminalized. The piece examines the porous nature of the boundary line between intangible and tangible resources, showing the at-times uncomfortable fit of the non-rivalrous label to

intellectual property. An analysis of the respective harms of the two types of violations follows. This symposium contribution shows how lawmakers have treated patents differently from other forms of intellectual property by choosing not to criminalize their infringement, due both to utilitarian reasons and public choice rationales. While historically the entities who pushed for harsher sanctions for copyright violations in particular have often not encountered resistance, a combination of large tech companies' and grassroots organizations' activism has thwarted attempts at strengthened enforcement in recent times. The political landscape of copyright lawmaking, however, may be on its way to the greater degree of equipoise between support and opposition to greater sanctions that one observes in the patent legislative context.

Intellectual property and investment law: An introduction

Christophe Geiger (Université de Strasbourg – CEIPI)

in: Christophe Geiger (ed.), "Research Handbook on Intellectual Property and Investment Law", Cheltenham (UK)/Northampton, MA (USA), Edward Elgar Publishing, 2019 Forthcoming
Centre for International Intellectual Property Studies (CEIPI) Research Paper No. 2019-10

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3486879

This short contribution constitutes the introductory chapter of the Research Handbook on Intellectual Property and Investment Law edited by Christophe Geiger and forthcoming in the Research Handbook series of Edward Elgar Publishing. The volume explores the complex and controversial interaction between intellectual property and investment law in the light of recent developments at international, European and national level. Indeed, international investment agreements often include specific references to IP rights in the list of 'investments' protected, thus allowing private parties to challenge States' measures through investor-state dispute settlement (ISDS) mechanisms. Furthermore, the Handbook critically examines the legitimacy of current practices with regard to the social function of IP rights and the regulatory autonomy of States to take measures of public interest, as well as the likely avenues for future developments in the field. All the high profile cases are discussed not only in their investor-state context but also in the framework of other fora where they have been adjudicated such as the World Trade Organization. The interaction with fundamental rights and ethics is also explored, as well as some specific implications for the EU, in particular in the context of proposed reforms for the controversial ISDS mechanisms in recently adopted bilateral agreements such as CETA.

IP & Litigation

The role of legal presumptions in patent litigation

Alice Guerra (Copenhagen Business School)

Tapas Kundu (Oslo Business School, Oslo Metropolitan University; School of Business and Economics, UiT the Arctic University of Norway)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3477505

We formally analyze the effects of legal presumptions in patent litigation. We set up a novel contest model to study litigation outcomes, judgement errors, and resource dissipation under three alternative presumption criteria: a presumption that the patent is valid; a presumption that the patent is invalid; no presumption regarding validity. Our findings reveal that any legal presumption – either in favor of validity or invalidity – is preferable than a no-presumption criterion when there is high uncertainty about the patent's objective merit.

An IPO pitfall: Patent lawsuits

Tolga Caskurlu (University of Amsterdam Business School)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3479253

The author documents a previously unexplored substantial cost of an initial public offering (IPO): patent lawsuits. She finds that firms become targets of excessive patent lawsuits shortly before IPO completions, and the litigation intensity persists after firms become public. However, firms that withdraw their IPO filings do not experience an increase after the withdrawal date. Unlike IPOs, seasoned equity offerings (SEO) do not yield an increase in lawsuits. Overall, these results show that going public makes firms vulnerable to costly lawsuits. Moreover, the percentage of IPO firms affected from patent lawsuits has been perilously soaring in the last two decades.

Cannabis trademarks and the First Amendment

Robert L. Greenberg (Farmingdale State College, SUNY)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3485100

A review of Supreme Court trademark litigation interpreting the First Amendment as well as recent trademark litigation at the state and federal levels. The prohibition on immoral trademarks has been steadily eroding as a result of First Amendment litigation at the United States Supreme Court. In light of recent Supreme Court decisions on trademark registrations and free speech, the question then becomes: Is the ban on cannabis trademark registrations justifiable in light of the First Amendment in view of these recent cases? The issue of whether the United States Patent & Trademark Office (USPTO) should or will issue registrations in light of this recent line of cases is discussed.

