La Ley de Competencia y la Salud Publica: Abuso de una Posicion de Dominio

Peter Maybarduk
Public Citizen - Global Access to Medicines
pmaybarduk@citizen.org - @PCMedsAccess - http://citizen.org/access

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Caso Atazanavir en Peru

- Alto precio
- Peru excluida del territorio de la licencia MPP
- Solicitud de licencia MINSA: resultados?

Remedia clara: Uso del gobierno / licencia obligatoria de la patente, por motivos de interes publico.

- Derecho soberano: En cualquier momento se lo puede conceder, sin justificacion adicional.

- Autoriza la competencia de genericos.

Ademas: practicas anticompetitivas? Analisis:

- Define el mercado
- Posicion de dominio?
- Abuso de posicion de dominio?

Remedios: licencia obligatoria sin pago de regalias; Multas.

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Relevancia: Legal; Politica.

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USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES

A guidebook for low- and middle-income countries

United Nations Development Programme

Principles of Competition Law

- British Statute of Monopolies, 1623
- US Sherman Antitrust Act of 1890: “protect the consumers by preventing arrangements designed, or which tend to, advance the cost of goods”

- Analyzing anti-competitive practices:
  - Define market
  - Dominant position in market?
  - Abuse of dominant position?

- Sanctions for exclusionary or exploitative conduct
  - Exclusionary: Improper exclusion of competitors
  - Exploitative: Abusive terms for consumers

- Horizontal or vertical anti-competitive activity
  - Horizontal: competitors (exclusion; price fixing)
  - Vertical: Supply chain controlled by competitor (minimum price requirements; exclusive grantbacks)

Patents and Competition Law

- Patent is a government-granted right to exclude -- so under what circumstances can exclusion nevertheless constitute an abuse? And when can a patent holder's conduct constitute exploitation?
    - Refusal to license
    - Denying access to an essential facility
    - Excessive pricing

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Patents and Competition Law

- The word ‘patent’ was coined by King Edward’s *quo warranto* campaign to regulate excessive pricing by holders of royal franchises
  - *Lettre patente* (“open letter”) in cases of excessive tolls
  - For centuries following this, balancing mandates between exclusive rights and pricing were common.

- Paris Convention for the protection of Industrial Property - 1883
  - Had working requirements to ensure patent holders would “remain bound” to country laws.
  - US states’ laws prior to the Constitution - had duties to prevent excessive prices.

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US Competition Law in IP cases

- 1910s-1930s applied Sherman Act to prohibit a series of restrictive licensing and sales terms by patent holders
- Many **restrictive licensing practices** were deemed to be prohibited as violations of competition law

BOX 1.a.1: US Department of Justice antitrust guidelines

The US Department of Justice and Federal Trade Commission, 'Antitrust Guidelines for the Licensing of Intellectual Property' (6 April 1995) describe three basic principles for interpreting competition law requirements applicable to uses and licensing of IP:

a) for the purpose of antitrust analysis, the agencies regard IP as being essentially comparable to any other form of property;

b) the agencies do not presume that IP creates market power in the antitrust context; and

c) the agencies recognize that IP licensing allows firms to combine complementary factors of production and is generally pro-competitive.

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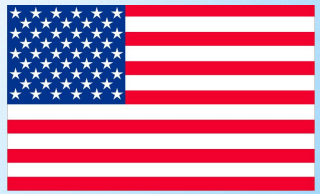

European Union

- EU competition law bans "exploitive" conduct
- Particularly law prohibits "unfair purchase or **selling prices** or other unfair trading conditions."
- For IP holders, unfair pricing becomes more complicated to assess, as R&D costs are factored in.

EU cases set up full set of standards for unilateral refusal to license IP.

In Article 82(b) of the European Commission Treaty:

> An illegal abuse of a dominant position "may, in particular consist in … (b) limiting production, markets or technical development to the prejudice of consumers.

