



Mexican Patent Litigation, International
Intellectual Property Treaties and the
Extension of Patent Term of Protection

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Patent Litigation in Mexico and the USMCA

1. Compare Litigation
2. TRIPs principles absent in the Mexican legal system
3. Litigation facts
4. Article 4 *bis* Paris Convention
5. The problem
6. USMCA

- An example of a **10 years litigation** case.
- More than **16 resolutions** or judgements.
- It did **not** reach to the point to award **damages**.

Patent Litigation in the U.S.

Article III Courts

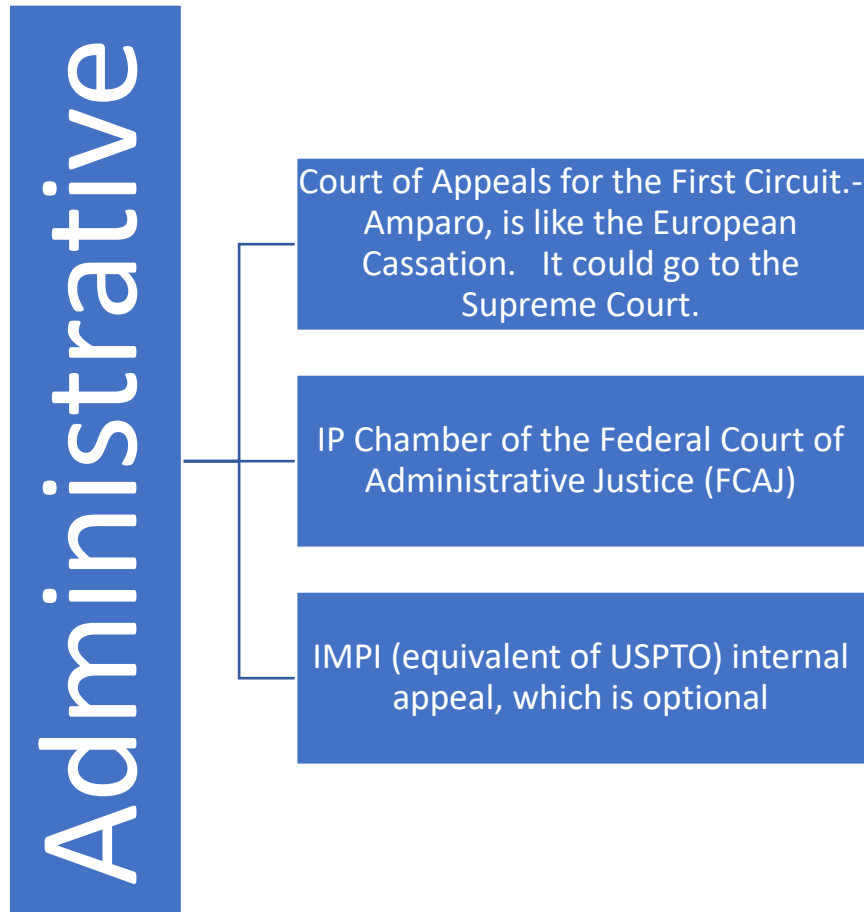
Supreme Court.- Can hear the case if it takes the *certiorati*.

Appeal.- Court of Appeals for the Federal Circuit (usually).- Panel (3), or it could go to the Bench by *Petition for Rehearing*.

