UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Federal Trade Commission,

Plaintiff,

v. Civil No. 08-6379 (JNE/JJG)

Lundbeck, Inc.,

Defendant.

ORDER

State of Minnesota,

Plaintiff,

v. Civil No. 08-6381 (JNE/JJG)

Lundbeck, Inc.,

Defendant.

Kyle Chadwick, Esq., and Philip Eisenstat, Esq., Federal Trade Commission, appeared for Plaintiff Federal Trade Commission.

Alan Gilbert, Esq., and Gabriel Gervey, Esq., Office of the Minnesota Attorney General, appeared for Plaintiff State of Minnesota.

Alfred Pfeiffer, Esq., Sean Berkowitz, Esq., and Karen Silverman, Esq., Latham & Watkins LLP, and Steve Gaskins, Esq., Flynn, Gaskins & Bennett LLP, appeared for Defendant Lundbeck, Inc.

After Lundbeck, Inc., had acquired the only drugs approved by the Food and Drug Administration (FDA) to treat patent ductus arteriosus (PDA), the Federal Trade Commission (FTC) and the State of Minnesota brought these actions against Lundbeck to redress alleged violations of antitrust laws by Lundbeck.[1] The cases are before the Court on Lundbeck's

[1] Ovation Pharmaceuticals, Inc., acquired the drugs and later became Lundbeck, Inc. For present purposes, the Court uses Lundbeck to refer to Ovation Pharmaceuticals and Lundbeck.

motions for summary judgment. For the reasons set forth below, the Court denies the motions. Notwithstanding the fact that the parties filed their motion papers under seal, the parties spoke freely in open court at the motion hearing, and this Order is not sealed.

I. BACKGROUND

PDA, a life-threatening condition that primarily affects premature infants, occurs when a duct between heart chambers fails to close soon after birth. Occasionally, PDA resolves on its own. Should medical treatment be required, the options consist of drug administration or surgery. The former is ordinarily the preferred course of treatment.

In August 2005, Lundbeck acquired Indocin (injectable indomethacin) from Merck & Co. At that time, Indocin was the only drug available to treat PDA in the United States. In September 2005, Lundbeck raised the price from $26 per vial to $36 per vial. A normal course of treatment is three vials.

Earlier that year, Lundbeck had learned of another drug to treat PDA, injectable ibuprofen. Though not approved to treat PDA in the United States at that time, injectable ibuprofen was used in Europe to treat PDA. On January 18, 2006, Lundbeck acquired the rights to NeoProfen (injectable ibuprofen) from Abbott Laboratories, Inc. Two days later, Lundbeck increased the price of Indocin from $36 per vial to $500 per vial.

In April 2006, the FDA approved NeoProfen for use in the United States to treat PDA. In July 2006, Lundbeck began sales of NeoProfen at $483 per vial. As with Indocin, a course of treatment is three vials.

Although the increased price of Indocin sparked interest from generic manufacturers, no generic manufacturer of injectable indomethacin has yet entered the market. Lundbeck claims

that generic entry is now imminent. NeoProfen is subject to the protections of the Orphan Drug Act.

The FTC claims that Lundbeck violated Section 7 of the Clayton Act, 15 U.S.C. § 18 (2006), and Section 5 of the FTC Act, 15 U.S.C. § 45 (2006), by acquiring the rights to NeoProfen and that Lundbeck violated Section 5 of the FTC Act by willfully maintaining its monopoly power in the market for the sale of drugs for the treatment of PDA in the United States. Minnesota claims that Lundbeck violated Section 7 of the Clayton Act by acquiring the rights to NeoProfen, that Lundbeck violated Section 2 of the Sherman Act, 15 U.S.C. § 2 (2006), by willfully maintaining its monopoly power in the market for the sale of drugs for the treatment of PDA in the United States, and that Lundbeck's conduct violated state law. The cases are before the Court on Lundbeck's motions for summary judgment.

II. DISCUSSION

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The movant "bears the initial responsibility of informing the district court of the basis for its motion," and must identify "those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the movant satisfies its burden, the party opposing the motion must respond by submitting evidentiary materials that "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2); *see Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In determining whether summary judgment is appropriate, a court must look at the record and any inferences to be drawn

from it in the light most favorable to the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Section 7 of the Clayton Act "is primarily aimed at arresting, at their incipiency, acquisitions and mergers that substantially lessen competition or tend to create a monopoly." *Midwestern Mach., Inc. v. Nw. Airlines, Inc.*, 167 F.3d 439, 442 (8th Cir. 1999); *see* 15 U.S.C. § 18. Section 2 of the Sherman Act makes it an offense to "monopolize . . . any part of the trade or commerce among the several States." 15 U.S.C. § 2; *see Rambus Inc. v. FTC*, 522 F.3d 456, 462 (D.C. Cir. 2008). To establish their monopolization claims, the FTC and Minnesota must demonstrate that Lundbeck possessed monopoly power in the relevant market and that Lundbeck "willfully acquired or maintained this monopoly power by anticompetitive conduct as opposed to gaining that power as a result 'of a superior product, business acumen, or historical accident.'" *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1060 (8th Cir. 2000) (quoting *United States v. Grinnell*, 384 U.S. 563, 570-71 (1966)). Monopoly power is the power to control prices or to exclude competition. *Id.*

