



International
Competition
Network

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ICN Unilateral Conduct Working Group

TELESEMINAR ON
UNILATERAL CONDUCT IN THE PHARMACEUTICAL SECTOR
2 NOVEMBER 2010

Introductory Remarks by Operator



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- Welcome by Operator
- Panelists and Participants please note:
 - This Teleseminar will be recorded and posted on the ICN website
 - Audience will be muted during most parts of the teleseminar call („Audience Call“)
 - Audience will be be unmuted during Q&A sessions

Welcome & Agenda by Randy Tritell



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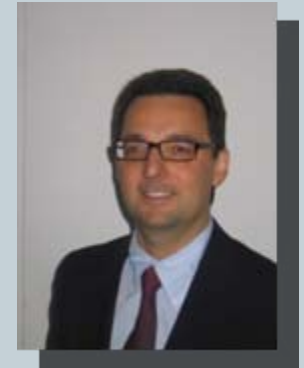
- I. Introduction
- II. Overview of Antitrust Enforcement in the Pharmaceutical Sector followed by Q&A
- III. Case Studies followed by Q&A
 - Excessive Pricing Strategies
 - Predatory Pricing Strategies
 - Life-cycle Management Strategies
- VI. Concluding Remarks



Introduction

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- **Importance of the Pharmaceutical Sector**
- **The Key Role of Innovation**
- **The Intersection of IP and Antitrust in the Pharmaceutical Sector**



Satish Sule

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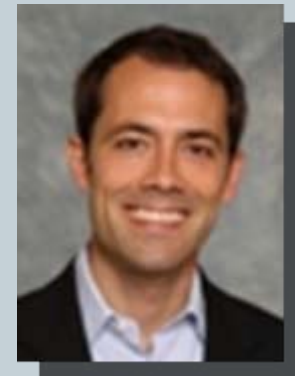
- **Satish Sule joined the European Commission in 2006 working in the Antitrust unit dealing with Pharma issues within the Directorate General for Competition.**
- **Satish studied law at the universities of Saarbrücken Germany and Exeter, UK. He graduated at Saarbrücken with the first and second German state exam for lawyers. He worked as research assistant and tutor at the university of the Saarland and as a lecturer at Cardiff Law School (Wales, UK). He holds a PhD and an LLM from the University of Saarbrücken.**



C. Scott Hemphill

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- **Scott Hemphill is a Professor of Law at Columbia Law School. Before joining the faculty in 2006, he served as a law clerk to Judge Richard Posner on the U.S. Court of Appeals for the Seventh Circuit, and to Justice Antonin Scalia on the United States Supreme Court.**
- **Trained as a lawyer and an economist, he holds a Ph.D. in economics from Stanford University and a J.D. from Stanford Law School, where he graduated first in his class. He is a graduate of Harvard and the London School of Economics, where he studied as a Fulbright Scholar. His writing has appeared in the law reviews of Columbia, NYU, and Stanford, the Wall Street Journal, and elsewhere.**
- **Professor Hemphill's research and teaching examine the balance between innovation and competition set by antitrust law, intellectual property, and other forms of regulation. His work on the pharmaceutical industry has provided the basis for congressional testimony and briefings to state antitrust enforcement officials.**



Sean-Paul Brankin

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- Sean-Paul Brankin is a lawyer in private practice with Crowell & Moring LLP. He represented generic industry clients in the context of the European Commission's pharmaceuticals sector inquiry and has published articles on a range of related subjects including the assessment of reverse payment settlements under EU law and the recent *Astra Zeneca* decision.
- Prior to joining Crowell & Moring, Sean-Paul was a Legal Director at the Office of Fair Trading, where he was among other roles head of internal case scrutiny.



Liberty Mncube

- **Liberty Mncube is a Senior Analyst in the Policy and Research Division of the Competition Commission of South Africa. At the Commission, his responsibilities include managing and coordinating research and policy development; managing and coordinating case analysis; contributing in building capacity for research and knowledge of competition policy; and undertaking analysis related to competition matters with regard to policy and regulation.**
- **Prior to joining the Commission, he was a Researcher at the Development Policy Research Unit at the University of Cape Town. Liberty holds a MSc in Economics from the University of York.**

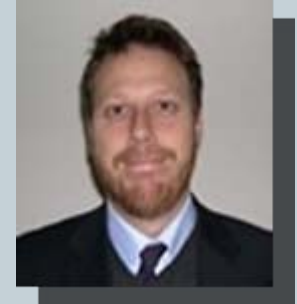


Ed Smith



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- Ed Smith heads the International team at OFT working across a range of multilateral (ICN, ICPEN, OECD and EU) and bilateral initiatives in the competition and consumer policy spheres.
- At OFT Ed previously led the Tobacco and NMD cases and worked as case officer on Napp Pharmaceuticals, the CA98 case, and on PPRS and generic medicines. He also undertook FTA work on Motorway Service Areas, vet medicines and a review of the beer orders.
- Between 2003 and 2008 Ed spent five years in Brussels working in the European Commission and the Council.



Natalie Timan



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- Natalie Timan is a senior economist working in the Economic Policy Team of the Office of the Chief Economist within the OFT.
- The Economic Policy Team provides economic advice and quality assurance for economic work carried out across the OFT, and provides economic input into policy discussions. The team also runs the OFT's programme of economic discussion papers.



Bradley S. Albert



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- **Bradley S. Albert is the Deputy Assistant Director of the Health Care Division of the Federal Trade Commission's Bureau of Competition in Washington, D.C.**
- **Brad has been involved in many of the FTC's major pharmaceutical initiatives, including investigations into possible anticompetitive practices of pharmaceutical firms to delay generic entry as well as administrative and federal court litigation challenging such conduct.**
- **He also supervises the review of the pharmaceutical patent settlement agreements received by the Commission.**

Overview of Antitrust Enforcement in the Pharmaceutical Sector

(Satish Sule)

- **Market definition:**

- Traditional Approach
- After AstraZeneca Judgement

- **Unilateral practices (EU perspective):**

- Practices observed during the EU Commission's Sector Inquiry 2008/2009
- Practices challenged by the EU Commission's AstraZeneca decision of 2005

- **Traditional approach as regards product market:**
- **Substitutability**
 - by product characteristics
 - prices and
 - intended use
- **Traditional starting point in COM decisions:
ATC 3**

