IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

ELORAC, INC.,)
Plaintiff,))
v.) Case No. 14 C 1859
)
SANOFI-AVENTIS CANADA, INC.,) Judge Jorge L. Alonso
Defendant.)

MEMORANDUM OPINION AND ORDER

Plaintiff Elorac, Inc. ("Elorac") brings this bad faith breach of contract action against defendant Sanofi-Aventis Canada, Inc. ("Sanofi"), alleging that Sanofi willfully breached a license agreement requiring it to make reasonable efforts to commercialize Elorac's Civamide cream pharmaceutical product, known as Zuacta, and pay Elorac royalties based on its sales. Following discovery, each party has moved to exclude the other's experts. For the following reasons, the motions are granted in part and denied in part.

I. BACKGROUND

Elorac is a pharmaceutical company that generally focuses on developing pharmaceutical products for the treatment of skin diseases and conditions. Winston Laboratories, Inc. ("Winston"), was a related company that developed pharmaceutical products for the relief and management of pain, including pain due to osteoarthritis. In particular, Winston developed a proprietary compound known as Civamide to treat the symptoms of osteoarthritis; Elorac later acquired Winston's interest in the product.

On October 20, 2008, Winston and Sanofi entered into a license agreement, in which Winston granted Sanofi an exclusive license to "use and commercialize" its Civamide cream

product ("the Product" or "Civamide Cream" 1) in Canada, and Sanofi agreed to "use Commercially Reasonable Efforts to Commercialize" the Product and to "sell and/or promote the Product in a manner consistent with sanofi-aventis' past marketing and sales practices or the customary practices within the industry." (2d Am. Compl., Ex. A, §§ 6.1, 6.2, ECF No. 222.) The license agreement defined the term "commercialize" to mean "to sell, offer for sale, import, export, transport, register, distribute, promote and market, together with other activities typically associated with maximizing the market penetration, profit margins and commercialization of a pharmaceutical product." (*Id.*, Ex. A, § 1.8.) The license agreement defined "Commercially Reasonable Efforts" to mean

efforts consistent with those generally utilized by companies of a similar size for their own internally developed pharmaceutical products of similar market potential, at a similar stage of their product life taking into account the existence of other competitive products in the marketplace or under development, the proprietary position of the product, the regulatory structure involved, the anticipated profitability of the product and other relevant factors. It is understood that such product potential may change from time to time based upon changing scientific, business and marketing and return on investment considerations.

(*Id.*, Ex. A, § 1.9.) The license agreement also required Sanofi to pay Winston royalties of 12% of all net sales of the Product, as well as lump-sum milestone payments if net sales reached certain levels. (*Id.*, Ex. A, §§ 7.6, 7.7.) After entering into the license agreement, the parties proceeded with efforts to secure regulatory approval to market the Product in Canada.

In May 2010, as the process of obtaining regulatory approval was drawing to a close, Sanofi began discussions with another pharmaceutical company, Valeant International ("Valeant"), about a sublicensing arrangement that would allow Valeant to take over Sanofi's obligations under the license agreement. While these discussions proceeded, Sanofi halted or

2

_

¹ The parties initially planned to launch the Product under the name "Civanex," but they ultimately launched it under the name "Zuacta." The Court will refer to it generically as "the Product" or "Civamide Cream" to avoid the possibility of creating confusion by seeming to refer to a specific time frame by using either "Civanex" or "Zuacta."

slowed most of its efforts to plan and prepare for the launch of the Product, expecting Valeant or another third party to take over those efforts. (*See id.* ¶ 73; *see generally id.* ¶¶ 59-73.)

The Product received Canadian regulatory approval on July 15, 2010, although it was approved only as an adjunctive therapy for patients already on oral anti-inflammatories (specifically, NSAIDs or COX-2 inhibitors) and only for a maximum time frame of three months, a more limited "indication" (i.e., recognized use as a treatment for a particular disease or medical condition) than originally sought. With regulatory approval, an eight-year data protection period began to run, during which generic products are barred by law from competing with the Product. Winston expected Sanofi to take full advantage of the data protection period by beginning to sell and promote the Product as soon as it secured regulatory approval, but it learned in early August 2010 that Sanofi intended to "out-license" the product to Valeant or another partner. (Id. ¶ 68.) Winston immediately advised Sanofi that it was displeased with this decision, and it continued to raise concerns with Sanofi's performance over the ensuing months. Sanofi attempted to address Winston's concerns in a December 8, 2010 conference call, assuring Winston that it would move quickly to conclude an agreement with Valeant or another partner, but it did not ultimately enter into a sublicensing agreement with Valeant until July 18, 2011, more than a year after the Product had received regulatory approval. Valeant subsequently hired a contract sales force from Vanguard Pharma Canada to sell and promote the Product.

The Product sold poorly, at least relative to the parties' initial expectations. Prior to the execution of the license agreement, Sanofi had represented to Winston that in the worst-case scenario, the Product would reach peak yearly sales of \$11.2 million (Canadian dollars) ("CAD"). (*Id.* ¶ 36.) Since the 2011 launch, total sales of the Product have been

On October 11, 2012, Winston transferred all rights and interests in the Product to Elorac, and assigned all of Winston's rights and interests under the license agreement to Elorac.² Elorac brought this suit, asserting that Sanofi's efforts to commercialize the Product have been unsatisfactory and Sanofi's failure to make "Commercially Reasonable Efforts" to sell and promote the product have caused the Product's low sales figures. Elorac also claims that Sanofi failed to properly calculate and pay royalties due under the license agreement.

Both parties have tendered expert witnesses, and each party has filed five separate motions to bar the other's experts from testifying.

II. LEGAL STANDARDS

"The admission of expert testimony is governed by Federal Rule of Evidence 702 and the principles outlined in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (extending application of *Daubert* factors to engineers and other non-scientific experts)." *Bielskis v. Louisville Ladder*, *Inc.*, 663 F.3d 887, 893 (7th Cir. 2011) (internal citations altered). Federal Rule of Evidence 702 provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

The rule imposes "three basic prerequisites." *See Weinstein's Federal Evidence* § 702.02[3]. "Under Federal Rule of Evidence 702 and *Daubert*, the district court must . . . determine whether

² The Court will occasionally refer to Winston and Elorac collectively as "plaintiff" where it might be confusing or cumbersome to specify and where it makes no difference which entity is meant, given their identical interests in this case.

the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue." *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010) (quoting *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007)). In assessing reliability, the district court must ensure that the proffered expert testimony is "well-grounded in methods and procedures of science," and it should consider factors such as "(1) whether the [expert's] theory can be and has been verified by the scientific method through testing; (2) whether the theory has been subjected to peer review; (3) the known or potential rate of error; and (4) the general acceptance of the theory in the scientific community." *Chapman v. Maytag Corp.*, 297 F.3d 682, 687 (7th Cir. 2002).

III. DEFENDANT'S MOTIONS TO EXCLUDE PLAINTIFF'S EXPERTS

A. Robert E. Baldini

Sanofi moves to exclude the testimony of Robert E. Baldini, a former pharmaceutical executive with a background in marketing who has been working in the pharmaceutical industry since 1957. He started his career working in marketing for Pfizer; he spent twenty years working in marketing for Ciba-Geigy; he spent thirteen years at Key Pharmaceuticals, at one point serving as the company's president; he spent eleven years at Kos Pharmaceuticals, Inc., at one point serving as Chief Sales & Marketing Officer; and since 2007, he has served as a consultant in corporate development at Arisaph Pharmaceuticals, where he is assisting with plans to launch and market two new products that are currently still in development. In his expert report, he analyzes whether Sanofi "acted in accordance with the pharmaceutical industry's standard customs and practices in . . . marketing and commercializing the Product," and he opines that Sanofi's effort to market the Product did not meet industry standards of commercial

reasonableness. (Def.'s Mem. in Supp. of Mot. to Exclude Testimony of Robert E. Baldini, Ex. B, Baldini Report at 1, ECF No. 260-1 at 134.)

