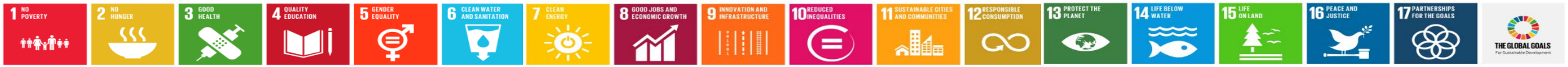
Access to Health Technologies, Patents and Prices: Capacity-building Consultation on the Use of Competition Law to Promote Affordable Access

Session 9: Competition litigation/prosecutions and sector-wide inquiries in healthcare and health technologies: Country experiences

ISAGS UNISUR
FioCruz
UNDP

Prof. Frederick Abbott
UNDP Consultant

5-7 December 2017
Rio de Janeiro, Brazil



Competition Authorities and Sector Inquiries

- Various approaches to health and pharmaceutical sector inquiries – activity in this area has expanded dramatically since UNDP initiated its work program 5+ years ago
- 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 Authorities and Sector Inquiries

- Competition Commission of India (CCI) undertaking baseline study/survey in the pharmaceutical sector and healthcare delivery systems/services
- French Competition Authority launches pharmaceutical sector inquiry November 20, 2017: http://www.autoritedelaconcurrence.fr/user/standard.php?id_rub=663&id_article=3068&lang=en

> "As part of its advisory powers, the Autorité de la concurrence is launching a vast sector-specific inquiry on the functioning of competition in the medicinal products and medical biology sectors. In particular it will look at the distribution of pharmaceuticals, their price regulation mechanism, as well as at the business development opportunities available to pharmacists."
> ,"… a sector-specific inquiry looks at the overall functioning of a sector and leads to the submission of an opinion, which has only a consultative value."

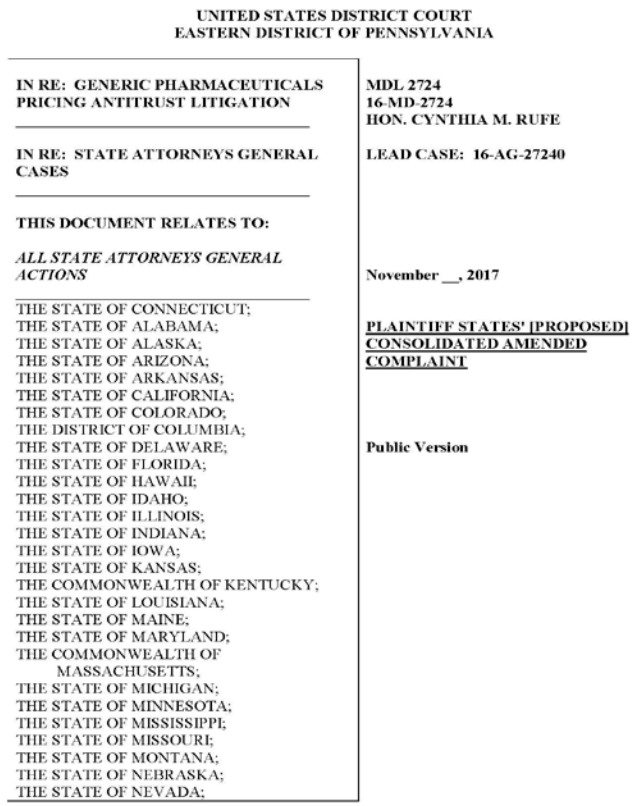
- Malaysia – UNDP and MyCC hosted September 2017 Workshop for ASEAN Competition, Health and IP Authorities
  - TWN has prepared draft pharmaceutical sector report for public distribution and comment: http://www.mycc.gov.my/node/1889

Competition Authorities and Sector Inquiries

Empowered lives.
Resilient nations.