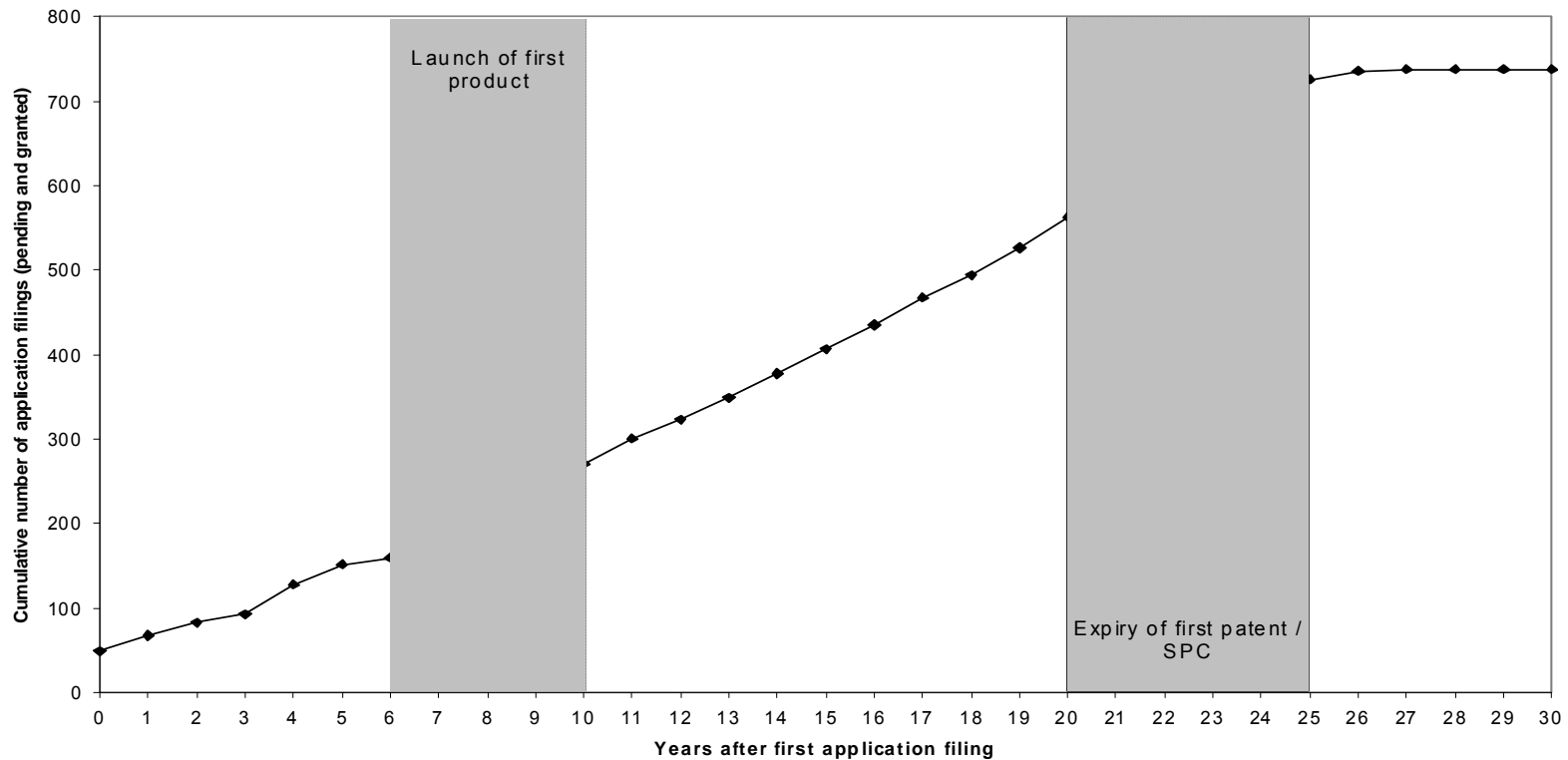
- AZ decision of the Commission departed from ATC 3 and included several aspects criticised by the industry
- General Court's conclusion on market definition
 - ✦ *The Commission based its assessment (that H2 blockers did not significantly constrain PPIs) on the greater efficacy of PPIs, the differentiated therapeutic use of PPIs and H2 blockers, the trend of asymmetrical substitution (...), price indicators (...) and the natural events (...) (para 219). (...) (T)hat evidence (...) constitutes, in the present case, a body of relevant data that is sufficient (...) (para 220).*

- EU Commission's Sector Inquiry (2008/2009)
 - indications of delay of generic entry and decline in innovation
- Unilateral practices observed:
 - Patenting strategies on **patent clusters** and **defensive patenting**
 - Patent disputes/ opposition and **litigation** procedures
 - **Interventions** before national authorities
 - **Life cycle management** (also called „product hopping“ or „evergreening“)
- Practices examined are not necessarily anti-competitive but may be depending on individual circumstances of the case

Unilateral Practices (SI): Patent (application) Strategies

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- Patent clusters: up to 90 patent families for one blockbuster medicine
- Defensive patents applied for in order to block development by competitor but not to develop own invention



Final outcome of patent litigation

- Number of patent litigation cases increased by a factor of four between 2000 and 2007
- Average duration to reach final outcome: 2.8 years
- Interim injunctions granted in almost half of the cases when requested (112 of 255 cases), average duration 18 months
- Generic companies won 62% of patent litigation cases

Final outcome of opposition procedures before EPO

- Opposition rate for pharmaceutical patents is higher than in other sectors
- 60% of opposition cases led to revocation of the patent (in addition scope of patent was restricted in additional 15%)
- Almost 80% of procedures before the EPO took more than 2 years

- Originator companies „intervene“ before national authorities raising alleged patent infringement and safety issues („patent linkage“)

- Originator companies launched second generation (follow-on) products for 40% of the medicines in our sample.

“[Our second generation product] represents the most effective initiative to counter generic [versions of our first generation product]”

- Originator companies made intensive use of marketing and promotion strategies and other instruments in order to switch patients to the second generation product before generic entry.

“if [generic products] come together with or prior to [second generation product] the switch rate is dramatically reduced. [...] Once [generic products] come in it becomes more difficult to get switches from [old originator product].”

