Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access

Session 1: Competition Law in the International Context

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The Multilateral Framework

- Efforts to incorporate competition law into international legal framework traced back to unfair competition rules in Paris Convention for the Protection of Industrial Property (1883), followed on by proposal to incorporate within 1948 Havana Charter for an International Trade Organization.

- Modest rules included within WTO TRIPS Agreement entering into force January 1, 1995

- Singapore WTO Round included working group to consider competition rules, but failed to advance

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WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

WORLD TRADE
ORGANIZATION

Changing Times

- Multinational corporate interests viewed risks of prosecution for anticompetitive behavior to exceed risks from absence of rules
- US antitrust authorities considered results of multilateral negotiations likely to reduce policy flexibility, and constrain enforcement
- Developing countries mainly concerned with requirements of national treatment reducing flexibility to favor national champions
- Emergence of major developing country economies and associated legal infrastructure rapidly shifting the calculus

Qualcomm to Pay $975 Million Antitrust Fine to China, Wall St. J., Feb. 2015

Medtronic fine is a warning shot to pharma, medical device firms in China, MLex, Dec. 2016

Monsanto again comes under CCI lens for unfair business ways, Economic Times of India, Mar. 2017

Regulating the Regulators

- Multinationals view risks associated with competition prosecution now exceed benefits of weak rules
- Change in perspective manifests itself in Competition Policy Chapter 16 of Trans-Pacific Partnership Agreement placing procedural obligations on competition authorities, though not subject to dispute settlement chapter
- “Soft” obligations in terms of dispute settlement should not mask the possibility for invocation and possibilities for disruption in implementation of agreement

U.S. Chamber Welcomes Report by Expert Group on Antitrust, Trade Policies

“But there is legitimate concern that some countries may be using their competition laws to distort competition and to favor their own interests at the expense of U.S. companies and global prosperity.”

Press release, Mar. 14, 2017

Competition and the Access Toolbox

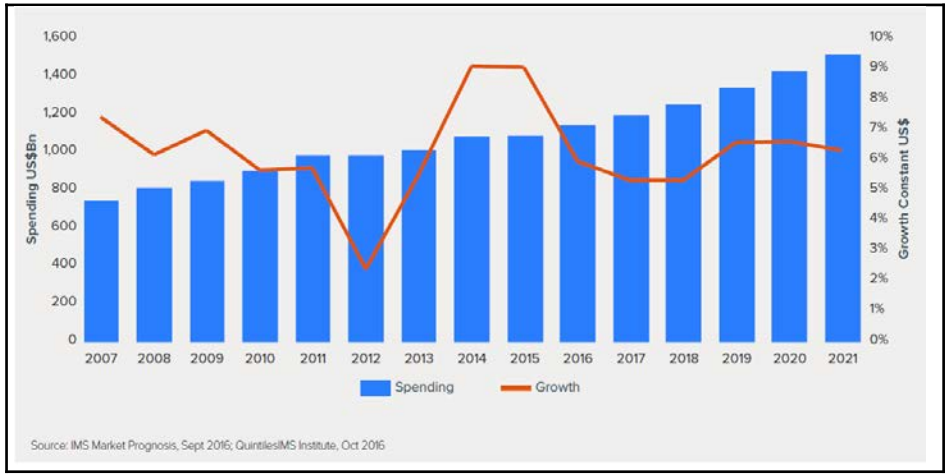
- Competition law generally designed to protect integrity of the market and the interests of consumers
- Competition authorities typically (though not always) less subject to political influence and do not require affirmative legislative acts
- Private causes of action (including by NGOs) add non-political element
    - Less common in lower income markets
- Use of competition law challenging based on need to acquire evidence for prosecution and persuading administrative or judicial authorities
    - Typically resource-intensive and time-consuming

"Competition policies are important levers that governments can employ to ensure that health technology markets operate competitively and that the public benefits from low prices and innovation. Should governments pay closer attention to competition law, it could serve as an important tool for increasing access to health technologies."

Report of the UN Secretary General's High Level Panel on Access to Medicines (2016)

Mechanisms for Providing Access

- Pharmaceuticals fit within broader context of health systems and occupy significant parts of global expenditure, national and private budgets
- Global pharmaceutical industry revenues exceed $1 trillion US annually, generally about 70% “originator” (protected) and 30% generic product by revenue
- National expenditures typically weighted heavily in favor of patent-protected products
- Various mechanisms for moderating prices available to governments: price controls, bulk procurement, use of formularies, generic substitution, government use and compulsory licenses, parallel importation, grant financing



“Global medicine spending will reach nearly $1.5 trillion by 2021 on an invoice price basis, up nearly $370 billion from the 2016 estimated spending level. Growth will be driven primarily by newer medicines in developed markets and increased volume in pharmerging markets.”

