Beyond Borders or Beyond Limits?

IP Provisions in TPP Exceed the Bounds of U.S. Law

Whereas trade agreements historically aimed to lower barriers to entry for goods and services so that countries could trade more efficiently, trade agreements which include IP requirements, like the TPP, aim to set out a multinational agreement for increasing IP standards (including litigation and enforcement practices, linkage etc.).

If a country's domestic laws do not comply with the international trade agreement standard, then the domestic law must be reformed. This means that all manufacturers, both domestic and multinational, operating/manufacturing/selling in any of the current TPP countries are affected by TPP. The TPP will set out the international law for IP for all signing countries.

Note too that TPP is not a closed agreement, meaning that in the future other countries can accede to the completed agreement and would have to change their domestic laws accordingly. Current TPP countries are: U.S.A., Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam. Countries which have expressed interest in joining TPP after it concludes: Colombia, Taiwan, Philippines, South Korea. China is considered likely to seek post-completion accession as well.

		US System	TPP	Impact on Generic Entry & Access to Medicines
☒	Promoting Competition For Pharmaceutical Industry	Balance between innovation and access	One-sided protection of patent holders	Entry of generics is delayed by every IPR provision related to pharmaceuticals
☑	"Linkage" between Regulator and Patent System	Regulator blocked from issuing market authorization through market approval process	Mandatory requirement for regulator tp blocked from issuing market authorization "through market approval process"	Mandatory requirement is a departure from the "May 10" agreement which set out *permissive* patent linkage in the Peru, Colombia and Panama FTAs. Most TPP countries do not currently have linkage, nor do they have the infrastructure or market size to sustain a linkage regime.
☒	Incentive/Reward for Generics	180-day market exclusivity to first generic to challenge the patents in Para. IV filing (i.e. demonstrating	No incentive or reward for generic companies to challenge the validity or applicability of a patent	Patent linkage without any incentives for generics to challenge brand patents will create skewed system where patent holders will always have incentive not to innovate, but to secure marginal, weak

		invalidity or non-infringement)		patents for the sole aim of prolonging delays to generic market approval.
☒	Non-infringing Generic Products	Generic can obtain market authorization by demonstrating non-infringement or invalidity of the patent	No mechanism to allow non-infringing generic product onto market. Only through patent holder's "consent or acquiescence".	Will result in absurd situation where non-infringing products cannot obtain market authorization on the basis of the existence of the patent which they don't infringe.
☒	Which Patents are Relevant in linkage	Limitation on types of patents that can be listed in Orange Book (product, formulation, method of treatment)	No limitation on which patents can be listed	Without any limitations, the potential number and type of patents which can be relied upon to delay generic market approval is enormous resulting in potentially indefinite evergreening.
☒	Automatic Substitution	Automatic substitution of generic medicines	No requirement for automatic substitution	It is often forgotten that Hatch-Waxman was designed to promote generic competition. Patent linkage was an invention that fit into a complex system to streamline generic market entry (setting out ANDA process, establishing basis for substitution through bioequivalence), and the linkage component was to appease PhRMA. Linkage on its own is nothing more than delaying generic entry
☒	Biosimilar Approval	No patent linkage for biologic products under the BPCIA	Patent linkage would apply to all "pharmaceutical products" including biologics	TPP clearly goes beyond US law in applying linkage to biologic products. Under BPCIA, FDA is not automatically blocked from approving a biosimilar based on mere existence of patents. There is a notification system, not a marketing-prevention system. Bc international law trumps domestic law, if TPP is concluded requiring a standard beyond US law, *then US domestic law would be subject to change in order to comply with the agreement.*

☒	Patent Term Extensions	Mandatory limitations on patent term extensions (eg kinds of products, product must be subject to regulatory review period, must be the first permitted marketing of the product, single patent extension, due diligence by applicant, max 5 years), effective patent term cannot be longer than 14 years	No limitations required, only “optional”	TPP is pushing for steady incremental increases to IP standards – a constant raising of the minimum standards whether in the length of the extensions, or, as in the case of patent term extensions, by steadily moving it from an optional extension to a mandatory requirement for all signing countries.
☒	Exclusivity Period for Biologics	12-years, with Congressional right to alter or change to reflect market realities, experience, internal debate, President Obama’s last five budget proposals reduce this period to 7 years.	12-years with no possibility to change	Removes the possibility in the future of Congress ever revising the exclusivity period – despite the fact that no one has visibility on how competitive the biosimilar market will be in the US or whether delays through DE will gut projected savings from biosimilars. The White House has itself called for a reduction from 12 to 7 years in order to realize savings to the budget.
☒	Exclusivity Period for Data	Exclusivity granted for 5 years for new pharmaceutical products, and for 3 years for new clinical investigations; A generic applicant may file for	Exclusivity would be granted for "at least" 5 years for new pharmaceutical products, and "at least 3 years" for new clinical information, Exclusivity for “new clinical *information*” Would block “same *or similar*” products	While in the US only “same products” are blocked by the DE, in TPP “similar” products are blocked – meaning that whole therapeutic classes could be kept off the market.

		marketing approval after 4 years; Blocks "same" products, not "similar" ones		
☒	Best Mode	US Law requires patent filer to disclose "Best Mode"	No requirement for best mode	The social contract underpinning the basis of patent monopolies is being undermined by removing any obligation for the patent holder to disclose the best mode of the invention
☒	Bolar Provision	Bolar provision exists meaning that "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or *import into the United States* a patented invention" and allows exception for exports for purposes of submitting information	More restricted definition which excludes "import" and does not include exception for export	Potential to impact the ability of Gx manufacturers to import product under patent for the purposes of R&D * *Most recent information is that Canada has succeeded in removing this problematic definition of Bolar and substituting with a simple requirement that all signatory countries have Bolar provision.*