IP AND COMPETITION LAW & POLICY, INCLUDING SOUTH AFRICAN LAW AND POLICY OPTIONS

Prof. Frederick M. Abbott

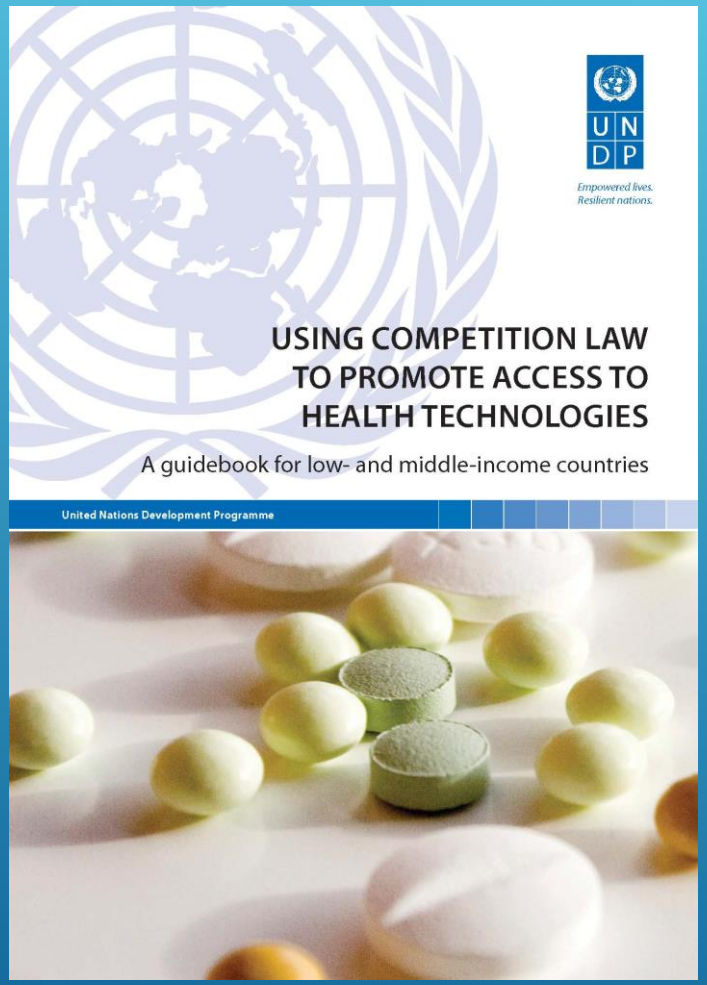
FSU College of Law/UNDP Consultant

CONSULTATIVE FRAMEWORK FOR INTELLECTUAL PROPERTY IN SOUTH AFRICA
28-30 September 2016 Pretoria / South Africa

Multilateral Competition Regulation and Patents

- That competition law is weakly regulated at the multilateral level is a well-documented story tracing back to the Havana Charter for an International Trade Organization
  - Followed by UNCTAD negotiations, competition on WTO Singapore agenda, competition working group at WTO, work program suspended (see F. Abbott, Public Policy and Global Technological Integration 1996 – SSRN: 1989042)
- WTO TRIPS Agreement references competition law in a non-restrictive manner leaving substantial flexibility
  - Incorporation of national treatment significant
  - See F. Abbott, *Are the Competition Rules in the WTO TRIPS Agreement Adequate?* 2004 – SSRN: 917108

UNDP Competition Work Program



Technical Assistance

Training

TYPOLOGY OF ANTI-COMPETITIVE PRACTICES

- Horizontal: between independent enterprises that are competitors in the production and/or distribution of the relevant goods or services
- Vertical: the supply and distribution chain from a single producer, such as the chain moving from manufacturing to supply of wholesalers and distributors to retail sellers
- Anti-competitive objectives of behaviors may be similar, but specific competition rules may vary

AGREEMENTS BETWEEN UNDERTAKINGS/ABUSE OF MONOPOLY-DOMINANT POSITION

- Anticompetitive conduct may involve an agreement among two or more parties to restrain trade, whether in horizontal or vertical relationship
- "Monopoly" and "dominant position" generally refer to a single firm capable of dictating pricing and terms of supply in relevant market
  - Ownership of a monopoly is not in itself wrongful
  - Competition law violations require abuse in obtaining or maintaining monopoly/dominant position

