Seventh United Nations Conference to review the UN Set on Competition Policy

Roundtable on:

Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers

***Wednesday* 8 July, 2015**

Pharmaceutical "Reverse Payments"

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Session Overview

1. Provide background on the U.S. regulatory context and the nature of generic drugs.
2. Explain what the FTC means by a “reverse-payment” agreement.
3. Examine what’s at stake for consumers.
4. Discuss the current state of the U.S. law.
5. Highlight a recent legal development.

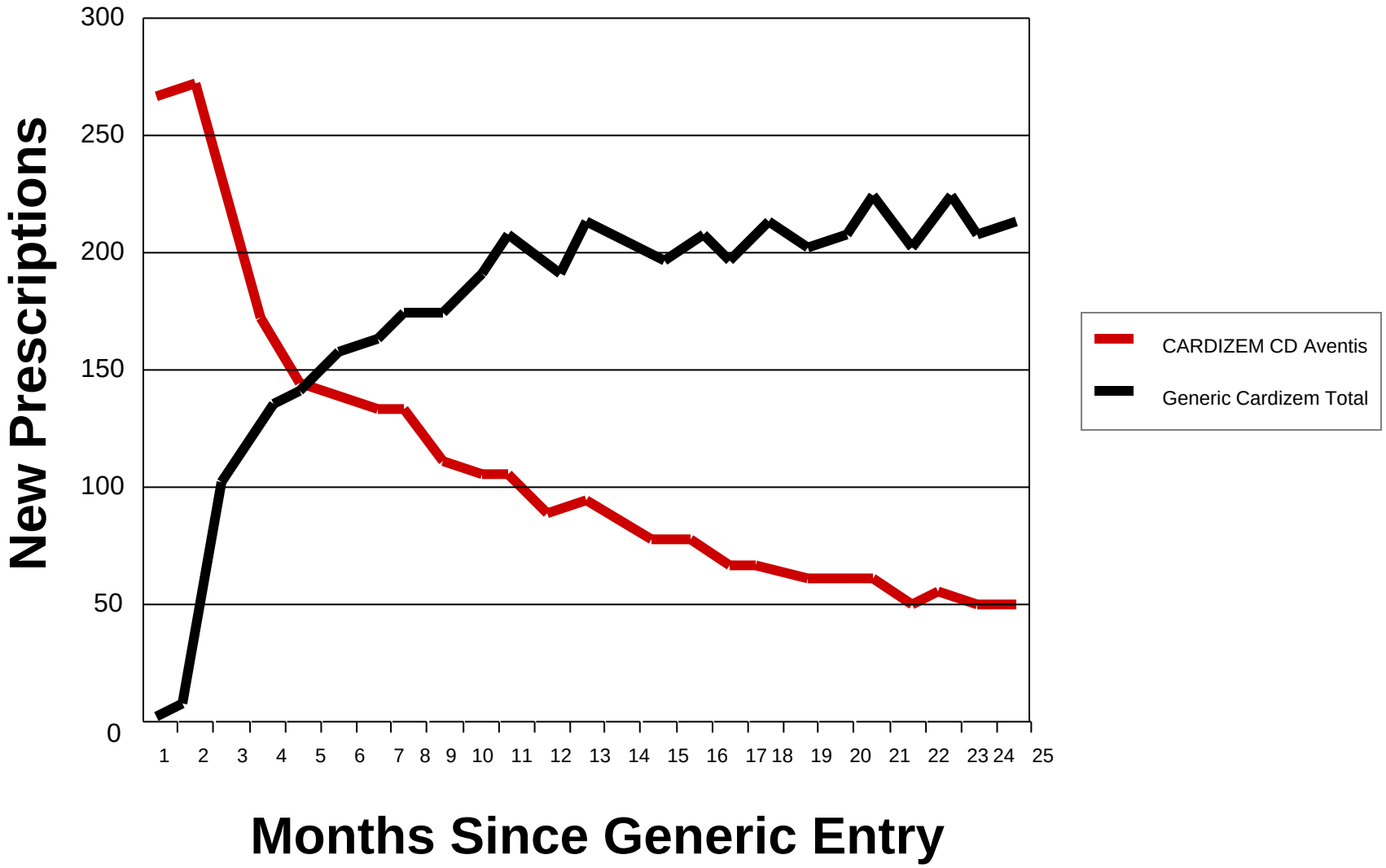
Regulatory Context: Hatch-Waxman Act (1984)

1. **Maintaining incentives to develop new drugs.**
   - E.g., patent term extensions, 5-year exclusivity for new chemical entities, 30-month stays
2. **Increasing availability of lower-priced generic drugs.**
   - Abbreviated process for FDA approval
   - Special procedures to facilitate patent challenges

Nature of Generic Drugs

- U.S. Food and Drug Administration evaluates whether generic is “therapeutically equivalent” to brand.
  1. **Bioequivalent** – comparable rate and extent of absorption of active ingredient in the body.
  2. **Pharmaceutically equivalent** – same active ingredient, dosage form, route of administration, strength or concentration.
- Under state laws, pharmacists may substitute prescriptions for a brand to a therapeutically equivalent generic.

