March 2018

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

**How essential are standard-essential patents?**
Mark A. Lemley (Stanford Law School)
Timothy Simcoe (Boston University – Questrom School of Business; NBER)
*Stanford Public Law Working Paper*

Courts, commentators, and companies have devoted enormous time and energy to the problem of standard-essential patents (SEPs) – patents that cover (or at least are claimed to cover) industry standards. With billions of dollars at stake, there has been a great deal of litigation and even more lobbying and writing about problems such as how if at all standard-setting organizations (SSOs) should limit enforcement of patent rights, whether a promise to license SEPs on fair, reasonable, and non-discriminatory (FRAND) terms is enforceable in court or in arbitration, what a FRAND royalty is, and whether a refusal to comply with a FRAND commitment violates the antitrust laws.

In this study, we explore what happens when SEPs go to court. What we found surprised us. We expected that proving infringement of a SEP would be easy – they are, after all, supposed to be essential – but that the breadth of the patents might make them invalid. In fact, the evidence shows the opposite. SEPs are more likely to be held valid than a matched set of litigated non-SEP patents, but they are significantly less likely to be infringed. Standard-essential patents, then, don’t seem to be all that essential, at least when they make it to court.

At least part of the explanation for this surprising result comes from another one of our findings: many SEPs asserted in court are asserted by non-practicing entities (NPEs), also known as patent trolls. NPEs do much worse in court, even when they assert SEPs. And the fact that they have acquired a large number of the SEPs enforced in court may bring the overall win rate down significantly.

Our results have interesting implications for the policy debates over both SEPs and NPEs. Standard-essential patents may not be so essential after all, perhaps because companies tend to err on the size of over-disclosing patents that may or may not be essential. The failure of NPEs to win cases even with
what seem like they should be a strong set of patents raises interesting questions about the role of NPEs in patent law and the policy efforts to curb patent litigation abuse.

**Switching costs, path dependence, and patent holdup**
Thomas F. Cotter (University of Minnesota Law School)
Erik Hovenkamp (Harvard Law School; Yale Law School)
Norman Siebrasse (University of New Brunswick – Fredericton – Faculty of Law)
*Working paper*

Patent holdup occurs when a patent holder extracts higher royalties ex post (after the payor has committed to use of the patented technology) than it could have negotiated ex ante, where the difference is not explained by an increase in the technology's value. To date, the literature principally has focused on — indeed, sometimes conflated — two potential sources of holdup: the sunk costs the user has incurred ex ante to adopt the technology, and the “switching costs” of adopting an alternative ex post. We demonstrate, however, that this literature tends either to over- or underestimate holdup risk, because holdup may arise even when sunk costs are zero, or be absent despite high ex post switching costs. More generally, we show that patent holdup is best understood as an opportunistic exploitation of path dependence, arising when prior commitment to a technology creates some dynamic distortion in the technology's incremental value over alternatives.

**Much ado about holdup**
Jorge L. Contreras (University of Utah – S.J. Quinney College of Law)
*University of Illinois Law Review, Forthcoming*

The policy debate surrounding patent hold-up in markets for standardized products is now well into its second decade with no end in sight. Fundamental questions including the definition of hold-up, whether it exists in the marketplace, and what impact it has on innovation, continue to bedevil scholars, policy makers and industry. Yet it is not clear that this debate needs to continue. Patent hold-up is a pattern of market behavior, not a legally-cognizable wrong. Whether it is commonplace or rare is largely irrelevant to liability in any given case. To the extent that hold-up behavior constitutes an abuse of market power, with resulting harms to competition, longstanding doctrines of antitrust and competition law exist to sanction it. To the extent that hold-up impedes the efficient operation of standard-setting processes, SDOs can, and have, adopted internal procedures, including disclosure and licensing requirements, to curtail that behavior. Thus, the ongoing hunt for empirical evidence of systemic patent hold-up in standardized product markets, or a lack thereof, seems a fruitless academic exercise. The absence of systemic hold-up actually tells us little about individual firm behavior that can and should be sanctioned by the law, and it may thus be time to close the debate over the systemic prevalence of this form of behavior.