Outlook for Global Medicines through 2021, QuintilesIMS, Dec. 2016

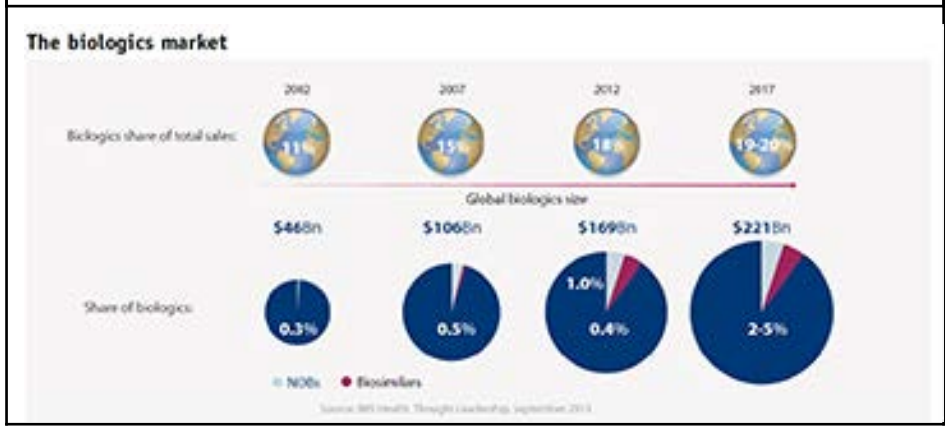
Important industry trends

- Originator shift toward focus on “biologic” drugs has resulted in changes to regulatory frameworks, including with respect to patents and regulatory market exclusivity
- Manifested, *inter alia*, in TPP requirement of 8 (or 5+3) years regulatory market exclusivity for biologics (recently suspended)
- Biologics markets function differently than chemical entity markets and will require specialized attention from competition authorities

“Biologic agents will continue to outpace overall pharma spending growth and are expected to represent 19-20% of the total market value by 2017.”

“In pharmerging markets, both governments and patients struggle to pay for biologics and hence NOBs [non-originator biologics], encouraged by market demand and government policy, have grown very quickly.”

QuintilesIMS, Global Use of Medicines through 2017 (2013)



Anticompetitive behaviors: originator and generics markets

- Generics markets generally see 2 types of behaviors
  - Price-fixing (in various forms) common to other products and markets, e.g., used to improve pricing in oversupplied markets
  - Market dominance achieved or maintained by design, e.g., long-used products subject to exceptional price increases
    - Situations of exceptional price increase have recently captured public attention

"In December, the Department of Justice announced charges against top pharmaceutical executives, Heritage Pharmaceuticals' Jeffrey Glazer and Jason Malek, for scheming to fix prices, rig bids, and allocate customers for certain generic drugs. The charges were filed as a part of a larger antitrust investigation into generic drug price fixing that sparked concerns over conspiracies among several companies …"

Investigations Unfold Major Generic Drug Price-Inflation Conspiracies, Pharmacy Times, March 20, 2017

"U.S. lawmakers on Wednesday blasted Mylan NV Chief Executive Heather Bresch for sharply increasing prices for the EpiPen emergency allergy treatment at a congressional hearing in which Republicans and Democrats questioned the reasons behind rising U.S. drug costs.

The House Committee on Oversight and Government Reform called Bresch to testify in the wake of public outrage over EpiPen, whose list price has risen to $600 for a pair of the devices compared with $100 in 2007."

U.S. lawmakers blast Mylan CEO over 'sickening' EpiPen price hikes, Reuters, Sept. 21, 2016

Anticompetitive behaviors: originator

- Global pharmaceutical system operates on assumption (perhaps flawed) that innovation dependent upon potential for supra-competitive pricing
- Holders of patents and regulatory marketing exclusivity may enjoy lawful position of protection against competition (e.g., patent office grants exclusivity based on meeting criteria of patentability)
- Nevertheless, patents and regulatory exclusivity subject to various types of anticompetitive abuse
- Most common are measures designed to delay entry of generic competition

"FTC Settlement of Cephalon Pay for Delay Case Ensures $1.2 Billion in Ill-Gotten Gains Relinquished; Refunds Will Go To Purchasers Affected By Anticompetitive Tactics"