Sanofi argues that Mr. Baldini's testimony should be excluded because, having been based in the United States for his entire career, he is insufficiently qualified to render a reliable opinion on the commercialization of pharmaceutical products in Canada in the twenty-first century. Further, according to Sanofi, Mr. Baldini's opinion is not reliable because, to the extent he relies on his general experience, he does not explain how his experience leads to his conclusion in the particular factual circumstances of this case; indeed, Sanofi argues, Mr. Baldini does not seem to have a firm grasp of the facts of this case. Additionally, according to Sanofi, Mr. Baldini's opinions are stated in prejudicial and inflammatory terms.

1. Familiarity with Canadian Pharmaceutical Marketing

Importantly, Sanofi does *not* argue that Mr. Baldini may not rely on his experience as the basis for his opinion on the standard for commercially reasonable sales and marketing efforts in the pharmaceutical industry, nor could it; Sanofi itself argues in this same round of *Daubert* motions that its own experts should be permitted to testify based on their experience, and it is true that under *Daubert* and the Federal Rules of Evidence, experience may serve as the basis for an expert opinion. *See Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) ("An expert's testimony is not unreliable simply because it is founded on his experience rather than on data; indeed, Rule 702 allows a witness to be 'qualified as an expert by knowledge, skill, *experience*, training, or education.'"). It is clear that Mr. Baldini has accumulated vast marketing experience over six decades in the pharmaceutical industry, and his assessment of Sanofi's marketing effort is based on that experience. However, Sanofi argues, a number of important factors distinguish pharmaceutical marketing in Canada from

pharmaceutical marketing in the United States, including stricter advertising restrictions, a second official language, a different prescription drug reimbursement system, and a different non-prescription drug landscape. According to Sanofi, Mr. Baldini is not sufficiently sensitive to these differences.

Elorac responds that despite the fact that Mr. Baldini has always been based in the United States, he worked for companies that sold pharmaceuticals in Canada and he has personal experience with marketing pharmaceutical products in Canada, having traveled there in connection with his work and been responsible for marketing conducted there and elsewhere in the world. Further, Elorac argues, his opinion is ultimately based on expertise that includes familiarity with generally applicable fundamentals of pharmaceutical sales and marketing, common to both Canada and the United States, and Sanofi's critique therefore goes to the weight his opinion should be given rather than its admissibility.

The Court agrees with Elorac that Sanofi's critique goes to weight rather than admissibility. While Mr. Baldini may not be as intimately familiar with the Canadian market as he is with the U.S. market, he has significant experience with the marketing of products in Canada over the course of his career, particularly the Theo-Dur and Claritin products during his time at Key Pharmaceuticals. (*See* Elorac Resp. Br. (Baldini) at 17, ECF No. 292.) His experience taught Mr. Baldini not only industry-standard methods for marketing pharmaceuticals, but also that "the Canadian pharmaceutical industry, as far as marketing a product, is [not] so different" from the United States pharmaceutical industry, based in part on "[his] own recollections of the Canadian market, things that we used to do up in Canada that we still do here in the United States." (*Id.* at 19 (quoting Baldini Dep., Ex. A at 127:19-128:3).) If Mr. Baldini may rely on his experience as the basis for his opinion on the applicable standard of

commercial reasonableness, he may also rely on it as the basis for his opinion that that same standard applies to the marketing of pharmaceuticals in Canada.

As for the specific factors that Sanofi claims differentiate the pharmaceutical market in Canada from others, Sanofi does not sufficiently explain how these factors make the Canadian market so unique that general expertise in pharmaceutical sales and marketing does not translate to Canada. In fact, as Elorac points out, Sanofi itself relied on a commercial assessment of the Product performed in the United States for Sanofi's United States affiliate, which "makes sense only if the U.S. and Canadian markets are quite similar." (Elorac Resp. Br. (Baldini) at 18-19, ECF No. 292.) Mr. Baldini testified at his deposition that the Canadian market is not so dissimilar that it requires dramatically different marketing tactics. (Id. at 19 (citing Baldini Dep., Ex. A at 127:19-128:3).) Although Sanofi seizes on the fact that, when asked to explain the basis for his testimony to that effect, he mentioned conversations with a colleague, the Court agrees with Elorac that Mr. Baldini seems to have relied on these conversations as a sort of self-check of his own opinion, rather than the principal basis for it. (*Id.* at 19-20.) The principal basis for his opinion is his own experience, and that basis is sufficiently reliable to survive a challenge under *Daubert* and the Federal Rules of Evidence, regardless of whether the resulting opinion proves to be too shaky to persuade the jury. See Gayton v. McCoy, 593 F.3d 610, 616 (7th Cir. 2010) ("[S]haky' expert testimony may be admissible, assailable by its opponents through cross-examination.") (quoting Daubert, 509 U.S. at 597). Sanofi may attempt to demonstrate or argue that the jury should not credit Mr. Baldini's opinions due to his limited familiarity with the Canadian market, but that is a question of the weight the jury should give the evidence rather than its admissibility.

2. Familiarity with Facts of the Case

Sanofi attacks Mr. Baldini's opinions based on the fact that he allegedly misstates or is unaware of certain factual details, such as whether Valeant

or whether Sanofi assisted Elorac in preparing a supplemental new drug submission ("SNDS") to attempt to remove the three-month time limit from the Product's approved indication. (*See* Def.'s Mem. at 20-22, ECF No. 260.) But the Court agrees with Elorac that the alleged errors Sanofi has cited are generally not so much factual errors as disputed facts, and an expert is entitled to base his opinion on assumptions about the truth of disputed facts. *See Richman v. Sheahan*, 415 F. Supp. 2d 929, 942 (N.D. Ill. 2006) ("There is a critical distinction between an expert testifying that a disputed fact actually occurred . . . and an expert giving an opinion based upon factual assumptions, the validity of which are for the jury to determine. The former is manifestly improper, the latter is not.")

To the extent that Mr. Baldini might have struggled to find support in the record for some of his factual assumptions, they are not so central to Mr. Baldini's analysis that any fuzziness on these factual details makes his opinion professionally unreliable. Mr. Baldini seems to have had a sufficiently firm grasp of the essential facts to satisfy the terms of Rule 702 that require his opinion to be based on sufficient facts or data and a reliable application of his experience to the facts of this case. On the whole, Mr. Baldini relies on facts that have at least some basis in the record. *See Richman*, 415 F. Supp. 2d at 942 ("The question is not whether the opinion is based on assumptions, but whether there is some factual support for them. If there is, it is for the jury, properly instructed, to determine the credibility of the witnesses and thus the weight to be given to the expert opinion."). Mr. Baldini reliably applies the lessons of his vast experience in pharmaceutical sales and marketing to these facts in order to evaluate Sanofi's marketing efforts.

To be sure, if Sanofi succeeds in demonstrating on cross-examination that Mr. Baldini has a shaky grasp of the factual details pertinent to the Product's launch, it will undermine his credibility with the jury, but that is of no consequence for purposes of the present motion. *Micro Chem., Inc. v. Lextron, Inc.*, 317 F.3d 1387, 1392 (Fed. Cir. 2003) ("[I]t is not the role of the trial court to evaluate the correctness of facts underlying one expert's testimony."). The bottom line is that Sanofi is free to argue, or demonstrate via cross-examination, that the jury should not credit Mr. Baldini's opinion on Sanofi's commercialization efforts because he did not sufficiently understand factors unique to the Canadian market or the Product's strengths and weaknesses vis-à-vis other osteoarthritis treatments in that market or even the full factual circumstances of the launch; but that is an issue of weight rather than admissibility.

