IP AND COMPETITION LAW & POLICY

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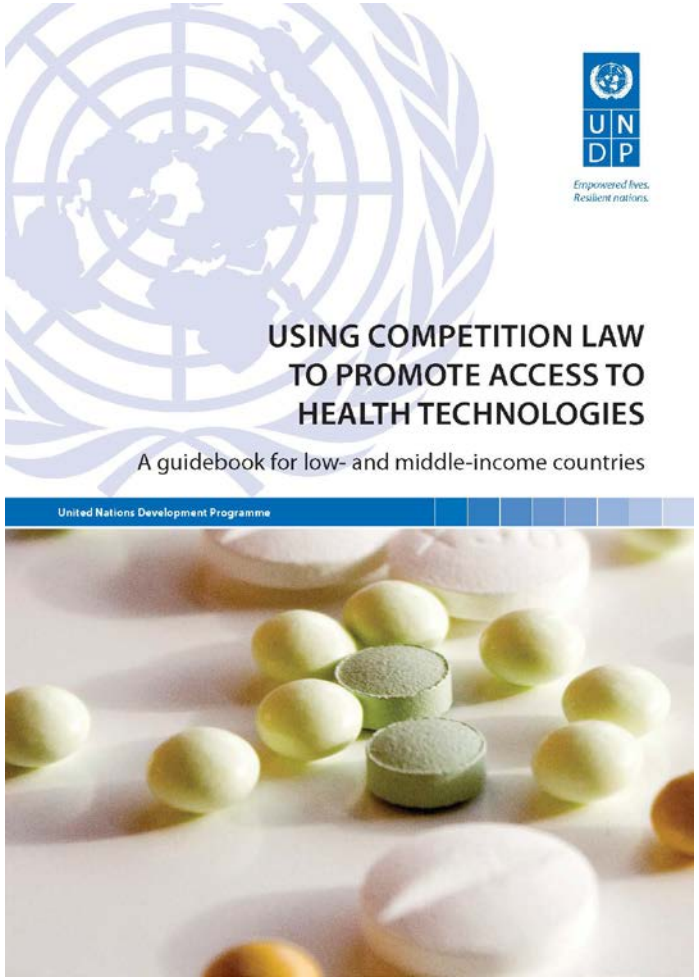
DRAFT INTELLECTUAL PROPERTY POLICY – PHASE I 2017
SOUTH AFRICA
Workshop
25 – 27 October 2017, Pretoria / South Africa

Empowered lives.
Resilient nations.

Draft Policy Recommendation

"Competition law and policy have, in the recent past, been applied to cases involving IP and the public interest. Building on this recent history, a joint effort is recommended, along with the Competition Commission, to clarify the remit and scope of the intersection between competition law and IP."

UNDP Competition Work Program



Global work program with national/regional competition authorities

Technical Assistance

Training

Research

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

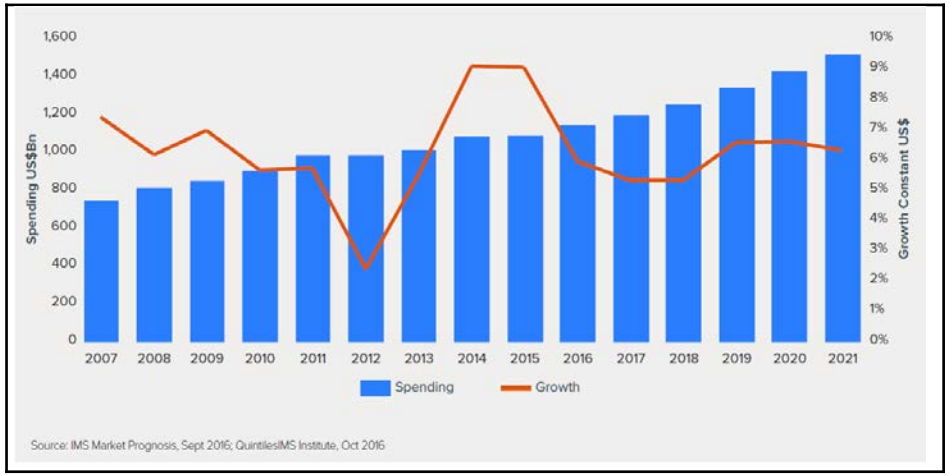
- Competition law generally designed to protect integrity of the market and the interests of consumers
- Competition authorities typically (though not always) less subject to political influence and do not require affirmative legislative acts
- Private causes of action (including by NGOs) add non-political 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

