IP Literature Watch

August 2021

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

**Why the New Administration Should Bury the New Madison Approach**

Michael A. Carrier (Rutgers Law School)

*CPI Antitrust Chronicle (July 2021)*


The “New Madison” approach sounds so promising. Old but new. Updating the classics for the modern era. What could be bad?

In a word: everything. The intersection of patent and antitrust law has a long pedigree. For decades, antitrust’s role in patent-based activity has been acknowledged. Patent licenses are subject to antitrust scrutiny. “Pay for delay” settlements are not entitled to antitrust immunity. And activity in the context of standard setting organizations could conceivably violate antitrust law.

That history has recently come under attack. Between 2017 and 2020, the head of the Department of Justice’s Antitrust Division, Makan Delrahim, introduced a radical framework — the “New Madison” approach — that extricated patent-based conduct from antitrust scrutiny. Such a gambit diverged from the longstanding bipartisan approach that had recognized antitrust’s role in policing standards-based conduct.

This essay introduces standards and then addresses five tenets of Delrahim’s approach. For each, it presents the argument and then discusses its flaws.

**Growing Convergence: The Limited Role of Antitrust in Standard Essential Patent Disputes**

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

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

Camila Ringeling (George Mason University, Antonin Scalia Law School)

*CPI Antitrust Chronicle, Summer 2021, Vol. 1, No. 2*

George Mason Law & Economics Research Paper No. 21-19


In the last couple of years, the United States Department of Justice (“DOJ”) and several European countries have reversed previous interventionist decisions and limited the role of antitrust in the resolution of disputes concerning Standard Essential Patent (“SEPs”). These jurisdictions recognize the
need to protect intellectual property rights ("IPRs") by making available injunctions against infringers. Courts have realized that hold-up by a patent holder demanding excessive royalties is not a widespread problem and that patent implementers may hold-out against paying any royalties whilst they continue to practice a patent. They have accordingly adopted new standards for granting injunctions in disputes involving SEPs with the goal of increasing efficiency and legal certainty. We discuss this shift and its implications for competition policy and innovation.

**IP & Licensing**

**Compulsory License under the Patents Act**
R. Satish Kumar (Galgotias University, School of Law)  
*Working Paper*  

During the present COVID-19 pandemic the protection of intellectual property rights would have to be balanced with the public welfare. One such mechanism for balancing the rights of the intellectual property holder and the general public is compulsory licensing. Compulsory licensing allows production of affordable drugs and increases availability and supply. The present research paper seeks to discuss the broad principles governing compulsory licensing, the judicial view that has been taken on the same, and whether the same can be resorted in the present pandemic situation where hundreds of lives are being lost every minute, critical expensive drugs like Remdesivir, Tocilizumab, Favipiravir etc., which are expensive and in short supply, can be licensed to increase production and improve affordability.

**IP Nationalism: Addressing the COVID Crisis and Beyond**
Cynthia M. Ho (Loyola University of Chicago School of Law)  
*Working Paper*  

This Article coins and explains the phenomena of IP nationalism. Just as some nations engage in vaccine nationalism by hoarding limited COVID vaccines, so, too, some nations are hoarding critical knowledge and technology by resisting modification of usual IP rules during the pandemic, such as a proposed waiver of international IP obligations. Countries that are home to IP-owning pharmaceutical companies often benefit from strong global IP rights, since that usually improves domestic GDP for IP-intensive products such as drugs. Even nations without strong IP exports may embrace IP nationalism because current international laws provide economic benefits to these countries in terms of increased trade for non-IP goods. As this Article explains, countries that embrace IP nationalism raise incomplete, or affirmatively false arguments asserting that barriers to accessing medicines are primarily caused by non-IP issues, which hides how IP and IP nationalism are nonetheless creating barriers to access.

