In re Impax Laboratories, Inc.
Docket No. 9373

Oral Argument
by Complaint Counsel
October 11, 2018

PUBLIC

ALJ findings not on appeal

- "Endo provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." *(ID 6-7)*

- The payment was unjustified *(ID 118-19)*

- Endo's sharing of its monopoly profits with Impax to eliminate the risk of competition was the relevant anticompetitive harm *(ID 100)*

FTC v. Actavis

"[P]ayment in return for staying out of the market [] simply keeps prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses."

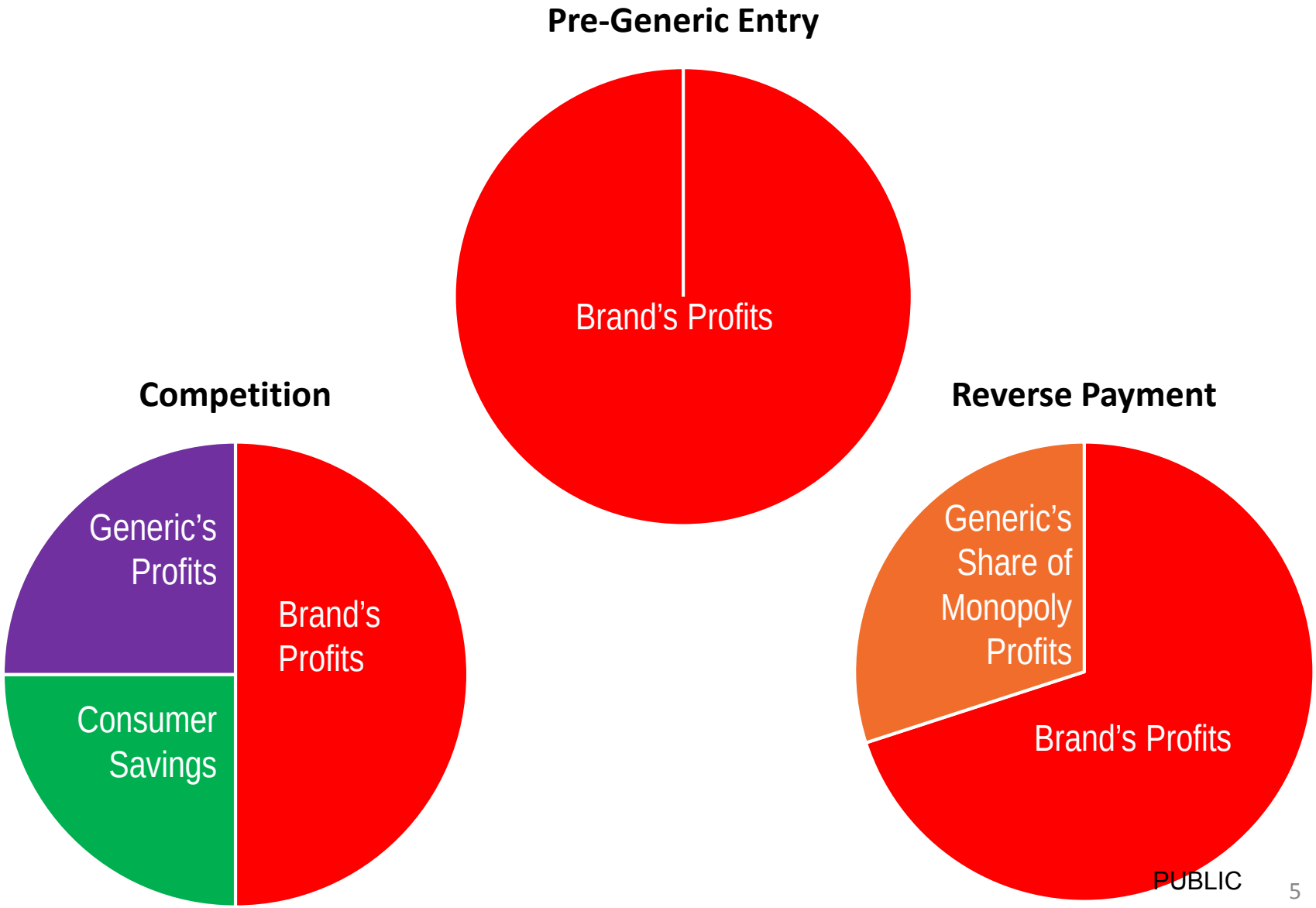
FTC v. Actavis, 570 U.S. 136, 154 (2013)

Eliminating the risk of competition is the relevant anticompetitive harm

"[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."