PER SE AND RULE OF REASON

- Per se or "hard-core" anticompetitive conduct: understood to be unjustifiably anticompetitive, i.e. not subject to balancing assessment
  - Includes price-fixing among horizontal competitors and horizontal output restraints
- "Rule of reason" assessment: potentially pro-competitive or neutral effects of agreements balanced with potentially market-restrictive effects to decide whether agreements are, on the whole, anti-competitive

BID-RIGGING, CORRUPT PAYMENTS AND RELATED PRACTICES IN PROCUREMENT

- IP is one aspect of competition law assessment of pharmaceutical and health sectors
- In some countries governments may be largest procurers of health products and services
- Competitive bidding used frequently, typically through secret bids
  - Lowest priced qualified bid meeting specifications accepted
- Creates temptation for prospective bidders to "rig" bidding by fixing lowest-priced bid, and allocating current (e.g., dividing supply under awarded contract) and/or future tenders among suppliers

BID-RIGGING, CORRUPT PAYMENTS AND RELATED PRACTICES IN PROCUREMENT

- Collusive bidding arrangements not infrequently accompanied by corrupt payments to government officials
  - To assure that evidence of bid-rigging is not explored or reported
- From competition law standpoint, bid rigging represents price-fixing among typically horizontal competitors (though may be "intra-brand" (i.e. same product) collusion among independent distributors)
- Examples of bid-rigging extend to provision of health-care services

DOMINANT POSITION AND PATENTS

- Patent confers on its owner right to exclude third parties from introducing an identical or equivalent (i.e. infringing) product onto the market
- Despite legislative monopoly, patents may be abused
- Filing and prosecuting patent applications may be undertaken in anticompetitive manner, *e.g.*, filing of application in bad faith near end of patent term to block generic competition
  - Also, litigation based on suspect patents may be commenced to delay generic entry
  - European Commission Competition Directorate Pharmaceutical Sector Inquiry Report (2009) detailed patent abuse

DOMINANT POSITION AND PATENTS

- The European Commission welcomes today's judgment by the Court of Justice of the European Union (Case C-457/10 P) dismissing an appeal brought by AstraZeneca against the judgment by the General Court of 2010…. The Commission had fined AstraZeneca €60 million for abusing its dominant position relating to its best-selling anti-ulcer medicine Losec. The Court of Justice ruled for the first time on a Commission decision on the abuse of a dominant market position in the pharmaceutical sector. Today's judgment is significant as it clarifies a number of issues of principle in relation to market definition, dominance and the concept of an abuse in the meaning of Article 102 TFEU. In particular, it confirms that misuses of regulatory procedures can in certain circumstances constitute abuses of a dominant position within the meaning of EU antitrust rules (Article 102 of the Treaty on the Functioning ofthe European Union).

BUYOUTS OF PATENT CHALLENGES

- Generic producers challenge the validity of patents for early market entry; patent owners decide their better financial interest served by "buy-out" of generic challengers rather than to risk adverse court decision invalidating patents
- Various forms of compensation
  - Straightforward cash payment
  - License to generic producer to market patented or other products
  - Allocation of geographic markets
- Objective to extend patent owner control to end of patent term

BUYOUTS OF PATENT CHALLENGES

- From standpoint of patent owner and generic producer, transaction is "win-win"
- Patent owner retains high revenue stream; generic producer may earn substantial income without litigation risk
- Prospective *loser is consumer/patient*, assuming generic challenge successful
- In 2013 US Supreme Court decided that buyout settlements of generic producer patent challenges are subject to "rule of reason" assessment under the antitrust laws

FEDERAL TRADE COMMISSION (FTC) V. ACTAVIS, U.S. SUP. CT., 526 U. S. 756 (2013)

"Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's anti-competitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well. And indeed, contrary to the Circuit's view that the only pertinent question is whether 'the settlement agreement ... fall[s] within' the legitimate 'scope' of the patent's 'exclusionary potential', ... this Court has indicated that **patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent.**" (bold added)

Sherman Antitrust Act Origins and the Chicago School

- US Supreme Court in seminal Standard Oil Company of New Jersey v. United States, 221 U.S. 1 (1911) decision identified protection of the individual as the core objective of antitrust law:

  "the main cause which led to the legislation was the thought that it was required by the economic condition of the times … combinations known as trusts were being multiplied, and the widespread impression that their power had been and would be exerted to oppress individuals and injure the public generally."