3. Prejudicial and Inflammatory Language

As for Sanofi's contention that Mr. Baldini expresses his opinions in inflammatory, prejudicial language, even if true, it provides no reason to bar Mr. Baldini from testifying. The Court agrees with Elorac that, if Mr. Baldini uses inflammatory or prejudicial language on the witness stand, Sanofi may make its objection and the Court will instruct him to moderate his language then. Sanofi's motion to exclude Mr. Baldini's testimony is denied.

B. Paula Clancy

Sanofi moves to exclude the testimony of Paula Clancy, a Canadian trademark lawyer. Sanofi claims that part of the reason it could not launch the Product immediately upon receiving regulatory approval in July 2010 was that Lundbeck A/S ("Lundbeck"), a multinational pharmaceutical company headquartered in Denmark, had formally opposed Winston's application for Canadian and European trademark registration of the Product's proposed name, Civanex. In the opposition proceeding, Lundbeck contended that the proposed Civanex mark

was too similar to the name of Lundbeck's own product, Cipralex, a registered trademark in Canada and Europe. On April 26, 2010, Lundbeck prevailed in its European opposition to Winston's Civanex trademark application. Ostensibly based on these developments, Sanofi insisted on pursing an alternative name for the product before launching it in Canada. Winston and Sanofi ultimately abandoned "Civanex" and, after some wrangling over the new name, agreed to launch the Product under the name "Zuacta." Elorac's theory is that the Lundbeck opposition proceedings did not pose any serious risk to the Canadian launch of the Product and, by insisting that there was some such risk, Sanofi was only stalling for time to find a sublicensee to take over its obligations under the license agreement.

In support of that theory, Elorac offers the testimony of Ms. Clancy, who opines that even if Lundbeck had prevailed in opposing the registration of the Civanex mark in Canada, that result would not actually have prohibited the parties from marketing the Product under the name "Civanex"; it would only have meant that the Civanex mark could not be registered. (*See* Def.'s Mem. in Supp. of Mot. to Exclude Testimony of Paula Clancy, Ex. A, Clancy Report at 9, ECF No. 264-1 ("[T]he commencement of opposition proceedings by Lundbeck could <u>not</u> have prevented or impeded the marketing in Canada of the CIVANEX osteoarthritis cream.").) Further, based on her review of (1) the Civanex trademark application, (2) the Civanex trade name analysis performed by Health Canada, the Canadian drug regulatory agency, (3) the trademark register, which revealed several similar pharmaceutical trade names with ci- prefixes or –ex suffixes, and (4) applicable decisional law, Ms. Clancy concludes that there was some chance that Winston would have prevailed in the Lundbeck opposition proceeding.

Ms. Clancy's opinions do not closely fit the facts of this case. There is no dispute that Winston *might* have been the prevailing party in the Lundbeck opposition proceeding.

Further, the fact that the pending opposition proceeding did not, in a technical sense, bar the parties from proceeding with the launch is of little relevance; the key question is whether it was prudent (or commercially reasonable, in the language of the license agreement) to proceed with the launch before the

Product's trademark issues were resolved.

In other words, the question the jury must answer with respect to the Civanex mark and the Lundbeck opposition is how a reasonable commercial actor in Sanofi's position would have weighed the risks and benefits of the alternatives available to it in light of the ongoing trademark issues. On the one hand, Sanofi could have chosen to take full advantage of the data protection period by proceeding immediately with the launch of the Product under the Civanex name, but this course of action would have carried the risk that Lundbeck might file a separate trademark infringement action in the future, which, regardless of the outcome, might have been a costly entanglement. On the other hand, Sanofi could have chosen to wait until it could resolve the trademark issues, one way or another, before proceeding with the launch, which would have protected the company from exposure to an infringement action, but would have wasted some portion of the period of exclusivity the parties enjoyed during the data protection period, when the Product was protected from generic competition.

The correct or likely outcome of the Lundbeck opposition proceeding, from a legal perspective, and its legal consequences are less important than the reasonableness of Sanofi's assessment of the risks from a *commercial* perspective. The Court agrees with Sanofi that Ms. Clancy's opinions would be of minimal use to the trier of fact in determining which course of

action was the commercially reasonable one, and admitting her testimony runs an unnecessary risk of prejudicing defendant by giving a misleading "gloss of expertise," cf. Victory Records, Inc. v. Virgin Records Am., Inc., No. 08 C 3977, 2011 WL 382743, at *2 (N.D. Ill. Feb. 3, 2011), to Elorac's position that the Civanex trademark issues were not serious enough to be the true reason why Sanofi delayed launching the Product. As Sanofi explains, Ms. Clancy's opinions are purely legal in nature, and they therefore provide little insight into how Sanofi's corporate decisionmakers should have weighed these risks. Any relevant insight they do provide in that regard is vastly outweighed by the danger of prejudice. See Harbor Ins. Co. v. Cont'l Bank Corp., 922 F.2d 357, 366 (7th Cir. 1990) (holding that by allowing a lawyer to give a legal opinion as an expert witness, the district court "allowed the jury to infer that it could look to that witness for legal guidance[,] and . . . impermissibly tilted the balance of power between the parties"); see also Joseph v. Carnes, No. 13-CV-2279, 2015 WL 2091903, at *2 (N.D. Ill. Apr. 30, 2015) (citing Harbor Ins. Co.). Ms. Clancy's proposed testimony is more prejudicial than probative. To the extent there is any dispute at trial about the potential legal consequences of a proceeding such as the Lundbeck opposition, which seems unlikely, the Court will be able to instruct the jury on these matters.³ Sanofi's motion to exclude Ms. Clancy's testimony is granted.

C. Ahnal Purohit

Sanofi moves to exclude the testimony of Dr. Ahnal Purohit. Dr. Purohit is president and chief executive officer of Purohit Navigation, a firm that provides marketing advice, advertising services and market research to health care and pharmaceutical companies. She opines that

_

³ The Court's reasoning that it will be able to instruct the jury on Canadian law may seem like overreaching, but the parties have already briefed issues of foreign law in this case (*see, e.g.*, Def.'s Mem. in Opp. to Pl.'s Mot. to Compel Deposition of Jon Fairest in Montreal, ECF No. 87, and Pl.'s Reply Br., ECF No. 105), and they will no doubt be able to assist the Court by doing so again, if necessary.

Sanofi's efforts to market, promote, and sell the Product were not consistent with those generally used by similar companies in similar circumstances. To reach her opinion, Dr. Purohit searched for pharmaceutical products that she judged to be analogous to the Product because they had similar indications or were in the same therapeutic category and had similar sales potential. She selected Pennsaid, a topical analgesic used to treat osteoarthritis, and Synvisc-One, an injection used for the same purpose, and compared the efforts made to market those products to Sanofi's efforts to market the Product. Dr. Purohit concluded that Sanofi did not make commercially reasonable efforts to market the Product because it did not devise a marketing plan tailored to the Product and it failed to execute even the standard sales tactics it included in its plan.

Sanofi argues that Dr. Purohit has no expertise in "commercialization" of pharmaceutical products; her expertise is in marketing and advertising, and in Sanofi's view, that expertise is too narrow to qualify her to opine on the broader issue of what constituted reasonable efforts to "commercialize" the Product under all the facts and circumstances. Further, Sanofi argues that Dr. Purohit is unqualified because she has no experience in Canadian marketing. Finally, Sanofi argues that Dr. Purohit's opinion is not reliable or helpful to the trier of fact because (a) she did not specifically analyze how similarly sized companies marketed internally developed products, which are key factors in the commercial reasonableness inquiry based on the language of section 1.9 of the license agreement, (b) she did not select appropriate analogs for the Product, and (c) she relied on false assumptions about the marketing efforts Sanofi and its sublicensees made, essentially making adverse inferences against Sanofi and its sublicensees whenever she did not have adequate evidence of the particular promotional activity she was expecting to find.