Actavis, 570 U.S. at 157

Consumers pay the price for reverse payments



Key events

- Dec. 2007: Impax is the first generic to challenge Endo's patents, entitling it to 180 days of generic ANDA exclusivity *(ID 14, 29)*
  - Barring forfeiture, the FDA cannot approve another ANDA application until 180 days after Impax begins marketing its generic oxymorphone ER product *(ID 30)*
- Jan. 25, 2008: Endo sues Impax for patent infringement, triggering a 30-month stay of FDA approval set to expire on June 14, 2010 *(ID 84)*

Key events

- May 13, 2010: Impax receives tentative FDA approval, with final approval expected upon expiration of 30-month stay in one month *(ID 85)*
- May 17, 2010: Endo initiates settlement discussions with Impax *(ID 22)*
- June 3, 2010: *Endo v. Impax* patent trial begins *(ID 85)*
- June 3, 2010: Impax and Endo reach agreement in principle on payment and entry date *(ID 26, 45)*
- June 5, 2010: Impax requests a license to future patents *(ID 29)*
- June 7, 2010: Impax and Endo settle the patent suit *(CCF ¶ 314; RRF ¶ 314)*
- June 14, 2010: Impax receives final FDA approval *(ID 15, 85)*
- Jan. 2013: Impax begins marketing generic oxymorphone ER *(ID 23)*

The large, unjustified reverse payment

- A No-AG provision worth between $23 and $33 million
  - "By agreeing not to compete with Impax through launching an authorized generic, Endo was promising to provide Impax with a monopoly on generic sales of Opana ER during Impax's 180-day exclusivity period, which would enable Impax to charge a higher price for generic Opana ER compared to a market that had two companies selling generic products." *(ID 106)*
- Secured by the Endo Credit
  - "[T]he intent and the design of the Endo Credit were to provide Impax with a payment approximating the profits Impax would lose if, during the two and a half year time period between the June 2010 settlement and the agreed January 2013 Impax entry date, Endo launched a reformulated version of Opana ER in such a way as to substantially eliminate the market for original Opana ER." (*ID 107)*
- Endo ultimately paid Impax $102 million under the Endo Credit *(ID 113)*

License to future patents is common

- Typical in the pharmaceutical industry *(CCF ¶ 1408; RRF ¶ 1408)*
  - Otherwise, licensing some patents while still blocking the licensee's product with others defeats the point of the license, which is to give the licensee freedom to operate *(CCF ¶ 1411; RRF ¶ 1411)*
- Impax regularly seeks such a license whenever it intended to launch and continue selling its generic product indefinitely *(CCF ¶ 282; RRF ¶ 282)*
- The Impax attorney who negotiated the license could not recall any Impax settlement with a brand company that did not include a license to future patents *(CCF ¶ 283; RRF ¶ 283)*

Defendant's burden to show the procompetitive justification of the challenged *restraint*

"An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the ***challenged term*** and showing the ***lawfulness of that term*** under the rule of reason.

Actavis, 570 U.S. at 156 (emphasis added)

Defendant's burden to show the procompetitive justification of the challenged *restraint*

A defendant must "articulate the specific link between the challenged restraint and the purported justification."

In re Polygram Holding, Inc., 136 F.T.C. 310, 347 (July 24, 2003), *aff'd* 416 F.3d 29 (D.C. Cir. 2005)

Defendant's burden to show the procompetitive justification of the challenged *restraint*

"An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint."

Areeda ¶ 1505a

Defendant's burden to show the procompetitive justification of the challenged *restraint*

"If the defendants have a procompetitive justification, it must have been a motivating factor for the restraint . . . ."

Herbert Hovenkamp, *The Rule of Reason*, 70 Fla. L. Rev. 81, 107 (2018)

No dispute that the license benefits did not flow from the use of the payment to eliminate the risk of competition

- "The 'restraint' in a reverse payment settlement agreement is . . . the use of the payment to restrain potential generic competition." *(ID 99)*
- Here, the challenged restraint is Impax's agreement not to enter until January 2013 in exchange for a large, unjustified payment
- Impax has never asserted, and the Initial Decision did not find, any connection between the challenged restraint and the license to future patents

The challenged term cannot be justified by other provisions in a broader agreement

The legitimate procompetitive objective of promoting amateurism could not justify the "specific restraints on football telecasts" when the challenged term was "not even arguably tailored to serve such an interest."

NCAA v. Bd. of Regents,
468 U.S. 85, 117-19 (1984)

The challenged term cannot be justified by other provisions in a broader agreement

"[N]ebulous 'teamwork' efficiencies" cannot justify horizontal price fixing where "NTSP has no theory as to how its proffered procompetitive effects . . . result from or are in any way connected to" challenged pricing practices.

N. Tex. Specialty Physicians v. FTC,
528 F.3d 346, 369 (5th Cir. 2008)

The challenged term cannot be justified by other provisions in a broader agreement

Defendant failed to justify the challenged restraint of a single provision within the society's code of ethics barring members from discussing fees prior to being hired.

Nat'l Soc'y of Prof'l Eng'rs v. United States, 435 U.S. 679, 684, 693 (1978)

The challenged term cannot be justified by other provisions in a broader agreement

The "efficiency-enhancing joint activity [of] . . . the creation and operation of the MLS [multiple listing service]" could not justify the challenged restraint of three MLS rules restricting the availability of information because "the restriction was [not] reasonably necessary to achieve that end."