"The settlement stems from a 2008 FTC lawsuit which charged that Cephalon unlawfully protected its Provigil monopoly through a series of agreements with four generic drug manufacturers in late 2005 and early 2006. The FTC alleged that Cephalon sued the generic drug makers for patent infringement and later paid them over $300 million in total to drop their patent challenges and forgo marketing their generic products for six years, until April 2012." US Federal Trade Commission Press Release, May 28, 2015

"EU regulators charge Teva over pay-for-delay drug deal"

"EU antitrust regulators charged Israeli drugmaker Teva on Monday with doing an illegal deal with Cephalon to delay selling a cheaper generic version of the latter's sleep disorder drug, putting it at risk of a fine.

The crackdown by the European Commission follows fines against scores of companies …

The EU competition enforcer's 2009 inquiry into the sector showed that so-called pay-for-delay deals cost European consumers billions of euros." Reuters, July 17, 2017

International Patent System

- Patent system theoretically "neutral" in terms of technologies, e.g., cell phones and pharmaceuticals
- A calculated negotiating demand of the US-EU-Japan in TRIPS Agreement negotiations
- Traditionally many countries maintained exemptions specific to nutrition and health products
- "Bargain" does not adequately account for social consequences of patenting health products
- Domestic rules may ameliorate social consequences through patent and other rules
- For example, by elevating threshold for obtaining patent protection (e.g. India Section 3(d)), or controlling prices
- Doha Declaration on the TRIPS Agreement and Public Health (2001), and subsequent amendment adding Article 31bis of TRIPS, confirms and expands flexibilities

Patents under WTO TRIPS Agreement: Protection Obligations

Without discrimination as to field of technology (Art. 27.1)

Without discrimination between imported and locally produced products (Art. 27.1)

Minimum 20-year term from date of filing (Art. 33)

Patents under WTO TRIPS Agreement: Flexibilities

Implementation of criteria of patentability (Arts. 1.1 & 27.1)

"Differentiation" versus "discrimination" (Art. 27.1 & *Canada-Generics* decision)

Limited exceptions (triple test) (Art. 30)

Compulsory licensing (Art. 31 & 31bis)

Special treatment for LDCs (Art. 66 and WTO decisions)

Competition law (and health) (Arts. 8 & 40)

Parallel Imports (Art 6)

International Regulatory Protection System

- National drug regulatory authorities (DRAs) grant commercial marketing approvals
- Relied on as basis for regulatory marketing exclusivity
- Duration of exclusivity and scope vary among countries
- Potential impediment to introduction of generics similar to that of patents
- May be more problematic because of difficulties in challenging

TRIPS Agreement regulatory data protection obligation (Article 39.3)

Based on submissions to DRA that does not encompass submissions to foreign DRAs, or foreign approvals

Against "unfair commercial use"

Limited to "new chemical entities" (does not cover "biologics") created with "considerable effort"

Limited to "undisclosed test or other data"

No duration specified

Obligation to protect against disclosure, except where necessary to protect public

Limitations = Impetus for bilateral/regional rules

Bilateral and Regional TRIPS-Plus Rules

<u>TRIPS-Plus measures negotiated to improve pharmaceutical patent owner position</u>

- Reduce flexibilities in application of patentability standards
- Extend patent terms based on regulatory delays
- Limit scope of exceptions
- Include patents within scope of investor to state dispute settlement

<u>TRIPS-Plus measures negotiated to improve pharmaceutical regulatory exclusivity obligations</u>

- Establish minimum term for NCEs: 5 years (plus extensions)
- Expressly incorporate biologics, with extended minimum term, 8 (or 5+3) years
- Prohibit reliance by third parties on foreign approvals
- Patent-regulatory approval "linkage" mandatory

New Generation Support for Pharmaceutical Industry: Authority to intervene in formulary and pricing determinations by government authorities (US-Australia, US-South Korea, TPP) - recently suspended in TPP

Pro- and Anticompetitive Effects of Exclusivity

Pro-competitively: provides incentive for innovation and/or clinical development that introduces new products displacing older products and beneficially disrupting market

Corollary effect is higher prices, strains on public and private budgets

Anti-competitively: prevents third parties from introducing comparable substitute products at lower prices, improving consumer access

Potential impact of lack of access to pharmaceuticals creates unique dynamic

Competition law seeks to assure anticompetitive and adverse social welfare effects do not predominate

In principle, the government should establish pro-consumer pharmaceutical policies, including adequate access measures. In practice, it may be left to the competition authorities to improve the balance.