None of these arguments is persuasive. First, Sanofi does not deny that marketing and advertising are a critical component of "commercialization," so it would seem to follow that if

Sanofi did not make commercially reasonable efforts to market, advertise, and promote the Product, then it did not make reasonable efforts to commercialize it. Thus, the Court fails to see why it should bar Dr. Purohit's testimony merely because she is not an expert in "commercialization"; an opinion on the commercial reasonableness of marketing efforts, to whatever extent (if at all) "commercialization" refers to something broder than these efforts, would certainly be of great assistance to the jury in determining whether Sanofi had made reasonable efforts to commercialize the Product.

Second, as the Court explained above with respect to the testimony of Mr. Baldini, the fact that Dr. Purohit may have limited experience with the Canadian pharmaceutical market goes to the weight the jury should give her testimony rather than its admissibility. As Elorac explains in its response brief, Dr. Purohit has long, vast experience in the field of pharmaceutical marketing (ECF No. 298 at 5-7), including significant experience in Canada (*id.* at 5-7, 16-18). Like Mr. Baldini, Dr. Purohit opined on generally applicable principles of marketing that will not vary significantly from market to market and jurisdiction to jurisdiction. (*Id.* at 18.) To the extent Sanofi believes that she is not sufficiently familiar with the Canadian market to credibly opine on the adequacy of Sanofi's marketing effort in this case, Sanofi is free to argue as much to the jury and to explore Dr. Purohit's experience on cross-examination, but the Court does not agree that this potential weakness in her testimony provides a reason to exclude it.

Similarly, Sanofi's criticism of Dr. Purohit's methodology goes to weight rather than admissibility. Sanofi is free to argue that Pennsaid and Synvisc-One are not close analogs to the Product, or that certain portions of Dr. Purohit's opinions are incorrect because they are based on an incorrect understanding of the facts; but as with Mr. Baldini, the core of her opinion is formed by applying her long experience in pharmaceutical marketing to the essential facts of this case to

opine on the adequacy of Sanofi's marketing effort and whether Sanofi and its sublicensees employed the standard marketing tactics she would have expected any reasonable marketer to employ. To the extent that Dr. Purohit may have overlooked good reasons to deviate from that standard in this particular case, as Sanofi argues, Sanofi must so demonstrate at trial; the Court will not bar Dr. Purohit's testimony simply because Sanofi thinks that Dr. Purohit is using the wrong drugs as analogs, *see Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806, 808 (7th Cir. 2013) ("[A]rguments about how the selection of data inputs affect the merits of the conclusions produced by an accepted methodology should normally be left to the jury."), or her opinion is based on incorrect factual assumptions, *see Richman*, 415 F. Supp. 2d at 942. Sanofi's motion to exclude Dr. Purohit's testimony is denied.

D. Richard L. Manning

Sanofi moves to exclude the expert testimony of Dr. Richard L. Manning. Dr. Manning is a partner at Bates White LLC, an economic and statistical consulting firm. As a member of the Life Sciences Practice Group, he specializes in economic and statistical analysis of damages in litigation, as well as the economics of business strategy and public policy issues, in health care and related industries. He regularly opines on claims of damages in the pharmaceutical, biotechnology and health care industries. (Elorac Resp. Br. (Manning) at 4, ECF No. 296.)

Dr. Manning opines on Elorac's damages from Sanofi's alleged failure to make reasonable efforts to commercialize the Product and its alleged miscalculation of royalties. Dr. Manning used a "benchmark" approach, akin to Dr. Purohit's, to calculate Elorac's damages from the lack of reasonable commercialization efforts; that is, analyzed the marketing expenditures that a different pharmaceutical company made to promote a benchmark product similar to Civamide Cream, and calculated based on that analysis how Civamide Cream would

have fared if Sanofi had made the same level of marketing investment. Dr. Manning selected Pennsaid, the "only other prescription topical analgesic for [osteoarthritis]-related knee pain available in Canada" (*id.*, Ex. B, Manning Report, ¶ 14), as his benchmark product.

According to Dr. Manning, economists commonly analyze the impact of marketing by treating marketing as an investment in the "stock" of a product. This mode of analysis recognizes that advertising and other promotional activities provide a benefit that may boost sales of a particular product not only while those activities are ongoing, but also for some time after they have ceased. Under this theory, a product's "stock" of marketing capital grows as marketing expenditures grow, but after they cease, it depreciates over time, just as a physical asset does, because consumers eventually forget the information they learned about the product.

Dr. Manning calculated the "capital stock" the marketing expenditures built in the Pennsaid product in order to measure the relationship between Pennsaid's marketing expenditures and product sales. Dr. Manning first calculated a depreciation rate for Pennsaid based on the rate at which Pennsaid sales declined after active marketing of Pennsaid ceased in 2010. Then, he calculated the initial marketing stock of Pennsaid by taking Pennsaid's marketing expenditures in 2003, the first year the product was on the market, and reducing the figure according to the depreciation rate. For each subsequent year, he added the marketing expenditures for that year to the existing marketing stock and reduced the figure according to the depreciation rate. By performing these calculations, Dr. Manning was able to determine Pennsaid's rate of responsiveness to marketing, *i.e.*, the rate by which an increase in marketing expenditures increased sales.

To calculate Elorac's economic damages, Dr. Manning applied Pennsaid's rate of marketing responsiveness to the yearly marketing expenditure projections Sanofi prepared for

the Product around the time it entered into the license agreement in order to estimate "but-for" yearly sales figures for the Product. For this portion of his analysis, Dr. Manning relied on a document (Aug. 31, 2016 Strongosky Decl., Ex. 7, ECF No. 279-1 at 34), which Sanofi prepared contained sets of hypothetical projections,

Sanofi argues that this method is unreliable for a number of reasons. First, Sanofi argues it is unreliable because Dr. Manning does not account for the possibility that factors other than the lack of marketing effort contributed to the Product's poor sales performance by performing a regression analysis⁴, which it claims the Seventh Circuit has adopted as "standard" (Def.'s Mem. in Supp. of Mot. to Exclude Dr. Manning's Testimony at 15, ECF No. 272) and which Dr. Manning must use unless he or Elorac can show that "some problem blocked the use of multivariate regression [or] other [such] statistical tools." *Zenith Elecs. Corp. v. WH-TV Broadcasting Corp.*, 395 F.3d 416, 419 (7th Cir. 2005). Second, Sanofi argues that Dr. Manning's analysis is flawed because he lacks the expertise to determine whether Pennsaid is an appropriate benchmark. Third, Sanofi argues that Dr. Manning's analysis is flawed because he relies on internal marketing projections that were not prepared with scientific rigor, and he is not

⁴ "Multiple regression analysis is a statistical tool used to understand the relationship between or among two or more variables. Multiple regression involves a variable to be explained—called the dependent variable—and additional explanatory variables that are thought to produce or be associated with changes in the dependent variable. For example, a multiple regression analysis might estimate the effect of the number of years of work on salary. Salary would be the dependent variable to be explained; the years of experience would be the explanatory variable." Daniel L. Rubinfeld, *Reference Guide on Multiple Regression, in* Fed. Judicial Ctr., Reference Manual on Scientific Evidence 303 (3d ed. 2011), *available at* https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf *and* 2011 WL 7724257.

qualified to assess their reasonableness and reliability himself. Finally, Sanofi argues that Dr. Manning's tacked-on opinion on miscalculated royalties will not assist the trier of fact because it is a simple matter of arithmetic that any layperson can perform.

