



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 & Licensing

FRAND patents in Europe in the post-Huawei era: A recent report from Germany

Matthias Leistner (Ludwig Maximilian University of Munich)

Chapter 16 in: Hilty/Liu (eds), SEPs, SSOs and FRAND – Asian and Global Perspectives on Fostering Innovation in Interconnectivity, Springer, 2018 (Forthcoming)

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3278769

Since 2015, the enforcement of FRAND patents in Europe is governed by the framework laid down in the Huawei/ZTE judgment of the CJEU. Influential post-Huawei/ZTE cases have been decided in Germany and the UK. After a brief outline of the development leading to Huawei/ZTE and of the contents of the Huawei/ZTE judgment, the present paper mainly reports on recent case law from Germany (with some comparative remarks and references on case law in England, the U.S. and China). Essentially, the paper argues that the German courts have specified the framework set by Huawei/ZTE, thereby tentatively answering many of the open questions raised by the rather generally framed judgment of the CJEU. Notwithstanding some remaining problems and some contradictions between the German courts' approach and the English High Court's as well as the Court of Appeal's approach in Unwired Planet/Huawei, the present paper argues that enforcement of FRAND patents in Europe has become considerably more predictable since Huawei/ZTE, and that the general framework, established by the CJEU, allows for the development of fair and workable procedural standards guiding the enforcement of SEP's and the possible competition law defense in Europe. In addition, the paper tries to identify and specify the fundamental considerations underpinning Huawei/ZTE. This allows to consider whether and to what extent the CJEU's Huawei/ZTE doctrine should be broadened beyond the realm of genuine SEPs, which lead to a dominant position of the right holder, in the future. Also some additional avenues for the solution of SEP problems (such as through further upstream regulation of the standardization process and institutions, contract law and/or civil procedural law) are briefly proposed, which should be further developed and tested in the future.

The Federal Trade Commission's hearings on competition and consumer protection in the 21st century, innovation and intellectual property Policy, comment of the Global Antitrust Institute, Antonin Scalia Law School, George Mason University

Tad Lipsky (George Mason University - Antonin Scalia Law School)

Joshua D. Wright (George Mason University - Antonin Scalia Law School, Faculty)

Douglas H. Ginsburg (U.S. Court of Appeals for the District of Columbia Circuit; George Mason University - Antonin Scalia Law School, Faculty)

John M. Yun (George Mason University - Antonin Scalia Law School, Faculty)

George Mason Law & Economics Research Paper No. 18-40

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3272402

This comment is submitted in relation to the Federal Trade Commission's ("FTC") Hearings on Competition and Consumer Protection in the 21st Century. We submit this Comment based upon our extensive experience and expertise in antitrust law and economics. As an organization committed to promoting sound economic analysis as the foundation of antitrust enforcement and competition policy, the Global Antitrust Institute commends the FTC for holding these hearings and for inviting discussion concerning a range of important topics.

In this Comment, we will discuss contemporary issues involving innovation, Standard Essential Patents ("SEPs"), and Fair, Reasonable, and Non-Discriminatory ("FRAND") pricing commitments. As we move forward in an era marked by constant innovation revolving around Intellectual Property ("IP") rights, it is imperative that the FTC recognize that these IP rights should be treated under the same analytical framework as other property rights and upheld regardless whether the setting is private licensing or FRAND commitments. Our modern law and jurisprudence are well-developed in the area of IP rights, and the reliance on IP rights in the standard-development process should not be accompanied by a move away from this well-developed body of law. In writing this Comment, we want to emphasize the importance of strong IP rights, the lack of evidence supporting the concern over holdup issues, and the need for the FTC to recalibrate priorities in the relationship between IP and antitrust.