Lundbeck contends that Indocin and NeoProfen are not in the same market. *See HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547 (8th Cir. 2007) (stating that plaintiff bears the burden of proving the relevant product market). "The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962); *see HDC Med.*, 474 F.3d at 547. Lundbeck maintains that doctors distinguish Indocin from NeoProfen based on clinical and safety attributes and that doctors do not switch between the drugs based on price. The FTC and Minnesota respond that Indocin and NeoProfen treat the same medical condition in the same patient population, that the differences between the drugs are

minor, that a hospital's pharmacy and therapeutics committee determines which drugs appear in the hospital's formulary, that a significant number of hospitals stock either Indocin or NeoProfen but not both, and that hospitals consider price when purchasing drugs. The Court's review of the record reveals that the FTC and Minnesota have raised a genuine issue of material fact as to whether Indocin and NeoProfen constitute a market for drugs that treat PDA.[2]

Lundbeck next argues that it has no market power because the entry of a generic manufacturer of indomethacin is imminent. The FTC and Minnesota respond that a generic manufacturer of indomethacin has not entered the market since Lundbeck's January 2006 price increase and that, if relevant, assessments prepared for Lundbeck indicated that entry of a generic manufacturer would take as long as forty-two months from the price increase. "[M]onopoly power may be inferred from a firm's possession of a dominant share of a relevant market that is protected by entry barriers. 'Entry barriers' are factors (such as certain regulatory requirements) that prevent new rivals from timely responding to an increase in price above the competitive level." *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (citation omitted). The parties disagree about when the relevant monopoly period begins and how long it runs—Lundbeck claims that the FTC and Minnesota are seeking a strict, two-year period. These legal issues need not be decided at this time. The Court does, however, reject Lundbeck's suggestion that the time begins to run from the date of oral argument on its motions for summary judgment.[3] Viewing the record in the light most favorable to the FTC and Minnesota, the Court concludes

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[2] Lundbeck contends that the FTC's and Minnesota's alleged failure to present evidence of cross-price elasticity mandates summary judgment in its favor. The Court rejects this argument. *See U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 995 (11th Cir. 1993); *Syufy Enters. v. Am. Multicinema, Inc.*, 793 F.2d 990, 995 (9th Cir. 1986); *Knutson v. Daily Review, Inc.*, 548 F.2d 795, 804 (9th Cir. 1976); *JamSports & Entm't, LLC v. Paradama Prods., Inc.*, 336 F. Supp. 2d 824, 841 (N.D. Ill. 2004).

[3] Oral argument on Lundbeck's motions took place on July 17, 2009.

that a reasonable finder of fact could conclude that Lundbeck possessed monopoly power. *Cf. Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 500-01 (2d Cir. 2004).

Moreover, the parties are not in agreement that generic indomethacin will be in the market this calendar year. The FTC and Minnesota point to the difficulties of manufacturing, including Lundbeck's own efforts and the time that has elapsed without a generic. Lundbeck cites deposition testimony indicating that a generic is ready but for problems with the way the drug looks. Nothing in the record firmly establishes how difficult the appearance problem might be to resolve.

Lundbeck also contends that it set Indocin's price without regard to the acquisition of NeoProfen. Viewing the record in the light most favorable to the FTC and Minnesota, the Court concludes that a reasonable finder of fact could find that Lundbeck's increase of Indocin's price and acquisition of NeoProfen were not independent.

Finally, Lundbeck raised several arguments with regard to the propriety of the remedies sought by the FTC and Minnesota. The FTC and Minnesota contend that Lundbeck's arguments are premature. The Court declines to consider Lundbeck's arguments at this time. If necessary, the Court will grant appropriate relief at trial.

The Court sets these cases for trial on Monday, December 7, 2009. In case of unavoidable conflicts, counsel shall immediately contact the undersigned's Calendar Clerk, Sheri Frette. A pretrial order will issue in due course.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Lundbeck's motions for summary judgment [Docket No. 85 in Civil No. 08-6379; Docket No. 67 in Civil No. 08-6381] are DENIED.

2. These cases are set for trial on December 7, 2009.

Dated: July 21, 2009

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge