# Patent Sovereignty and International Law October 16, 2015 UC Irvine School of Law ABSTRACTS

#### The Undiscovered Country in Multilateral IP Regulation: Evolving Competition Law Doctrines for Regulating Patent Abuse

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Competition law is increasingly visible as an instrument for balancing the interests of the public and IP right holders. Competition law is not the subject of broad multilateral regulation, including with respect to patents. The WTO TRIPS Agreement establishes modest disciplines, but preserves wide flexibility. There are few multilateral instruments that impose legal disciplines on the adoption and implementation of competition law. This reflects policy of the United States that has long opposed the negotiation of multilateral competition law standards. US concerns have historically been based in two sets of interests: those of the multinational business community reluctant to encourage international competition law enforcement, and those of the Department of Justice reluctant to surrender policy flexibility. As competition authorities in the European Union and emerging market countries such as China, India, Brazil and South Africa have stepped up competition law enforcement, the multinational business community based in the United States may be starting to rethink its perspective regarding the negotiation of multilateral standards. For example, in voicing opposition to enforcement of competition law by Chinese authorities, the US Chamber of Commerce and other groups have found it difficult to point to legal disciplines that might act as constraints.

The US Supreme Court recently affirmed that protection of patent owner rights and enforcement of competition law are not mutually exclusive. A patent owner may engage in competitive abuse even when operating within the legitimate zone of patent protection. This is a positive step, but it remains to further develop the relationship between competition law and patent protection in the United States, and to encourage its evolution elsewhere in terms of doctrines that are tailored to relevant subject matter and public interest. Competition law can redress the tendency of trade negotiators to support rules that favor purely mercantile interests, and protect the sovereign right of nations to govern for the public benefit. Rather than multilateral restraints on competition law, further development of competition law doctrines that can reign in abusive practices is needed. This paper argues for the development of a new doctrinal approach with respect to patents and other forms of marketing exclusivity that focuses on the consumer protection aspect of antitrust or competition law, as compared with the more recent US focus on supply-side industrial policy.

### Show AND Tell?: Genetic Resource Disclosure of Origin Requirements and TRIPS

Margo A. Bagley

Requiring applicants to deposit ("show") a sample of material necessary to reproduce a claimed invention is a fairly standard patent system feature. What is not standard, but is becoming more common, is states also requiring applicants to disclose ("tell") the source or origin of biological material used in creating an invention. While disclosure of origin may aid in the determination of the novelty and non-obviousness of an invention, the purpose of such provisions is also to facilitate an assessment of whether such biological material has been used with permission and if it is subject to benefit sharing.

The "Declaration on Patent Protection: Regulatory Sovereignty under TRIPS" provides a long-needed, authoritative view of the flexibilities retained by States after signing onto the TRIPS Agreement and its elevated minimum standards for patent protection. According to the Declaration: "States are not prevented from making the grant of a patent subject to revealing the origin of claimed biological material and associated traditional knowledge." This is a bold statement, for which no support is directly provided in the Declaration, and on which commentators disagree. Comments by delegates in World Intellectual Property Organization (WIPO) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) meetings as recently as June 2015 also suggest some countries remain uncertain regarding whether the TRIPS Agreement allows them to require patent applicants to disclose the origin of biological resources and associated traditional knowledge.

Is the Declaration accurate? Is it an overstatement? If accurate, does TRIPS impose any limitations on genetic resource DOO requirements? This paper will explore answers to these questions in the context of the IGC, where active negotiations are currently on hiatus but expected to resume in 2016, and where countries remain divided over many issues, including whether to adopt a genetic resource DOO requirement and if so, how much or little regarding disclosure should be mandated at the international level.

#### On Aiding Technological Development: the Max Planck Declaration on Patent Protection

Rochelle Dreyfuss Esteban Donoso

The Declaration on Patent Protection is a welcome addition to the Max Planck Institute's work on the flexibilities available under the TRIPS Agreement. Like the previously published Copyright Declaration, it improves on the WTO's interpretations of the threepart open-ended exceptions provisions of the TRIPS Agreement. Furthermore, it attempts to clarify the other regulatory options that are retained under TRIPS. Here, we contend, the Declaration makes three mistakes. First, its aggressive interpretations of certain provisions undermine its credibility, making it a less useful resource than a document prepared by such notable scholars might be. Second, the options, if adopted in toto, would almost completely undermine incentives to invent. Yet the Declaration does not provide guidance on which options a state that is intent on encouraging innovation should adopt. Third, the Declaration's focus on TRIPS' sovereignty deficits misses the Agreement's failure to fully coordinate the global innovation enterprise. We argue that two dramatic revisions to TRIPS—a change in the term of patent protection and in the rule on international exhaustion—would make the agreement more equitable and more efficient. These changes would also provide countries more freedom to experiment with the flexibilities correctly identified by the Declaration and might also lead nations to entertain the idea of abandoning at least some of them.