As the Court will explain below, Sanofi's arguments are without merit.

1. Failure to Use Regression Analysis or Show That It Could Not Be Used

Sanofi places great importance on the fact that Dr. Manning did not perform a regression analysis, but contrary to Sanofi's contention, the Seventh Circuit has not held that regression analysis, or something like it, is necessary to establish economic damages from breach of contract in commercial litigation.

In Zenith, the case on which Sanofi principally relies, a company that broadcast a digital television signal in San Juan, Puerto Rico, and sold television set-top boxes to allow customers to receive it, claimed that its supplier breached its contract by providing inferior set-top boxes. The company's expert's theory was that if the boxes had met the company's specifications, the company would have experienced "rapid growth paralleling that of DirecTV," the leading satellite broadcaster at the time, 395 F.3d at 418. Based on data describing DirecTV's actual market penetration in Puerto Rico from 1999 to 2002, the expert calculated projections of DirecTV's subscriber growth from 2002 through 2008. See Zenith, No. 01 C 4366, 2003 WL 21506808, at *2-3 (N.D. III. June 27, 2003). Then, the expert estimated what percentage of the projected new DirecTV subscribers would have subscribed to the company's digital broadcasting service. But when asked how he had generated the post-2002 projections for DirecTV, he cited only his own industry experience and expertise. Zenith, 395 F.3d at 418. He did not use DirecTV's experience in other markets for guidance, contending instead that experience in other markets is irrelevant because each market is unique. Under such circumstances, the Seventh

Circuit concluded that it was impossible even to identify a scientific or technical methodology underlying the expert's opinion. *Id.* ("He either had no method or could not describe one. He was relying on intuition, which won't do."). Further, the court rejected the expert's contention that he could not rely on data from markets other than San Juan because no other market was sufficiently analogous, explaining that while it was undoubtedly true that "cities differ in size, average income, levels of education, availability of over-the-air TV signals, and other factors that might affect . . . demand . . . , social science has tools to isolate the effects of multiple variables and determine how they influence one dependent variable," such as sales of the company's settop boxes. *Id.* at 418-19. The court cited regression analysis as "perhaps the leading tool" in that regard. *Id.* at 419.

Thus, in *Zenith*, the Seventh Circuit cited regression analysis merely to show that there was no merit in the expert's claim that he had to rely on what was essentially just "intuition" because there was no scientific method that would have been suitable under the circumstances. But that conclusion is of limited applicability here because Dr. Manning *did* employ a scientific method. As the Court described above, Dr. Manning explained that he proceeded by selecting a benchmark product, analyzing the relationship between its sales and the amount of money spent to market it, and using the benchmark product's rate of responsiveness to marketing to calculate what sales of Civamide Cream might have been if Sanofi had spent what it originally planned to spend to market it. Dr. Manning did not vaguely cite his own experience and expertise or rely on his own "intuition," nor was he unable to describe his method, and nothing in *Zenith* or any other Seventh Circuit case required him to use a particular methodology such as regression analysis.

The question Dr. Manning and Elorac must answer is not why he did not use regression analysis, but whether the method he did use is reliable. Elorac cites a number of cases in which

courts have accepted similar "benchmark" or "yardstick" methods. (*See* Elorac Resp. Br. (Manning) at 8-9, ECF No. 296.) The Court is persuaded that benchmarking is a valid methodology, and to the extent Sanofi argues that other factors besides its marketing expenditures likely affected the performance of the Product, it merely raises "issues of causation," which are "questions of fact that a jury is well equipped to weigh." *See, e.g., Orthofix Inc. v. Gordon*, No. 13-CV-01463, 2016 WL 1273160, at *3-4 (C.D. Ill. Mar. 1, 2016).

Sanofi argues that the cases Elorac cites are distinguishable because, in this case, so many factors distinguish Pennsaid from the Product that Pennsaid's responsiveness to marketing is not instructive. But this objection goes to the weight of the expert's testimony, rather than its admissibility. The Seventh Circuit has explained that an expert's reliability is "primarily a question of the validity of the methodology employed by an expert, not the quality of the data used in applying the methodology." *Manpower*, 732 F.3d at 806. "The district court usurps the role of the jury, and therefore abuses its discretion, if it unduly scrutinizes the quality of the expert's data and conclusions rather than the reliability of the methodology the expert employed." *Id.* "The reliability of data and assumptions used in applying a methodology is tested by the adversarial process and determined by the jury." *Id.* at 808. "[A]rguments about how the selection of data inputs affect the merits of the conclusions produced by an accepted methodology should normally be left to the jury." *Id.* The Pennsaid data are among the "data inputs" Dr. Manning used, and scrutiny of such data is "normally" reserved for the jury.

A district court should exclude proposed expert testimony based on the unreliability of the data inputs only when they have "no quantitative or qualitative connection to the methodology employed." *Id.* If there is some "rational connection between the data and the opinion[,] an expert's reliance on faulty information is a matter to be explored on cross-

examination," rather than a matter for the Court to decide on a *Daubert* motion. *Id.* at 809 (citing *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000)). In this case, there was a "rational connection" between the Pennsaid data and Dr. Manning's damages opinion. There is copious evidence, including some in Sanofi's own records, that Pennsaid is a closely analogous product to Civamide Cream in terms of its indication and application.

(Elorac Resp.

Br. (Manning) at 18.) See Eike v. Allergan, Inc., No. 12-CV-1141, 2015 WL 6082310, at *3 (S.D. Ill. Sept. 14, 2015) ("[Like] the opponents of the expert testimony in Manpower, Defendants are challenging the reliability of the data inputs Dr. Kriegler used in his model. However, his use of data supplied in discovery was not improper or unreliable as experts commonly use data supplied in litigation. While the propriety of Dr. Kriegler's selection of data inputs may be relevant to the weight to be accorded his testimony, it [has no bearing on admissibility] under Daubert."); cf. Loeffel Steel Prods., Inc. v. Delta Brands, Inc., 387 F. Supp. 2d 794, 813-14 (N.D. Ill. 2005) (barring expert's damages opinion based on a "yardstick" approach because the expert "knew nothing about . . . such critical factors as what services the [yardstick] companies provided . . . and other critical aspects of the businesses" other than that they were in the same broad industry as the plaintiff, and he therefore could not reliably opine on whether they were suitably comparable yardsticks).

Sanofi will be free to argue that, based on key differences between the Product and Pennsaid, the Product never would have responded to marketing as well as Pennsaid did regardless of how much Sanofi spent, but that is a matter for the jury to consider. Sanofi has not established that Pennsaid lacks any "rational connection" to the Product, so Dr. Manning's use of Pennsaid as a benchmark provides no reason to exclude his testimony.

2. Scope of Expertise and Selection of Pennsaid as Benchmark

Sanofi makes the related argument that Dr. Manning is not qualified to select Pennsaid as an analog because he is an economist without formal training in pharmacology or medicine, and as such, he is unable to assess whether the market for Pennsaid might critically differ from the market for the Product based on contraindications with other drugs or other such factors. Dr. Manning explained in his report that Pennsaid is the "only other prescription topical analgesic for [osteoarthritis]-related knee pain available in Canada," and he relied on evidence in the record, including evidence of marketing materials produced by Sanofi

. (Def.'s Mem., Ex. B, Manning Report at 9, ECF No. 272-1.) To the extent the products differed, it was possible that the differences might make Civamide Cream *more* responsive to marketing, rather than less, (*Id.*, Ex. B at 10.) In any case, Dr. Manning found evidence in the record that Sanofi had "done market research and surveyed physicians and others" (*id.*, Ex. A, Manning Dep. at 73:4-73:16) in assessing how the Product might stack up against competitors, and he searched the documents Sanofi produced for other potential benchmarks, but he believed Pennsaid was the closest match because it was the only other prescription topical analgesic available in Canada; the potential competitors identified in the documents he reviewed were all either oral or non-prescription. Further, he explained that in selecting Pennsaid, he relied on his "expertise as an economist with deep familiarity with the pharmaceutical industry" (*id.*, Ex. A at 76:11-21), and on "basic economic reasoning" dictating that in selecting a benchmark, he should "keep...constant" as

many "quality characteristics" as possible (id., Ex. A at 71:14-72:7).