IP Law & Policy

Promoting the progress and ensuring patent quality through rigorous policy evaluation and piloting

Colleen V. Chien (Santa Clara University – School of Law; Stanford University – Management Science & Engineering)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3477517

Article I, Section 8, Clause 8, of the United States Constitution grants Congress the power "to promote the progress of science and useful arts." The core function of the US Patent and Trademark Office is to determine what inventions truly represent progress in view of the prior art. While to date most conversations about patent quality have centered on back-end measures, like inter partes review, or the use of weak patents over abstract ideas to get injunctions, in this testimony I make three arguments. First, more attention should be paid to the most important, front-end tool that the patent office has to issue valid patents: prior art vetting. While 11%-15% of office actions involve section 101, over 90% of patents are subject to a prior art rejection and my research suggests that there is a gap between the USPTO examiners and others and that this gap is correlated with outcomes. Second, the USPTO should use rigorous pilots to create hard evidence for hard decisions: There are many unknowns with respect to patent quality, and it would be premature to adopt wholesale some of the suggestions being made. However, the USPTO can fill these gaps in knowledge by being much more rigorous and deliberate in its evaluation of past and future policy pilots, using causal inference and other statistical tools to estimate, when it rolls out or pilots changes or interventions, their impact. Third, consider not

only time, but team, fee and other quality levers: the USPTO and Congress should take an expansive view of rigorous piloting to ensure patent quality looking at a variety of levers including: a) Time: The USPTO already has tried giving examiners more time, for example, when it implemented various Second Pair of Eyes programs over the years, and more counts were given to examiners. It also tried and is currently trying a number of different approaches to improving access to prior art. These should be evaluated rigorously. b) Team: The USPTO has smartly worked to provide not just more time but more “team” to Examiners, with foreign examiners (through the Global Dossier), applicants and industry (through programs like STEPP, PETTP, SEE and the Crowdsourcing prior art, 3P prior art submission, Track One, Prior Art Partnerships), other US examiners (through collaborative search efforts). We must use rigor to learn from these interventions. c) Prior Art Curation/IDS Policies: Examiners need context and curation, not just references. Though both contain prior art, large IDS are much less useful than carefully crafted international search reports and PTAB petitions. More rigorous policy attention should be paid here. d) Defensive Only Patents/Maintenance Fees: Most patents are held for defensive reasons and don’t need to be “litigation grade.” It’s not always known upfront which patents these are, making front-end gold-plating proposals challenging to the point of being unworkable. As described in my Article, Opening the Patent System, the USPTO should pilot offering a “back-end lead plating” option, what the author calls a “defensive only” patent option. Though this idea may sound novel, it’s not, it’s a version of the License on Right patent option that Germany and England offer, in the form of a discount on maintenance fees in exchange for a disclosure that the patent is being held for defensive reasons only. We can learn from prior sector commitments like OIN and LOT to perfect the US version for piloting. e) Continuations Practice: The USPTO examination process has a high tolerance for examiner mistakes, because it allows applicants to refile their rejected applications, and in many cases, get these cases allowed. While the practice limits the negative consequences associated with any bad Examiner decision, it makes Examiner inconsistency and mistakes tolerable, in turn, driving lower patent quality and satisfaction. Let’s test out ways to not only encourage but compel compact prosecution, for example by publishing grant rates on continued applications or making sure information on repeat filings is available to examiners. f) Inclusion Pilots: The applications of women and small and micro entity inventors have a lower success rate, with perverse distributional consequences including the higher application, lower grant rates to discounted entities and a higher grant rate to Asian female vs. US female inventors, my research suggests (see figures below). My paper, Rigorous Policy Pilots the Patent Office Could Try, suggests pilots to get at the root causes of these issues.