Worldwide FRAND licensing standard

Garry Gabison (Queen Mary University of London - Centre for Commercial Law Studies) *Working Paper*

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3279549

Worldwide licenses linked to the standard setting process are being challenged on antitrust and jurisdictional grounds. While, so far, most courts have batted away these challenges, some courts have not recognized their validity. If worldwide licenses were to not be enforce globally, then the patent exhaustion doctrine could further eat into the patent holders' returns. Raising cost of enforcement linked to local licenses and lower returns linked to patent exhaustion would de-incentivize standard setting participants. These worldwide licenses are essential to the standard system and must be protected as such: the standard setting organizations, Antitrust authorities, and courts have part to play to ensure the standards survive these attacks.

IP & Economics

Price discrimination & intellectual property

Ben Depoorter (University of California Hastings College of Law; Ugent - CASLE; Stanford CIS)

Michael J. Meurer (Boston University - School of Law)

UC Hastings Research Paper No. 303

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3271247

This chapter reviews the law and economics literature on intellectual property law and price discrimination. We introduce legal scholars to the wide range of techniques used by intellectual property owners to practice price discrimination; in many cases the link between commercial practice and price discrimination may not be apparent to non-economists. We introduce economists to the many facets of intellectual property law that influence the profitability and practice of price discrimination. The law in this area has complex effects on customer sorting and arbitrage. Intellectual property law offers fertile ground for analysis of policies that facilitate or discourage price discrimination. We conjecture that new technologies are expanding the range of techniques used for price discrimination while inducing new wrinkles in intellectual property law regimes. We anticipate growing commentary on copyright and trademark liability of e-commerce platforms and how that connects to arbitrage and price discrimination. Further, we expect to see increasing discussion of the connection between intellectual property, privacy, and antitrust laws and the incentives to build and use databases and algorithms in support of price discrimination.

Who profits from patents? Rent-sharing at innovative firms

Patrick Kline (University of California, Berkeley - Department of Economics)

Neviana Petkova (Government of the Italian Republic (Italy) - Department of the Treasury)

Heidi L. Williams (MIT Department of Economics; National Bureau of Economic Research (NBER))

Owen Zidar (Princeton University)

NBER Working Paper No. w25245

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3282909

This paper analyzes how patent-induced shocks to labor productivity propagate into worker compensation using a new linkage of US patent applications to US business and worker tax records. We infer the causal effects of patent allowances by comparing firms whose patent applications were initially allowed to those whose patent applications were initially rejected. To identify patents that are ex-ante valuable, we extrapolate the excess stock return estimates of Kogan et al. (2017) to the full set of accepted and rejected patent applications based on predetermined firm and patent application characteristics. An initial allowance of an ex-ante valuable patent generates substantial increases in firm productivity and worker compensation. By contrast, initial allowances of lower ex-ante value patents yield no detectable effects on firm outcomes. Patent allowances lead firms to increase employment, but entry wages and workforce composition are insensitive to patent decisions. On average, workers capture roughly 30 cents of every dollar of patent-induced surplus in higher earnings.

This share is roughly twice as high among workers present since the year of application. These earnings effects are concentrated among men and workers in the top half of the earnings distribution, and are paired with corresponding improvements in worker retention among these groups. We interpret these earnings responses as reflecting the capture of economic rents by senior workers, who are most costly for innovative firms to replace.

Patent disclosure and price discovery

Deepak Hegde (New York University (NYU) - Leonard N. Stern School of Business)

Baruch Lev (New York University - Stern School of Business)

Chenqi Zhu (New York University (NYU) - Leonard N. Stern School of Business)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3274837

We focus in this study on the exogenous event of the enactment of American Inventor's Protection Act of 1999 (AIPA), which disseminates timely, detailed, and credible public information on R&D activities through pre-grant patent disclosures. Exploiting the staggered timing of patent disclosures, we identify a significant improvement in the efficiency of stock price discovery. This improvement is stronger when patent disclosures reveal firms' successful, new, or technologically valuable inventions. This improvement is more pronounced for firms in high-tech or fast-moving industries, or with a large institutional ownership or analyst coverage. We also find stock liquidity rises and investors' risk perception of R&D drops after the enactment of AIPA. Our results highlight the importance of timely, detailed, and credible disclosures of R&D activities in alleviating the information problems faced by R&D-intensive firms.