Dr. Manning applied his expertise and long experience in the economic analysis of health care and pharmaceutical issues to the facts he found in the record to confirm that Pennsaid was a close enough analog to serve as a fair benchmark. The Court concludes that he was qualified to perform this analysis and his analysis is reliable in this respect; if he erred by choosing the wrong benchmark product, Sanofi may attempt to so demonstrate on cross-examination, but it provides no reason to bar his testimony.

3. Use of Sanofi's Marketing Projections

Sanofi challenges Dr. Manning's use of the projections of marketing expenditures on the grounds that Dr. Manning was not qualified to assess whether these figures represented reasonable amounts to spend on the marketing of the Product, and therefore using them undermines the reliability of his model. But, as the Court explained above, the proper subject of a Daubert motion to exclude expert testimony is the reliability of the methodology, not the reliability of the data inputs, assuming there is a "rational connection between the data and the opinion." Manpower, 732 F.3d at 809. There certainly is such a "rational connection" here; Dr. Manning uses the very figures that Sanofi planned to spend on marketing the Product when it contracted to do so. These figures may have been preliminary, and the evidence at trial may show that it was commercially reasonable to deviate from them in light of later events, but these are matters Sanofi can explore on cross-examination, prove by putting on its own evidence, and explain to the jury at argument. Nothing prevents a damages expert from making a reasonable assumption in calculating damages. See, e.g., Orthofix, 2016 WL 1273160, at *3 ("It is entirely appropriate for a damages expert to assume liability for the purposes of his or her opinion. To hold otherwise would be illogical.") (quoting Sys. Dev. Integration, LLC v. Computer Scis. Corp., 886 F. Supp. 2d 873, 882 (N.D. III. 2012)).

Sanofi again relies heavily on *Zenith*, in which the Seventh Circuit barred the television company from using its internal projections of subscriber growth as the basis for its expert's estimate of lost profits because its own internal growth projections "represent[ed] hopes rather than the results of scientific analysis." 395 F.3d at 420. But *Zenith* is inapposite on this point. Dr. Manning did not use hopeful projections of the Product's sales potential, *cf. Target Mkt. Pub., Inc. v. ADVO, Inc.*, 136 F.3d 1139, 1145 (7th Cir. 1998) (distinguishing business's unduly speculative projection of "target profit" from "projection of actual profits"), or even sober projections of the Product's expected-case performance; what he used was the plan for marketing expenditures _______, which Sanofi had used _______. Because it was a plan for expenditures, not a projection of sales, the _______ marketing plan was not an exercise in speculative or hopeful prognostication in the sense that it depended on factors outside the parties' direct control, such as

What Dr. Manning's opinion boils down to is a projection of what Sanofi's sales would have been if Sanofi had actually spent what it planned to spend to market the Product, based on the benchmark rate of responsiveness to marketing that he calculated. Sanofi will be free to attempt to establish, through cross-examination, evidence or argument, that it was ultimately not commercially reasonable to spend the amounts it had planned to spend at the time it entered into the license agreement. A jury is well equipped to weigh the evidence bearing on the matter and make its own determination as to whether the marketing projections provide a sufficient foundation for Dr. Manning's opinion; this Court would usurp the role of the jury by making its own determination.

physician or patient preferences, as projected sales growth might. Rather, Sanofi would always

have been in full control of how much it chose to spend to market or promote the Product.

4. Miscalculation of Royalties

Finally, Sanofi argues that Dr. Manning's testimony on Sanofi's alleged miscalculation of royalties should be excluded because it is mere arithmetic, which a layperson is competent to perform. But as one court of this district has recently explained, simplistic damages calculations are not necessarily inadmissible if they would be helpful to the trier of fact:

As the Seventh Circuit has stated, "[a] jury cannot keep in mind all of the figures that might enter into a determination [of damages]. Computations and summaries based upon evidence before the Court, in many instances, would be very helpful to a jury." *Wirtz v. Turner*, 330 F.2d 11, 14 (7th Cir. 1964) (holding that expert testimony of an accountant on the issue of damages calculations under the FLSA would assist the trier of fact and was ultimately admissible).

Smith v. Family Video Movie Club, Inc., No. 11-CV-1773, 2015 WL 1542663, at *5 (N.D. Ill. Mar. 31, 2015). There can be no doubt that Dr. Manning's calculations would be helpful to the jury. Sanofi argues that admitting Dr. Manning's testimony on this point will "lend gravitas to Elorac's incorrect interpretation of the License Agreement." (Def.'s Mem. at 24, ECF No. 272.) But adequate instructions will prevent the jury from confusing an issue of damages with an issue of liability. The jury will undoubtedly be able to understand that it may not award damages, regardless of whether the evidence reveals a valid measure of damages, if Elorac does not establish its right to them by proving that its interpretation of the contract is correct. There is no danger of undue prejudice from these calculations.

Sanofi's motion to exclude Dr. Manning's testimony is denied.

E. Edward Walton

Sanofi moves to exclude the testimony of Dr. Edward Walton. Dr. Walton has a Ph.D. in genetics and is the CEO of PharmaVentures Ltd., a company that facilitates licensing transactions in the health care industry. He opines that, if the Product's Canadian launch had been a commercial success, lucrative licensing opportunities would have followed in the United

States, Europe, and Japan. Specifically, Dr. Walton opines that if the Product had reached its short-term sales target of partners, plaintiff would have been able to find licensing partners in other markets within a year. According to Dr. Walton, these licensing partners would have been willing to fund the clinical studies necessary to secure regulatory approval in markets such as the United States, Europe, and Japan. Armed with the studies these licensing partners would have funded, Dr. Walton opines, plaintiff could have obtained regulatory approval for the Product in these three markets and begun selling them there within three years of the Canadian launch. Dr. Walton also offers an opinion on the present value of Elorac's Canadian damages based on Sanofi's Canadian projections.

Dr. Walton calculated the sales potential of the Product in the United States, Europe and Japan by using Sanofi's February 2011 Canadian sales forecast as a starting point. He calculated an "epidemiology factor," which accounts for the relative prevalence of osteoarthritis in Canada, the United States, Europe and Japan, as well as a "pricing factor" which accounts for differences in the relative prices of pharmaceuticals in those markets, and extrapolated from the February 2011 Canadian forecast, applying the epidemiology factor and pricing factor for each individual market, to create sales forecasts for the Product in those markets. Then, Dr. Walton used benchmark products to estimate the licensing fees Civamide Cream could have commanded based on the sales forecasts he created, ultimately concluding that Elorac's damages due to lost revenue in these markets totaled somewhere between \$360 million and \$490 million.

Sanofi argues that Dr. Walton's opinion is not based on sufficient facts or data and is connected to the data only by his *ipse dixit* (or say-so). According to Sanofi, its internal Canadian sales projections are not sufficiently reliable data to support Dr. Walton's opinion; in fact, Dr. Walton admitted that in his ordinary practice outside the context of litigation, he would

generate his own projections rather than rely on another party's. Further, Sanofi argues that Dr. Walton is unqualified to assess the Product's prospects for attaining regulatory approval in the United States, Europe and Japan because his expertise is in licensing pharmaceutical products, not obtaining regulatory approval for them.