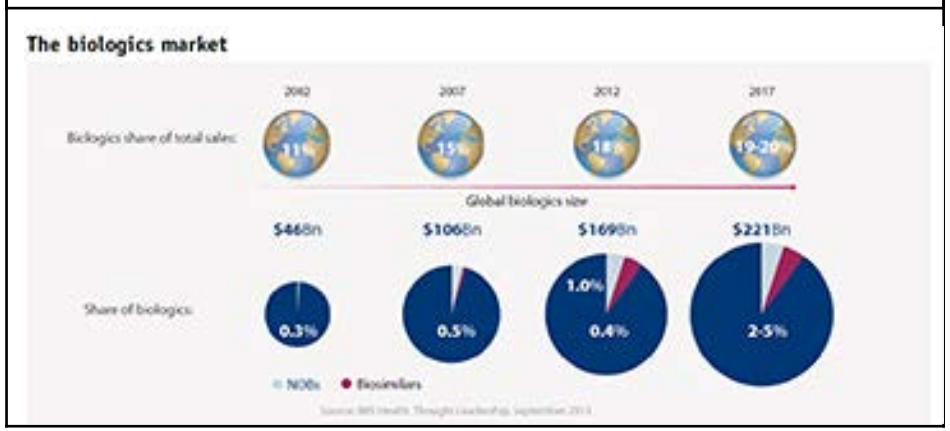
Important industry trends

- 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
- 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

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)

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 evolving
  - 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 OECD 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

Excessive Pricing

- Paradigm case Sovaldi/sofosbuvir introduced by Gilead at $84,000 for 12-week course of treatment
  - Acquired through purchase of Pharmasett for US$11 billion in 2011
    - Planning to introduce at US$35,000 for course of treatment
  - Gilead revenues approximately US$14 billion in each of first two sales years
    - Pure financial engineering
- Three pricing options proposed by investment bankers: red light, yellow light, green light
- Gilead selected yellow light that represented price that would not quite bankrupt state public health purchasing authorities, while generating mid-range pricing backlash

Excessive Pricing: Cost-Plus

- Excessive pricing evidentiary issues (e.g., establishing reasonable benchmark prices, transparency
- Establishing risk-adjusted R&D costs and mark-up
  - Pharmaceutical industry R&D budgets are carefully managed, not a "black box"
  - Contrary to originator position, the cost of R&D reflecting successful and unsuccessful efforts reasonably proximate to approved product can be determined
  - Factual/evidentiary issues not uncommon in litigation, including expert assessment of whether particular R&D efforts within scope of approved product

Transparency

- Transparency issue: pharmaceutical originators have not been required to disclose R&D costs, especially at "granular level"
  - Originators provide information to investment bankers in context of prospective mergers and acquisitions
- Exclusions from costs: government-funded R&D and excessive officer compensation packages
- Governments clearly have authority in context of competition investigations to require furnishing of cost information

Excessive Pricing

- Pharmaceutical prices substantially higher in a particular market may suggest underlying anticompetitive conduct
- "Retail" price comparisons across markets may be useful in assessing individual markets
- See, e.g., case law of Court of Justice of European Union using price differentials across markets as assessment tool for excessive pricing
  - Very recent: *Latvian Author's Association (AKKA/LAA) v. Competition Council, Latvia*, CJEU, Case C—177/16, 14 Sept. 2017
  - "There is in fact no minimum threshold above which a rate must be regarded as 'appreciably higher ', given that the circumstances specific to each case are decisive in that regard" (para. 55)

JUDGMENT OF THE COURT (Second Chamber)

14 September 2017 (*)

(Reference for a preliminary ruling — Competition — Article 102 TFEU — Abuse of a dominant position — Concept of 'unfair price' — Fees collected by a copyright management organisation — Comparison with rates charged in other Member States — Choice of reference Member States — Assessment criteria for prices — Calculation of the fine)

In Case C-177/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the Augstākā tiesa, Administratīvo lietu departaments (Supreme Court, Administrative Cases Division, Latvia), made by decision of 22 March 2016, received at the Court on 29 March 2016, in the proceedings

Autortiesību un komunicēšanās konsultācijas aģentūra / Latvijas Autoru apvienība

v

Konkurences padome,

THE COURT (Second Chamber),

composed of M. Ilešič, President of the Chamber, A. Prechal (Rapporteur), A. Rosas, C. Toader and E. Jarašiūnas, Judges,

"It should first be recalled that, when an undertaking holding a dominant position imposes scales of fees for its services which are appreciably higher than those charged in other Member States, that difference must be regarded as indicative of an abuse of dominant position..." (CJEU, Case C-177/16)