IP & Litigation

Prior art in the district court

Stephen Yelderian (Notre Dame Law School)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3286022

This article is an empirical study of the evidence district courts rely upon when invalidating patents. To construct our dataset, we collected every district court ruling, verdict form, and opinion (whether reported or unreported) invalidating a patent claim over a six-and-a-half-year period. We then coded individual invalidation events based on the prior art supporting the court's analysis. In the end, we observed 3,320 invalidation events based on 817 distinct prior art references.

The nature of the prior art relied upon to invalidate patents informs the value of district court litigation as an error correction tool. The public interest in revoking erroneous patent grants depends significantly on the reason those grants were undeserved. Distinguishing between revocations that incentivize future inventors and those that do not requires understanding the reason individual patents are invalidated.

While prior studies have explored patent invalidity in general, no study has reported data at the level of detail necessary to address these questions.

The conclusions here are mixed. On one hand, invalidations for lack of novelty bear many indicia of publicly beneficial error correction. Anticipation based on obscure prior art appears to be quite rare. When it comes to obviousness, however, a significant number of invalidations rely on prior art that would have been difficult or impossible to find at the time of invention. This complicates — though does not necessarily refute — the traditional view that obviousness challenges ought to be proactively encouraged.

Brief for Samuel L. Bray as amicus curiae supporting petitioners, Merck & Co. v. Gilead Sciences, Inc.

Samuel L. Bray (Notre Dame Law School)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3272600

One of the long-standing maxims of equity is that “he who comes into equity must come with clean hands.” It is closely related to the maxim that “he who seeks equity must do equity.” These equitable principles are “an historical reflection of the fact that courts of equity began as courts of conscience.” In this country and throughout the common law world, unclean hands has traditionally been a defense to equitable claims, but not to legal claims.

Yet in the case below the Federal Circuit applied the equitable defense of unclean hands to a legal claim for damages for patent infringement. The Federal Circuit repeatedly relied on precedents of this Court that characterize unclean hands as an equitable defense that constrains a court of equity. The Federal Circuit provided no support whatsoever for applying the equitable defense of unclean hands to a legal claim for damages, especially when that equitable defense would displace the verdict of a jury.

A patent reformist Supreme Court and its unearthed precedent

Samuel Ernst (Golden Gate University School of Law)

Fordham Intellectual Property, Media & Entertainment Law Journal, Forthcoming

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3263634

How is it that the Supreme Court, a generalist court, is leading a project of innovation reform in our times while the court of appeals established to encourage innovation is having its precedent stricken down time and again? This decade the Supreme Court has issued far more patent law decisions than in any decade since the passage of the Patent Act of 1952. In doing so, the Supreme Court has overruled the Federal Circuit in roughly three-quarters of the patent cases in which the Supreme Court has issued opinions. In most of these cases, the Supreme Court has established rules that favor accused infringers over patent holders, and the result has been an era of patent litigation reform far more impactful than anything Congress has achieved. Scholars have observed that the Supreme Court tends to overrule Federal Circuit decisions that (1) impose rigid legal rules as opposed to flexible standards; (2) adopt special rules for patent law cases rather than applying general principles of law and equity applicable to

