

Patents in Latin America:

Is it worth it?

Tokyo

October 2012

Latin America 2011

LAC32

Population: 572,000,000

GDP: USD 6,837,162 MM

Per capita: USD 11,770

Wikipedia: “Latin America and the Caribbean, taken as a whole, would rank as the **world's fourth largest economy**, after the European Union, the United States and China, and above Japan.”



Latin America

- [http://en.wikipedia.org/wiki/List_of_Latin_American_and_Caribbean_countries_by_GDP_\(PPP\)](http://en.wikipedia.org/wiki/List_of_Latin_American_and_Caribbean_countries_by_GDP_(PPP))
- All members of TRIPS
 - With the exception of Venezuela, all are (essentially) TRIPS-compliant
- Various countries with bilateral agreements with US, EU, EFTA and Japan (see also TPP and APEC)

Japanese trade with LA

- Between 2005 and 2009, Japanese exports to Latin America and the Caribbean increased by 34 percent—more than exports to any other region.
- During the same period Japanese imports from LAC rose by 26 percent, the second highest percentage increase in relation to imports from other regions.

Our secret filing list

- Where to file in LA?
 - LIST 1
 - Mexico, Brazil
 - LIST 2
 - Argentina, Colombia, [Venezuela], Chile
 - LIST 3
 - Guatemala, Costa Rica, [Panama], Peru, Ecuador, [Uruguay]
 - LIST 4 (the rest)

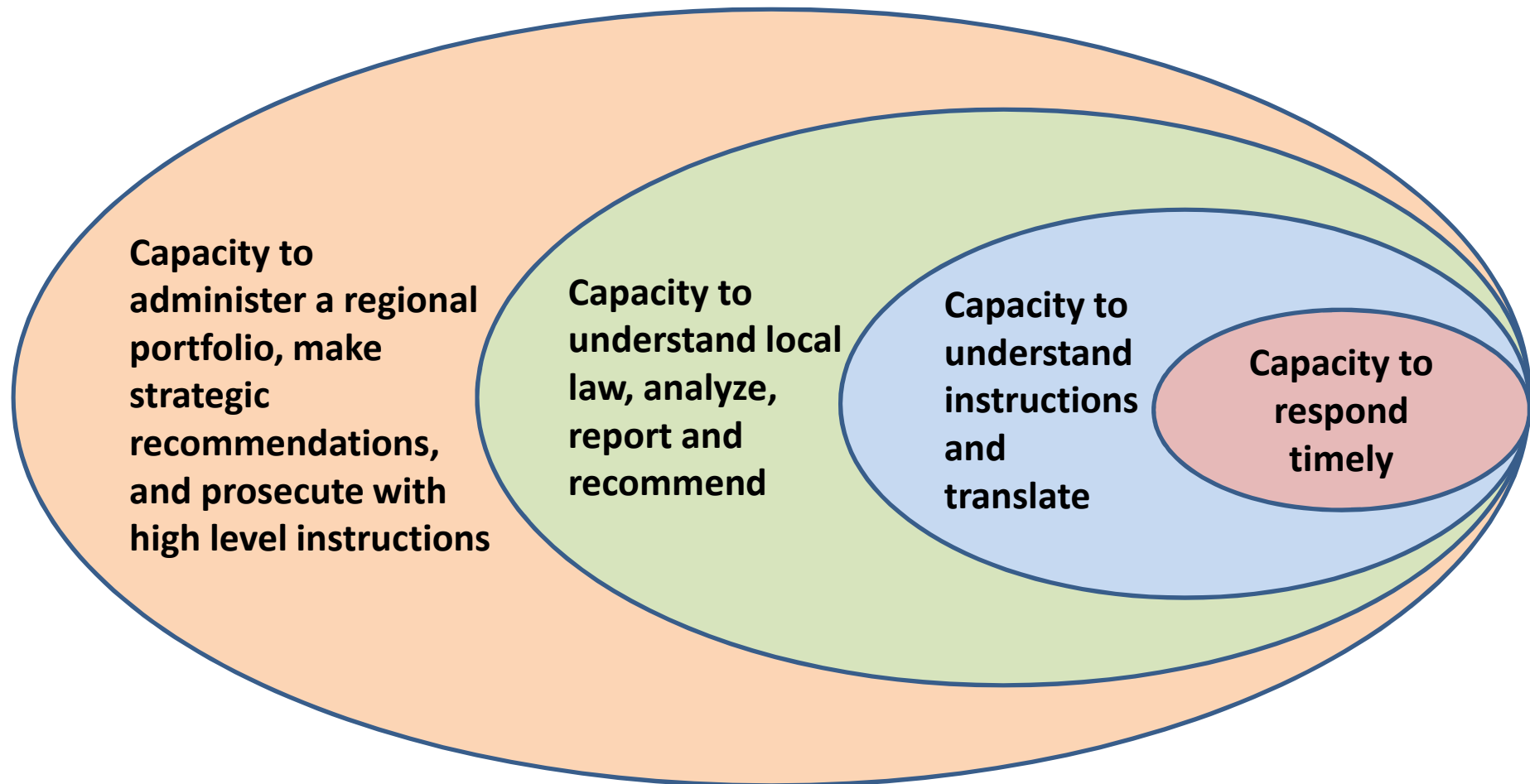
General Remarks re LA Patent Practice

- Latin American practice is very young, but developing at a rapid pace
 - Little outbound work, but growing
- Beware of IP professionals that are not patent experts

General Remarks re LA Patent Practice

- Prosecution is very similar worldwide; do not be afraid to ask and suggest (you will often be right)
- Delays: from the acceptable to the ridiculous
 - Always ask about availability of patent term compensation/restoration
 - Many countries have implemented FTA obligations

What kind of Patent Agent you need?