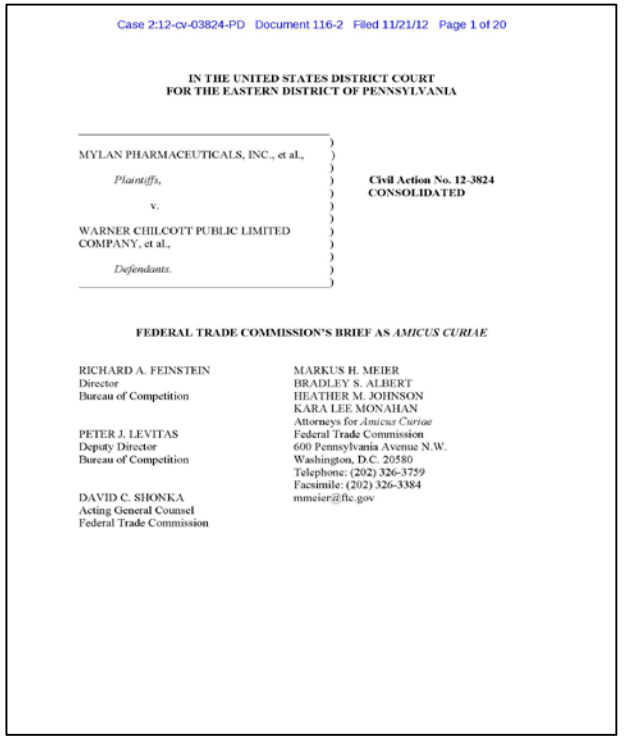
FTC v. Cephalon (Teva)

Federal Trade Commission v. Cephalon, Inc., 551 F. Supp. 2d 21 (D.D.C. 2008) (complaint filed February 13, 2008); (transferred to E.D. Pa. April 28, 2008) (stipulated order for permanent injunction and equitable relief filed June 17, 2015) (https://www.ftc.gov/enforcement/cases-proceedings/061-0182/cephalon-inc). The complaint alleged that Cephalon engaged in an anticompetitive course of conduct to prevent the entry of lower-cost generic competition to Provigil, its branded prescription drug used to treat certain sleep disorders, forcing patients and other purchasers to pay hundreds of millions of dollars a year more for Provigil. According to the complaint, Cephalon unlawfully protected its Provigil monopoly through a series of unlawful settlements with four generic drug makers, all of whom were first to challenge the Provigil patent (considered first filers by the FDA for generic Provigil). According to the complaint, the agreements not only prevented competition from the four first filers, but also blocked competition from other generic manufacturers because of the 180-day exclusivity held by the first filers under the Hatch-Waxman Act.

Under the terms of the stipulated order for permanent injunction and equitable monetary relief, Teva Pharmaceutical Industries, Ltd., which acquired Cephalon in 2012, was required to pay $1.2 billion to compensate purchasers who overpaid because of Cephalon's illegal conduct. The stipulated order also prohibits Teva from entering into the type of reverse payments that Cephalon used to protect Provigil. Specifically, it prohibits agreements in which the branded drug manufacturer makes a monetary payment or otherwise compensates the settling generic and (1) makes that transfer of value expressly contingent on settlement of existing patent litigation, or (2) the transfer occurs 30 days before or after the patent settlement.

FTC Product Switching or Hopping

- FTC Files Amicus Brief Explaining That Pharmaceutical "Product Hopping" Can Be the Basis for an Antitrust Lawsuit
- November 27, 2012
- https://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf



Case 2:12-cv-03824-PD Document 116-2 Filed 11/21/12 Page 1 of 20

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC., et al.,
Plaintiffs,
v.
WARNER CHILCOTT PUBLIC LIMITED COMPANY, et al.,
Defendants.

Civil Action No. 12-3824
CONSOLIDATED

FEDERAL TRADE COMMISSION'S BRIEF AS *AMICUS CURIAE*

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Bureau of Competition

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FTC Product Switching or Hopping

"The potential for anticompetitive product redesign is particularly acute in the pharmaceutical industry."

Product hopping can work in the following way: first, the brand manufacturer makes minor non-therapeutic changes to the brand product, such as a dosage or form change. Next, prior to generic entry, it removes the original product from the marketplace, or accomplishes this indirectly, such as by recalling supply of the original product or raising the price of the original product by a meaningful amount above the reformulated one. Such conduct can push patients and physicians to abandon the original product. In this way, a brand manufacturer can convert existing market demand for the original product to its reformulated product … simply because the original product is no longer as available or is more costly.