all federal cases; and/or (3) fail to grant sufficient discretion to the district courts. This paper examines the twenty-eight Supreme Court opinions overruling the Federal Circuit since 2000 and quantifies their rationales to discover that, while these reasons are often invoked, the Supreme Court's most common rationale is that the Federal Circuit has disregarded or cabined its older precedent from before the 1982 creation of the Federal Circuit, from before the 1952 Patent Act, and even from before the 20th Century. The Court has relied on this rationale in twenty-one of the twenty-eight cases. The paper then seeks to probe beneath the surface level patterns to discover the deeper roots of the discord between the Supreme Court and the Federal Circuit. Constitutional law scholars have observed that the Supreme Court's policy preferences are the primary, unstated motivation behind its decisions. The Court writes opinions that rely on the flexible tools of precedent and stare decisis in order to implement its policy choices while maintaining its institutional reputation for neutrality. The Court does this by influencing precedent vitality; the Court selects which of its precedent to rely upon and augment and which of its precedent to distinguish and narrow. This process runs in direct conflict with the Federal Circuit, a court that was originally conceived and viewed by some of its members as a court intended to bring uniformity to patent law in a way that would reinvigorate patent rights. The Federal Circuit would implement the 1952 Patent Act in a way that would draw patent law out of the nineteenth century. But for the Supreme Court, the 1952 Act was a mere codification of patent law as developed by the courts for over a hundred years. Hence, the Federal Circuit seeks to influence precedent vitality at direct cross-purposes with the Supreme Court. The result of the Supreme Court's project has been a new era of common law patent reform in favor of accused infringers, which is gaining momentum as the Supreme Court decides far more patent cases than it has since the passage of the Patent Act of 1952.

IP Law & Policy

Patent policy and American innovation after eBay: An empirical examination

Timothy Simcoe (Boston University - Questrom School of Business; NBER)

Filippo Mezzanotti (Kellogg School of Management - Department of Finance)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3183402

The 2006 Supreme Court ruling in *eBay vs. MercExchange* marked a sea change in U.S. patent policy. The *eBay* decision removed the presumption of injunctive relief. Subsequent legal and policy changes reduced the costs of challenging patent validity and narrowed the scope of patentable subject matter. Proponents of these changes argue that they have made the U.S. patent system more equitable, particularly for sectors such as information technology, where patent ownership is fragmented and innovation highly cumulative. Opponents suggest the same reforms have weakened intellectual property rights and curtailed innovation. After reviewing the legal background and relevant economic theory, we examine patenting, R&D spending, venture capital investment and productivity growth in the wake of the *eBay* decision. Overall, we find no evidence that changes in patent policy have harmed the American innovation system.

Philosophical approaches to intellectual property law scholarship

Jeremy N. Sheff (St. John's University School of Law)

Handbook on Intellectual Property Research (Irene Calboli & Maria Lilla Montagnani, eds.), Oxford University Press (Forthcoming)

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3273926

Intellectual property (IP) law and philosophy is an interdisciplinary approach to scholarship that applies insights and methods from philosophy to the legal, normative, theoretical, political, and empirical questions presented by the project of organizing and regulating the creation and dissemination of knowledge, technology, and culture. In this chapter, I outline four types of IP-law-and-philosophy scholarship, focusing specifically on the discipline of analytic philosophy (with appropriate caveats about the coherence of that discipline). These modes of scholarship can be categorized as (1) the jurisprudence of the IP system, (2) philosophical analysis of IP law, (3) applied philosophy in IP, and (4) normative theory of IP. Category (4) is obviously a special case of category (3), focusing specifically on applications of moral philosophy. Within each category, I provide illustrative examples of past scholarship and suggestions for further research.

Expanding the patent office's regulatory footprint: A proposal for reimbursing invalidity challenges

Jeremy Bock (Tulane University Law School)

Denver University Law Review, Vol. 96 (2019 Forthcoming)

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3267754

The patent system's apparent resilience to changes in the law, and the persistent complaints about abusive patent assertions, might reflect the futility of patent reform efforts over the past several decades. But there may be another factor contributing to the patent system's resistance to change: the regulatory coverage provided by the two primary regulatory entities in the patent system — the federal courts and the U.S. Patent & Trademark Office (PTO) — may be inadequate. Because the regulatory footprint of the federal courts is limited by Article III considerations, the possibilities for expanding the PTO's regulatory footprint warrant greater attention. Given its limited mandate of examining applications and granting patents, the PTO has taken a hands-off approach to patents once they are issued. The PTO's post-issuance passivity has left the job of policing abusive assertions — and by extension, patent quality — predominantly to accused infringers, for whom the high cost of validity challenges often encourages the payment of nuisance settlements, which makes abusive assertions profitable and promotes the further procurement and assertion of patents in problematic ways.

