

Competition Doctrines for the Medicines Sector: Innovation and Affordability

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UNDP ENCOURAGES USE OF COMPETITION LAW TO PROMOTE ACCESS

- All countries throughout the world face public health budgetary pressures based on costs of procuring medicine supply
 - Formerly discussed mainly as a developing country issue, concerns now prevalent in high income countries
 - Confirmed in presentations to the UN Secretary General's High Level Panel on Access to Medicines
- Competition law has advantages over solutions requiring legislative action because, in general, competition authorities act independently and with fairly broad mandates

COMPETITION AUTHORITIES AND SECTOR INQUIRIES

- Various approaches to health and pharmaceutical sector inquiries
- EU Competition Directorate undertook deep analysis of role of patents and other market exclusivity mechanisms – report in 2009 <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>
 - Instituted continuous monitoring of validity challenge settlements
 - Dutch government investigating price impact of patent extensions and regulatory exclusivity rules
- South Africa Competition Commission undertaking private healthcare sector inquiry
 - <http://www.compcom.co.za/healthcare-inquiry/>
- China's competition authorities (MOFCOM, National Development and Reform Commission (NDRC) and the State Administration for Industry and Commerce (SAIC), undertaking pharmaceutical industry review accompanied by enforcement actions
- Competition Commission of India (CCI) undertaking baseline study/survey in the pharmaceutical sector and healthcare delivery systems/services

COMPETITION LAW A FLEXIBLE SET OF DOCTRINES AND INSTRUMENTS

- Competition law maintains doctrines capable of addressing both common and unusual circumstances
- Horizontal and vertical restraints
- Abuse of dominant position
- Agreements between undertakings
- Hardcore (per se) and rule of reason analysis

FIELD OF MEDICINES HAS DISTINCT CHARACTERISTICS

- Originator pharmaceuticals protected by patents and other forms of market exclusivity (e.g., regulatory exclusivity)
- Enjoy legislatively created exclusive rights with inherent exclusionary characteristics
- Competition authorities face challenge of balancing legal entitlement to exclude with abusive anticompetitive behavior
- Important US Supreme Court Decision, *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223 (2013), making clear that patents do not insulate owners from antitrust laws

TYPES OF ANTICOMPETITIVE BEHAVIORS IN PHARMACEUTICAL SECTOR

- Bid-rigging in procurement processes
 - Form of price-fixing, may include corrupt payments
- Efforts by originators to delay introduction of generic competition
 - Filing and enforcing spurious secondary patents
 - Withdrawing product registrations (product switching)
 - Buying out patent challenges

EXCESSIVE PRICING AS ABUSE OF DOMINANT POSITION

- Most competition laws expressly or by application of general principles authorize actions against excessive pricing
- Enforcement actions traditionally modest, but increasing
- See recent action by UK Competition Authority action against Pfizer (December 2016), record fine of 84 million British pounds
- Evidentiary issues (e.g., establishing reasonable benchmark prices) can be successfully addressed

MERGERS AND ACQUISITIONS MAY RAISE SERIOUS ISSUES

- M&A may eliminate competition among therapeutic classes (ATP) of medicines
- M&A may eliminate potentially competitive research programs
- Pre-merger requirements of divestiture an option

COMPETITION LAW REMEDIES TO MEET CIRCUMSTANCES

- Competition law characterized by wide range of potential remedies
 - Settlements and consent decrees
 - Fines and criminal penalties
 - Price controls
 - Compulsory licensing of patents
 - Reimbursement to procurement authorities and consumers

BE WARY OF PROPOSALS FOR HARMONIZED GLOBAL RULES

- International law presently provide substantial flexibility for application of competition law
- As more countries have moved to implement competition law, multinational business is becoming more receptive to rules that would restrict flexibilities
- Approach proposals for harmonized global rules with caution as the impetus may come from interest in blocking application of competition law, particularly in pharmaceuticals sector