Prosecuting Patents

- Claim Drafting practices
 - Generally acceptable style: EPO practice
 - Functional characterizations normally not allowed
 - Overly broad claims are generally objected (e.g. large Markush claims)
 - In many countries, Examiners will limit you to exemplified embodiments

Prosecuting Patents

- Typical subject matter exclusions:
 - Second uses
 - Methods of treatment
 - Matter isolated from nature (unmodified)
 - Software *per se*
 - Business methods

Prosecuting Patents

- Prosecution issues
 - High to ridiculously high nonobviousness standard
 - E.g. “could have been invented”; “obvious to try”
 - Burden to raise *prima facie* obviousness objection is relatively low
 - Comparative data used to rebut *prima facie* case cannot easily be extrapolated to situation where data does not apply

Prosecuting Patents

- Prosecution issues
 - Oppositions: normally pre-grant, but not an independent procedure (i.e. in theory, no additional delay)

Prosecuting Patents

- Reinstatement of rights for PCT National Phase (Rule 49.6)
 - Flexibility
 - Standards
 - Due care; due diligence
 - Unintentional
 - Costs

Prosecuting Patents

- Beware of non-PCT countries of importance:
 - Venezuela: a special case, is it worth seeking protection there?
 - Argentina
 - Paraguay and Uruguay: beware of the cost of certified translations – can exceed attorney+government fees!
 - Bolivia

Prosecution Tips

- Don't be afraid to ask and suggest
 - many times local law and practice are silent; don't expect automatic boilerplate recommendations
 - US/EPO/JPO law and practice are by far the most sophisticated in the world; chances are, local practice will adopt US/EPO/JPO practice

Prosecution Tips

- ASK: How many office actions do I get, and until when can I modify my claims?
 - always have limited dependent claims just in case
- When in doubt, **obtain an Examiner interview**

Prosecution Tips

- What are my options to expedite?
 - Requesting early publication
 - Making an examination request/payment as early as possible
 - Providing evidence of granted counterparts and conforming (e.g. EPO and Andean Community grants for AC countries)
 - **PPH** (e.g. Mexico, Colombia)
 - Special cases (e.g. imminent product launch)

Prosecution Tips

- Pharma: think about your objectives and the jurisdiction
 - Do you really need that broad claim?
 - Is a narrow claim covering a lead compound enough?
 - What are the real possibilities there will be local design-around?
 - What are your options with divisionals?
 - Will you eventually have additional data available for the genus or a specific back-up compound?

Patent Enforcement

- Patent Enforcement or “Great, I have a patent, is it enforceable?” – PHARMA examples:
 - In general, for a basic compound and with experienced counsel, YES
 - Basis: actual litigation, preliminary injunctions, or settlements.
 - In general, for other improvement patents (e.g. methods, polymorphs), results are more mixed

Patent Enforcement

- Preliminary injunctions
 - PHARMA: No Orange Book-style linkage (except MX)
 - In many countries, requesting a PI is an *ex parte* procedure, with a relatively low evidentiary burden (e.g. an expert opinion)
 - Many countries require plaintiff to post a bond (amount is often arbitrary)
 - reversal of a PI is possible with the posting of a counter-bond

Patent Enforcement

- Damages
 - Calculated based on:
 - Lost profits and actual damages
 - Unjust enrichment
 - Reasonable royalty
 - Very few cases get to damages stage (preliminary injunction is often enough)

Patent Enforcement

- Standing to seek invalidity: **NONE**
- Discovery
 - Contrary to popular belief, broad pre-litigation discovery requests are many times available, including:
 - Document production, inspections and depositions (but no interrogatories)
 - Be careful with negative inferences

Patent Enforcement

- Rights granted by the patent: *beware* of jurisdictions where grant is the right **to use** the patented invention (not just exclude others from exploiting)
 - Examples: Mexico, Venezuela

Patent Enforcement

- Litigation Tips
 - Again: don't be afraid to ask and suggest
 - Make sure you understand where you will be litigating (The IP Office? A judge? Different judges? Criminal?)
 - Understand your discovery rights, obligations and liabilities
 - Define your litigation objectives as best you can; manage expectations

Patent Enforcement

- Pharma R&D Example
 - Why do companies file in LA?
 - Market exclusivity
 - this is the first generation of country managers operating under exclusivity conditions; i.e. **it is becoming an expectation**
 - Even in the smaller markets, exclusivity often pays for portfolio
 - Facilitate public bid awards

Test Data Protection (Pharma)

- Have a 5-year term of protection in their books and in practice:
 - Colombia
 - Peru (currently not biologics)
 - Chile (important time entry limitations)
 - Guatemala
- TDP requires molecule to be a New Chemical Entity

Test Data Protection

- Other jurisdictions rely (mostly unsuccessfully) on theories of unfair competition (TRIPS Art. 39.3)

Genetic Resources and Traditional Knowledge

- Relevance for patents
- Convention on Biological Biodiversity
- Andean Community Decision 391: regional law for access to GR and TK
- Access procedure and practice
- Potential for biotech companies and patents in LA

Genetic Resources and Traditional Knowledge

- Formal requirement of Access to GR/TK Contract
- Nullity Action (invalidity) of patents based on lack of compliance with Decision 391 for failure to provide GR/TK access contract
- Cases and discussion
- Nagoya Protocol 2010

どうもありがとうございました

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ありがとうございました

ご質問等ございましたら、下記までお気軽に
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