**On unknown opportunities and perils: reflections on Carrier and Minniti’s ‘Biologics: The New Antitrust Frontier’**
Thomas F. Cotter (University of Minnesota Law School)
*University of Illinois Law Review Online, 2018, Forthcoming*

In their forthcoming article “Biologics: The New Antitrust Frontier,” Michael Carrier and Carl Minniti predict what antitrust problems will arise from conduct on the part of biologic and biosimilar drug manufacturers in the near future, and how these problems will differ (in terms of frequency and severity) from the more
familiar issues arising from the discovery, regulation, and marketing of small-molecule compounds. In this responsive essay I argue that, while there are certain types of cases the frequency of which in this context we can predict with a fair degree of confidence, and for which courts have more-or-less standard analytical frameworks available, precisely how various possible threats to innovation and competition will play out in the years to come remains to some degree both unknown and unknowable. The frontier beyond the frontier remains ever elusive.

IP & Licensing

Non-discrimination and FRAND commitments
Jorge L. Contreras (University of Utah – S.J. Quinney College of Law)
Anne Layne-Farrar (Charles River Associates; Northwestern University)

A pledge to license standard essential patents (SEPs) on a non-discriminatory basis is a common element of SDO IPR Policies, part of the larger commitment to license on Fair, Reasonable, and Non-Discriminatory (FRAND) terms. In this chapter we consider what non-discrimination pledges imply for SDO member conduct. We review the basic variants of such pledges, how they may be informed by broader legal and economic definitions of discrimination, and recent cases and agency guidance interpreting such commitments. We conclude with open questions regarding the legal implications of non-discriminatory licensing pledges.

IP & Innovation

Intellectual property and technology startups: what entrepreneurs tell us
Stuart J.H. Graham (Georgia Institute of Technology – Scheller College of Business)
Ted M. Sichelman (University of San Diego School of Law)

This chapter provides evidence on how young technology startups are employing intellectual property (IP) protection when innovating and competing in the United States. Although researchers and teachers of university technology transfer often think only in terms of patents and the Bayh-Dole Act, this chapter suggests that adopting a more nuanced view of IP rights is appropriate. After reviewing the primary non-patent types of IP protection available in the U.S. (copyright, trademark, and trade secret), we explain that while patents are often considered the strongest protection, for some entrepreneurs – particularly those operating in the U.S. software and Internet sectors – patents may be the least important means of capturing value from innovation. We present evidence from the 2008 Berkeley Patent Survey to demonstrate that IP is used by U.S. startups in very different ways, and to different effects, across technology sectors and other company-specific characteristics. Contrary to the common assumption in academic discourse, we show that different forms of IP protection often serve as complements, rather than substitutes.
Parties frequently obtain patents for one purpose, only to use those patents for another. This Article calls such divergences between parties’ initial motivations to obtain patents and those patents’ predominant uses later on “patent schisms.”

Because traditional patent law theories treat the purposes of patents as static, scholars have neglected to explicitly examine patent schisms and the reasons behind them. This is so despite the pervasiveness of patent schisms in a variety of important contexts. Those contexts include the patenting behaviors of early-stage companies, later-stage companies, so-called “patent trolls,” and universities. In fact, patent schisms lie at the heart of some of the most controversial patent law topics, including whether patents should be considered a form of personal property or, instead, as a regulatory right.

This Article examines patent schisms and adds to the patent literature in three principal ways. First, it provides an account of the ubiquity of patent schisms in a variety of important settings. Second, it articulates three theories explaining how and why patent schisms arise. These hypotheses include the proposition that patenting an invention often creates economic and psychological incentives to ultimately use that patent in defiance of a party’s original motivation to obtain the patent. Finally, the Article examines the normative and theoretical implications of the pervasiveness of patent schisms and the explanations behind them. These include assessing whether treating patents as a form of personal property is the correct approach to ensuring that the patent system serves its constitutional purpose of promoting the progress of “science and the useful arts.”

