

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANESTA AG, APTALIS PHARMATECH, INC.)	
and IVAX INTERNATIONAL GMBH,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 08-889-SLR
)	
MYLAN PHARMACEUTICALS, INC. and)	
MYLAN INC.,)	
)	
Defendants.)	

MEMORANDUM ORDER

At Wilmington this 14th day of August, 2014, having reviewed defendants' motions for partial summary judgment and to exclude, and the papers submitted in connection therewith;

IT IS ORDERED¹ that the motion for partial summary judgment of no lost profits (D.I. 351) is denied, the motion for partial summary judgment of no willfulness (D.I. 352) is granted, and the motions to exclude (D.I. 357, 360) are denied, for the reasons that follow:

1. **Background.** This case arises from defendants' at risk launch of their generic versions of plaintiffs' patented Amrix® products. More specifically, on May 12, 2011, following a bench trial, I issued an opinion finding, *inter alia*, that defendants'

¹I concluded that the issues presented were not so complex as to require oral argument. Therefore, the August 19, 2014 proceeding will be limited to those issues raised in the joint pretrial order.

generic products infringed the patents-in-suit,² but that the asserted claims were obvious. *In re Cyclobenzaprine*, 794 F. Supp. 2d 517, 544 (D. Del. 2011). The next day, on May 13, 2011, defendants began selling their generic products. On May 20, 2011, I granted plaintiffs' motion for a temporary restraining order, thereby halting defendants' sales; I issued a preliminary injunction order on May 24, 2011 that prohibited defendants from selling their generic products pending appeal to the Federal Circuit. (Civ. No. 09-MD-2118, D.I. 290) The injunction order required defendants to "take all reasonable steps to recall" their generic products from the market. (*Id.* at 1-2)

2. On May 25, 2011, defendants filed an emergency motion in the Federal Circuit to stay the injunction, which was granted by the Federal Circuit pending review of the briefing on the stay. *In re Cyclobenzaprine*, 424 Fed. App'x 952 (Fed. Cir. 2011). Defendants began selling their generic products again. On July 7, 2011, the Federal Circuit ruled on the merits of the stay motion, denying it in part (prohibiting the sale of defendants' generic products pending appeal) and granting it in part (staying the recall provision pending resolution of the appeal). *In re Cyclobenzaprine*, 449 Fed. App'x 35 (Fed. Cir. 2011).

3. On April 16, 2012, the Federal Circuit reversed the finding of invalidity and dismissed defendants' appeal of the preliminary injunction. *In re Cyclobenzaprine*, 676 F.3d 1063 (Fed. Cir. 2012). On April 4, 2013, the court entered a stipulated dismissal of counterclaims, final judgment and permanent injunction with no recall requirement. (Civ. No. 09-MD-2118, D.I. 429)

²U.S. Patent Nos. 7,387,793 and 7,544,372.

4. **Standard of review.** “The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 574, 586 n.10 (1986). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motions only), admissions, interrogatory answers, or other materials,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 415 U.S. at 587 (internal quotation marks omitted). The court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

5. To defeat a motion for summary judgment, the non-moving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 415 U.S. at 586-87; *see also Podohnik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of

a genuine issue”) (internal quotation marks omitted). Although the “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment,” a factual dispute is genuine where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 411 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 411 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial”).

6. **Willfulness.** I agree with defendants that, although their launch was at risk, it was not illegal when it took place and, absent a directive from the Federal Circuit to recall their generic products, defendants had no legal obligation to do so. Having committed no illegalities vis a vis the launch, and willfulness generally being irrelevant in the context of ANDA cases, I grant defendants’ motion for partial summary judgment in this regard. (D.I. 352)

7. **Lost profits.** Defendants argue that plaintiffs should be precluded from claiming lost profits because their expert, Dr. Maness, failed to consider price elasticity in his lost profits analysis. When asked at his deposition about price elasticity, Dr. Maness explained that price elasticity under the circumstances at bar was “relatively modest” and “offset” by other factors. (D.I. 370 at 10) Defendants maintain that such an opinion is insufficient substantively and procedurally.