IP nationalism is harmful. Failure to modify traditional IP rights has contributed to inadequate supply of COVID vaccines, which will likely result in more variants that threaten global health and suppress global economic recovery due to disruption of global supply chains. Even outside a pandemic, where IP nationalism could economically benefit countries with IP-intensive exports, it still creates other harms. For example, IP nationalism results in strong global IP rights that often make necessary goods, such as life-saving medicines, unaffordable to many people worldwide. Furthermore, these rights primarily promote innovation that is most profitable, rather than what is most socially desirable. For example, companies are incentivized to pursue and market treatments of questionable utility, such as the newly approved Alzheimer’s drug that may not even be effective, simply because they generate substantial profits. In contrast, vaccines beyond COVID and antibiotics, though desperately needed by all, are generally not pursued due to low profitability.
This Article argues that IP for essential treatments such as COVID vaccines should be considered “global public goods” available to all, contrary to beliefs held by supporters of IP nationalism. This would be an admittedly radical, yet necessary change from current norms. First, this could encourage countries to embrace the proposed waiver of international IP rules for COVID treatments. Although waiving traditional IP rights will not immediately increase vaccine supply, it would permit available and interested companies to expand vaccine capacity and create competition that would likely increase supply and lower costs, allowing poorer countries greater access to the vaccine. In addition, recognition of IP covering pandemic treatments as global public goods would help avoid replicating the current vaccine apartheid in subsequent pandemics and begin to counteract well-documented racial and ethnic disparities regarding access to medicines.

IP & Litigation

What Litigators Can Teach the Patent Office About Pharmaceutical Patents
S. Sean Tu (West Virginia University College of Law)
Mark A. Lemley (Stanford Law School)
Working Paper

Pharmaceutical patents listed in the FDA’s “Orange Book” are some of the most valuable patents in the world. Accordingly, for this valuable subset of patents, it is paramount that the Patent & Trademark Office (PTO) correctly issue valid patents and preclude invalid patents from issuing.

In this paper, we study what happens to those patents in litigation, reporting the results for every Orange Book patent case that resulted in a merits decision. We find that about 25% of active Orange Book patents were invalidated in court. Since these invalid patents could wrongly increase the costs of prescription drugs, we investigate what happens during prosecution of these patents at the PTO. Our study is the first to link the prosecution of Orange Book patents directly to litigation outcomes. Our goal is to determine if there are ways to identify and prevent the issuance of these later invalidated Orange Book patents.

We find that litigated Orange Book patents have unique characteristics that distinguish them from other pharmaceutical patents. They are issued by a relatively small number of examiners. Most litigated patents (90%) are “secondary” patents – patents on smaller tweaks to an existing drug rather than a patent on a new chemical. The owners of these later-litigated patent applications treat them very differently than they do other patents in the same field. They are part of large patent families, suggesting that the applicants are trying to build a patent fence around a known product. They frequently employ a procedural device known as “Track One” to obtain quicker patent prosecution. They are more likely to be subject to rejections based on double-patenting. When initially rejected by the patent examiner, owners of these applications are more likely to fight back rather than amend their claims. All of this suggests that applicants enter prosecution with these patents knowing that they are important and likely destined for litigation, and that they are deliberately creating patent “thickets” to make it harder for generics to enter the market.

Remarkably, we find that while patent examiners already have more time to spend on Orange Book patents than on other patents, the prosecution history of many of these invalidated patents are identical. That is, many of these invalidated patents have the same assignee, the same examiner and the same prosecuting attorney cut and paste rejections as well as responses, thus creating identical or very similar prosecution histories.
We also find that while the patents that end up being litigated are clearly distinguishable from other pharmaceutical patents during patent prosecution, there is little difference in the PTO between the patents that end up surviving a court challenge and the ones that are invalidated.

Our data offer important guidance for reforming the process of prosecuting Orange Book patents. We can and should take advantage of advance knowledge about the importance of these patents to give them a more thorough examination early on. At the same time, the experience with cut-and-paste rejections suggests that we cannot simply give examiners more time and hope that they will do a more thorough job. That not only helps inform the policy suggestions we offer, but it sheds light on a long-standing academic debate about how much time and money we should spend examining patents.

Further, our data highlight the importance of secondary patents and patent thickets in Orange Book litigation. We offer a number of suggestions to simplify and streamline patent prosecution and litigation to make it harder to exclude generic entry with a thicket of bad patents.