IP & Litigation

Top tens in 2017: patent, trademark, copyright and trade secret cases
Stephen M. McJohn (Suffolk University Law School)
Northwestern Journal of Technology and Intellectual Property, Forthcoming

The Supreme Court loosened the grip of patentees on their products, holding that contractual restrictions on patented product are ineffective to preserve patent rights. The Court also loosened the grip of the Eastern District of Texas on patent cases, announcing a narrower standard that will send more cases to Delaware. The Federal Circuit cases piled up on applying the Alice standard to filter nonpatentable abstract ideas from patentable inventions. Meanwhile, even as the constitutionality of the Patent Trial and Appeals Board pends before the Supreme Court, hundreds of PTAB decisions on the validity of patents move onward to the Federal Circuit. Other notable patent cases concerned sovereign immunity (such as transferring patents to avoid PTAB proceedings), the doctrine of assignor estoppel, the scope of prior art, and patent rights to the gene-editing tool CRISPR-Cas9. In trademark, the Court held the bar against disparaging marks was an invalid restraint on freedom of expression. Lower courts addressed a number of issues in the same area, such as the rights to use marks in titles of work and other expressive purposes. Courts also addressed whether such terms as “google,” “tequila,” and “Universal” have become generic. In copyright, the Supreme Court gave some guidance on the line between copyrightable expression and nonprotected functional matter. Other notable cases addressed the copyrightability of standards and the meaning of “noncommercial” in open source licenses, along with fair use in new settings. In trade secret, courts looked at such key issues as the scope of the Computer Fraud and Abuse Act, the intersection between trade secret and international trade, and protection for data bases.
**Paths or fences: patents, copyrights, and the Constitution**  
Derek E. Bambauer (University of Arizona – James E. Rogers College of Law)  
*Iowa Law Review (2018 Forthcoming)*  

Congressional power over patents and copyrights flows from the same constitutional source, and the doctrines have similar missions. Yet the Supreme Court has approached these areas from distinctly different angles. With copyright, the Court readily employs constitutional analysis, building fences to constrain Congress. With patent, it emphasizes statutory interpretation, demarcating paths the legislature can follow, or deviate from (potentially at its constitutional peril). This Article uses empirical and quantitative analysis to show this divergence. It offers two potential explanations, one based on entitlement strength, the other grounded in public choice concerns. Next, the Article explores border cases where the Court could have used either fences or paths, demonstrating the effects of this pattern. It sets out criteria that the Court should employ in choosing between these approaches: counter majoritarian concerns, institutional competence, pragmatism, and avoidance theory. The Article argues that the key normative principle is that the Court should erect fences when cases impinge on intellectual property’s core constitutional concerns – information disclosure for patent and information generation for copyright. It concludes with two examples where the Court should alter its approach based on this principle.

**Joining the dots in India’s big-ticket mobile phone SEP litigation**  
Rohini Lakshané (Centre for Internet and Society)  
*Working paper*  

Nearly three years after litigation over patents and designs associated with big-ticket mobile technology started in the US, the first salvo in the patent wars was fired in India. Sweden-based Ericsson, a provider of communications infrastructure and services, sued home-grown budget smartphone manufacturer Micromax in early 2013. Patent litigation in the arena of mobile phone technology has steadily risen since. Lei Jun, the chairman of China's largest smartphone manufacturer Xiaomi once said that facing a patent lawsuit “can be considered a rite of passage for a company that is coming of age”. The first part of this paper, “Compilation of lawsuits” is an attempt to chronicle the significant developments in big-ticket lawsuits pertaining to mobile technology patents filed in India. The second part, “Commonalities and differences in the lawsuits” is an attempt to join the dots between the developments that were either remarkably common or notably different. All information presented in this paper has been gathered from publicly available sources and is up-to-date till the time of writing (October 31, 2017). This paper has been published as a part of the Pervasive Technologies project at the Centre for Internet and Society (CIS). Invaluable research assistance was provided by Nayana Dasgupta, Sampada Nayak and Suchisubhra Sarkar (in alphabetical order).