Effects of Generic Entry: Cardizem Example



Savings from Generic Drugs

http://www.gphaonline.org/print/media/press-releases/2011/gpha-ftc's-mi...

GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

Press Release

GPhA: FTC's Misguided Policy on Patent Settlements Would Be Costly for Consumers and the Government

Contact: David Bellan 202-249-7124

Patent Settlement Ban Would Delay Generic Versions of Most Needed Drugs

Washington, D.C. (October 25, 2011)—Generic Pharmaceutical Association (GPhA) President and CEO Ralph G. Neas today issued the following response to the Federal Trade Commission's staff report regarding patent settlements.

"The FTC's flawed policy on banning patent settlements would be costly for consumers, the health care system, and state and federal governments because it would result in delaying access to lower cost generic medicines. Indeed, the FTC continues to miss the fundamental point: Patent settlements speed up the availability of less costly generic drugs and save money for everyone; banning settlements and forcing drugs makers to continue lengthy litigation with uncertain outcomes will be costly.

"The facts are indisputable. Empirical data collected over the past decade show that generic companies win just 48 percent of the drug patent cases that are litigated to conclusion. This means that generics are delayed from entering the market until the brand patent expires in more than half the cases where there is no settlement. But, when companies enter into settlement agreements, the generic drug enters the market before patent expiration in 100 percent of the cases. Patent settlements have never delayed access to the generic past the patent expiration date, but instead provide the one sure way of getting the lower cost generic to consumers and patients before the patent expires on the counterpart brand drug.

"This year alone, 16 of the 22 first-time generic medicines that will become available in the U.S. are entering the market prior to patent expiration because of a settlement agreement. Included among these new products are generic versions of Lipitor®, Plavix® and Effexor XR®, three of the most-prescribed drugs in America. If settlements were banned, as the FTC wants to do, none of these medicines would be available as generics until next year or later.

"Furthermore, a number of recent studies conducted by Jonathan Orszag, former Director of the Office of Policy and Strategic Planning and member of President Clinton's National Economic Council, and others (here, here and here) conclude that the savings projected by the FTC and the Congressional Budget Office are based on faulty assumptions.

"The generic industry supports current law that requires drug companies to submit patent settlements to the FTC and the U.S. Department of Justice for review. These government agencies are authorized to reject any patent settlement that they deem to be anti-competitive. But, as the federal courts have ruled in no fewer than five settlement decisions, it's the patent that delays the generic from coming to market, not the settlement. Settlements allow generics to

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"Thanks to the 1984 Hatch-Waxman Act, generic pharmaceuticals constitute the quintessential American success story. An independent analysis released in September 2011, shows that the use of generic prescription drugs in the U.S. has saved consumers and the health care system $931 billion over the last 10 years, $158 billion in 2010 alone. That's an astounding $3 billion in savings every week."