District Court

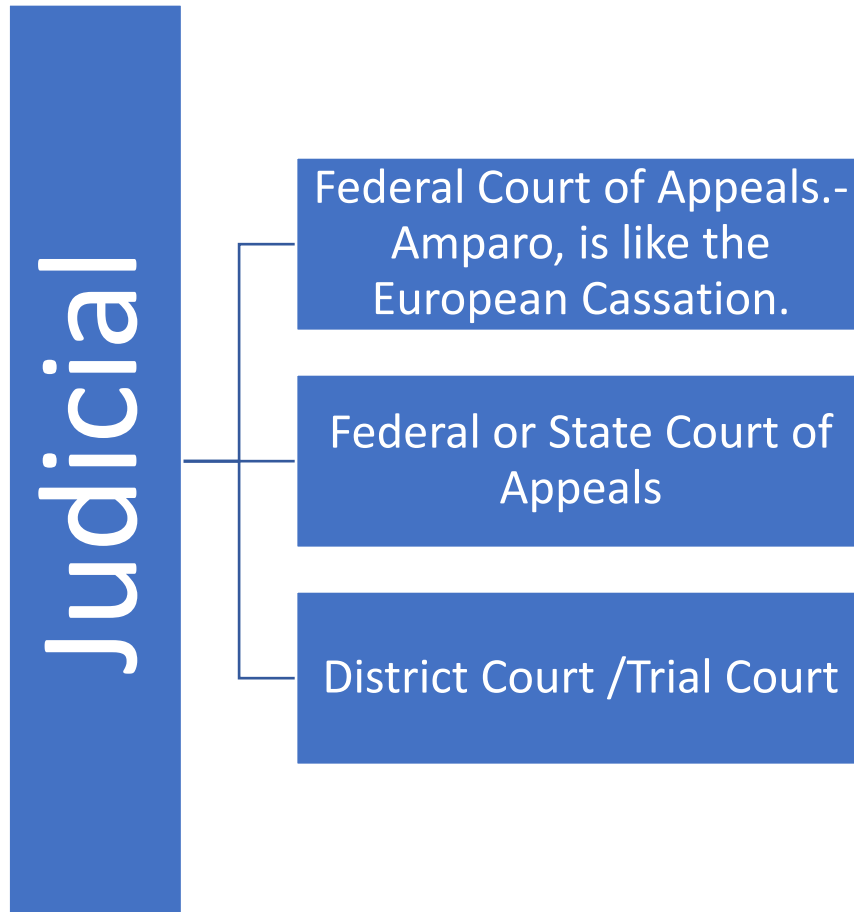
- One Stop Shopping Litigation:
 - Injunctive Relieve
 - Damages
 - Courts may rule on patent validity
- Sometimes PTO concurrent invalidation patent procedures.

Patent Litigation in Mexico



- Injunctive Relieve
- No Damages
- IMPI can hear about patent validity.
- You have to start all over again in a Federal District Court, or even in a State Trial Court in order to get damages.
- You need the resolution from IMPI in order to file an infringement action claiming damages. So, you cannot start litigation directly in any court.

Patent Litigation in Mexico



- Injunctive Relieve, not clear (even TRIPs 45)
- Damages
- The cannot rule on patent validity.
- You have to start all these after years on litigation under the previous slide administrative litigation.

TRIPs Agreement

Article 41

1. Members shall ensure that enforcement procedures...are available under their law so as to permit effective action against any act of infringement ...expeditious ... deterrent to further infringements....
2. Procedures ...shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

Article 49.- Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

The Litigation: FACTS

- The invention originated in **Japan**; the owner, a pharmaceutical company called Takeda Pharmaceutical Company Limited (**Takeda**), filed two applications there.
- The first one was dated **January 19, 1985**. However, it was abandoned in favor of another new application dated **January 9, 1986**.
- That is to say, we are facing a priority date of 1985, which was not claimed in Mexico until 1992.
- The foregoing, of course, **does not reflect the normal progression of an international application**, neither by applying the principles of the Paris Convention for the Protection of Industrial Property (Paris Convention), nor by applying those of the Patent Cooperation Treaty (PCT).
- In 1986, they did not attempt to register the patent in Mexico because the **Industrial Property Act of 1976**, in force in those days, did not include patent protection for pharmaceutical products.