- Indonesia – UNDP is working in cooperation with Indonesian competition authority on developing framework for price comparison study – UNDP and KPPU conducted Workshop in May 2017
- ASEAN Competition Authorities in preliminary discussions for regional cooperation on pricing and patent/exclusivity data, and other transparency measures
- To what extent can inquiries and results entail international collaboration? The global enforcement environment is complicated

State Attys Gens v. Mylan et al.



UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUST LITIGATION

IN RE: STATE ATTORNEYS GENERAL CASES

THIS DOCUMENT RELATES TO:

ALL STATE ATTORNEYS GENERAL ACTIONS

THE STATE OF CONNECTICUT;
THE STATE OF ALABAMA;
THE STATE OF ALASKA;
THE STATE OF ARIZONA;
THE STATE OF ARKANSAS;
THE STATE OF CALIFORNIA;
THE STATE OF COLORADO;
THE DISTRICT OF COLUMBIA;
THE STATE OF DELAWARE;
THE STATE OF FLORIDA;
THE STATE OF HAWAII;
THE STATE OF IDAHO;
THE STATE OF ILLINOIS;
THE STATE OF INDIANA;
THE STATE OF IOWA;
THE STATE OF KANSAS;
THE COMMONWEALTH OF KENTUCKY;
THE STATE OF LOUISIANA;
THE STATE OF MAINE;
THE STATE OF MARYLAND;
THE COMMONWEALTH OF MASSACHUSETTS;
THE STATE OF MICHIGAN;
THE STATE OF MINNESOTA;
THE STATE OF MISSISSIPPI;
THE STATE OF MISSOURI;
THE STATE OF MONTANA;
THE STATE OF NEBRASKA;
THE STATE OF NEVADA;

MDL 2724
16-MD-2724
HON. CYNTHIA M. RUFE

LEAD CASE: 16-AG-27240

November __, 2017

PLAINTIFF STATES' [PROPOSED] CONSOLIDATED AMENDED COMPLAINT

Public Version

- 46 US States pursue civil antitrust action against 10+ generics producers, including senior executives (personally) for wide-ranging conspiracy to fix prices and allocate markets for 15 drugs
- Complaint includes detailed evidence of anticompetitive practices based on emails, telephone records, documents and testimony

State Attys Gens v. Mylan et al.

- Practices include:
- Bid-rigging for pharmaceutical benefit manager (PBM) and public procurement
- Agreements to allocate customers and restrict output
- Informal enforcement mechanisms

- Means for carrying out conspiracy:
- Executive informal dinners
- Meetings at trade shows
- “Girls’ nights out”
- Emails and texts
- Telephone calls
- Deliberate efforts to eliminate “paper trail”

State Attys Gens v. Mylan et al.

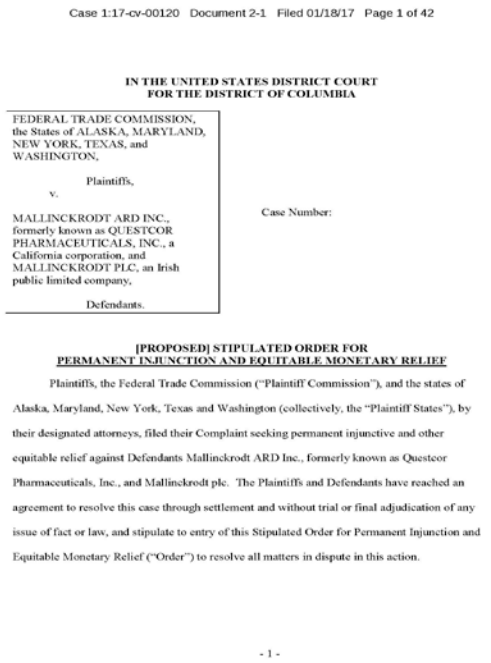
- Illustrates that anticompetitive behaviors not limited to originators and patents
- "Artificial" short supply used to dramatically raise prices
- Generics producers are easier targets for competition authorities because of lesser political influence and propaganda
- US Congress avoids originator controls, but will target generics

- … "including but not limited to, the markets for the following fifteen (15) generic drugs: Acetazolamide, Doxycycline Hyclate Delayed Release, Doxycycline Monohydrate, Fosinopril-Hydrochlorothiazide, Glipizide-Metformin, Glyburide, Glyburide-Metformin, Leflunomide, Meprobamate, Nimodipine, Nystatin, Paromomycin, Theophylline, Verapamil and Zoledronic Acid."