- Under the influence of the Chicago School antitrust/competition law in the United States shifted its focus to maintaining competition among producers, and away from consumer protection
  - See, e.g., 1995 Department of Justice and Federal Trade Commission Intellectual Property Licensing Guidelines

Doctrinal Gaps Flow from Producer Focus

- Use of competition law to protect interests such as public health requires that attention be redirected toward consumer protection
- The impact of monopoly or abuse of dominant position falls more directly on the individual consumer/patient than on potential producer competitors
- Doctrines relating to "excessive pricing" and "access to essential facilities" are not well developed in US or EU competition law
  - EU law somewhat better developed, in particular regarding essential facilities
  - Canada uses excessive pricing as basis for controlling prices of patented medicines

SOUTH AFRICA & EXCESSIVE PRICING

- South Africa's Competition Act expressly identifies the charging of an excessive price as a competition law violation, providing:
- 1. Definitions and interpretation
- (1) In this Act -
- (i) …
- (ix) 'excessive price' means a price for a good or service
- which –
- (aa) bears no reasonable relation to the economic value of that good or service; and
- (bb) is higher than the value referred to in subparagraph (a);

- 8. Abuse of dominance prohibited
- It is prohibited for a dominant firm to –
- (a) charge an excessive price to the detriment of consumers;…
- The South African report for the Roundtable indicates that the excessive pricing provision of the Competition Act is based on the two-part test developed by the ECJ in the United Brands case

THE PHARMACEUTICAL SECTOR IN SPECIFIC

- Markets can be delineated based on various criteria, including range of available product (and service) substitutes, geography, number of producers/suppliers, natural barriers to entry, price elasticity, and others
- Pharmaceutical products are intended to prevent and treat disease, and the presence or absence of substitutes to accomplish that purpose are critical to assessment of the relevant market
- Pharmaceutical products are classified under the Anatomical Therapeutic Chemical (ATC) Classification System at 5 levels

DEFINING THE RELEVANT MARKET

- ATCs in descending order of specificity:
- Level 1 indicates the anatomical main group. There are 14 main groups
- Level 2 indicates the therapeutic main group
- Level 3 indicates the therapeutic/pharmacological subgroup
- Level 4 indicates the chemical/therapeutic/pharmacological subgroup
- Level 5 indicates the chemical substance
- Patient ability to switch among different drugs is dependent on a variety of factors; most importantly whether a substitute will be effective

COURT APPROACHES

- South Africa: Hazel Tau, market definition and access to treatment for HIV
  - In 2002, Complainants alleged GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) were acting in violation of section 8(a) of the Competition Act 89 of 1998 by charging excessive prices for certain of their ARV medicines to the detriment of consumers, being directly responsible for premature and avoidable deaths
  - Complainants alleged that each of the relevant patented ARVs constituted its own market, and that the accused producers were dominant in those markets
- Competition Commission found that producers had abused dominant position, but did not identify relevant markets. Producers granted voluntary licenses before Competition Tribunal took up the matter for determination based on Commission recommendation
  - Case had substantial positive impact in opening up South Africa market to generic ARVs

Determining What Is "Excessive"

Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health

Frederick M. Abbott

Florida State University - College of Law

January 19, 2016

UC Irvine Law Review, Volume 6, Issue 3, forthcoming Spring 2017

Available at SSRN: http://ssrn.com/abstract=2719095

Frederick M. Abbott
Edward Ball Eminent Scholar
Professor of International Law
Florida State University College of Law
425 W. Jefferson St.
Damon House
Tallahassee, FL 32301 USA
http://frederickabbott.com
http://www.law.fsu.edu/our-faculty/profiles/abbott
direct tel. + 1-850-644-1572
fax + 1-917-591-3112

March 3, 2016

Dear Senators Wyden and Grassley,

Thank you for this opportunity to provide feedback regarding the report on "The Price of Sovaldi and its impact on the U.S. Health Care System" of December 1, 2015 (Senate Print 114-20), as referenced in your letter of January 21, 2016.

