Secondary Rights in International Law: The Gray Area of Law

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- Regardless their definition or the distinction between primary and secondary rights, recurrent concerns about them are related to the correlation each set of rights has over the other.

- Those interactions are not always logical, or relevant; actually, more than once secondary rights contradict or make irrelevant primary rights

- But this is not new, is the result of years of lobbying and pervasive influence of IP holders.

- Unlike other areas of law, IP holders are in charge of the law-making process.

- They control the drafting of national statutes, they push litigation in order to obtain rulings interpreting favorably the statute.

- Finally they push those local victories on the texts of IP international treaties

- The outcome will not always make sense and the result will be a Frankenstein area of law, full of concepts, and remedies with no coherent relationship among them, and totally opposed to policies supposedly behind its reason to exists.

- The problem is, when those rights are implemented on national statutes.

- Sometimes, they are not implemented at all.

- Sometimes, those rights are just ignored by national courts

- The Uruguay Round sealed several important changes.

- The first one, negotiations were not carried out under the traditional international forum on intellectual property, the World Intellectual Property Organization (WIPO), but rather those negotiations took place in an international trade forum that led to the creation of the WTO.

- Second, for the first time in a treaty on intellectual property, a section of enforcement of rights was included.

Secondary Rights

- In the case of Mexico, WIPO Internet Treaties of 1996 have not been implemented.
- There is no protection against the circumvention of technological measures.
- Treaty could be self-executing, but he language of these provisions, necessary require implementation in national statutes.

Not secondary, but ignored by the Mexican Supreme Court

- NAFTA 1705(3)(a)

"…any person acquiring or holding economic rights may freely and separately transfer such rights by contract for purposes of their exploitation and enjoyment by the transferee…"

USMCA

- Chapter 20 of the USMCA contains provisions establishing patent term “adjustments” in two not well-defined scenarios. The first one is when “there are unreasonable delays” in the issuance of a patent.

- The second is for pharmaceutical products when there is an “unreasonable curtailment of the effective patent term as a result of the marketing approval process.

- It also contained data exclusivity provisions.

Not the same safegards existing in the place those rights were created

- Patent term extensions as defined by USMCA do not include several safeguards existing in the U.S. legal system.
- When the U.S. Congress amended the Patent Act through a reform called the Hatch-Waxman Act, it tried to balance interests of brand pharmaceutical companies and generic producers.
- That is why the U.S. Patent Act provisions are somehow more balanced than USMCA adjustment term provisions. The Hatch-Waxman Act establishes extensions on the patent term of protection in order to compensate for a portion of the term of protection lost when pharmaceuticals seek FDA marketing approval.
- However, it also establishes the Abbreviated New Drug Application Procedure (ANDA), which allows generic medication producers to rely on original brand drugs safety and efficacy data after data exclusivity rights have elapsed.

- Like the USMCA, the Hatch-Waxman Act provides extensions on patent term of protection and data exclusivity of 5 years for safety and efficacy data for big brand pharmaceuticals. H
- However, unlike the Hatch-Waxman Act, the USMCA does not guarantee to producers of generics the use of a brand’s data once the exclusivity time has elapsed, nor does it offer any abbreviated marketing approval procedure.

Secondary Rights = Gray Area of Law

- Today, there is no legal protection for data provided by pharmaceuticals to the Mexican equivalent to FDA.
- However, pharmaceuticals push litigation in almost all the cases through Unfair Competition Provisionsm cominng from NAFTA and TRIPs agrement.
- Therefore, this uncertainty causes, the U.S. provisions been more balanced than Mexican Law.
- With USMCA, there is no waranty that generic producers are going to have acces to data, after the 5 years of exclusivity have elapsed.

- The result would be, difficult.

- If there was not proper implementation or if courts just ignored provisions, on easy things; on data protection and patent term extensions the result will be uncertain.