Submission of misleading information to the patent office:

- Submission of wrong/misleading information in order to obtain prolonged exclusivity (SPC)
- Commission's decision (2005) upheld by General Court in its decision of July 2010:

„The submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits (...). Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position (...).“ (para 355)

Deregistration and withdrawal of capsules of 1st generation product from the market (replacement by tablets)

- Losec capsules were required reference product for generic market authorisation
- Deregistration but not withdrawal constituted an abuse
- General test
 - ✦ *(...) whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests (...) it cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests (...). (para 672)*

Relationship between IPRs and antitrust law

- Perceived tension (exclusive rights) but
- same objective: promote innovation and consumer welfare
- IPRs indispensable for dynamic competition but
- not immune from competition law intervention

Limitations to antitrust interventions

- No substituting for the patent office
- Exceptional circumstances (e.g. refusal to supply/licence case-law)

Enforcement actions concerning unilateral practices following the SI:

- Perindopril and Citalopram cases

Broadening the view

(Sean-Paul Brankin)

Innovation driven:

- Development of new drugs is central to consumer benefits and industry profitability
- Profits from successful drugs fund R&D
- Patents reward innovation through exclusive rights

Highly unusual demand structures (particularly in EU):

- Doctors prescribe drugs
 - Patients consume drugs
 - Health systems/social insurance pay for drugs
- => Split between (i) decision maker (ii) consumer and (iii) purchaser

AstraZeneca:

- Therapeutic use/prescribing practices of doctors central to market definition
- Regulatory intervention does not call into question normal approach to market definition – and supports narrow market definition
 - “the reimbursement levels granted to PPIs to a large extent prevented the lower prices of H2 blockers from exercising a competitive constraint over them ... The fact that the absence or insignificance of those competitive constraints is due to the regulatory framework ... does not affect the relevance, in the context of market definition, of the finding that those competitive constraints are non-existent or insignificant” (§ 174)

Similar approach in recent merger cases

- *Teva/Barr*: “The market investigation has indicated that ... competition takes place between drugs based on the same molecule ... in particular for serious conditions” (§ 17)
 - *Sanofi-Aventis/Zentiva*: “The market investigation in the present case indicates that it is only in a minority of cases that products based on alternative active pharmaceutical ingredients ... can be considered as perfect substitutes” (§ 18)
- => “Molecule markets” (for single active substance) not unusual?**

Infringements with limited risk of chilling innovation

- Monopolization by deception
 - misleading applications to patent authorities (*AstraZeneca*, 1st abuse)
 - litigation based on misleading representations (*AstraZeneca*, 1st abuse)
 - interventions before national authorities
- Abuse of process
 - withdrawal of marketing authorization with ‘sole purpose’ of frustrating generic entry (*AstraZeneca*, 2nd abuse)
- Infringements in relation to off-patent products
 - *NAPP* (UK case) – predatory pricing
 - *Reckitt Benckiser* (UK case) – life-cycle management/evergreening

Potentially more controversial infringements

- Patent clusters / Blocking patents
- Life-cycle management/evergreening involving patented products
- Refusals to supply/license (*Genzyme* (UK case))
- Excessive pricing

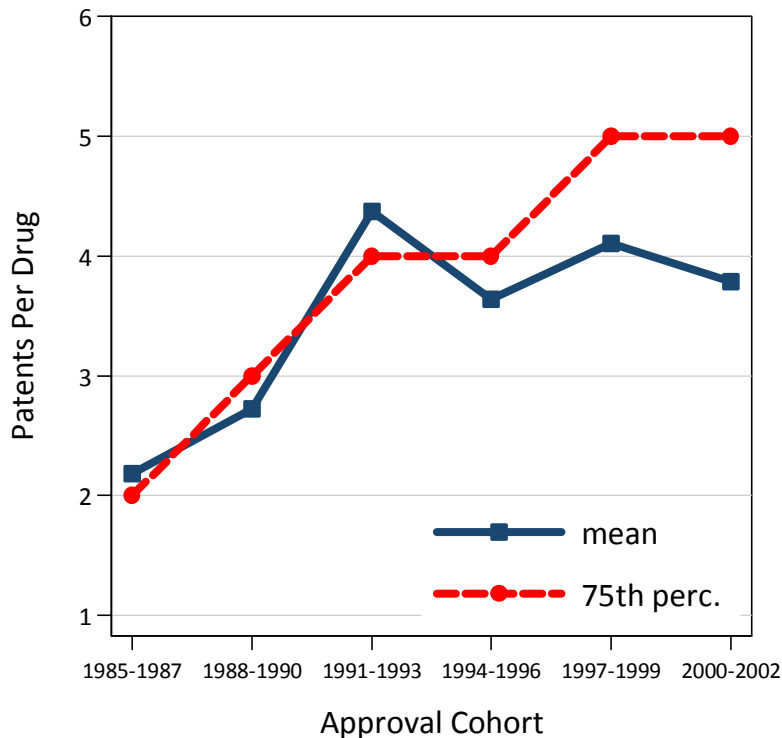
Further observations

(Scott Hemphill)

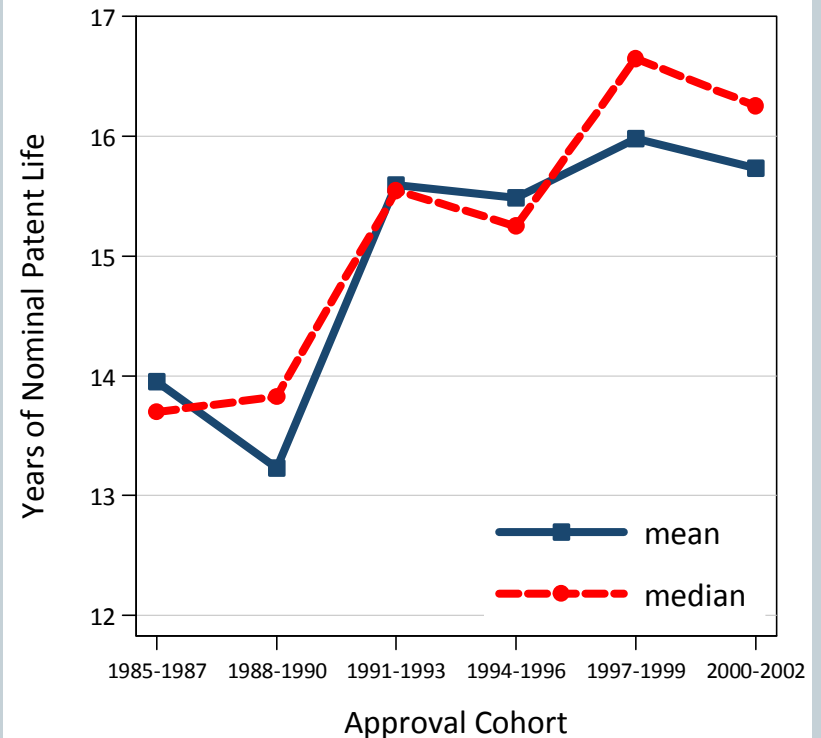
Trends in U.S. Drug Patenting

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Patents per drug by approval cohort