I have previously sent to members of your staff an email expressing my appreciation for their preparation of the Report on Sovaldi. The Report is a most valuable resource for researchers in the field of pharmaceutical regulation and it reflects a high level of objectivity and professionalism.

Your letter raises several specific questions regarding information that would be useful in further addressing policy issues raised by the Report. Like others with interests in this general subject matter area, I have written and published a number of books and papers regarding ways that mechanisms for promoting innovation in the pharmaceutical sector and making improved treatments available to the public at affordable prices might be improved. In this brief response, I confine myself to the attached paper (forthcoming article) that benefited particularly from the information and analysis assembled in the Report.

The attached paper, "Excessive Pharmaceutical Prices and Competition Law: doctrinal development to protect public health" (forthcoming UC Irvine Law Review, Volume 6, Issue 3, Spring 2017), recommends that US antitrust law, and in particular the Sherman Act, should be used to address excessive prices charged by pharmaceutical producers and suppliers. The article notes that US courts have been reluctant to address excessive pricing "as such". Federal courts have generally expressed the view that producers with lawfully secured monopolies should be allowed set prices however they wish as a reward for their skill, acumen or good fortune. The courts have been reluctant to evaluate whether prices are reasonable (or not) on grounds that judges are not specialized regulatory authorities. Federal courts and antitrust authorities consider that excessive prices may evidence underlying anticompetitive conduct that may be addressed by correcting underlying market defects or abuses. Excessive prices are not unlawful in themselves.

DOMINANT POSITION AND PATENTS

- Patient/consumer demand distorted by potentially absolute need for treatment; demand "inelastic“ (higher price does not diminish demand)
- Excessive pricing: is there an unreasonable relationship between the price being charged for a medicine and the expenses of the patent owner?
  - Often a lack of reliable information from patent holder/producer regarding the costs of development and production
  - Competition authorities may use subpoena power to compel provision of such information

Determining What Is "Excessive"

- Starting is baseline of "reasonable price“
- Manufacturing costs generally known
- Cost of R&D the element with greater indeterminacy
- Most of paper devoted to methodology for construction of "reasonable price" through determination of cost basis including R&D costs
- Not an insoluble problem

METHODOLOGIES

- Cost-plus profit, adjusted for risk
  - Preferred approach
- Reference pricing
- Bargaining between monopoly supplier and monopsony purchaser
- Cost based on corporate assessments of acquisition targets
- Cost based on reporting of R&D and related expenditures to tax authorities
- Cost based on securities and exchange commission reporting

ADJUSTING FOR RISK

- Drug development risk varies in relation to number of unknowns
- Government (e.g., NIH) funds basic research seeking to reduce unknowns and concomitant risk factors
- Level of risk varies depends on structure of investigating institutions (e.g., single or multi-focus)
  - Multi-focus institutions typically subdivide budget among research units
- Certain costs should be excluded
  - Basic research funded by government, executive salaries above established limits, opportunity cost of money, tax incentives

Supra-baseline “Excess”

- After determining cost: must establish what constitutes a price "excessive" in relation to it
- Difficulty with comparing other Pharma originators is that historical pricing practices may reflect excess
- In recent cases where the medical community and public have been "shocked" by pricing practices, may not be difficult to determine that prices are excessive, but establishing reasonable price plus profit may be necessary for remedial purposes

DOMINANT POSITION AND PATENTS

- A determination that prices are unaffordable to patient/consumers could establish a presumption that pricing is excessive, shifting burden to patent owner to justify pricing
- In refusing to overturn Patent Office grant of compulsory license on Bayer anticancer drug, Indian Supreme Court (2014) referred to patent owner's failure to furnish data supporting its claims regarding development costs
- Canada's Patented Medicine Prices Review Board (PMPRB) reviews prices that patentees charge for each individual patented drug product in Canadian markets. If a price found to be excessive, Board can hold public hearings and order price reductions and/or an offset of excess revenues