To enable and induce the PTO to take a more active role in policing abusive assertions, this Article draws from the lessons of the auto insurance industry to propose that Congress should require the PTO to collect an annual, individualized fee on each patent-in-force — which is set according to the risk of invalidation of that patent — to fund a program to reimburse the expenses incurred by accused infringers who prevail in challenging a patent at the PTO's administrative tribunal, the Patent Trial and Appeal Board. This arrangement would help create a regulatory feedback loop that could expand the

PTO's regulatory footprint in the patent system, with several potential benefits: (1) it would further encourage challenges to weak patents, as an alternative to paying nuisance settlements; (2) it would allow the PTO to indirectly regulate or influence the behavior of patentees with respect to post-issuance activities such as assertion; (3) it would provide a mechanism for the PTO to incentivize patentees to adopt quality-enhancing prosecution habits; and (4) it would create a source of fiscal pressure for the PTO that may prompt it to make operational changes to improve patent quality, in the face of possible opposition from its patentee "customers."

Irrational ignorance at the patent office

Michael Frakes (Duke University School of Law)

Melissa F. Wasserman (The University of Texas at Austin - School of Law)

Vanderbilt Law Review, Vol. 72, 2019, Forthcoming

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3284109

There is widespread belief that the Patent Office issues too many bad patents that impose significant harms on society. At first glance, the solution to the patent quality crisis seems straightforward: give patent examiners more time to review applications so they grant patents only to those inventions that deserve them. Yet the answer to the harms of invalid patents may not be that easy. It is possible that the Patent Office is, as Mark Lemley famously wrote, "rationally ignorant." In *Rational Ignorance at the Patent Office*, Lemley argued that because so few patents are economically significant, it makes sense to rely upon litigation to make detailed validity determinations in those rare cases rather than increase the expenses associated with conducting a more thorough review of all patent applications. He supported his thesis with a cost-benefit calculation in which he concluded that the costs of giving examiners more time outweighs the benefits of doing so.

Given the import of the rational ignorance concept to the debate on how best to address bad patents, the time is ripe to revisit this discussion. This Article seeks to conduct a similar cost-benefit analysis to the one that Lemley attempted nearly fifteen years ago. In doing so, we employ new and rich sources of data along with sophisticated empirical techniques to form novel, empirically driven estimates of the relationships that Lemley was forced, given the dearth of empirical evidence at his time, to assume in his own analysis. Armed with these new estimates, this Article demonstrates that the savings in future litigation costs associated with giving examiners additional time per application alone more than outweigh the costs of increasing examiner time allocations. Thus, we conclude the opposite of Lemley: society would be better off investing more resources in the Agency to improve patent quality than relying upon ex-post litigation to weed out invalid patents. Given its current level of resources, the Patent Office is not being "rationally ignorant" but, instead, irrationally ignorant.

Copyright Law

Zombie Cinderella and the undead public domain

Rebecca Curtin (Suffolk University Law School)

86 Tennessee Law Review, Forthcoming

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3273631

This Article takes a recent case from the Trademark Trial and Appeal Board as the basis for an argument that trademark doctrine needs stronger protection against the exclusive commercial appropriation of characters that are in the public domain. In that case, a new doll company sought to register the mark “Zombie Cinderella” for dolls. The examining attorney initially refused registration because “Zombie Cinderella” dolls were found to be confusingly similar to “Walt Disney’s Cinderella” dolls. This ruling would have implied that Disney had the exclusive right to market dolls using the “Cinderella” name, a name that carries with it the long legacy of a canonical fairy tale, beloved since at least its first print publication in the seventeenth century. The T.T.A.B. overturned the refusal to register on appeal, but it largely relied on doctrine that characterized the “Cinderella” part of Disney’s trademark as a “conceptually weak” indicator of Disney as the source of the dolls, in part because of other participants in the doll market using the word “Cinderella” to describe their dolls. This doctrine on some level denies Disney exclusive rights to the word “Cinderella” merely because the company’s commercial appropriation of the character has not been complete enough. I argue that we need a doctrine that would deny even the first market entrant the ability to appropriate such a public domain character. I argue in favor of extending the doctrine of aesthetic functionality, which denies trademark protection to features of a product that confer a non-reputationally-related advantage on the trademark holder, to cultural elements in the public domain.