Makes the distinction that **refusal to license** does not violate law, unless it harms competition or appearance of a new innovative product to meet demand.

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Refusal to license inhibits development of new product

BOX 1.a.2 *(continued)*

RTE v Commission ('Magill'), 1995 ECR I-743

Magill sought to publish a combination television guide featuring the copyrighted listings of various broadcasters which each supplied their own individual guides. The ECJ ultimately held that the refusal to license violated Article 82(b) because of the "exceptional circumstances" that there was potential consumer demand for the new product, the company had a *de facto* monopoly over the listings, the licence was an indispensable input for the new product, and the copyright holders did not themselves offer the new product to consumers. The opinion is often cited as establishing the viability of an 'essential facility' doctrine in EU law—accessing the copyright licences under question being essential to the production of the combination guide sought to be produced.

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Canada

- 1969 amendment to the Patent Act: in favor of granting compulsory licenses for health technologies
  - taken out in 1992 when Canada entered into NAFTA
- Current Competition Law still contains process to authorize compulsory licenses for broad range of competitive infractions
- **"Competitive harm should follow directly from the refusal to license"** in order to grant anti-competitive conduct

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The Competition Commission of South Africa, the Competition Act: an Introduction

The Competition Commission would consider the following principles when analysing a situation with an interface between intellectual property rights and competition law:

1. Competition law should recognise the basic rights granted under intellectual property law. The creation and maintenance of innovation markets are necessary for economic progress and development.
2. Intellectual property does not necessarily create market power.
3. A practice involving intellectual property should not be prohibited if the practice leads to a less anti-competitive situation than without the said practice.
4. The long-term pro-competitive benefits should outweigh the short-term 'anti-competitive' effects of intellectual property rights.

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South Africa

- September 2002: complaint by Hazel Tau and the South African Treatment Action Campaign against GlaxoSmithKline and Boehringer Ingelhiem
  - zidovudine and lamivudine 3-10x more expensive than generic versions
- South Africa's Competition Commission found that high prices and refusal to license Indian generic constituted 3 abuses of dominance under Section 8 of the Competition Act
  - excessive pricing
  - refusing to give competitor access to facility
  - engaging in exclusionary conduct if anti-competitive effect of the act outweighs its technological gains

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India

- In 2005, India reformed its patent laws to conform with TRIPS.
- Put in protections for public.
- Article 83(e) of Indian Patent Law states “Patents granted to do not in any way prohibit Central Government in taking measures to protect public health.
- 84(g) patented product must be available “at reasonably affordable prices.”

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India on reasonable requirements of the public

84(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied—

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,—

(i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading manufacturing in India is prejudiced; or

(ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or

(iii) a market for export of the patented article manufactured in India is not being supplied or developed; or

(iv) the establishment or development of commercial activities in India is prejudiced;

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

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Compulsory License: sorafenib

- Nexavar (sorefenib) patented in 2008 by Bayer for pain assoc. with cancer
- Sold for Rs.280,000 ($5,200) a month
- Only met 2% of demand
- Turned down voluntary licensing request from Natco to provide for $180 per month
- Went to Intellectual Property Appelate Board
- IPAB found Bayer failed to meet demand on reasonable terms.
- Compulsory license granted to Natco.

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Peru

Constitucion Art. 61

"El Estado facilita y vigila la libre competencia. Combate toda práctica que la limite y el abuso de posiciones dominantes o monopólicas …"

Decretos 701 y 1034

Comunidad Andina 486, Art. 66 (y 65)

"EL ABUSO DE LA POSICIÓN DE DOMINIO EN EL MERCADO EN LA LEGISLACIÓN NACIONAL," JUAN FRANCISCO ROJAS, INDECOPI

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Define el mercado

- Anatomical Therapeutic Chemical Classification System
  - divides medicines into groups based on organ on which they act, pharmacological and chemical properties