Patent trolls and the market for acquisitions

Arash Dayani (University of Oregon, Charles H. Lundquist School of Business, Department of Finance)
Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3470292

Frivolous patent-infringement claims increase the cost of innovation for small businesses and force them to exit via premature and discounted acquisitions. This study investigates the effect of abusive patent-infringement claims by patent trolls on acquisitions of small firms. The author exploits the staggered adoption of anti-patent troll laws in 35 states as a quasi-natural experiment and finds that the laws have two effects on acquisitions. First, the number of acquisitions of small businesses by large firms declines after these laws are passed. Second, the anti-troll laws increase the acquisition price for large firms. The author finds that the market reflects the increased cost of acquisition following the passage of anti-troll laws as measured by the lower acquisition announcement returns. Moreover, there is evidence that large firms increase R&D expenditure after the adoption of state laws. Using a sample of acquisitions that are plausibly unaffected by the state laws, he disentangles alternative explanations

such as local economic shocks, industry-wide changes and merger waves. Overall, the findings suggest that the anti-patent troll laws increase the value of small innovative firms.

Brief of Amici Curiae professors of patent and administrative law in support of respondent, *Thryv, Inc. v. Click-To-Call Technologies, LP*, No. 18–916 (Sup. Ct., Nov. 4, 2019)

Saurabh Vishnubhakat (Texas A&M University School of Law; Duke University School of Law)
Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3480811

This case implicates a significant balance in the patent system between the competing powers of the federal courts and the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“PTAB”) to review patent validity. Congress allocated those powers through several provisions of the America Invents Act, including the one-year time bar of 35 U.S.C. § 315(b). The Federal Circuit, starting with its en banc decision in *Wi-Fi One, LLC v. Broadcom Corp.*, 878 F.3d 1364 (Fed. Cir. 2018), has been taking proper account of that balance of power by exercising judicial review over the PTAB’s application of the one-year bar.

Judicial review of § 315(b) time-bar determinations is foundational to safeguarding the court-agency balance of patent powers, whose scope and impact extend well beyond the PTAB and into the courts. Accordingly, the Federal Circuit’s conclusion that such review is available correctly applies this Court’s guidance in *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131 (2016), and is strengthened even further by this Court’s subsequent decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018).

Moreover, detailed empirical evidence reveals that litigants use the PTAB to a significant extent as a strategic substitute for courts in reevaluating patent validity. Strategic substitution is subject to important statutory constraints, especially the one-year bar of § 315(b). These constraints promote repose for litigants, conservation of both court and agency resources, and inter-branch respect for the judgments of competing tribunals. Accordingly, in evaluating the reviewability of the PTAB’s timeliness determinations under § 315(b), this Court should take careful account of the significant scope and impact that § 315(b) has beyond the inter partes review setting in preserving the balance of power that Congress has allocated to the PTAB and to the courts.

Copyright, Trademark, & Trade Secret Law

Trademark registration: Understanding the distinction between standard character mark and stylised mark

Ademola Adeyoju (Independent)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3479044

When registering a trademark, one of the most vital decisions that trademark owners must make is choosing whether to register the trademark as a standard character mark or as a stylised mark. Understanding the difference between these types of trademark is crucial. An incorrect choice can have serious unintended consequences in the short- and long-run.

Where practicable, it is usually advised that both the standard character mark and the stylised mark should be registered in separate applications. This affords comprehensive protection and allows the trademark owner to use or display the words and logo in their trademark differently and separately, in

any form, orientation, or arrangement, without offending the 'material alteration rule' and without needing to refile the various displays or placements as new trademarks.

This essay briefly considers the meaning and functions of trademark. It then goes on to describe the distinctions between standard character mark and stylised mark.

Fair use in the United States: Transformed, deformed, reformed?

Jane Ginsburg (Columbia University – Law School)

Columbia Public Law Research Paper No. 14-639

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3484949

Since the US Supreme Court's 1994 adoption of "transformative use" as a criterion for evaluating the first statutory fair use factor ("nature and purpose of the use"), "transformative use" analysis has engulfed all of fair use, becoming transformed, and perhaps deformed, in the process. A finding of "transformativeness" often foreordained the ultimate outcome, as the remaining factors, especially the fourth (impact of the use on the market for or value of the copied work), withered into restatements of the first. For a time, moreover, courts' characterization of uses as "transformative" seemed ever more generous (if not in some instances credulous).