Derivative works and making sense of the maxim that 'others are free to copy the original. They are not free to copy the copy.'

David E. Shipley (University of Georgia School of Law)

University of Daytona Law Review, Forthcoming

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3273463

This is a paper about some of the most entertaining and challenging cases in America’s copyright law jurisprudence concerning derivative works as copyrightable subject matter, and the closely related right to prepare derivative works. The cases are entertaining because they involve very familiar works of authorship, and they are challenging because the rulings are often difficult to reconcile due to the fact that the courts are grappling with copyright’s elusive originality standard as applied to derivative works as well the copyright owner’s right to prepare derivative works. Instead of attempting to say something ‘original’ about originality, my goal for this article is to make sense out of these entertaining and sometimes contradictory decisions concerning derivative works.

I do this by discussing seven recurring problems and common scenarios, and relate these situations to how courts have handled these problems and scenarios in the context of the familiar maxim announced by Justice Holmes in 1903 about how it is permissible to copy the original but not to copy the copy. Although Justice Holmes made this statement in connection with his discussion of copyright’s originality standard, it relates to my article’s goals because a derivative work is a copy of the copy in that it adapts or modifies a preexisting work of authorship; this copy of the copy infringes if it is done without permission of the owner of copyright on the preexisting work, but this copy of the copy might be copyrightable as a derivative work when it is done with permission.

Providing this kind of structure is more than an exercise of selecting and sorting. Rather, the problems and scenarios illustrate the basic copyright law challenge of balancing the intellectual property and ownership rights of authors as an incentive to create against the need for subsequent authors to build upon and adapt the works of others. After all, derivative works by definition build upon preexisting works, and a court said long ago that few things are “strictly new and original throughout,” and every work “in literature, science and art, borrows, and must necessarily borrow, and use much which was well known and used before.”

The use of copyrighted works by AI systems: Art works in the data mill

Giovanni Sartor (European University Institute Law Department)

Francesca Lagioia (European University Institute - Department of Law (LAW); University of Bologna - Research Center of History of Law, Philosophy and Sociology of Law, and Computer Science and Law (CIRSFID))

Giuseppe Contissa (European University Institute - Department of Law (LAW); University of Bologna - Research Center of History of Law, Philosophy and Sociology of Law, and Computer Science and Law (CIRSFID))

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3264742

We shall first introduce some technical aspects involved in the use of AI in producing new intellectual works, distinguishing approaches based on knowledge representation and on machine learning. Then we shall provide an overview of some of the significant applications of AI to the production of intellectual work, distinguishing the extent to which they depend on pre-existing works, and the different ways in such works are used in the creative process.

Finally, we shall discuss the legal aspects of AI-reuse of copyrighted works, focusing on the rights of the authors of such works relatively to the process and the outputs of AI.

Other IP Topics

Patents used in patent office rejections as indicators of value

Christopher Anthony Cotropia (University of Richmond - School of Law)

David L. Schwartz (Northwestern University - Pritzker School of Law)

Working Paper

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3274995

The economic literature emphasizes the importance of patent citations, particularly forward citations, as an indicator of a cited patent’s value. Studies have refined which forward citations are better indicators of value, focusing on examiner citations for example. We test a metric that arguably is closer tied to private value—the substantive use of a patent by an examiner in a patent office rejection of another pending patent application. This paper assesses how patents used in 102 and 103 rejections relate to common measures of private value—specifically patent renewal, the assertion of a patent in litigation,

and the number of patent claims. We examine rejection data from U.S. patent applications pending from 2008 to 2017 and then link value data to rejection citations to patents issued from 1999 to 2007. Our findings show that rejection patents are independently, positively correlated with many of the value measurements above and beyond forward citations and examiner citations.