Empowered lives.
Resilient nations.

FTC v. Mallinkrodt

- FTC Press Release: Mallinckrodt Will Pay $100 Million to Settle FTC, State Charges It Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants
- https://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it
- https://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_stipulated_final_order.pdf



Case 1:17-cv-00120 Document 2-1 Filed 01/18/17 Page 1 of 42

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, the States of ALASKA, MARYLAND, NEW YORK, TEXAS, and WASHINGTON,

Plaintiffs,

v.

MALLINCKRODT ARD INC., formerly known as QUESTCOR PHARMACEUTICALS, INC., a California corporation, and MALLINCKRODT PLC, an Irish public limited company,

Defendants.

Case Number:

[PROPOSED] STIPULATED ORDER FOR PERMANENT INJUNCTION AND EQUITABLE MONETARY RELIEF

Plaintiffs, the Federal Trade Commission ("Plaintiff Commission"), and the states of Alaska, Maryland, New York, Texas and Washington (collectively, the "Plaintiff States"), by their designated attorneys, filed their Complaint seeking permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., and Mallinckrodt plc. The Plaintiffs and Defendants have reached an agreement to resolve this case through settlement and without trial or final adjudication of any issue of fact or law, and stipulate to entry of this Stipulated Order for Permanent Injunction and Equitable Monetary Relief ("Order") to resolve all matters in dispute in this action.

- 1 -

FTC V. Mallinkrodt

- "The complaint alleged that, while benefitting from an existing monopoly over the only U.S. adrenocorticotropic hormone (ACTH) drug, H.P. Acthar Gel, Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., illegally acquired the U.S. rights to develop a competing drug, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH drug, preserving Mallinckrodt's monopoly and allowing it to maintain extremely high prices for Acthar. Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, and a drug of last resort to treat several other serious medical conditions – including nephrotic syndrome, flare-ups of multiple sclerosis, and rheumatoid disorders. Since 2001, Mallinckrodt has raised the price of Acthar from $40 per vial to over $34,000 per vial – an 85,000% increase.
- Under the stipulated court order, Mallinckrodt must make a $100 million monetary payment to the Commission. Mallinckrodt must also grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission."

In the Complaint, Plaintiff Commission charges that Defendants engaged in anticompetitive acts and practices that constitute an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a). Plaintiff States charge that Defendants engaged in monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, …

FTC v. Shire

Federal Trade Commission v. Shire ViroPharma Inc., Civil Action No. 1:17-cv-00131-RGA (D. Del.), FTC File No. 1210062 (complaint filed February 7, 2017) (https://www.ftc.gov/enforcement/cases-proceedings/121-0062/shire-viropharma). The complaint alleged that Shire ViroPharma Inc. ("ViroPharma") abused government processes to delay generic competition to its branded Vancocin Capsules. Vancocin Capsules are used to treat a potentially life-threatening gastrointestinal infection. Specifically, the complaint alleged that ViroPharma waged a campaign of serial, repetitive, and unsupported filings with the U.S. Food and Drug Administration ("FDA") and courts to delay the FDA's approval of generic Vancocin Capsules and competition to its drug product. ViroPharma submitted 43 filings with the FDA and filed three lawsuits against the FDA between 2006 and 2012. According to the complaint, ViroPharma's filings lacked supporting clinical data, which ViroPharma understood it needed to have any chance of persuading the FDA ViroPharma also allegedly knew that its petitioning was obstructing and delaying the FDA's approval of generic Vancocin Capsules. The Commission seeks a court order permanently prohibiting ViroPharma from submitting repetitive and baseless filings with the FDA and the courts, and from similar and related conduct as well as any other necessary equitable relief, including restitution and disgorgement.