**Sue first, negotiate later**  
Michael Risch (Villanova University Charles Widger School of Law)  
*Working paper*  

One of the more curious features of patent law is that patents can be challenged by anyone worried about being sued. This challenge right allows potential defendants to file a declaratory relief lawsuit in their local federal district court, seeking a judgment that a patent is invalid or noninfringed. To avoid this home-court advantage, patent owners may file a patent infringement lawsuit first and, by doing so, retain
the case in the patent owner’s venue of choice. But there is an unfortunate side effect to such preemptive lawsuits: they escalate the dispute when the parties may want to instead settle for a license. Thus, policies that allow challenges are favored, but they are tempered by escalation caused by preemptive lawsuits. To the extent a particular challenge rule leads to more preemptive lawsuits, it might be disfavored.

This article tests one such important challenge rule. In MedImmune v. Genentech, the U.S. Supreme Court made it easier for a potential defendant to sue first. Whereas the prior rule required threat of immediate injury, the Supreme Court made clear that any case or controversy would allow a challenger to file a declaratory relief action. This ruling had a real practical effect, allowing recipients of letters that boiled down to, “Let’s discuss my patent,” to file a lawsuit when they could not before.

This was supposed to help patentees, but not everyone was convinced. Many observers at the time predicted that the new rule would lead to more preemptive infringement lawsuits filed by patent holders. They would sue first and negotiate later rather than open themselves up to a challenge by sending a demand letter. Further, most who predicted this behavior—including parties to lawsuits themselves—thought that non-practicing entities would lead the charge. Indeed, as time passed, most reports were that this is what happened: that patent trolls uniquely were suing first and negotiating later. But to date, no study has empirically considered the effect of the MedImmune ruling to determine who filed preemptive lawsuits. This Article tests MedImmune’s unintended consequences. The answer matters: lawsuits are costly, and increased incentive to file challenges and preemptive infringement suits can lead to entrenchment instead of settlement.

Using a novel longitudinal dataset, this article considers whether MedImmune led to more preemptive infringement lawsuits by NPEs. It does so in three ways. First, it performs a differences-in-differences analysis to test whether case duration for the most active NPEs grew shorter after MedImmune. One would expect that preemptive suits would settle more quickly because they are proxies for quick settlement cases rather than signals of drawn out litigation. Second, it considers whether, other factors equal, the rate of short lived case filings increased after MedImmune. That is, even if cases grew longer on average, the share of shorter cases should grow if there are more placeholders. Third, it considers whether plaintiffs themselves disclosed sending a demand letter prior to suing.

It turns out that the conventional wisdom is wrong. Not only did cases not grow shorter – cases with similar characteristics grew longer after MedImmune. Furthermore, NPEs were not the only ones who sued first and negotiated later. Instead, every type of plaintiff sent fewer demand letters, NPEs and product companies alike. If anything, the MedImmune experience shows that everyone likes to sue in their preferred venue.

IP Law & Policy

Is patent enforcement efficient?
Mark A. Lemley (Stanford Law School)
Robin Feldman (University of California Hastings College of the Law)
Boston University Law Review, Vol. 98, 2018

Traditional justifications for patents are all based on direct or indirect contribution to the creation of new products. Patents serve the social interest if they provide not just invention, but innovation the world would not otherwise have. Non-practicing entities ("NPEs") as well as product-producing companies can
sometimes provide such innovation, either directly, through working the patent or transferring technology to others who do, or indirectly, when others copy the patented innovation. The available evidence suggests, however, that patent licensing demands and lawsuits from NPEs are normally not cases that involve any of these activities.

