TRIPS@25 - Webinar
TRIPS and Competition

Perspectives on the IP-Competition Nexus

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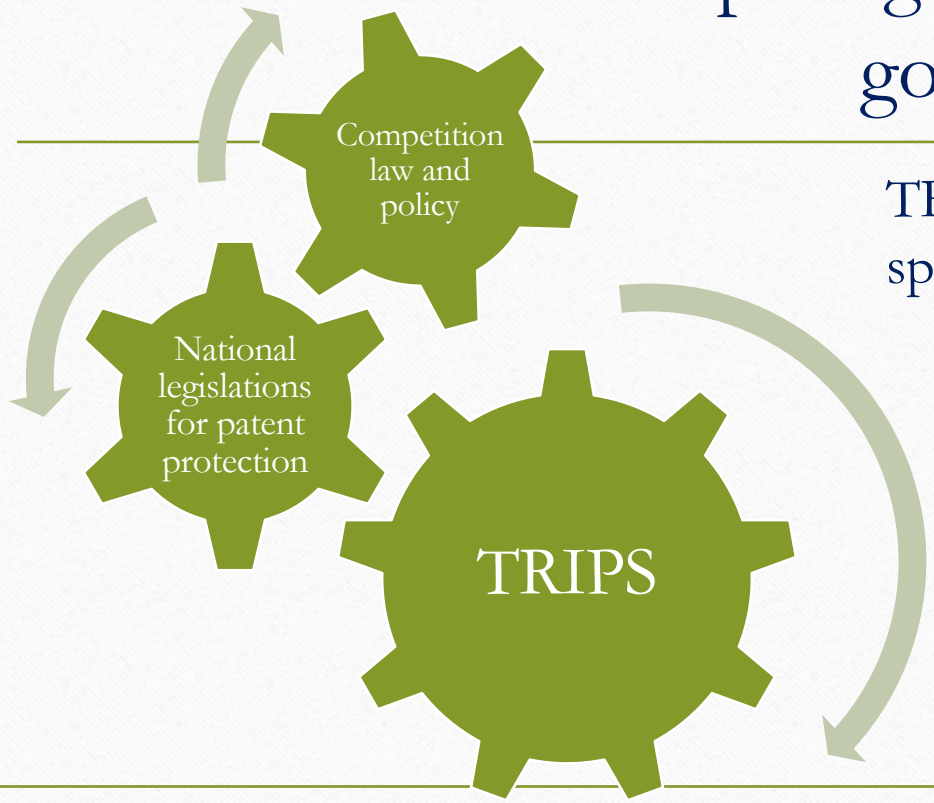
Patents at the crossroad of IP and Competition
A look into the pharma sector!

A patent on a pharmaceutical compound or formulation will often result in a 'potential' monopoly, in the economic sense, on the supply of drugs for the treatment of particular medical conditions

A monopoly return on the *minority* of pharmaceutical drugs that are market successes is important to compensate firms for the larger set of sunk investments!

Competing public policy goals?



TRIPS Agreement includes specific recognition of:

- The legitimate interest of WTO Members to protect public health.
- The role of competition policy vis-à-vis IPRs as important element of that overall balance.

Competition Policy and Intellectual Property in Today's Global Economy

- Reverse payment patent settlements or pay-for-delay agreements
- Product switching practices
- Evergreening of patents

Do the characteristics of pharmaceutical markets and existing regulatory mechanisms, including those that seek to ensure generic market entry, serve as enablers facilitating anti-competitive practices?

Patent settlements – thwarting generic competition?

- Restrict generic or biosimilar market entry in exchange for benefits transferred from the originator to the generic or biosimilar company.
- Brand-name pays or bestows some other benefit (non-monetary) to generic firm.
- Limits independent efforts to enter the market: non-compete/ duration/ restricted entry.

As emphasized by the EU-Commission:

"such agreements may result in delayed market entry of cheaper generic medicines, to the detriment of patients and taxpayers financing the health systems."

Product switching – commercial strategy or anti-competitive consumer coercion?

- Soft vs hard switches: withdrawal of older product and introduction of a new (slightly) reformulated drug.
- Hinders the operation of regulatory laws that allow pharmacists to substitute brand-name drugs with their generic versions.
- Product switching schemes exploit this type of regulation given that, at least for a while, the generic is not able to substitute the new drug, allowing the brand company to effectively delay generic competition in the market for its reformulated product.

Abuse of the patent system? Is patentability criteria in some jurisdictions facilitating such scheme?

Evergreening concerns

- The evergreening of patents – especially when it doubtfully extends the patent's commercial life – has also been a focus point in some jurisdictions.
- Patenting minor variations or modestly reformulated products, extending the life-cycle of the drug.
- This resulted in some regulatory revisions and amendments – enhanced efficacy criterion. See India, Australia, and Argentina.

If the reformulation confers little or no therapeutic benefit in relation to the original version, then monopoly power is being preserved with no offsetting pro-competitive effects.

Issues to consider!

- *General framework of the IP and patent system* - the incidence of reverse patent settlements protecting weak patents can be expected to decrease in IP regimes in which the conditions for the grant of patents are stringently enforced by the authorities.
- In sectors like the pharmaceutical industry, in which patents may have a stronger than usual exclusionary effect, patent examiners need to be aware of the competitive impact of their decisions on patentability.

Differentiate between investments in innovation vs investments in impairing (generic) competition

The LATAM experience: the COFECE Study and other identified market failures

- Generic entry is slower and delayed by 2 years in average
- Generic do not pose sufficient competitive constraint
- Regulation affects competition: generics need to be prescribed + patent linkage is limited

The LATAM experience: Regulatory framework + public policy + advocacy

Set clear patent linkages rules to avoid abusive claims as well as specific criteria related to granting secondary or minor patents

Increase access to information so as to promote generic entry - Bolar provisions.

Implement substitution laws, facilitating the entry and prescription of generics

Promote the use of generics as valid substitutes!

Competition Enforcement

Surveillance of the market

Advocacy

International dialogue

Wider IP/Public Health/ Trade context

IP-Competition policy implementation