Litigation: FACTS

- The time elapsed between the Japanese filings and the filing date in Mexico poses the problem of **novelty**, a fundamental requirement in order to obtain a patent.
- That is, to obtain protection, an invention is weighed against **the state of the art**, which is considered **globally**.
- **Transitory Article Twelve** of the Mexican Industrial Property Act (1991).
- This statutory provision created an **unusual regime** for this type of inventions, especially those that **would not meet the novelty requirement** because they had been previously published in their countries of origin during the prosecution process.
- Specifically, Transitory Article Twelve benefits pharmaceutical products and inventions that the outdated **Industrial Property Act of 1976** had not protected by a patent, but through an obsolete Russian inspired **certificate of invention**

Article 4 bis of Paris Convention

- Transitory Article Twelve of the Mexican Industrial Property Act offered an opportunity for certain inventions.
- However, it also created a huge problem, since it **linked the termination** date of the term of protection in Mexico **to the termination date in the country of origin** for those inventions
- This is different from the normal term of protection (MXIP Act art. 23): 20 years, starting from the filing date of the application in Mexico.
- Article 4 *bis* of the Paris Convention establishes the principle of independence of rights in an “unrestricted sense,” establishing that patents applied in one country **shall be independent from those patents applied in other countries**, regarding nullity, forfeiture, and **the term of duration**.

Don't drink Tequila while legislating

- Consequently, if the date of application of the patent on litigation was on **June 17, 1992**, then the expiration date would have been accordingly on **June 17, 2012**.
- However, instead of an expiration date of **June 17, 2012** they got **January 15, 2006**, the date originally indicated in the title.

Litigation

- Before filing the infringement action, or requesting any preliminary injunction, the plaintiff **Takeda** filed an appeal, for practical purposes.
- Actually, it was a contentious administrative proceeding against a resolution issued by the **IMPI on January 25, 2005**.
- In this resolution, the **IMPI ruled inadmissible any modification** of the term of protection of the patent object of the litigation.

Litigation

- Takeda began its arguments alleging that although the **IMPI had denied extending** the term of protection of the patent, this was not what it had asked the IMPI to do; instead it had requested **the correction of the term of protection**
- However, Takeda argued that the **original filing was withdrawn** in favor of another one that it subsequently filed, and that new filing generated a patent that would expire on the requested date, that is to say on **January 9, 2011.**
- The term of protection of a patent in Mexico, should be based on the term of protection of the patent granted in the country of origin, not on the date of filing, **“since applications are not valid....”**

Litigation

1. IMPI **denied modification**
2. FCAJ reversed, **extending term**
3. Court of Appeals confirmed FCAJ's
4. Defendant not allowed because **no "standing"**
5. Takeda ask for preliminary injunction relieve before the time court of Appeals confirmed FCAJ's ruling.
6. Defendant filed several constitutional actions called Amparo against not being allowed. Unsuccessful by **res judicata** principles.
7. IMPI decreed the **preliminary injunctions**.
8. Defendant presented counter bail bound to lift preliminary injunctions. (**TRIPS art 50**).
9. IMPI declare infringement, Takeda got its bail bound and the defendant's counter bail bound.
10. FCAJ ruled against defendant, **RIMSA**
11. Defendant won at federal court, but **limited effects**. The argument was infringement procedure should not be resolved until the resolution of a procedure of nullity filed against the alleged infringed patent became final.

Big Problem

- A journal note published on September 12, 2010, remarked how pervasive the problem was. It also made reference to the present litigation:

“... the problem says the national producers of generic medications, is that **more than a quarter of drugs patents published today** in the gazette exist because of a judicial mandate, that is to say, that a judge ordered the IMPI to protect them despite the fact that IMPI itself had refused to do so....”

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 safeguards 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.
- 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.

Challenges Ahead

- 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 Provisions coming from NAFTA and TRIPs agreement.
- Therefore, this uncertainty causes, the U.S. provisions been more balanced than Mexican Law.
- With USMCA, there is **no warranty that generic producers are going to have access to data**, after the 5 years of exclusivity have elapsed.

Don't drink Tequila while negotiating

- The result would be, **difficult**.
- It is a promise of long litigations ahead, and **uncertainty**.
- Access to **cheap medication** will be **curtailed**.
- Not to mention complexities, coming from article 14.1(f) of the USMCA establishing intellectual property rights as covered investment. The door is open for right holders to initiate **investor-state dispute settlement arbitration procedures**. Remember *Ely Lilly v. Canada*.
- This was negotiated by a leftist Mexican government.