Reverse-Payment Agreements

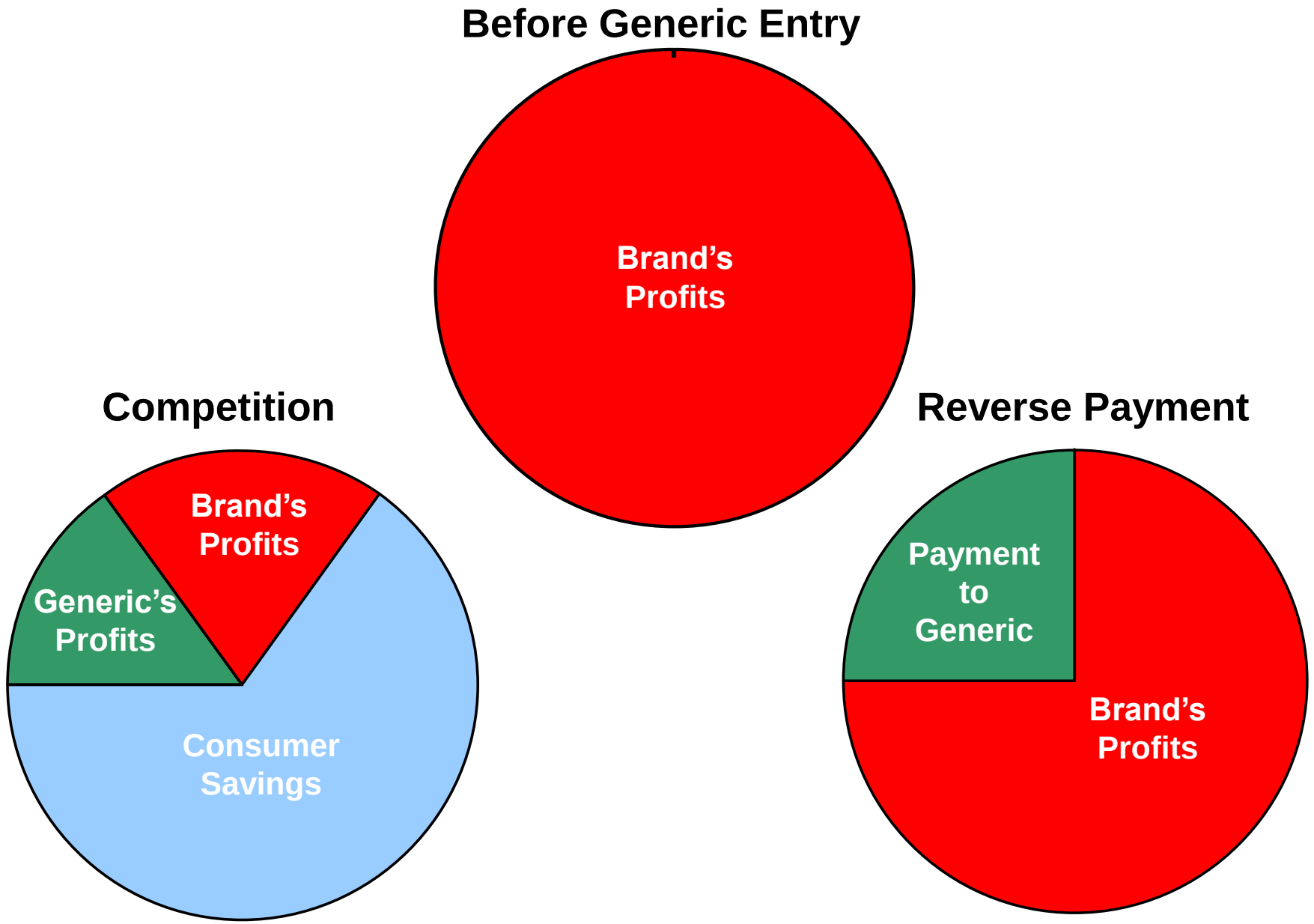
Brand and generic pharmaceutical companies in patent litigation enter an agreement whereby:

1. Generic agrees to refrain from going to market until a certain date.

2. Brand agrees to compensate the generic.

   – Possibly including: cash; IP licenses; co-promotion, co-development, manufacturing, API supply, or “no AG” agreements.

Incentives to Enter Reverse Payment



FTC Study (2010)

- FTC staff conducted a study of the cost of reverse-payment agreements to U.S. consumers and purchasers.
- Study found that agreements with compensation restrict generic entry an average of 17 months longer than agreements without.
- Study estimated that reverse-payment agreements cost U.S. consumers and purchasers $3.5 billion a year.

Overview of Final Settlements (2004-2013)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Final Settlements	14	11	28	33	66	68	113	156	140	145
Potential Pay-for-Delay	0	3	14	14	16	19	31	28	40	29
	0%	27%	50%	42%	24%	28%	27%	18%	29%	20%
Final Settlements Involving First Filers	8	5	11	16	29	32	49	54	43	41
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18	23	13
	0%	40%	82%	69%	45%	47%	53%	33%	53%	32%
Drugs Subject to Final Settlements	13	11	20	28	26	33	45	46	53	46
Drugs Subject to Potential Pay-for-Delay	0	5	7	12	10	14	19	20	28	13
	0%	45%	35%	43%	38%	42%	42%	43%	53%	28%

FTC v. Actavis (2013)

- Supreme Court rejects the "scope-of-the-patent" test adopted by three U.S. courts of appeal.
- Reverse-payment agreements must be analyzed under the antitrust "rule of reason." (p. 2237)
  - Reverse payments have the potential for "genuine adverse effects on competition." (p. 2234)
- "[P]atent and antitrust policies are both relevant in determining the 'scope of the patent monopoly' . . . that is conferred by a patent." (p. 2231)

FTC v. Cephalon

•Trial scheduled to start on June 1, 2015, but FTC announced case settlement on May 28, 2015.

- Judge approved the settlement and entered court order on June 17, 2015.
- Settlement includes Cephalon's (and its parent Teva's) agreement to pay $1.2 billion dollars into a settlement fund.
- Fund will be used to pay drug purchasers who overpaid for Provigil.

The Challenge: Balancing Patent & Competition Law

- Patent gives the right to exclude others from making, using, offering for sale, or selling an invention, through litigation, the threat of litigation, or a refusal to license.
- The “scope of the patent” does not include using monopoly profits to pay off potential competitors.
- Where an agreement among competitors is secured by sharing monopoly profits, rather than the strength of the patent, patent rights do not trump competition law.

www.ftc.gov