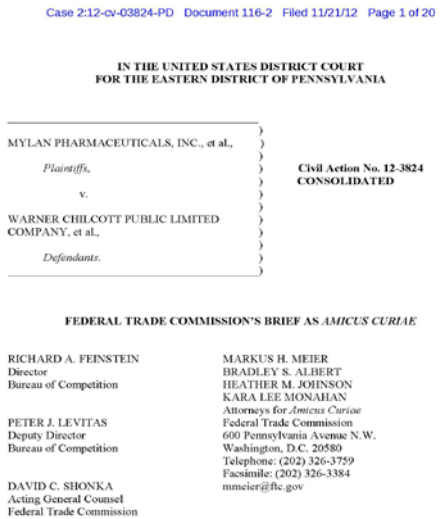
FTC v. Cephalon (Teva)

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*

RICHARD A. FEINSTEIN
Director
Bureau of Competition

PETER J. LEVITAS
Deputy Director
Bureau of Competition

DAVID C. SHONKA
Acting General Counsel
Federal Trade Commission

MARKUS H. MEIER
BRADLEY S. ALBERT
HEATHER M. JOHNSON
KARA LEE MONAHAN
Attorneys for *Amicus Curiae*
Federal Trade Commission
600 Pennsylvania Avenue N.W.
Washington, D.C. 20580
Telephone: (202) 326-3759
Facsimile: (202) 326-3384
mmeier@ftc.gov

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."

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

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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.

CMA v. Actavis (UK)

CMA Press release

Pharmaceutical company accused of overcharging NHS

From: Competition and Markets Authority

Part of: Competition Act and cartels

Published:16 December 2016

The CMA has provisionally found that Actavis UK has broken competition law by charging excessive prices to the NHS for hydrocortisone tablets.

"In a statement of objections issued to the company today, the CMA has alleged that in doing so it broke competition law by charging excessive and unfair prices in the UK for the tablets."

"The pharmaceutical company Actavis UK (formerly Auden Mckenzie) has increased the price of 10mg hydrocortisone tablets by over 12,000% compared to the branded version of the drug which was sold by a different company prior to April 2008. For example, the amount the NHS was charged for 10mg packs of the drug rose from £0.70 in April 2008 to £88.00 per pack by March 2016.

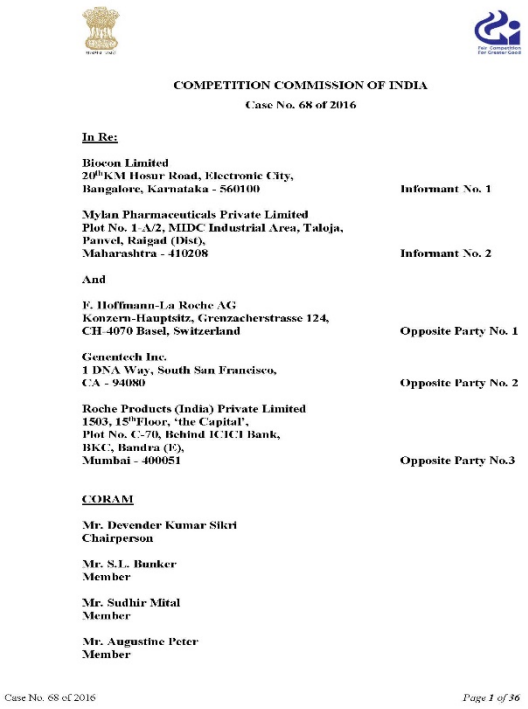
The company also increased the price of 20mg hydrocortisone tablets by nearly 9,500% compared to the previous branded price, equating to charges to the NHS of £102.74 per pack by March 2016, when it had previously paid £1.07 for the branded drug. De-branded (genericised) drugs are not subject to price regulation."

CMA v Concordia, Nov. 2017

On 21 November 2017 the CMA issued a statement of objections alleging that Concordia has breached UK and EU competition law by charging excessive and unfair prices in relation to the supply of liothyronine tablets in the UK.

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.