The Court has already explained, in its discussion of Dr. Manning's opinion, that scrutiny of "the quality of the expert's data and conclusions," as opposed to his methodology, is "normally" reserved for the jury. *Manpower*, 732 F.3d at 806. The court concerns itself with "assessing the reliability of the methodology—the framework—of the expert's analysis," whereas "the reliability of data and assumptions used in applying a methodology" is the jury's concern. *Id.* at 808.

But this is "a far cry from an ironclad rule" that a court may never exclude an expert opinion on the ground that it is "too speculative as a matter of law," if the opinion is based on unrealistic assumptions. *Target Mkt. Pub.*, 136 F.3d at 1143 (internal quotation marks omitted); see Fail-Safe, L.L.C. v. A.O. Smith Corp., 744 F. Supp. 2d 870, 891–93 (E.D. Wis. 2010) (citing Target). The Supreme Court has upheld the exclusion of expert testimony that "did not rise above subjective belief or unsupported speculation," reasoning that "[t]rained experts commonly extrapolate from existing data[, but] nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 140, 146 (1997) (internal quotation marks omitted). If an expert makes assumptions that create "too great an analytical gap between the data and the opinion proffered," then it is proper to exclude his testimony as "unsupported speculation." Target, 136 F.3d at 1144 (quoting Joiner, 522 U.S. at 140, 146); see also Lester v. Resolution Trust Corp., 994 F.2d 1247, 1252-53 (7th Cir. 1993) (affirming

district court's ruling that expert testimony on lost profits for Phases II and III of a failed construction project should have been excluded because the assumption that Phase I and the underlying infrastructure would have ever been completed, regardless of whether the opposing party breached its contract, was mere speculation).

The Court agrees with Sanofi that Dr. Walton's opinion is not reliably rooted in facts or data because it is based on assumptions that are essentially speculative. First, the foundation for Dr. Walton's opinion is Sanofi's February 2011 internal projections, and Sanofi, relying heavily on the Seventh Circuit's decision in *Zenith*, argues that these projections are not sufficiently reliable to support expert testimony. *See* 395 F.3d at 420 (holding that internal sales projections offered into evidence to prove damages were unreliable and inadmissible because they "represent[ed] hopes rather than the results of scientific analysis"). Elorac attempts to distinguish the decision in its brief, but *Zenith* is squarely on point. *See id.* (citing *Target*, 136 F.3d at 1145-46).

Elorac argues that Dr. Walton used Sanofi's own projections, rather than building up independent projections himself (which he admitted he might have done in advising a client outside the litigation context), precisely because Sanofi prepared them, so they should be uncontroversial and unobjectionable to Sanofi. (Def.'s Mem. in Supp. of Mot. to Exclude Testimony of Dr. Walton, Ex. A, Walton Dep. at 184:12-185:1, ECF No. 276-1; *see also id.* at 124:16-126:1 (explaining that Dr. Walton attempted to select "the most conservative numbers" in reliance on "Sanofi's own judgment on the performance of the product in Canada")). But as the Seventh Circuit explained in *Zenith*, an expert opinion must rest on a scientific analysis, not on someone's "say-so, whether the person doing the saying is a corporate manager [such as the person who prepared Sanofi's projections] or a putative expert." 395 F.3d at 420. Elorac has not

demonstrated that the February 2011 sales forecast was the product of a sufficiently reliable forecasting process, rather than a hopeful sales target. Under such circumstances, the expert opinion is not a permissible extrapolation from existing data but an exercise in speculation that is "connected to existing data only by the *ipse dixit* of the expert." *Id.* (quoting *Joiner*, 522 U.S. at 146).⁵

Even if the February 2011 sales forecast were sufficiently reliable to form the basis for Dr. Walton's analysis, Dr. Walton made other assumptions that are also essentially speculative. First, he assumed that if the Product's launch was successful, which he defined as exceeding in sales in its first year, lucrative licensing opportunities outside of Canada would arise—but he never explained with any degree of specificity why his experience or his expert analysis led him to believe that Canadian sales of a certain magnitude would be the factor that would push other pharmaceutical companies to extend licensing offers to Winston. Upon examination on this point, Dr. Walton could not articulate why the figure was important other than that it would give the Product a record of success. (Def.'s Mem., Ex. A, Walton Dep. at 120:15-121:9, ECF No. 276-1.) But he also testified that the figure represented a success because it was a target Sanofi set. It is unclear why a potential licensing partner should have cared about Sanofi's internal sales target, and Dr. Walton could not further or any particular sales figure was necessary to entice prospective explain why licensees. (See id. at 130:21-131:5.) In short, Dr. Walton could not explain why or how the Product's sales record should have had an effect on licensing opportunities, and since the failure

⁵ Sanofi also argues that Dr. Walton's Canadian damages opinion should be excluded because it is based on basic math. The Court need not address this argument because the Canadian damages opinion also uses the February 2011 Canadian projections as its starting point; therefore, like the foreign damages opinion, it must be excluded on that basis.

to meet the sales goal is the basis for the whole analysis, the methodology collapses as unreliable.

But even if the Court were to leave aside the issue of the sales threshold necessary to attract licensees, Dr. Walton's estimates of the potential lost revenue to Elorac from American, European and Japanese licensing deals are unreliable for the additional reason that they assume, without adequate justification, that the product would have obtained regulatory approval in those markets. (Aug. 31, 2016 Strongosky Decl., Ex. 10 at 24, ECF No. 279-1 at 119.) (*Id.*, Ex. 17 at 1, ECF No. 279-2 at 74.) Winston knew that, to obtain regulatory approval in markets worldwide, it would have to perform additional studies and supply additional information, which it could not afford to

Dr. Walton never describes what form the additional studies should have taken in order to satisfy the regulatory authorities of Europe, the United States and Japan, or what the likelihood

do without the support of a well-funded licensing partner. (See id., Ex. 31, Elorac 30(b)(6) Dep.

at 79:17-81:20, ECF No. 279-3 at 160; id., Ex. 32, Joel E. Bernstein, M.D., Dep. at 56:8-58:2,

ECF No. 279-3 at 165-66.)

would have been of achieving results in those studies that would have satisfied those authorities.

Dr. Walton simply assumes that a hypothetical competent licensee would have been able to fund appropriate studies and otherwise "take the best approach" to obtaining regulatory approval and "getting entry" into the pharmaceutical markets in Europe, the United States, and Japan—in fact, he testified that he believes it to a "certainty"—because "the product was already approved in Canada" and cases in which developed nations disagree on approval of a drug are a "minority." (Def.'s Mem., Ex. A, Walton Dep., at 58:23-60:4, 62:4-64:4, ECF No. 276-1.) But he concedes that he is "not a regulatory expert," and he is unable to explain what justifies his "certainty" on this point. (See id. at 52:16-53:2, 62:4-65:11, 68:15-70:9, 223:1-224:10.) He recognizes that drugs are sometimes approved in one jurisdiction but not another; for example, Dr. Walton admitted that he knows that Pennsaid 2% has been approved in the United States but not in Canada, but he did not consider why the United States and Canada might have differed in that case but would not in this one. (Id. at 367:8-368:10.) At one point he appears to use marketing materials to assess the likelihood of regulatory approval in markets beyond Canada based on the fact , without explaining how that would have been sufficient to permit the Product to obtain approval in other jurisdictions or to satisfy the concerns that the regulatory authorities in the U.S. and Europe had already expressed. (*Id.* at 71:4-73:23.)