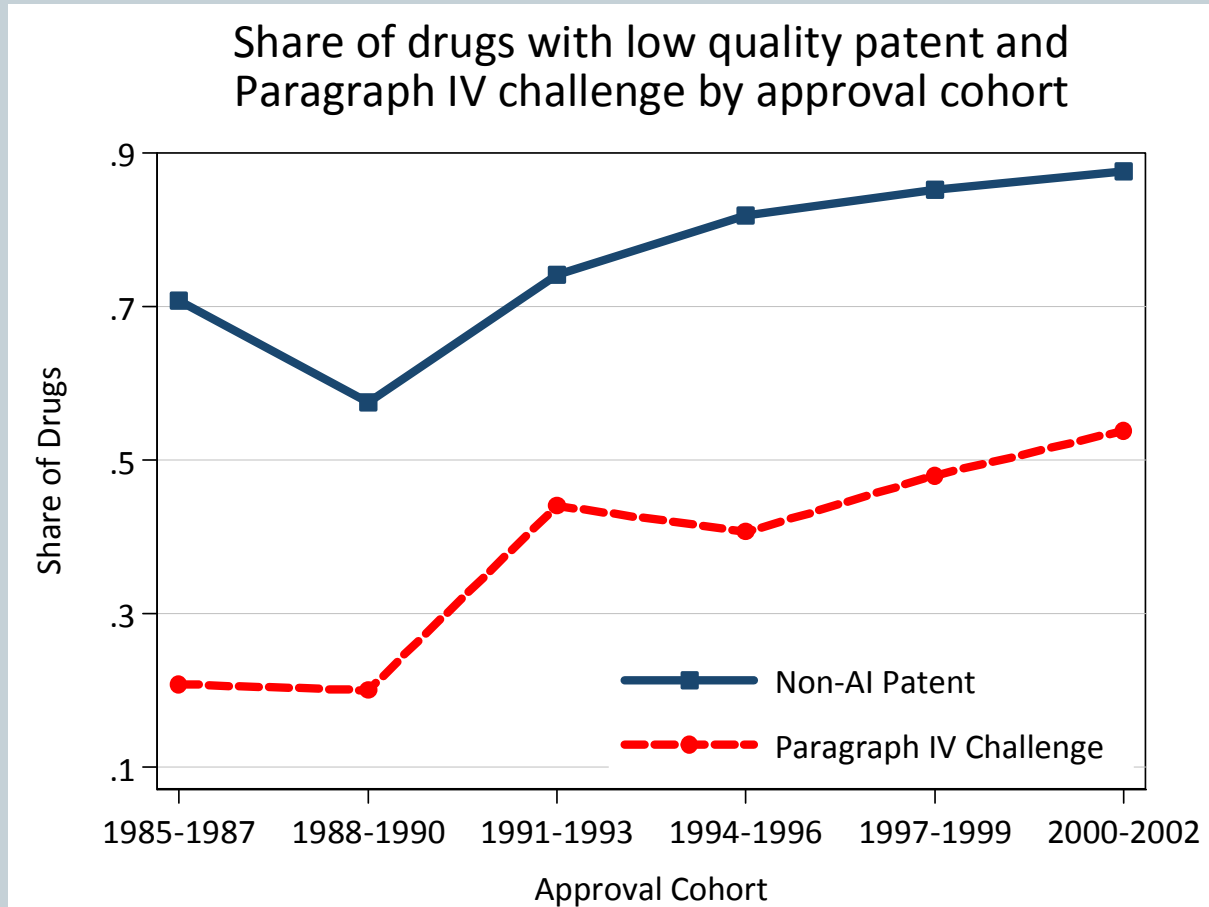


Nominal patent life by approval cohort



Trends in U.S. Drug Patenting (II)

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Overview of Antitrust Enforcement in the Pharmaceutical Sector

Q&A

(Moderator: *Markus Lange*)

Case Study 1

Hazel Tau & others v. GSK & BI

(Liberty Mncube)

Background



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- South Africa has the highest population of people with HIV/AIDS of any country in the world.
 - In 2000 an estimated 5-6 million infected individuals. Without effective prevention and treatment, 5-7 million cumulative AIDS deaths were anticipated by 2010.
- Antiretroviral treatment (“ART”) is the main type of therapy available for HIV/AIDS.
- Although not a cure, it has been proven effective in combating the impact of the HIV/AIDS pandemic.
- The availability of ART, accessibility remains the biggest challenge in South Africa.
- According to the World Health Organisation and UNAIDS, more than 800 000 HIV/AIDS infected individuals urgently required ART.
 - In addition 10-15% of people currently estimated to be living with HIV and AIDS have progressed to a stage of 200 CD4 or below and therefore may need ARVs. This figure was also expected to increase overtime due to the high rate of infections.

The Complaint

- In 2002 Hazel Tau, a person living with HIV and others filed a complaint that GSK and BI had contravened the Competition Act by charging excessive prices for their patented ARV medicines.
- The Commission expanded the investigation to include refusing to give competitors access to an essential facility when it is economically feasible to do so and engaging in exclusionary conduct.
- At the time of the investigation:
 - GSK held patents in South Africa on *AZT* (branded as Retrovir), *Lamivudine* (branded as 3TC) and *AZT/Lamivudine* (branded as Combivir)
 - BI held patents in South Africa on *Nevirapine* (branded as Viramune).
- The complainants sought to compel the respondents to license these ARV medicines to generic manufacturers.

Dominance

- **Market definition**
 - The relevant markets were the South African product markets for each specific ARV subject to the complaints, i.e. using Anatomical Therapeutic Classification (ATC) 5 (corresponding to the market for each active ingredient).
 - Medical evidence demonstrated that ARV medicines are not substitutable for each other
 - Economic evidence
- GSK had a 100 % market share in South Africa for the manufacture and sale of AZT, the manufacture and sale of 3TC and the manufacture and sale of Combivir.
- BI had a 100 % market share in South Africa for the manufacture and sale of Nevirapine.
- Both companies had substantial market power in each of the relevant markets.
- GSK and BI each control patents that enabled them to block generic competition for AZT, 3TC, Combivir and NVP
- And allowed them to charge supracompetitive prices for their products.

- Excessive Pricing
- Section 8(a) of the Act prohibits dominant firms from charging an excessive price to the detriment of consumers.
 - An excessive price is defined in the Act as a price for a good or a service which bears no reasonable relation to the economic value of that good or service; and
 - is higher than the value referred to above.
- The analysis compared the respondents prices to estimates of costs and to reference prices.
- Furthermore,
 - Different standards for excessive pricing of **essential goods / non essential goods**.
 - Evaluation is different when the price of the goods is based upon the **value of intellectual property**.