Lately, however, the fair use pendulum's outward swing may have arrested, as courts express greater skepticism concerning what uses actually "transform" content copied into new works or repurposed into copyright-voracious systems. As a result, courts may be reforming "transformative use" to reinvigorate the other statutory factors, particularly the inquiry into the impact of the use on the potential markets for or value of the copied work. The restored prominence of the fourth factor should also occasion renewed reflection on its meaning. As digital media bring to the fore new or previously under-examined kinds of harm, courts will need not only to continue to refine their appreciation of a work's markets, but also to expand their analyses beyond the traditional inquiry into whether the challenged use substitutes for an actual or potential market for the work. Courts should acknowledge that the statute's designation of "the value of the copyrighted work" identifies an independent kind of harm, and entails considerations distinct from market substitution. Those include creators' economic and moral interests in being recognized as the authors of the copied works.

Should dissimilar uses of trade secrets be actionable

Camilla Alexandra Hrdy (University of Akron School of Law)

University of Pennsylvania Law Review Online Vol. 167: 78, 2019

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3475119

Joseph Fishman and Deepa Varadarajan challenge the current approach for determining misappropriation in trade secret law — which assesses whether a defendant's end use is "substantially derived" from the plaintiff's trade secrets. They argue the law should instead take into account the plaintiff's and defendant's end uses for the allegedly infringing information. They suggest that if the defendant's end use is highly dissimilar from the plaintiff's, the law should not, as a general matter, prohibit it.

This response shows that the article's thesis — that trade secret law should imitate copyright law's willingness to permit substantially dissimilar uses of content — conflicts with trade secret law's fundamental purpose: to protect the integrity of secret information. Trade secret law already has a doctrine that addresses many of the harms with which the authors are concerned.

Whereas Fishman and Varadarajan have turned to copyright law for help, it makes more sense to focus on improving the doctrines we already have. Improving existing doctrines will do more to ameliorate concerns about hindering innovative new uses, while maintaining trade secret law's fundamental goals.

Other IP Topics

Give me your tired, your poor, your high-skilled labor: H-1B lottery outcomes and entrepreneurial success

Stephen G. Dimmock (Nanyang Technological University – Division of Finance)
Jiekun Huang (University of Illinois at Urbana-Champaign – Department of Finance)
Scott J. Weisbenner (University of Illinois at Urbana-Champaign – Department of Finance; National Bureau of Economic Research (NBER))

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3468544

The authors study how access to high-skill labor affects the outcomes of start-up firms. They obtain exogenous variation in firms' ability to access skilled labor by using win rates in H-1B visa lotteries. Relative to other firms that also applied for H-1B visas, firms with higher lottery win rates are more likely to receive additional venture capital funding and to have a successful exit via an IPO or acquisition. H-1B visa lottery winners also subsequently receive more patents and patent citations. Overall, the results show that access to high-skill labor is a critical determinant of success for start-up firms.

Gender and Australian patents

Vicki T. Huang (Deakin University, Geelong, Australia – Deakin Law School; University of Melbourne - Law School)

Sue Finch (University of Melbourne)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3476126

For the past two decades, successive Australian governments have sought to increase the participation of women in STEM-related fields. One reason for this is the advancement of social equality; another reason is the popular theory that STEM-based-innovation is and will be a primary driver of future economic growth. Rigorous intellectual property law (particularly patent law), supports this strategy by facilitating the commercialisation of innovative ideas. A patent provides the inventor(s) with an opportunity to monetise their work, and (in exchange) the technology disclosed can be used by the public to further scientific progress.

One measure of female participation in STEM, is participation as an inventor in the patents system. There is some evidence that Australian patent applications with female inventors have increased over the last 30 years. However, while applications have increased, it is unclear whether women are as successful as men in having their patent application proceed to grant. In 2018, Yale researchers examined 2.7 million US patent applications and found that inventors with female sounding names were less likely to be granted a patent than inventors with male or neutral sounding names. The researchers concluded that some bias was evident from the examiner-side and suggested that the examination process be blinder to the identity of participants.

This study will work with large data sets from IP Australia to determine whether the gender of the inventor impacts Australian patent application outcomes. The findings from this project could have

major implications on patent prosecution procedures and long term strategies for gender equity in STEM fields.

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