In re Realcomp II Ltd., 2007 WL 6936319, at *27, *29 (F.T.C. Oct. 30, 2009)

The challenged term cannot be justified by other provisions in a broader agreement

"[T]he essential inquiry remains the same – whether or not the challenged restraint [of one section within the association's broader ethics code] enhances competition."

Cal. Dental Ass'n v. FTC,
526 U.S. 756, 780 (1999)

Elimination of the risk of competition is not a "largely theoretical" harm *(ID 156)*

- "The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."

Actavis, 570 U.S. at 157

- Antitrust law "does not condone the purchase of protection from *uncertain* competition any more than it condones the elimination of *actual* competition."

Areeda ¶ 2030b (emphasis added)

The FTC and private plaintiffs "stand in different shoes"

"Private plaintiffs and the FTC as government enforcer stand in different shoes . . . . 'The interest of private plaintiffs is to remediate an injury they have suffered or may suffer. The interest of the government is to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause.'"

In re Nexium (Esomeprazole) Antitrust Litig.,
842 F.3d 34, 60 (1st Cir. 2016)
(quoting FTC *Nexium* Amicus Brief)

Violation established by proving payment to eliminate the risk of competition, not by establishing "actual delay"

"The jury's 'yes' answers to Questions 2 and 3 (large and unjustified payment with anticompetitive effects) confirm its finding that some antitrust violation resulted from the [] settlement. Question 4, by contrast, inquires whether these private plaintiffs have suffered an 'injury of the type the antitrust laws were intended to prevent' by asking whether Ranbaxy . . . [w]ould have launched a generic earlier . . . [b]ut for the antitrust violation found in Question 3."

In re Nexium (Esomeprazole) Antitrust Litig.,
842 F.3d 34, 60 (1st Cir. 2016)

Violation established by proving payment to eliminate the risk of competition, not by establishing "actual delay"

- The FTC does not have "to show that the settlements *actually* delayed entry. That may well be true, but that is not what the FTC needs to prove in order to show an antitrust harm . . . . [T]he FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market."

  In re Androgel Antitrust Litig. (No. II)., 2018 WL 2984873, at *10 (N.D. Ga. June 14, 2018) (emphasis in original)

- "[T]he actual validity of the patent is irrelevant to the question of whether the reverse payments violated the antitrust laws. Paying the Generics to stay out of the market for the purpose of avoiding the risk of competition is an antitrust harm, *regardless* of whether or not the patent is actually valid and infringed. Put another way, even if the patent was valid and infringed, the Defendants took away the opportunity to know that for sure by settling before the end of the litigation. If they did so for the purpose of avoiding the risk that a court would find otherwise, however small a risk they considered it to be, that is an antitrust violation under *Actavis*."

  Id. at *11 (emphasis in original)

Impax could have obtained the license without the reverse payment

"[T]he fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point. Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement."

Actavis, 570 U.S. at 158

Relevant product market is limited to products exhibiting cross elasticity of demand

"For every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose cross-elasticities of demand are small."

Times-Picayune Pub. Co. v. United States, 345 U.S. 594, 612 n.31 (1953)

Relevant product market is limited to products exhibiting cross elasticity of demand

Cross elasticity "measures the responsiveness of the demand for one product to changes in the price of a different product."

Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 438 n. 6 (3d Cir. 1997)

Relevant product market is limited to products exhibiting cross elasticity of demand

"[I]f competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price."

In re Aggrenox Antitrust Litig.,
199 F. Supp. 3d 662, 667 (D. Conn. 2016)

No evidence of cross elasticity of demand between Opana ER and non-oxymorphone LAOs

- Both Impax and Endo viewed Opana ER and generic oxymorphone ER as ***uniquely close*** economic substitutes *(CCF ¶¶ 585-627)*
- The switching rate among all LAOs for any reason is only 3% *(CCRF ¶¶ 747, 749)*
  - Clinical considerations – and not small price changes – drive LAO prescribing patterns *(CCRB at 27)*
  - Impax's own medical expert testified that he would not generally be aware of an LAO price change unless it was "dramatic" *(CCF ¶ 565, CCRF ¶ 894)*
- Promotional efforts to build market demand through product differentiation – and not price – ***builds*** market power and makes switching for price less likely *(CCRF ¶¶ 878-98; CCF ¶¶ 726-36, 769, 781-83; CCRB at 29)*
- Generic oxymorphone ER could not have driven down prices and taken substantial sales upon entry in January 2013 if Opana ER prices were already competed down to a competitive level *(CCF ¶¶ 630, 636-37; CCRB at 25-26)*

Actavis on market power

"[W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At least, the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay 'large sums' to induce 'others to stay out of its market.'"

Actavis, 570 U.S. at 157
(internal citations omitted)

Notice of Electronic Service

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