Evaluation of Excessive Pricing



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- Based on these considerations,
 - The first inquiry requires determination of the “economic value” of the good.
 - The second inquiry requires determining whether the prices set by the dominant firm bear a reasonable relationship to the economic value and are higher than that value.
- For essential goods that are protected by intellectual property,
 - a price can be presumed to be higher than the economic value if substantial numbers of people who need the medicine do not purchase it (through individual or pooled incomes)
- In the present case competitive provision of the good was feasible,
 - GSK and BI could have either priced their medicines to be affordable to most people or licensed their patents to competitors in return for reasonable royalty.
 - Only tiny fraction of persons living with HIV could afford the prices set.



- Refusal to supply
- Section 8(b) prohibits dominant firms from refusing to give a competitor access to an essential facility when it is economically feasible to do so.
- GSK and BI 's patents were non duplicable
- Access to the GSK and BI 's patents was necessary to provide goods
- GSK and BI refused competitors access to their patents
- Economically feasible

The Commission's Findings



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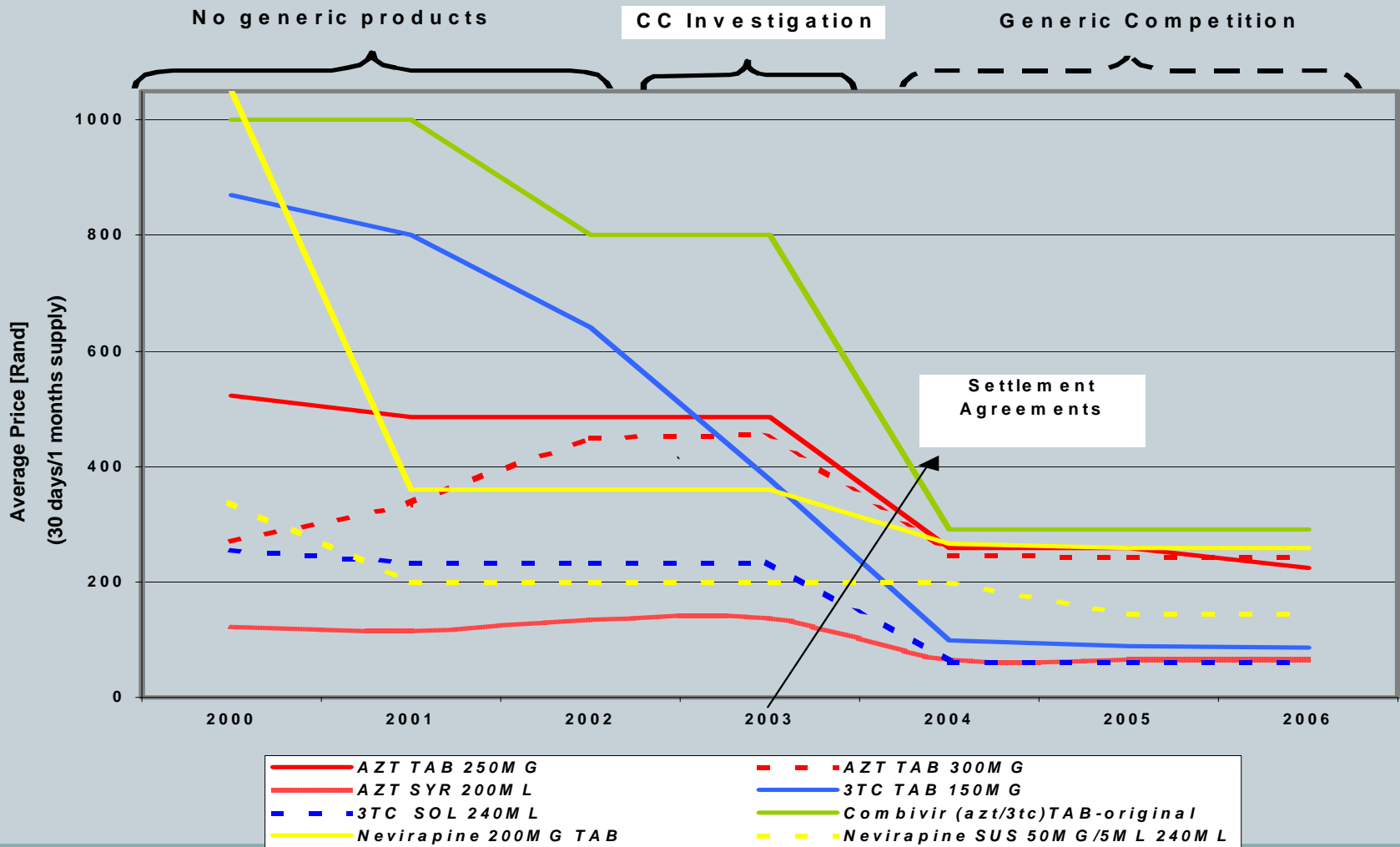
- The Commission developed a case that both GSK and BI had contravened the Competition Act by:
 - (1) charging excessive prices;
 - (2) refusing to grant a competitor access to an essential facility;
 - (3) engaging in exclusionary conduct.
- Before the Commission could refer the case to the Competition Tribunal for prosecution, GSK and BI decided **to settle the case and agreed to:**
 - grant licences to generic manufacturers;
 - permit the licensee's to export the relevant ARV medicines to sub-Saharan African countries;
 - where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only, provided all the regulatory approvals were obtained;
 - permit licensees to combine the relevant ARV's with other ARV medicines; and
 - not require royalties in excess of 5% of the net sales of the relevant ARV's.