Once the original version of the brand product is less available or more expensive, physicians will stop writing prescriptions for it. Because the prescription must contain, among other things, the same dosage and form as the generic for a pharmacist to substitute it for the brand, a product switch will effectively eliminate substitution at the pharmacy counter and thus meaningful generic competition. As the author of the leading antitrust treatise put it: "Product-hopping seems clearly to be an effort to game the rather intricate FDA rules. . . . The patentee is making a product change with no technological benefit solely in order to delay competition."

FTC v. Abbvie

Sham patent litigation to delay generic entry

FTC succeeds in establishing that originator filing of patent infringement claim to block market entry by generic producers was "objectively baseless" grounded in knowledge that "prosecution history estoppel" precluded asserted scope of claims

"The FTC is entitled to partial summary judgment on the objective baselessness element of the sham litigation prong of their illegal monopolization claim."

Judge Bartle, 2017 WL 4098688, E.D. Penn., Sept. 15, 2017

CMA v. Pfizer

- UK Competition and Markets Authority, CMA fines Pfizer and Flynn £90 million for drug price hike to NHS, Press Release, Dec. 7, 2016
- https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs

5/18/2017 CMA fines Pfizer and Flynn £90 million for drug price hike to NHS - GOV.UK

GOV.UK

1. Home (https://www.gov.uk/)
2. Competition (https://www.gov.uk/topic/competition)
3. Competition Act and cartels (https://www.gov.uk/topic/competition/competition-act-cartels)

Press release

CMA fines Pfizer and Flynn £90 million for drug price hike to NHS

From: Competition and Markets Authority (https://www.gov.uk/government/organisations/competition-and-markets-authority)
Part of: Competition Act and cartels (https://www.gov.uk/topic/competition/competition-act-cartels)
Published: 7 December 2016

The CMA has fined pharma companies Pfizer and Flynn Pharma nearly £90 million for charging excessive prices to the NHS for an anti-epilepsy drug.

The Competition and Markets Authority (CMA) has imposed a record £84.2 million fine on the pharmaceutical manufacturer Pfizer, and a £5.2 million fine on the distributor Flynn Pharma after finding that each broke competition law by charging excessive and unfair prices in the UK for phenytoin sodium capsules, an anti-epilepsy drug. The CMA has also ordered the companies to reduce their prices.

The fines follow prices increasing by up to 2,600% overnight after the drug was deliberately de-branded in September 2012. For example, the amount the NHS was charged for 100mg packs of the drug rocketed from £2.83 to £67.50, before reducing to £54.00 from May 2014. As a result of the price increases, NHS expenditure on phenytoin sodium capsules increased from about £2 million a year in 2012 to about £50 million in 2013. The prices of the drug in the UK have also been many times higher than Pfizer's prices for the same drug in any other European country.

Phenytoin sodium capsules are used in the treatment of epilepsy to prevent and control seizures, and are an important drug for an estimated 48,000 patients in the UK. Epilepsy patients who are already taking phenytoin sodium capsules should not usually be switched to other products, including another manufacturer's version of the product, due to the risk of loss of seizure control which can have serious health consequences. As a result, the NHS had no alternative to paying the increased prices for the drug.

https://www.gov.uk/government/news/cma-fines-pfizer-and-flynn-90-million-for-drug-price-hike-to-nhs 1/3

CMA v. Pfizer

The Competition and Markets Authority (CMA) has imposed a record £84.2 million fine on the pharmaceutical manufacturer Pfizer, and a £5.2 million fine on the distributor Flynn Pharma after finding that each broke competition law by charging excessive and unfair prices in the UK for phenytoin sodium capsules, an anti-epilepsy drug. The CMA has also ordered the companies to reduce their prices.

The fines follow prices increasing by up to 2,600% overnight after the drug was deliberately de-branded in September 2012.