Some scholars have argued that patents can be valuable even without technology transfer because the ability to exclude others from the market may drive commercialization that would not otherwise occur. We demonstrate that even if various commercialization theories can sometimes justify patent protection, they cannot justify most NPE lawsuits or licensing demands.

**Patents, property, and prospectivity**
Jonathan S. Masur (University of Chicago – Law School)
Adam Mortara (Bartlit Beck Herman Palenchar & Scott LLP)

When judges change the legal rules governing patents, those rule changes are always retroactive. That is, they apply equally to patents that have already been granted and patents that do not yet exist. There are benefits to making a rule retroactive, particularly if the new rule is an improvement over what preceded it. But there are costs as well. Retroactive rule changes upset reliance interests. This can be particularly harmful when those reliance interests involve rights or entitlements that form the basis for substantial financial investment, as is often the case with patents. What is more, judges are aware that their decisions can do violence to existing reliance interests. This makes judges wary of changing patent rules in the first place, which can lead to the law becoming stultified. Reducing the rate of legal change is not an adequate solution. Neither is takings law, which is commonly applied to solve similar problems that arise in the context of real property but is a poor fit for intellectual property. Rather, to ameliorate the reliance concerns generated by legal change, federal judges should be afforded the latitude to make their rulings purely prospective. And patent judges should exercise this discretion in the many cases where forward-looking change is called for, but backwards-looking change will do more harm than good.

**Innovation nationalism**
Sapna Kumar (University of Houston Law Center)
*Working paper*

Nationalism has experienced a global resurgence, with many world leaders advocating a return to a glorious, and often illusory, past. In the United States, economic nationalism has received support from Democrats and Republicans alike, fueled by growing public backlash to free trade. These changes are having a major impact on U.S. patent policy. Over the past several decades, the government has cultivated an identity of the United States as being an innovative country. It has implemented patent policies that reinforced this identity, such as strengthening domestic patent rights and requiring trading partners to adopt U.S.-style patent and intellectual property laws. Many times, these policies had negative consequences, such as forcing U.S. consumers to subsidize chosen industries through paying higher prices for goods. This innovation-driven approach to economic nationalism, however, is changing under the Trump administration. Trump has chosen to advance a national identity of nativism and cultural traditionalism, in which foreign people and foreign ideas are viewed with suspicion. With regard to economic policy, he has embraced a strong sovereign model of governance, implementing protectionist import tariffs and threatening unilateral trade sanctions against China. This Article looks to political science and international political economy research to understand what economic nationalism is and how U.S. patent policy helps advance it. It looks at the emergence of innovation nationalism under prior administrations and examines how shifting national identity under the Trump administration is impacting it.
What causes polarization on IP policy?
Maggie Wittlin (University of Nebraska at Lincoln – College of Law)
Lisa Larrimore Ouellette (Stanford Law School)
Gregory N. Mandel (Temple University – James E. Beasley School of Law)
*UC Davis Law Review, Forthcoming*

Polarization on contentious policy issues is a problem of national concern for both hot-button cultural issues such as climate change and gun control and for issues of interest to more specialized constituencies. Cultural debates have become so contentious that in many cases people are unable to agree even on the underlying facts needed to resolve these issues. Here, we tackle this problem in the context of intellectual property law. Despite an explosion in the quantity and quality of empirical evidence about the intellectual property system, IP policy debates have become increasingly polarized. This disagreement about existing evidence concerning the effects of the IP system hinders democratic deliberation and stymies progress.