MERGERS AND ACQUISITIONS

- Market definition important
  - Combination of hospitals or doctors' practices may create anticompetitive situation in comparatively small geographic area as consumers/patients range of travel limited
  - In the pharmaceutical sector, combining companies may have overlapping portfolio of therapies (patented or non-patented), and elimination of competing therapies may raise prices of reduced portfolio to purchasers
- Pharmaceutical originator merger may result in reduction of R&D targets and expenditures

MERGERS AND ACQUISITIONS

- Market concentration may limit opportunities for smaller scale researchers to out-license or sell medical innovation
- Competition authorities typically have power to review mergers and acquisitions, and to establish conditions for approval (e.g., divestiture of part of drug portfolio to third-party)
- In absence of voluntary divestiture or agreement to conditions, competition authorities may need to sue to block combination
  - Global scale of some businesses makes control by national competition authorities problematic

VERTICAL RESTRAINTS IN TECHNOLOGY MARKET

- Health technologies affected by various intellectual property (IP) rights: patent, trademark, trade secret, copyright and regulatory data protection
  - Each potentially may be used anti-competitively
  - IP may be used by owner or licensed to third-party
- EU and USA guidelines establish combined market share thresholds pursuant to which technology licensing presumed not anticompetitive

VERTICAL RESTRAINTS

- Limiting geographic territory in which purchasers may distribute/resell (i.e. territorial allocation)
  - Whether parallel trade into market may be restricted depends on relevant intellectual property law rule of exhaustion
  - Where parallel trade otherwise allowed by IP law, territorial restraints may be anticompetitive
    - An attempt to limit price competition from imported products
    - IP owner may attempt to circumvent IP rule by limiting quantity of goods placed on market
- Foregoing practices typically assessed under rule of reason (i.e. do procompetitive benefits outweigh anticompetitive harms?)

VERTICAL RESTRAINTS IN TECHNOLOGY MARKET

- Patent owner may require that licensee "grant back" innovations made with respect to patented technology. When licensee may not use technology, referred to as "exclusive grant back".
  - In EU, hard-core prohibition of exclusive grant backs. In USA assessed under rule of reason.
- Licensee may be precluded from challenging the validity of patent (i.e. no challenge clause)
  - Prohibited by EU, rule of reason assessment in USA

REMEDIES

- Remedial actions may be initiated by public authorities or private parties
  - In many jurisdictions, public authorities play principal enforcement role
  - Competition actions may be time-consuming and costly, involving significant evidence gathering
- USA may be unique in allowing private antitrust actions with triple damages
  - An encouragement to initiate and pursue claims
- Courts and competition authorities may use compulsory licenses as remedy

TRENDS AND IDEAS FOR REMEDIAL ACTIONS FOR PHARMACEUTICAL SECTOR

- Australia adopted legislation (Amendments to Therapeutic Goods Act, 2005) requiring pharmaceutical patent owners initiating legal actions under its patent/regulatory approval 'linkage' mechanism to certify they are proceeding in good faith against the generic company applying for market entry
- If court or administrative authority later determines patent claim not brought in good faith, patent owner subject to substantial fine and recovery by government of cost to public health system of delayed market entry
- Remedial orders more generally might include provisions designed to accelerate generic market entry, such as requiring originator to authorize generic producer to rely on drug approval master file

PUSHBACK TO BE ANTICIPATED

- Historic multinational business community resistance to multilateral competition rules may be diminishing as threats grow
- US Chamber of Commerce response to activities of Chinese competition authorities founders on absence of rules
- Benefits of rules may begin to exceed risks of being enforcement targets

PRESERVING DOCTRINAL FLEXIBILITY

- Developing countries should be wary of surrendering flexibilities
- Developing country competition authorities should promote development of doctrine suitable to country conditions
- Cooperation among developing country competition authorities should promote investigative capacity, doctrinal development and enforcement capacity