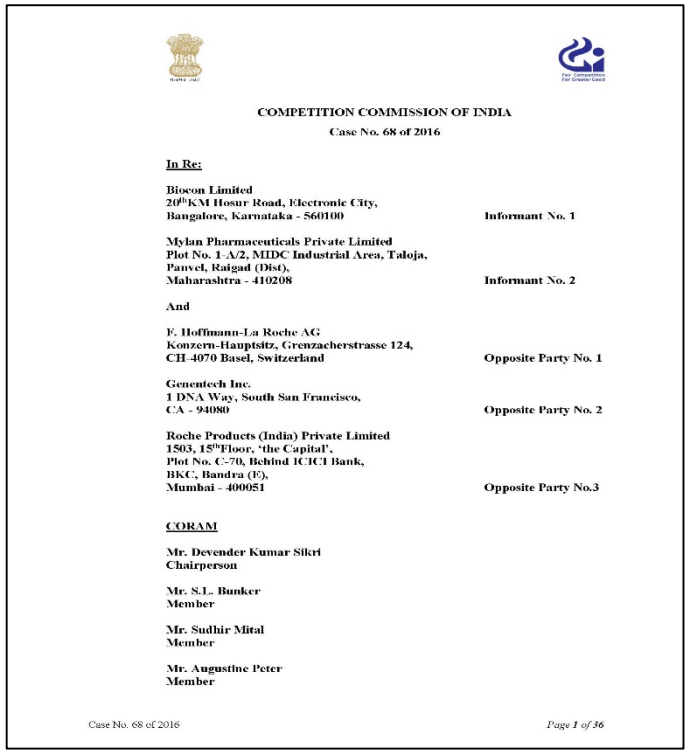
The NHS can rely on the CMA's infringement decision if making a claim in the courts for damages against the companies concerned. It will be for the court to determine the level of any damages.

The Chapter II prohibition of the Competition Act 1998 prohibits the abuse of a dominant position by one or more undertakings which may affect trade within the UK or a part of it. Similarly, Article 102 of the Treaty on the Functioning of the European Union prohibits the abuse of a dominant position which may affect trade between EU member states.

The CMA may impose a financial penalty on any business found to have infringed the Chapter II prohibition or Article 102 (or both) of up to 10% of its annual worldwide group turnover. In calculating financial penalties, the CMA takes into account a number of factors including seriousness and duration of the infringement(s), turnover in the relevant market and any mitigating and/or aggravating factors.

Biocon v. Roche (India)

- India Competition Commission
- India watchdog orders antitrust probe into Roche cancer drug (Reuters), April 27, 2017
- http://www.cci.gov.in/sites/default/files/68%20of%202016_0.pdf



COMPETITION COMMISSION OF INDIA

Case No. 68 of 2016

In Re:

Biocon Limited
20th KM Hosur Road, Electronic City,
Bangalore, Karnataka - 560100 — Informant No. 1

Mylan Pharmaceuticals Private Limited
Plot No. 1-A/2, MIDC Industrial Area, Taloja,
Panvel, Raigad (Dist),
Maharashtra - 410208 — Informant No. 2

And

F. Hoffmann-La Roche AG
Konzern-Hauptsitz, Grenzacherstrasse 124,
CH-4070 Basel, Switzerland — Opposite Party No. 1

Genentech Inc.
1 DNA Way, South San Francisco,
CA - 94080 — Opposite Party No. 2

Roche Products (India) Private Limited
1503, 15th Floor, 'the Capital',
Plot No. C-70, Behind ICICI Bank,
BKC, Bandra (E),
Mumbai - 400051 — Opposite Party No.3

CORAM

Mr. Devender Kumar Sikri
Chairperson

Mr. S.L. Bunker
Member

Mr. Sudhir Mital
Member

Mr. Augustine Peter
Member

Case No. 68 of 2016 — Page 1 of 36

Biocon v. Roche (India)

14. It has been alleged that Roche Group holds a dominant position in both the broader market as well as the narrower sub-markets based on various factors enshrined under Section 19(4) of the Act. It has been contended that, till February, 2014, Roche Group had a 100% market share in the broader as well as the narrower relevant markets. Even after the introduction of biosimilars by the Informants, i.e. in February, 2014, Roche Group continued to maintain a 100% market share, in terms of volume and value of sales, in two of the narrower relevant markets, i.e. the 'market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive early breast cancer within the territory of India'; and the 'market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic gastric cancer within the territory of India'.

In the broader relevant market and in the narrower relevant market, i.e., the 'market for sale of biological drugs (including biosimilars) used in the targeted therapy of HER-2 positive metastatic breast cancer within the territory of India', it is stated that Roche Group has a market share of 70% in terms of value of sales. It is further stated that Roche Group's size and resources in India and worldwide, contribute towards its position of dominance. Further, it has a comparative advantage over its competitors on account of being the innovator of the biological drug, Trastuzumab, in a market which has high entry barriers. Further, consumers' dependence on Roche's products is also stated to be one of the factors contributing to Roche Group's dominant position.

15. It is alleged that Roche Group, having a dominant position, has implemented or attempted to implement a series of actions to impede the entry and/or growth of biosimilar Trastuzumab in India, and thus, adversely affected competition in the relevant market.

Effects of Exclusivity and the Draft IP Policy

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

Draft IP Policy seeks to assure adequate tools for Competition Commission to appropriately address abuses contrary to public interest