Based on a survey of U.S. IP practitioners, this Article investigates the source of polarization on IP issues, with the goal of understanding how to better enable evidence-based IP policymaking. We hypothesized that, contrary to intuition, more evidence on the effects of IP law would not resolve IP disputes but would instead exacerbate them. Specifically, IP polarization might stem from “cultural cognition,” a form of motivated reasoning in which people form factual beliefs that conform to their cultural predispositions and interpret new evidence in light of those beliefs. The cultural cognition framework has helped explain polarization over other issues of national concern, but it has never been tested in a private-law context.

Our survey results provide support for the influence of cultural cognition, as respondents with a relatively hierarchical worldview are more likely to believe strong patent protection is necessary to spur innovation. Additionally, having a hierarchical worldview and also viewing patent rights as property rights may be a better predictor of patent strength preferences than either alone. Taken together, our findings suggest that individuals’ cultural preferences affect how they understand new information about the IP system. We discuss the implications of these results for fostering evidence-based IP policymaking, as well as for addressing polarization more broadly. For example, we suggest that empirical legal studies borrow from medical research by initiating a practice of advance registration of new projects in which the planned methodology is publicly disclosed before data are gathered to promote broader acceptance of the results.

Copyright Law

*Emojis and the law*
Eric Goldman (Santa Clara University – School of Law)

Emojis are an increasingly important way we express ourselves. Though emojis may be cute and fun, their usage can lead to misunderstandings with significant legal stakes—such as whether someone should be obligated by contract, liable for sexual harassment, or sent to jail.

Our legal system has substantial experience interpreting new forms of content, so it should be equipped
to handle emojis. Nevertheless, some special attributes of emojis create extra interpretative challenges. This Article identifies those attributes and proposes how courts should handle them.

One particularly troublesome interpretative challenge arises from the different ways platforms depict emojis that are nominally standardized through the Unicode Consortium. These differences can unexpectedly create misunderstandings.

The diversity of emoji depictions isn’t technologically required, nor does it necessarily benefit users. Instead, it likely reflects platforms’ concerns about intellectual property protection for emojis, which forces them to introduce unnecessary variations that create avoidable confusion. Thus, intellectual property may be hindering our ability to communicate with each other. The Article will discuss how to limit this unwanted consequence.

Copyright as a property right? Authorial perspectives in eighteenth-century England
Simon Stern (University of Toronto – Faculty of Law)
8 UC Irvine Law Review (2018)

In recent decades, various scholars have questioned the proposition that copyright must necessarily be rooted entirely in a property paradigm, and have sought to show how, over the last century and a half or so, that paradigm has been applied increasingly strictly and its logic has been extended with ever greater force. In response, others have contended that copyright has always been understood as a property right. An examination of eighteenth-century sources shows that the conception of copyright as a form of property was neither the only, nor even the dominant, paradigm in circulation at the time. Moreover, when studying these sources, we must ask who is using the language of property: judges, members of the bookselling industry and their lawyers, writers and their counsel, or some combination of these? Building on earlier work that traces some aspects of the property framework as it developed in eighteenth-century British jurisprudence, I show how members of the publishing industry were able to convert the liability rule furnished by the Statute of Anne into a property rule. Next, shifting the focus to contemporaneous writers, I show that they were far cagier about the language of property than were their colleagues in the bookselling industry, sometimes adopting this language equivocally, sometimes repudiating it emphatically. Finally, looking at eighteenth-century literary culture more generally, I note that accusations of plagiarism and the convention of the “found manuscript”--both of which would seem (to modern eyes) to be redolent with concerns about property--were rarely if ever couched in these terms. I conclude that discovering the word “property” in eighteenth-century discussions of copyright marks the beginning, not the end, of an inquiry into its significance at this time.