The Impact of the Settlement Agreement

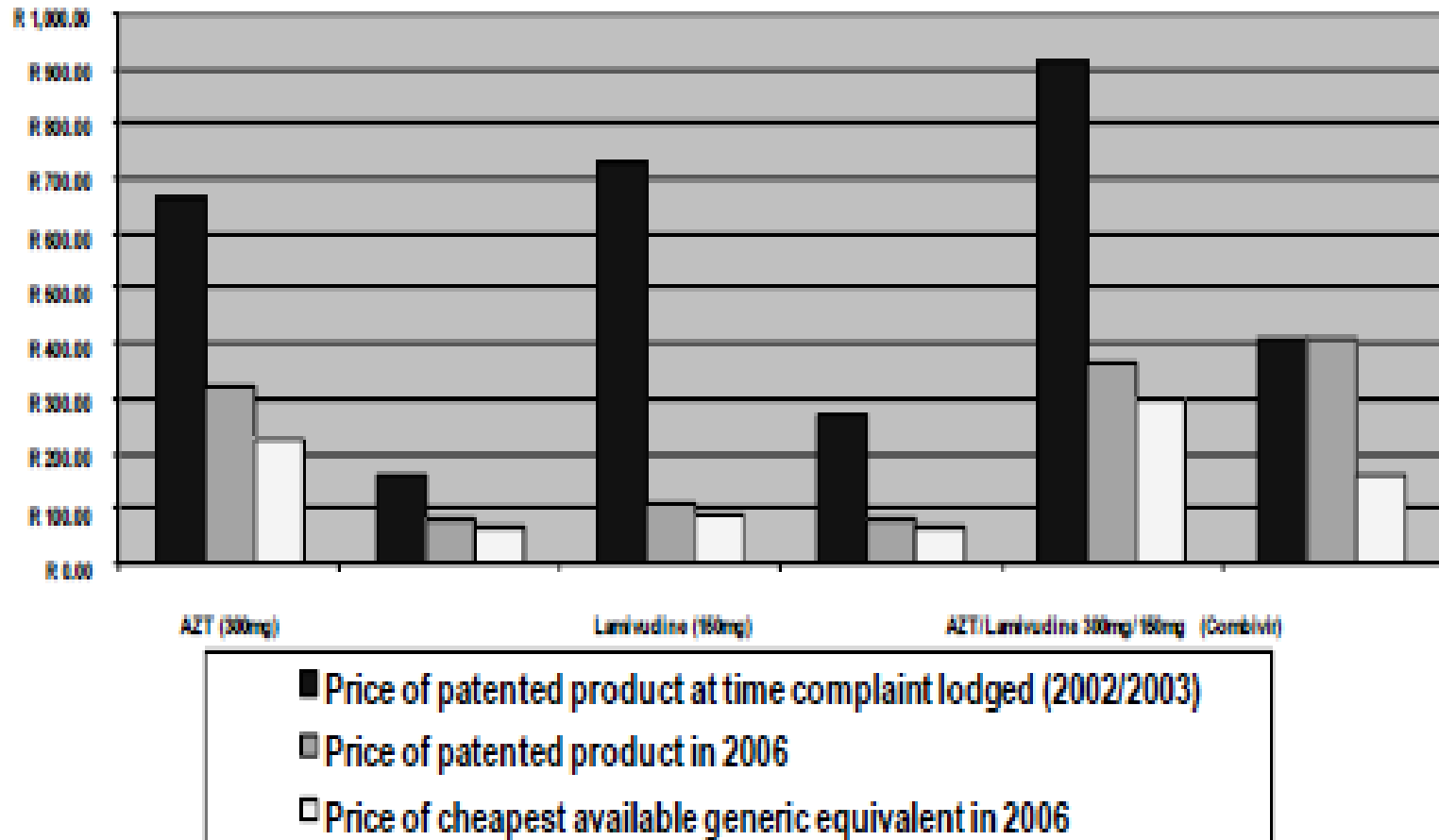
Patent Manufacturer	Generic Manufacturer (Licensees)	Date of Agreement	Products	Royalty Requirement
GSK	Aspen	10 October 2003	Lamivudine Combivir	5%
	Biotech	25 November 2004	Lamivudine Retrovir	5%
	Feza Pharmaceuticals	17 August 2004	Lamivudine Retrovir	5%
	Cipla Medpro	30 November 2004	Lamivudine Retrovir	5%
	Adcock Ingram	9 November 2005	Lamivudine Retrovir	5%
BI	Aspen	23 February 2004	Viramune	5%
	Cipla Medpro	27 December 2004	Viramune	5%
	Biotech	25 March 2006	Viramune	5%

Price Movements (2002-2006)

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Price Comparisons (excluding South Africa's value added tax)



Conclusion

- Promotion of generic competition
 - Low cost and affordable medicines
- The Commission's assessment did not view IPR as beyond competition scrutiny
- Remedies imposed required access to originator companies to out-licence their patented product to generic manufacturers.

Case Study 1

Q&A

(Moderator: *Markus Lange*)

Case Study 2
Napp Pharmaceuticals
(Ed Smith & Natalie Timan)

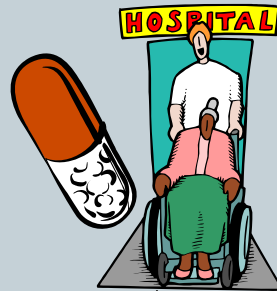
Some Basic Facts

- Sustained Release Morphine used for palliative care (cancer)
- MST held patent on SR. Ended 1992. 'Me too' branded generics entered in mid 1990s, but forced to leave in 2000

Basic Facts cont'd

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HOSPITAL SEGMENT (10%)



Follow-on prescriptions

Endorsement and Reputation effects



Strategic gateway to



COMMUNITY SEGMENT (90%)

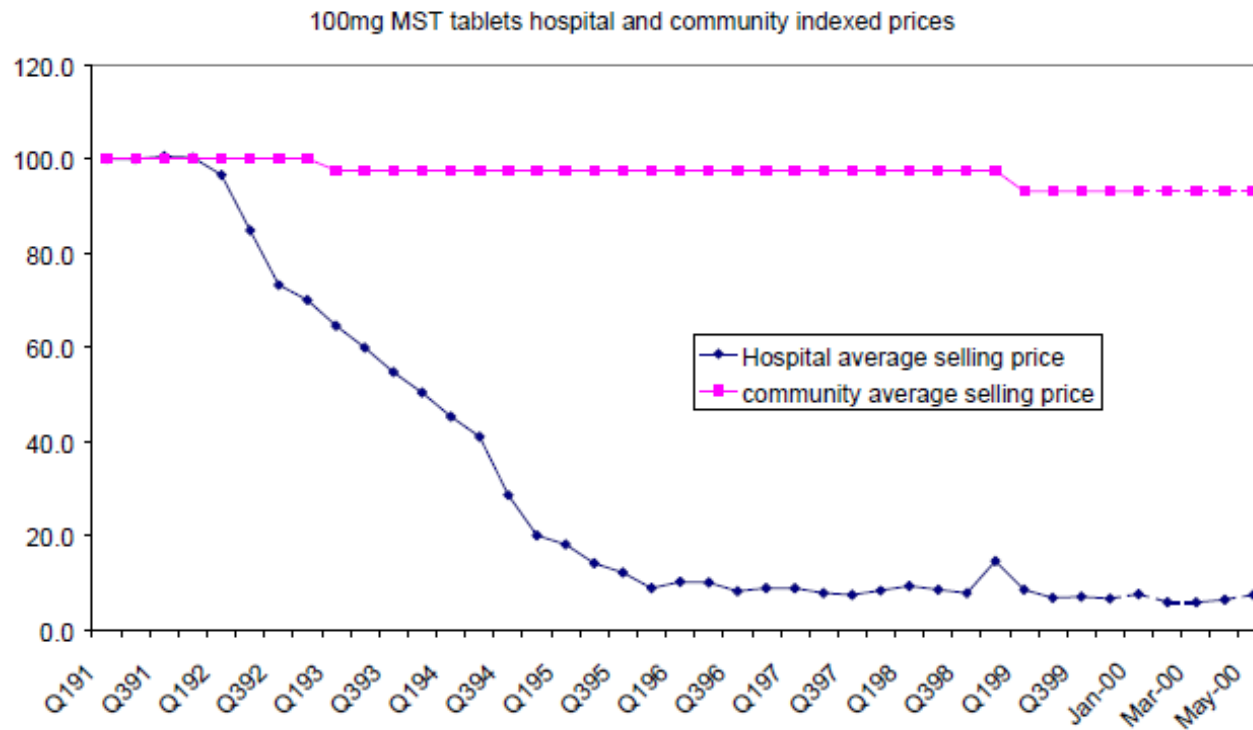
- **Non-morphine products, immediate release morphine**
 - ATC classifications
 - Prescribing Guidelines, GP Surveys
 - Pricing data, event analysis (but price sensitivity)
 - Supply side substitutability
- **Hospital v Community**

Napp – Dominance Issues

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- Sustained high market shares (c. 90%)
- Barriers to entry
 - Regulatory authorisation, parallel imports
- Reputation and switching inertia
- Pharmaceutical Price Regulation Scheme
- Buyer Power

Chart 1: Hospital and Community indexed prices of MST tablets (100mg) Q1 1991 = 100



Source: OFT calculation based on data from Napp
NB: figures for 2000 are given monthly, not quarterly

Exclusionary Abuses

- **Selective targeted hospital discounts $< AVC$**
 - Measurement issues
- **Discounts targeted at competitor contracts**
- **Heavy discounts for exclusivity 2-3 years**
- **Proving Foreclosure Effect. Key issues**
 - Follow on prescriptions
 - Reasons for competitor failure

Exploitative Abuses

- **Excessive pricing in Community segment**
 - Comparison with competitor prices/margins
 - Comparison with patent protection price
 - Comparison with export prices
 - But no whole-life cost assessment
- **Finding dependent on foreclosure abuse**
 - Other side of the coin

Case Study 2

Q&A

(Moderator: *Makus Lange*)

Case Study 3

Life-cycle Management

(Bradley S. Albert)

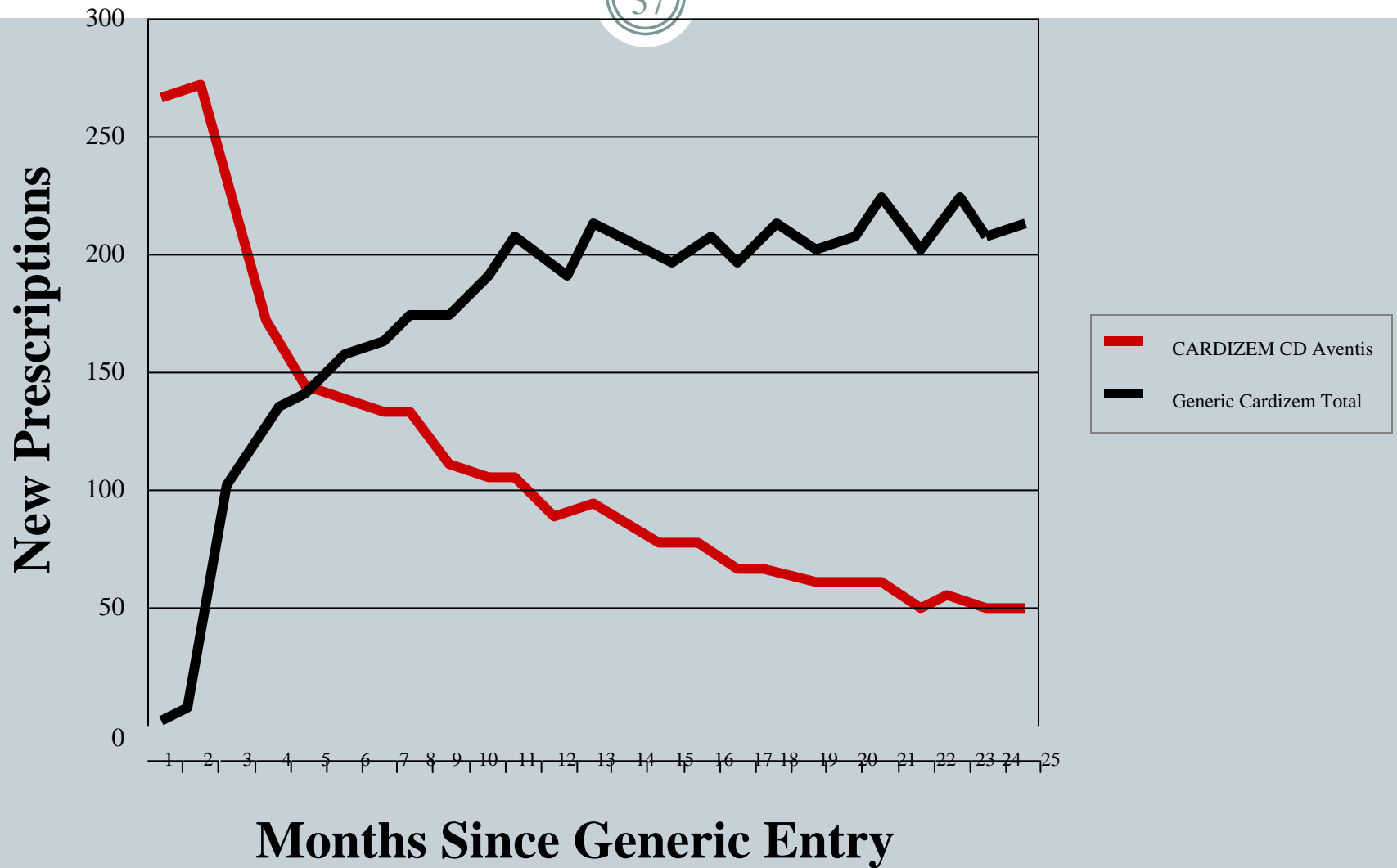
Life-cycle Management

1. Broad definition – Any action a branded pharmaceutical company takes to preserve its market share in the face of actual or potential brand or generic competition.
2. Narrower definition – Any changes made to a branded drug in order to prevent automatic substitution of a generic at the pharmacy.

- FDA deems as “**therapeutically equivalent**”:
 - **Bioequivalent** – comparable rate and extent of absorption of active ingredient in the body, and
 - **Pharmaceutically equivalent** – same active ingredient, dosage form, route of administration, strength or concentration.
- Under state law, pharmacists may automatically substitute prescriptions for a brand to an AB-rated generic.