**No Free Launch: At-Risk Entry by Generic Drug Firms**
Keith Drake (Greylock McKinnon Associates)
Robert He (Greylock McKinnon Associates)
Thomas G. McGuire (Harvard University - Department of Health Care Policy)
Alice Ndikumana (Harvard University)
*NBER Working Paper No. w29131*

After receiving FDA approval, a generic drug manufacturer can launch “at risk” before conclusion of any patent infringement litigation, but it risks paying damages if it loses. The generic can eliminate the risk by waiting to launch until the appeals process is complete but waiting has downsides too. We develop a model that implies that, after the generic has won a district court decision, at-risk entry is generally profitable and will occur quickly unless the cost of waiting for the appeal is very low. We examine generic drug applications that have received FDA approval with “first-filer” status (which precludes later filing generics from entering before the first filer). In our data, the generic and brand usually settled prior to the conclusion of litigation. For the remainder, drugs that received FDA approval prior to a favorable district court decision were always launched at risk. Generics without FDA approval before a favorable district court decision launched upon approval unless the approval was close in time to the appeal decision or it had forfeited the first filer exclusivity (indicating a low cost of waiting). We also consider implications of at-risk entry for social welfare, arguing that at-risk entry is analogous to a “buy out” of the patent with favorable welfare implications in both the short run (consumer prices) and long run (efficient incentives for R&D).

**IP & Innovation**

**Do patent pledges accelerate innovation?**
Gaëtan de Rassenfosse (Ecole Polytechnique Fédérale de Lausanne)
Alfons Palangkaraya (Centre for Transformative Innovation, Faculty of Business and Law, Swinburne University of Technology)
*Working Paper*

This paper estimates the effect of patent pledges, commitments made voluntarily by patent holders to limit the enforcement of their patents, on follow-on inventions. Patent pledges have been gaining popularity in recent years thanks to the highly visible pledges of companies such as Google and Tesla.
Nascent literature discusses the legal and strategic implications of patent pledges, but we know very little about the societal aspects of such pledges. The empirical analysis exploits original data on more than 1,200 patents pledged from across technological fields between 2005 and 2017. We implement recent advances in conditional difference-in-differences estimators for staggered, dynamic event study settings to account for unobserved endogenous selection. We build the matched control group based on similarity measures of the full text of patent documents. The results suggest that patent pledges spur technological progress as reflected by increased citations received by the pledged patents, especially for high-quality pledged patents. The effect, however, appears to be much more limited for software patent pledges, perhaps because they often come with more restrictive use conditions. The results bear implications for discussions about competition policy and the role of intellectual property on technology diffusion.

**Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond**

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Sven Bostyn (University of Copenhagen - Faculty of Law)

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Almost every aspect of the COVID-19 response, from vaccines, diagnostics, and therapeutics to medical equipment, tracking systems, software, and other innovations, are or will become subject to some form of exclusive rights. Many of these involve intellectual property rights (IPRs). By offering innovators the exclusive right to exploit their innovations while recouping the costs of research, development, and other expenditures, IPRs may incentivize the development of new technologies. But IPRs may also preclude others from important research, manufacturing, and distribution. In the same vein, these exclusionary rights allow right holders to set prices in the absence of competition. Since this may limit access to innovations that are crucial for tackling pandemics, IPRs are a key factor in pandemic response and preparedness. Consequently, they have generated much controversy around the globe.

Many of these debates have concentrated on traditional IPRs, particularly patent rights. Numerous existing patent claims cover new chemical or molecular entities. Patents are also filed for repurposed drugs and vaccine platforms (e.g., COVID-19 mRNA platforms), with separate patent protection for the vaccine and its elements, including viral particles, adjuvants, and vaccine boosters. Even in situations where no patent protection is available, many COVID-19 therapeutics and vaccines will also obtain regulatory, data, and market exclusivities. Consequently, the specific design and new areas of application for regulatory exclusivities have become an increasingly important issue in general innovation policy debates.