Notice and takedown: online service provider and rightsholder accounts of everyday practice
Jennifer M. Urban (University of California, Berkeley – School of Law) 
Joe Karaganis (Columbia University – The American Assembly) 
Brianna Schofield 
64 J. Copyright Soc'y 371, Forthcoming 

Section 512 of the Digital Millennium Copyright Act established both “safe harbors” from liability for online service providers and the well-known “notice and takedown” process for removing online infringements of copyrighted material. In the ensuing two decades, the notice and takedown process has become a primary tool for raising and resolving copyright disputes in the United States.
But despite its influence, there is little empirical research describing § 512's operation or its effectiveness. This article digests findings from a qualitative study, reported fully in the three-study report, Notice and Takedown in Everyday Practice (available at https://ssrn.com/abstract=2755628) and peer-reviewed here, that helps fill this gap. Through detailed surveys and interviews with nearly three dozen respondents, we provide the first detailed account of how § 512 is implemented and experienced by online service providers and large rightsholders. All respondents agreed that the § 512 safe harbors and the ability to take down infringing material remain fundamental. But the online copyright enforcement ecosystem is also highly diverse, and all participants face challenges. The findings suggest that the notice and takedown system is important, under strain, and that there is no “one size fits all” approach to improving it. Based on the findings, we suggest a variety of best practices and limited legal reforms.

IP & Trade

Geoblocking and 'legitimate trade'
Marketa Trimble (University of Nevada, Las Vegas, William S. Boyd School of Law)
INTELLECTUAL PROPERTY AND OBSTACLES TO LEGITIMATE TRADE (Christopher Heath, Anselm Kamperman Sanders & Anke Moerland eds., Wolters Kluwer, 2018 Forthcoming)

This chapter discusses the use of tools that facilitate the linking of the internet to physical geography and the obstacles that the use poses for free trade. Using examples of digital goods and services (“content”) protected by intellectual property (“IP”) rights, the chapter reviews whether and how trade law rules, including the concept of “legitimate trade,” and the rules of competition law apply to the use of the tools.

The chapter begins by introducing the current trend of linking the internet to physical geography (the “territorialization” trend), and the geolocation and geoblocking tools that make territorialization possible. The chapter then evaluates from the trade law and competition law perspectives the legality of using geoblocking to partition markets, and it presents recent developments in the European Union that concern the legality of geoblocking. The chapter contemplates the characteristics of geoblocking that might justify treating geoblocking differently from other methods of market partitioning.

The chapter discusses i.a. the new EU Anti-Geoblocking Regulation and the proposed SatCab Regulation.

Data exclusivities in the age of big data, biologics, and plurilaterals
Peter K. Yu (Texas A&M University School of Law)
Texas A&M Law Review Arguendo, Vol. 5, 2018

The past decade has seen many new developments impacting on the intellectual property system. The introduction of big data analytics has transformed the fields of biotechnology and bioinformatics while ushering in major advances in drug development, clinical practices and medical financing. The arrival of biologics and personalized medicines has also revolutionized the healthcare and pharmaceutical industries. In addition, the emergence of bilateral, regional and plurilateral trade agreements have raised serious, and at times difficult, questions concerning the evolution of domestic and international intellectual property standards.

One topic that has linked all three developments together concerns the development of international
standards to protect clinical trial data that have been submitted to regulatory authorities for the marketing approval of pharmaceutical products. During the TPP negotiations, for example, the protection of clinical trial data submitted for the marketing approval of biologics was highly contentious. Although the United States' withdrawal in January 2017 has since placed the TPP Agreement and its data exclusivity provisions for pharmaceuticals and biologics on life support, the debate on the protection of clinical trial data will continue and will emerge in future bilateral, regional and plurilateral trade negotiations, including the NAFTA renegotiations.

This article begins by reviewing the protection of clinical trial data under Article 39.3 of the WTO TRIPS Agreement. Even though the provision covers both pharmaceutical and agricultural chemical products, this article focuses only on the former. The article then examines the additional protection clinical trial data have received through TRIPS-plus bilateral, regional and plurilateral trade agreements. It concludes by outlining five specific recommendations to help advance the debate on such protection in the age of big data, biologics and plurilateral trade agreements.

**The need of and justification for a general competition-oriented compulsory licensing regime**

Kung-Chung Liu (Singapore Management University)

*Working paper*


There seems to be little or no discussion about the need of and justification for a general compulsory licensing that could be applicable to all IP laws. This author has previously argued, by referencing to competition law, in 2008 that it is paramount for the WTO to revise the TRIPS Agreement, so as to include substantive grounds for granting compulsory patent licenses. In so doing, the preservation of competition should be factored in as one of the public policy objectives. As a follow-up study this paper takes an IP-internal approach (therefore will only consult competition law in a very limited fashion) and strives to present a general compulsory licensing doctrine that can be included as an inherent and integral element of IP laws. However, any general theory runs the risk of overstating convergence and oversimplifying divergence. Bearing this possible shortcomings in mind, this paper focuses solely on one aspect of compulsory licensing, namely the protection of market competition, and leaving other public interests, such as the prevention of an epidemic, and access to information out of its ambit.

**Other IP Topics**

**Assessing patent strength using data-driven inputs: characteristics of patents and patent owners that drive success in inter partes review**

Chris Katopis (Independent)

*Les Nouvelles - Journal of the Licensing Executives Society, Volume LIII No. 1, March 2018*


The environment for patent licensing and enforcement is rapidly transforming. Inter partes review and other post-grant proceedings under the America Invents Act, changes to legal standards governing patent eligibility, and increasingly stringent review of patent damage awards have all combined to alter substantially the risk profile associated with patent licensing and enforcement. In this highly dynamic environment, patent holders, capital investors, and potential licensees alike increasingly look for data-driven quantitative inputs to evaluate patent-related risk.

This paper details our analysis of objective, publicly available patent data to evaluate the relative strength of patent portfolios. This type of data-driven analysis can provide valuable inputs to parties selecting
patents for potential licensing, evaluating potential investments in patent-related enterprises, and evaluating potential risks associated with patent licensing and enforcement.

Evaluating the overall strength of a patent portfolio is a highly fact-intensive undertaking, and approaches to evaluating patent strength can vary widely depending upon the purpose of the evaluation. Fundamentally, however, patents grant legal rights, and any measure of patent strength must consider the ability of the patent holder to withstand a legal challenge to its patent rights. Thus, a key indicator of patent strength is the relative probability that a patent will survive a challenge in an Inter Partes Review (IPR) proceeding, compared to similar patents. By “similar patents,” as will become clear, we mean patents that share publicly available, machine-extractable characteristic(s) with the subject patent. This definition includes characteristics of patents’ assignees.

A complete analysis of patent strength should, of course, include other important inputs. These include, for example, the ability to withstand invalidity challenges that cannot be raised in an IPR, and whether sufficiently valuable infringement can be proven. These other inputs are perhaps susceptible to the type of quantitative data-driven analysis reflected in this paper. But given the substantial growth in the number of IPR challenges, the impact of these proceedings on patent enforcement, and our ability to quantify IPR data, the relative ability of a patent to survive an IPR challenge is perhaps the key quantifiable input to the evaluation of risk in patent licensing and enforcement. Moreover, even where a portfolio owner has no interest in enforcing its portfolio, potential licensees will likely evaluate the prospect of a successful IPR challenge when considering alternatives to licensing. Accordingly, we argue that the techniques described below form the basis for portfolio valuation that every portfolio owner should consider using.

Broadcom’s proposed acquisition of Qualcomm: a bad deal for innovation and consumers
Lisa Kimmel (Crowell & Moring LLP)
Morning Consult, Forthcoming

Broadcom’s proposed acquisition of Qualcomm faces significant regulatory hurdles — which will result in protracted review and significant distraction to Qualcomm at a critical time in the industry. Anyone looking forward to the next generation of wireless communications and connected devices should hope these two companies remain vigorous competitors, pursuing their separate visions for what tomorrow should look like, for many years to come.

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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