The patent option

Daniel J. Gervais (Vanderbilt University - Law School)

North Carolina Journal of Law and Technology, Vol. 20, 2019

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3266580

There is a shift in the shape of intellectual property (IP) tools used to strengthen and lengthen the right of pharmaceutical companies to exclude others from making and marketing their products. Patents have traditionally been the tool of choice. Over the past two decades, however, pharmaceutical companies have increased their degree of reliance on a right known as “data exclusivity.” This right, which now exists in most major jurisdictions, is the right to prevent third parties from relying on the clinical trial data submitted by another pharmaceutical company to obtain marketing approval for a bioequivalent or biosimilar product. The right is included in most international trade agreements.

The patent and data exclusivity regimes are different. The patent regime is one-size-fits-all; it protects new, useful and nonobvious inventions subject to sufficiency of disclosure. In contrast, the data exclusivity regime has both a different target (only pharmaceuticals) and purpose (efficacy & safety). The two systems are administered independently. Yet they apply to the same products and the two rights belong to the same entities.

This Article proposes to prioritize data protection over patents by offering an extension of data exclusivity periods in exchange for not applying for a patent, or letting the patent lapse. As the Article explains, this would create stronger incentives to perform clinical research on molecules that may have positive outcomes in clinical trials including naturally occurring substances and other subpatentable inventions.

The Article conditions the proposed extension on fuller disclosure of clinical data, which would benefit both the public and scientists. Although public disclosure of an invention is a key function of patent law, it is often of poor quality due to excessive use of “patentese.” In the specific case of pharmaceuticals, it is further weakened by the fact that patents are normally applied for well before human clinical trials have been concluded. Under current rules, clinical trial data submitted to governments are often not made public.

Finally, the Article proposes text to be used in future trade agreements—with specific modalities for developing and least-developed countries.

Third strike: The WTO panel reports upholding Australia's tobacco plain packaging scheme

Tania Voon (University of Melbourne - Law School)

Forthcoming in (2019) Pre-edited draft Journal of World Investment & Trade

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3275074

Two of the four disputes against Australia's tobacco plain packaging scheme in the World Trade Organization (WTO) have now been resolved, with the Dispute Settlement Body's adoption of the Panel Reports upholding Australia's tobacco plain packaging scheme with respect to Cuba and Indonesia. The fifth dispute, brought by Ukraine, was previously abandoned. The Panel's lengthy decision deserves close examination, particularly as regards the balance in WTO law between WTO Members' legitimate policy objectives (such as promoting public health) and restrictions on (i) trade (under Article 2.2 of the Agreement on Technical Barriers to Trade) or (ii) trademarks (under Article 20 of the Agreement on Trade-Related Aspects of Intellectual Property Rights). The Panel's approach to the fundamental concepts of trade-restrictiveness (with respect to technical barriers to trade) and unjustifiability (with respect to encumbering trademarks) did not conform with the position put forward by either Australia or the complainants. These areas represent core aspects of the ongoing appeals by Honduras and the Dominican Republic against the Panel Reports. Although Australia did not appeal any of the Panel Reports, its own arguments before the Panel provide further insights into the Panel's approach. The significance of the Panel Reports is heightened by the continuing United States blockage of appointments to the WTO Appellate Body, which is likely to lead to significant delays in completing the two appeals.

Contact

For more information about this issue of *IP Literature Watch*, please contact the editor:

Anne Layne-Farrar

Vice President

Chicago

+1-312-377-9238

alayne-farrar@crai.com

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