8. With respect to the substantive aspects of the dispute, I start with an analysis of defendants' primary case, *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336 (Fed. Cir. 2001). In that case, the Federal Circuit acknowledged that it "has affirmed lost profit awards based on a wide variety of reconstruction theories where the patentee has presented reliable economic evidence of 'but for' causation." *Id.* at 1355. The Federal Circuit went on to affirm a lost profits award in *Crystal* because "the record contain[ed] sufficient evidence to support the jury's lost profit award for Crystal's market share based on market segmentation, even discounting [the] expert opinion" offered by Crystal. *Id.* at 1356. The issue of price elasticity was not addressed in connection with the Court's lost profits analysis.

9. In its discussion of price erosion, the Federal Circuit concluded that the record did not contain sufficient evidence "to show the reaction of the market if, 'but for' infringement, Crystal would have tried to charge . . . more" for its product, based on the general principle that "consumers will **almost always** purchase fewer units of a product at a higher price than at a lower price." *Id.* at 1359 (emphasis added). Based on its understanding of economics as applied to the facts of the case before it, the Court went on to explain that, in order to establish "but for" causation for lost profits due to lost sales or for price erosion, "a patentee must produce credible economic evidence to show the decrease in sales, if any, that would have occurred at the higher hypothetical price." *Id.* Because Crystal presented "no evidence of the elasticity of demand" in the proper market, the Court found that Crystal had not made a showing of "but for" causation of price erosion.

10. The lesson I take away from *Crystal* is not that the Federal Circuit has a rigid formula for judging economic analyses, but that its demand for a "credible economic analysis" can be met by a variety of evidence - both fact and expert - depending on the facts of the case and the nature of the markets at issue. Therefore, I will not preclude the presentation of a lost profits analysis by plaintiffs. In this regard, plaintiffs have presented plausible evidence that the case at bar presents an unusually complex set of facts vis a vis calculating lost profits, due in part to the unique nature of the relevant market³ and due in part to the brevity of the damages period. Having rejected defendants' proposition that there are rigid standards applicable to every case, I decline to take the issue of lost profits damages away from the jury.

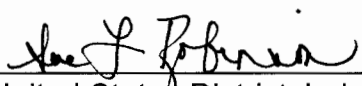
11. With respect to defendants' procedural concerns, I agree that the issue of price elasticity was not discussed by Dr. Maness in his expert report. I have held that he was not required *per se* to do so. Moreover, the issue was apparently addressed at his deposition, and defendants have his best thoughts through that discovery tool on why he did not consider price elasticity in his analysis. Dr. Maness will be limited to the evidence of record.

12. I decline to exclude Dr. Maness' lost profits analysis based on defendants' now rejected argument that price elasticity is always in play; that is fodder for cross

³As explained by plaintiffs, the prices patients pay for prescription drugs like Amrix® (i.e., patient copays) are determined by insurance company formularies. If the formulary position of a drug does not change during the relevant time period, the price patients pay for that drug does not change, even if the price to wholesalers and pharmacies increases. If the price patients pay is the relevant price for evaluating the elasticity of demand, then the market at issue may be that "rare" inelastic market, a fact for the jury to determine. (D.I. 370 at 11; see *Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1379 (Fed. Cir. 2003)).

examination. Therefore, both defendants' motions for partial summary judgment (D.I. 351) and to exclude the expert testimony of Dr. Maness (D.I. 360) are denied.

13. Defendants' motion to exclude the expert testimony of Dr. Steiner (D.I. 357) likewise is denied, as his clinical expertise relating to the use of Amrix® and other SMR products was recognized in the liability phase of the trial, *see, e.g., In re Cyclobenzaprine*, 676 F.3d at 1083, and is relevant to the damages phase as well.



United States District Judge