This chapter addresses exclusivity issues, with a particular emphasis on regulatory exclusivities for vaccines and therapeutics. We begin with a basic overview of the current regulatory exclusivity landscape in Europe and the US, followed by a discussion of current developments in COVID-19 vaccines and therapeutics. Next, we describe the influence of these technological developments on debates surrounding regulatory exclusivities while describing their relationship to other forms of exclusivities. From these assessments, we draw some lessons for market exclusivity, innovation, and access during the COVID-19 pandemic and beyond.
Understanding Intellectual Property: Expression, Function, and Individuation
Mala Chatterjee (NYU School of Law; NYU Department of Philosophy; Yale Law School)
Working Paper

Underlying the fundamental structure of intellectual property law—specifically, the division between copyright and patent law—are at least two substantive philosophical assumptions. The first is that the artistic works and inventions are importantly different, warranting differently structured legal regimes: copyright on the one hand, and patent on the other. And the second is that particular artistic works and inventions can be determinately individuated from each other, thereby being subjects of distinct legal rights. But neither the law nor existing scholarship provides a comprehensive analysis of these categories, what distinguishes them, or why their distinctions should matter to law. This Article defends a novel theory substantiating and unifying these assumptions: that artistic works are author-individuated, whereas inventions are structure-individuated. In other words, drawing on philosophical thinking, thought experiments, and existing practices surrounding expression and functionality, this Article argues that two acts of authorship cannot result in the same artistic work (only "structurally identical" works), but two acts of invention can result in the same invention. The Article then explains how these "individuation theses" vindicate certain core features of intellectual property law, as well as what they mean for different theories of what justifies intellectual property rights. Finally, the Article teases apart possible implications from the individuation theses for refining existing doctrine, including for copyrights' and patents' structures, domains, and rules for works with expressive and functional overlap. It concludes by outlining complications that the individuation theses raise for theorizing about authorship and functionality in future work.

Strengthening IPR Protection and Innovation
Jun Chen (Renmin University of China - School of Business)
Zhao Jin (Cheung Kong Graduate School of Business)
Working Paper

Though much of the theoretical economics literature have assumed a positive relationship between intellectual property rights (IPR) protection and innovation, there has been no empirical evidence that clearly supports such a relationship. In particular, this relationship may also depend on the measures of innovation. Exploiting the establishment of Chinese specialized IP courts across regions over time as a shock to the IPR protection, we empirically investigate how IPR protection impacts innovation. Measuring innovation by both input and output, we find that establishing an IP court reduces the number of patents filed by public firms located in the IP court's jurisdictional area by about 10%, while increasing those firms' R&D spending (scaled by firm assets) by 6%. These seemingly contradictory findings suggest that the relationship between strengthening IPR protection and firm innovation is a subtle one: it increases firms' incentives to innovate on one hand, while reducing their incentives to rely on the patent system to protect their innovation on the other hand. The finding that stronger IPR protection leads to a lower number of patents also points to a litigation cost channel in which firms reduce their patent filings concerning of the litigation risks brought by those patents. Overall, our findings suggest that IPR protection changes firms' innovation incentives and their interaction with the patent system.
National security concerns often arise between the U.S. and the People’s Republic of China (PRC), and routinely involve cutting-edge technology. These include the race to fifth-generation (5G) wireless mobile technology, cybersecurity, and IP theft; but traditionally they have not extended to patent policy writ large. As national security depends largely on innovative technologies, and patent policy fosters or hinders such innovation, the U.S. should modify its patent policies to recognize state-sponsored entities that can use U.S. patents to drain resources from domestic investment into new technologies. For instance, the United States Patent and Trademark Office (USPTO) currently has no mandatory recordation requirement to identify the attributable owners of patent applications. The USPTO receives and publishes only patent ownership information that the applicant or patent owner voluntarily submits, among myriad other concerns. Given that neither the Patent Act nor USPTO regulations require any recordation of assignee information, USPTO records provide poor notice regarding current ownership of patents. Thus, the U.S. government itself does not know how many U.S. patents international companies own, license, control, or could assert in U.S. federal court. While international agreements rightfully prohibit the USPTO from discriminating against foreign applicants, the U.S. cannot be blind to the fact that patents are already serving as a strategic tool for international competitors to harass or to leverage against American companies in court, draining their financial resources by extracting royalty fees and settlements that then flow into overseas coffers. And because the U.S. government has no effective means to record, or even internally track, the number or identity of patents international companies own, license, or could assert in even sensitive technologies, the extent and potentially negative ramifications of this problem are not well understood.

We analyze the serious gaps in U.S. patent recordation law and propose basic recordation solutions that U.S. government, and the USPTO in particular, could implement to address, mitigate, or, at a minimum, better understand the magnitude of this issue.

Copyright Law & Trade Secrets

The Hysteresis Thesis: An Empirical Study of Copyright Injunctions After eBay
Matthew Sag (Loyola University Chicago School of Law)
Pamela Samuelson (University of California, Berkeley - School of Law)
Working Paper

The Supreme Court’s 2006 decision in eBay v. MercExchange seemingly heralded a major change in not only patent law but also copyright law. The Court ruled that injunctions for patent infringement should no longer be granted automatically; instead, plaintiffs must establish the need for injunctive relief in particular and that such relief would be in the public interest. Although eBay concerned a patent claim, its reasoning relied on three copyright decisions, making its application to copyright cases compelling. Nevertheless, lower courts in some early post-eBay copyright cases rebuffed arguments that the Court’s ruling affected grants of injunctive relief. A 2012 empirical study of the first four years of post-eBay copyright cases seemed to show that those early cases were not aberrations, reporting that courts rarely cited eBay and continued to grant injunctions in a high percentage of copyright cases. Those
conclusions were broadly accepted by the field. This Article tests these claims and finds statistically significant differences in the grant rate for both preliminary and permanent injunctions in copyright cases after the eBay decision. The impression of eBay lacking effect appears to be a product of hysteresis—a time lag between cause and effect, as lower courts initially delayed but eventually embraced eBay. This study reveals, moreover, that the earlier empirical study was flawed by biased sampling, most notably by including a large number of unreported cases and default judgments. This Article offers a corrective analysis and provides a more accurate understanding of the copyright injunction landscape, both pre- and post-eBay. It shows that eBay was in fact a landmark case for copyright law, both in terms of jurisprudence—it is highly cited—and real-world effect—it has a dramatic impact on case outcomes.

The Value in Secrecy
Camilla Alexandra Hrdy (University of Akron School of Law; Yale University - Information Society Project) Working Paper

Trade secret law is seen as the most inclusive IP regime for protecting inventions and proprietary business information. Keep it secret, the wisdom goes, and you can protect it under trade secret law even if patent and copyright law are unavailable. But keeping information secret does not magically transform it into a trade secret. The holder of the secret also must derive actual or potential economic value from concealing the information from others. This elusive and under-studied statutory requirement—called “independent economic value”—is a vestige of the common law, under which trade secrets had to impart a “competitive advantage.”

Today, the conventional view is that courts generally ignore independent economic value or give it a rubber stamp. However, this article reveals that, while most courts apply a comparatively low bar, a surprisingly large number find the standard is not met. This casts doubt on the assumption that independent economic value is a toothless, check-the-box requirement.

Along with this descriptive account, the article provides a much-needed explanation of the nature and function of independent economic value in trade secret law. At first glance, a legal requirement of economic value appears redundant. After all, if information had no economic value, why would anyone bother to keep it secret, and why would the parties litigate over the right to use it? By drawing on insights from patent law’s surprisingly analogous requirement of “utility,” the article reveals that—far from being toothless or self-enforcing—trade secret law’s independent economic value requirement plays a central role in establishing the contours of trade secrecy. When properly construed, it controls not just the amount of value that qualifies, but also the type of value that qualifies and the timeframe during which a trade secret can be protected. Most subtly, independent economic value ensures the information’s asserted value is caused specifically by its secrecy. This raises the bar on what can be protected and simultaneously fortifies the secrecy requirement itself.