Generic Cardizem Entry

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Examples of Life-cycle Strategies



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- **Changes in Formulation**
 - Metabolites – e.g., Claritin ► Clarinex
 - Chiral switches – e.g., Prilosec ► Nexium
 - Polymorphs – e.g., Paxil (waters of hydration)
 - Strength – e.g., Tricor (200mg ► 160mg ► 145mg)
 - Combination therapies – e.g., Caduet (Lipitor + Norvasc)
- **Changes in Method of Delivery**
 - Dosage form – e.g., Ovcon ► Femcon (chewable)
 - Route of administration – e.g., DDAVP (oral ► GI track)
- **Changes in Indications or Labeling**
 - Indications – e.g., Neurontin (epilepsy +)
 - Labeling – e.g., Tricor (food effects)

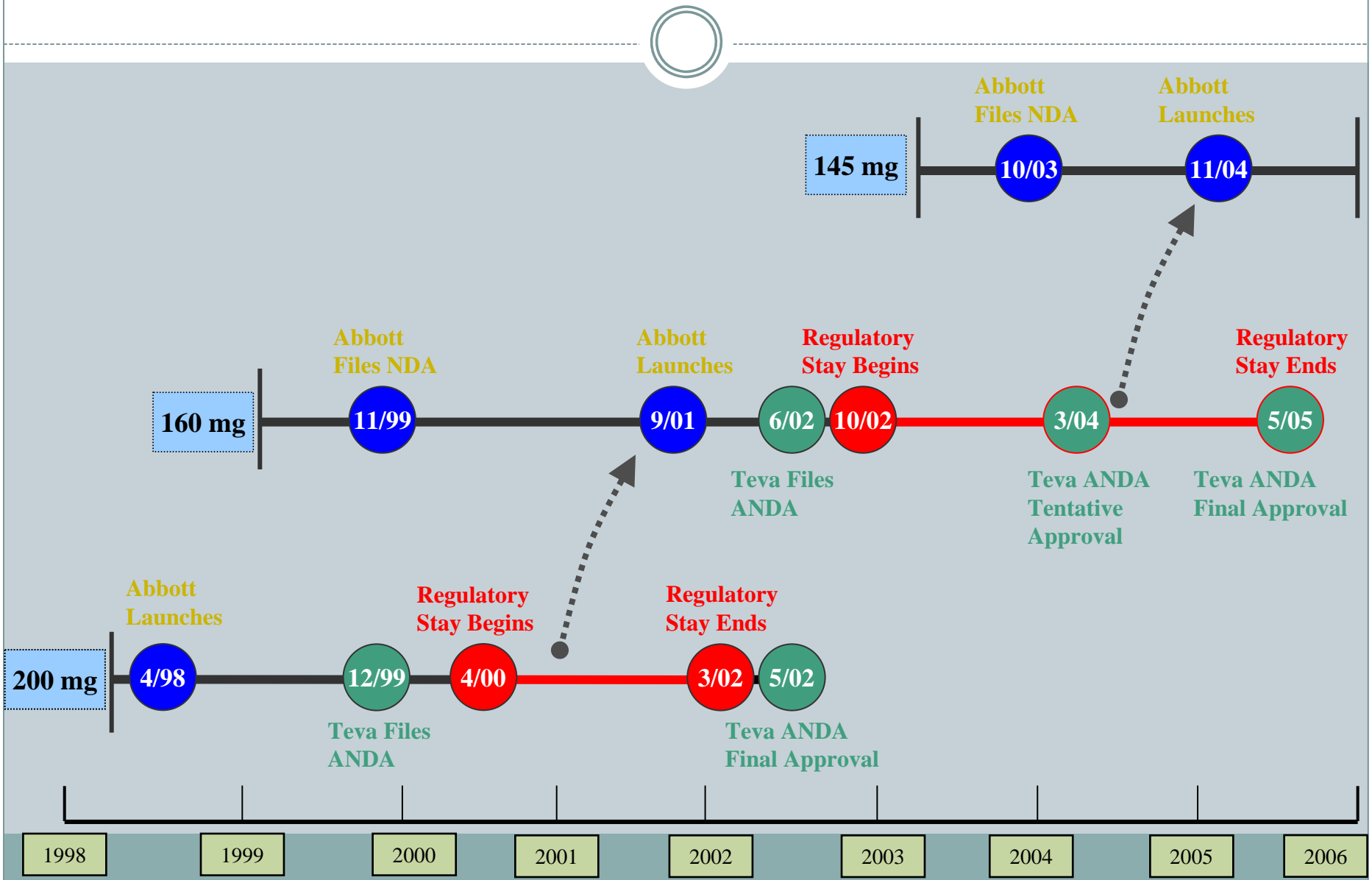
Product Hopping: Tri Cor



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- Involved Tricor dosage form and strength switches before AB-rated generic entry
- Generics sought to enter and had to keep catching up with new formulations
- Abbott took other steps to convert market to new formulation
 - Withdrew original formulation from market
 - Purged distribution of original formulation
 - Deleted “National Drug Code” from “National Drug Data File”

TriCor Product Hopping Timeline



Abbott Labs v. Teva



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“Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version Rather, . . . if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.”

432 F.Supp 2d 408, 422 (D.Del. 2006) (ruling on motion to dismiss).

“[P]roduct-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. . . . [S]uch a change could qualify as a predatory product change if it lacks substantial medical benefits.”

Hovenkamp & Lemley, *IP and Antitrust*, 2006 Supplement, § 12.5 at 12-45 – 12-46.

The Washington Post

June 5, 2002, p. A 22



Abbott Labs. v. Teva

- Generics, pharmacies, wholesalers, insurers, and state AGs filed suit
- Abbott settled, paying more than \$184 million

● *Walgreen Co. et al. v. AstraZeneca*

- Involved Prilosec to Nexium chiral switch
- Astra does not withdraw Prilosec from market
- Case dismissed on 12(b)(6) motion on 2/25/08

No law enforcement action to date directly challenging product switching.

- Actions involving allegations that product switching may enhance consumer harm
 - *FTC v. Warner Chilcott, et al.*, Civil Action No. 1:05-cv-2179-CKK (D.D.C. 2005) – PI and order.
 - *FTC v. Watson, et al*, Civil Action No. 1:09-cv-955-TWT (N.D. Ga. 2009)
 - *FTC v. Cephalon*, Civil Action No. 2:08-cv-2141 (E.D. Pa. 2008)

Case Study 3

Q&A

(Moderator: *Markus Lange*)

Concluding Remarks



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Thank you for your participation !!

*Looking forward to seeing you in Brussels for the
UCWG Workshop !!*

Find ICN at:

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