### The Declaration on Patent Protection and Regulatory Sovereignty Under TRIPs and the Trans Pacific Partnership Agreement

Sean Flynn

A handful of pacific rim countries are claiming to be on the verge of crafting new international intellectual property standards that aim to ultimately bind the globe – in the Trans Pacific Partnership Agreement. It was in the midst of the early days of the TPP's negotiations, and in the context of leaks of the initial proposals of the agreement, that a group of academics and researchers released the Declaration on Patent Protection and Sovereignty. Several years later, negotiators claim to be nearly finished with the TPP negotiation. In this context, this article analyzes the evolution the TPP patent provisions to determine whether they bend in the direction of the declaration. The article concludes with observations about the impact of academic advocacy on international IP policy debates.

### The Power of Ideas: The Declaration of Patent Protection and New Approaches to International Intellectual Property Lawmaking

Donald P. Harris

In 2014 the Max Planck Institute of Innovation and Competition drafted *The Declaration on Patent Protection: Regulatory Sovereignty under TRIPS*. The Declaration purports to clarify the regulatory options states retain under TRIPS. It does not. Rather, the Declaration goes beyond merely clarifying policy space left within TRIPS and appears intended to modify existing legal rules under TRIPS and/or to limit the adverse effects of WTO decisions interpreting various TRIPS' provisions. Paradoxically, the Declaration simultaneously undermines TRIPS and extends TRIPS' influence.

To be clear, this is not a criticism of the Declaration. The majority of the Declaration indeed identifies legitimate policy space, and this Article agrees with the Declaration's ultimate goal of providing states with greater discretion to implement domestic intellectual property laws more consistent with states' technological and economic development. Moreover, changed circumstances since the adoption of TRIPS may justify changes to existing law. But, in notable areas, the Declaration pronounces as law interpretations that are difficult to reconcile with current law. This Article highlights those areas.

The Declaration is a significant statement of the state of contemporary IIP law, but is just as significant for what it teaches about contemporary IIP lawmaking. Traditional modes of lawmaking involve strategies and changes within a particular structure or organization (i.e., horizontal lawmaking). Shifts in governance over time have allowed for different modes of lawmaking, such as "regime shifting," whereby states and non-state actors change law by relocating rulemaking processes to other venues to effect more favorable outcomes. The drafters of the Declaration might, too, change existing law, but from outside the state-centric world of international organizations. Their approach might be characterized as a "bottom-up" approach.

Key criteria that should exist for an effective bottom up process include at a minimum (1) strategic planning by a group of experts with legitimacy and shared beliefs to create alternative policies, (2) building transnational solidarity around the alternative policies,

(3) establishing both formal and informal channels of communication to states' policymakers; and (4) using the influence of the transnational network to foster an international dialogue that confronts states' policymakers to consider the consequences of adopting (or not adopting) the alternative policies, thereby provoking a fundamental change in mindset.

Seen from this perspective, the Declaration and this approach ultimately invite us to rethink the various dimensions of power. Rather than the *market power* of the IP world, or the *material power* of well-organized and well-financed trade associations that can effectively lobby to secure their interests in legislation, or the *political power* of the United States in international negotiations, or even the *institutional power* of the WTO vis-à-vis other international organizations, the Declaration reminds us of another, sometimes hidden, dimension of power -- the power of ideas.

## A Collision Course: Investor-State Proceedings Challenging International IP Norms

Cynthia Ho

This article discusses an important, yet understudied threat to patent, as well as other intellectual property sovereignty under TRIPS: pending and potential challenges by companies under international agreements protecting investments. Although such agreements have existed for decades, Philip Morris and Eli Lilly are blazing a new path for companies to sue countries they claim interfere with their intellectual property rights through so-called investor-state arbitrations. These suits seek hundreds of millions in compensation and even injunctive relief for alleged violations of internationally agreed intellectual property norms. The suits fundamentally challenge TRIPS flexibilities at the very time the Declaration on Patent Protection and Regulatory Sovereignty under TRIPS seeks to clarify these flexibilities and encourage countries to utilize them. Although only two countries are currently targets of these disputes, they could have a chilling effect. This is particularly a concern when countries such as South Africa, are considering substantial reforms to better utilize TRIPS flexibilities. Given the importance of this threat to TRIPS and domestic sovereignty, this article analyzes the pending disputes and offers some proposals for how to promote TRIPS flexibilities and sovereignty.

#### **Patent Working Requirements**

#### Marketa Trimble

At the beginning of the 20<sup>th</sup> century, commentators referred to patent working requirements as the most contentious contemporary concept in patent law, and working requirements were at the center of discussions about the revisions of the Paris Convention. By the end of the 20<sup>th</sup> century working requirements attracted very little attention, and the TRIPS Agreement did not even expressly address working requirements. However, some TRIPS Agreement provisions do arguably relate to such requirements, and some commentators believe that the TRIPS Agreement prevents countries from maintaining such requirements.

This paper discusses the origins and the development of patent working requirements and examines the rationales for and purposes of the requirements. The paper points out the links and interactions between working requirements and the other components of patent systems and shows that all of the components, including working requirements, serve to calibrate the systems to the particular needs of individual countries. To the extent that international patent law harmonization continues to allow some leeway for countries to calibrate their national patent systems according to their national needs, and to the extent that international law does not prevent countries from maintaining working requirements, countries should be able to use working requirements as they create patent systems that best serve their needs.