The article has a clear message for courts. In any given trade secret case, a party may fail to meet the independent economic value requirement; a litigant’s cost-benefit analysis about whether to pursue a lawsuit will not necessarily screen out trade secrets that do not have independent economic value. Courts and commentators who ignore or trivialize independent economic value are wrong to do so.
To augment the global production and distribution of Covid-19 medical products such as vaccines, drugs and other therapeutics, countries are negotiating for temporarily waiving certain provisions of the TRIPS agreement at the WTO. Depending on the conditions that would govern the waiver, countries would amend their domestic intellectual property (IP) laws to effectively implement the waiver. While the waiver would provide immunity to IP-related regulatory measures from legal claims at the WTO, multinational pharmaceutical companies can use the investor-State dispute settlement (ISDS) mechanism under bilateral investment treaties (BITs) to challenge such IP-related regulatory measures. In case of such a challenge to IP-related regulatory measures, will the host State be able to defend these measures? The paper answers this question by dividing the investment treaty practice into those BITs that contain carve-out for IP and those that don’t. The former set of treaties provides greater regulatory autonomy to implement the TRIPS waiver. However, given the fragmented and incoherent nature of the ISDS mechanism, the final outcome would depend on arbitral discretion.

International intellectual property (IP) law for pharmaceuticals has fundamentally shifted in the twenty-first century from a property-centric to a human rights view. Scholars tend to explain this transformation in the context of both the power struggle between developing and developed countries, and the influence of a social movement that criticized IP rights as hindering access to essential medicines. Yet, these explanations leave out the central role of two international organizations, the World Trade Organization (WTO) and the World Health Organization (WHO), and particularly their permanent staffs, whose boundary disputes have shaped international IP law at the intersection of trade and global health. Bringing into conversation historical and legal literatures on global health and IP, this article traces how a human rights perspective on IP emerged as a strategy to reconcile the WHO staff’s sociomedical views of health with an increasingly dominant set of global IP rules. It shows how the WHO staff used the language of economics—an analytical frame favored by the WTO—to advance a then unorthodox economic understanding of IP as a type of governmental regulation. This allowed the WHO to argue that states should enjoy regulatory autonomy to curtail IP rights in order to meet broader state objectives, such as human rights protection. Paradoxically, despite their divergent views on the nature of IP, both WTO and WHO engagement with it heralded the emergence of a new technocratic view of global health that focuses on patentable medicines and technologies, and that has ultimately turned away from the WHO’s sociomedical roots.
Other Topics

**Revealing Private Information in a Patent Race**
Pavel Kocourek (Charles University in Prague - CERGE-EI (Center for Economic Research and
Graduate Education - Economics Institute))
*CERGE-EI Working Paper Series No. 693*

In this paper I investigate the role of private information in a patent race. Since firms often do their
research in secrecy, the common assumption in patent race literature that firms know each other's
position in the race is questionable. I analyze how the dynamics of the game changes when a firm's
progress is its private information, and I address the question whether revealing it might be to a firm’s
advantage. I find that a firm has an incentive to reveal its breakthrough only if its rival has not done so,
and only if the research is costly.

**Racial Bias in Algorithmic IP**
Dan L. Burk (University of California, Irvine School of Law)
*106 Minnesota Law Review Headnotes (forthcoming 2022)*

Machine learning systems, a form of artificial intelligence (AI), are increasingly being deployed both for
the creation of innovative works and the administration of intellectual property (IP) rights associated with
those works. At the same time, evidence of racial bias in IP systems is manifest and growing. Legal
scholars have already noted that as AI becomes part of the intellectual property landscape, the biases
present in existing IP systems may infect algorithmic processes trained on data from past practices.
Unfortunately, much of the discussion to date conflates technical biases in AI systems with social
biases, requiring disambiguation of the two. The latter type of bias, social bias, is already endemic
throughout IP, and so the addition of AI systems requires special consideration only to the extent that
they present special problems.

In this essay I begin identifying such social bias problems that are particular to algorithmic
determinations through AI processing. One set of problems relates to the illusion of numerical
objectivity; AI outputs tend to be assigned undue weight due to the universal but fallacious impression
that they are objective and neutral. A second set of problems relates to the performative nature of
algorithmic processes; they tend to produce the effects that they assume, and in the intellectual property
context hold the potential for altering the nature of protected works. Identifying these problems indicates
that currently proposed solutions will be inadequate, and points toward a different approach to dealing
with racial bias in algorithmic IP.
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