- ATC level 1: anatomical main group (14 main groups, such as dermatologicals, medicines that work on the cardiovascular system, and anti-infectives for systemic use);
- ATC level 2: therapeutic subgroup (dermatologicals, for example, are divided into 11 therapeutic subgroups, including antifungals for dermatological use, antiseptics and disinfectants, and anti-acne preparations);
- ATC level 3: pharmacological subgroup (antifungals for dermatological use are divided into two pharmacological subgroups: antifungals for topical use and antifungals for systemic use);
- ATC level 4: chemical subgroup (antifungals for topical use are divided into three chemical subgroups: imidazole and triazole derivatives, antibiotics and 'other antifungals for topical use'; and
- ATC level 5: chemical substance (there are 21 imidazole and triazole derivatives that are recognised as antifungals for topical use, including clotrimazole, ketoconazole and fluconazole).

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Market definition in abuse of dominance cases

- Health technology that is patented: presumed it has its own product market
- Health technology no longer patented: presumed that originator drug and all its bioequivalents constitute single product market
  - Thus, use ATC level 5 as starting point for market definition in any abuse of dominance matter

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Define el mercado: Atazanavir en Peru

- No se lo puede sustituir con otro producto
  - ATV preferible para su perfil de seguridad
  - Se reserva el otro compuesto en inhibidores de protease, LPV/r, para los casos en que ATV/r no funciona
- Costo de fabricacion menor
- Vidas en juego

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BMS y Atazanavir: Posicion de dominio?

- BMS tiene una patente para el sal / bisulfato; supuestamente excluye cualquier competencia en el mercado ATV

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Abuso de Posicion Dominante?

Exclusion: Negar de licenciar

- Con resultados:
  - Exclusion de competidores
  - *Combinaciones / nuevos productos preferidas no disponible en Peru*
    - Essential facility?
    - Combinaciones / Presentaciones
    - BMS no ofrezca la misma combinaciones que otros proveedores

- Alto costo al publico: sector sensible
  - *Costo > beneficio*

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Refusal To License

- A refusal to license a patent is not a per se violation of competition law.
- Can violate law when it has a substantial anticompetitive effect, outweighing pro-competitive gain. This can happen when:
  - IP holder refuses to make medicine available at a reasonably affordable price, and refuses to license.
  - Refusal to license extends market power beyond patent law.
  - Refusal is motivated by anticompetitive spirit, rather than legitimate business justification.
  - Denies access to essential facilities

Abuso de Posicion Dominante

Explotacion: Precio Excesivo

Evaluar:

- Capacidad de las personas pagar
  - Se puede comparar con GDP o sueldo promedio de funcionario publico
  - El hecho de que es el sistema publica que paga no impide el analisis comparativa a los ingresos promedios
- Rol del producto en el sector: Sensible a la explotacion
  - Producto esencial
  - Demanda inelastica
- Costos y precios: I y D, fabricacion, precios en otros mercados
  - Contribucion razonable del pais a IyD
- Costos al sistema publica y la salud publica

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Excessive Pricing (UNDP Guidebook)

- Excessive price of needed medicine presumed when price maintained by dominant supplier does make benefit of patented invention available at reasonably affordable prices to the public
- IP holder may rebut this if:
  - owner has open licensed technology to all potential competitors on reasonable and non-discriminatory terms
  - competitive provision of good is not economically feasible (ie: small market size, price reasonable relative to production cost)
- Reward for R&D should be proportionate to country's resources (GDP per capita)

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Abusive or Excessive Pricing

- Many times patented drugs are the only treatment on the market for a given ailment.
- Competition authorities may take action against a patent holder when there is not a reasonable solution between the price charged for a medicine and expenses of the patent holder.
- This is a form of abuse of the patent right, or the dominant position, given that consumers have no viable alternative.

Remedios

Licencia Obligatoria

- Sin obligacion de negociacion previa o remuneracion (pago de ragalias)
- OMC ADPIC Art. 31; CAN 486 Art. 66

Multas.

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Competition Law and Public Health: Abuse of a dominant position

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