In short, Dr. Walton assumes that the Product would have been approved in other jurisdictions because it was approved in Canada, but this assumption appears to be based on little more than a vague sense that the regulatory authorities of developed nations tend to reach similar conclusions on approval of pharmaceuticals. Even assuming it is true that, in Dr. Walton's experience, developed nations usually agree on approval of pharmaceuticals, Dr. Walton is unable to connect that principle to this case based on any particularized facts such as aspects of the Product or the particular regulatory regimes of the markets on which he is opining. *See Crawford Supply Grp., Inc. v. Bank of Am., N.A.*, No. 09-CV-2513, 2011 WL 4840965, at *3 (N.D. Ill. Oct. 12, 2011) (rejecting expert's proposed testimony based on his prior experience because "he never draws explicit connections between specific incidences or lessons from his professional history and the [facts of the case]"); Fed. R. Evid. 702, Advisory Comm. Notes ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts.").

Under these circumstances, Dr. Walton's opinion does not establish damages that are reasonably certain to have flowed from the breach, rather than from weaknesses in the Product itself. ⁶ *See Lester*, 994 F.2d at 1252-53. Because there is no firm factual basis for his assumptions that Sanofi's February 2011 sales forecast is reliable and that early Product sales

⁶ The Court is mindful of the fact that Dr. Walton conceives of his opinion as a damages opinion, not a causation opinion; as he explained at his deposition, other experts will opine on whether Sanofi made commercially reasonable efforts to commercialize the Product, and his task is merely to quantify the damage caused by any breach of that obligation, assuming it occurred. (*Id.* at 120:15-122:7.) But even assuming Sanofi's liability under the contract, Elorac must still establish that it is reasonably certain that the damages it seeks are a consequence of the breach, not some other factor. The Court fails to see how Dr. Walton's damages opinion assists the trier of fact if, as Dr. Walton's testimony sometimes seemed to suggest, it does not bear on whether the damages flow from the alleged breach; any opinion that purports to measure damages without making a judgment as to which effects stem from the breach and which do not is useless. Dr. Walton confuses the question of whether Sanofi may have "caused" a violation of the license agreement with the question of whether Sanofi's violation of the license agreement, assuming it happened, "caused" Elorac's damages; he can assume the first kind of causation but not the second.

would have drawn potential licensees who would have been able to obtain regulatory approval to market the Product in other jurisdictions, there is too great an "analytical gap between the data and the opinion," which amounts to "unsupported speculation" based on little more than Dr. Walton's *ipse dixit*. ⁷ *See Target*, 136 F.3d at 1144 (citing *Joiner*, 522 U.S. at 140, 146). The motion to exclude Dr. Walton's testimony is granted.

IV. PLAINTIFF'S MOTIONS TO EXCLUDE DEFENDANT'S EXPERTS

A. John Buckingham

Elorac moves to exclude the testimony of John Buckingham, a consultant and former executive in the pharmaceutical industry with experience marketing pharmaceutical products in Canada. Mr. Buckingham opines that, weighing all the various facts and circumstances, Sanofi used commercially reasonable efforts to bring the Product to market.

Elorac argues that Mr. Buckingham's testimony should be excluded because (1) he offers legal conclusions as to ultimate issues, (2) his opinions on Sanofi's efforts to assist with obtaining regulatory approval are not relevant, (3) he should not be permitted to testify on subjects on which he has no expertise, such as trademark law or global economics, (4) he should not be permitted to opine on the credibility of witnesses such as Elorac's Dr. Joel Bernstein or Sanofi's Manon Decelles or the state of mind of Sanofi management personnel, and (5) he should not be permitted to testify based on his experience at Optimer and Ipsen because, at his deposition, he refused to divulge particulars of that experience based on alleged confidentiality agreements.

-

⁷ Sanofi also argues that Dr. Walton's opinion must be excluded because he is unqualified to select the appropriate benchmark products in order to calculate the potential value of any American, European, or Japanese licensing deals. The Court need not address this argument because, even assuming that Dr. Walton chose correct benchmark products, his opinion is too speculative to be reliable.

1. Legal conclusions on ultimate issues

Elorac's broadest argument is that Mr. Buckingham should be barred from testifying that Sanofi used commercially reasonable efforts to market the Product, which, Elorac argues, is an impermissible legal conclusion on an ultimate issue.

Although Federal Rule of Evidence 704 removes the absolute prohibition some older decisions had imposed against opinions on ultimate issues by providing that an opinion "is not objectionable just because it embraces an ultimate issue," the Advisory Committee Notes explain that Rule 704 does not "lower the bar so as to admit all opinions." Rules 701 and 702, which require opinions to be helpful to the trier of fact, and Rule 403, which permits exclusion of evidence if its probative value is outweighed by other factors such as undue prejudice or waste of time, "afford ample assurances against the admission of opinions which would merely tell the jury what result to reach." Fed. R. Evid. 704, Advisory Comm. Notes. These rules also "stand ready to exclude opinions phrased in terms of inadequately explored legal criteria," *id.*; in other words, an expert may not opine on legal issues on which a judge will instruct the jury. *United States v. Sinclair*, 74 F.3d 753, 758 n.1 (7th Cir. 1996). Thus, an expert may not invade the province of the jury by simply telling it whose side to take on disputed issues of fact, nor may he invade the province of the court by instructing the jury on legal issues; in either case, the expert's testimony is unhelpful.

In this case, the license agreement sets out a standard of "commercially reasonable efforts" that Sanofi must meet. Contract meaning is typically a question of law, but "what is commercially reasonable" under the circumstances of this case is a "question of fact." *See Metavante*, 619 F.3d at 763. In *Metavante*, the Seventh Circuit held that the district court did not err by admitting opinion testimony offered by an expert with extensive experience in the relevant

industry on whether a party performed its contract in a "commercially reasonable manner," as the terms of the contract explicitly required. *Id.* at 761-62. The Seventh Circuit did not directly address whether the expert's opinion was an inadmissible legal conclusion, but one court in this district has directly addressed—and rejected—that argument. *See Crawford*, 2011 WL 4840965, at *2 (citing *Metavante*, 619 F.3d at 761-62). In *Crawford*, the court explained that expert testimony on the commercial reasonableness of a party's conduct may be admissible if it would "assist the jury in determining a material fact" by providing information on industry norms that are not matters of common knowledge. ** *Id.* at *2.

This Court agrees with the reasoning of *Crawford* and finds it applicable here. "[O]pinions phrased in terms of inadequately explored legal criteria" may be inadmissible, Fed. R. Evid. 704, Advisory Comm. Notes, but Mr. Buckingham's opinion will not be "inadequately explored." He will explain his opinion at length, as he has done in his report and his deposition testimony. Additionally, the Court will instruct the jury "that it is not required to accept an opinion witness's conclusions," which will help to "eliminate any potential unfair prejudice" to Elorac. See Dowe v. Nat'l R.R. Passenger Corp., No. 01-CV-5808, 2004 WL 887410, at *1 (N.D. Ill. Apr. 26, 2004). With full explanation by the expert and proper instruction by the Court, "testimony regarding the reasonableness or unreasonableness of particular conduct will assist the jury in understanding the evidence and determining facts in issue, and will not simply tell the jury what result to reach." *Id.* (internal quotation marks omitted). Elorac's motion is denied on this ground.

⁸ The court in *Crawford* ultimately did not admit the testimony because the expert did not sufficiently connect his experience, which was the basis for his opinion, to the facts of the case, but Mr. Buckingham's proposed testimony does not suffer from this defect.

⁹ Of course, Elorac is offering its own experts on the reasonableness of Sanofi's commercialization efforts, which makes its position on Mr. Buckingham's testimony surprising.

2. Relevance of efforts to secure regulatory approval

Elorac seeks to exclude Mr. Buckingham's testimony to the extent he will render an opinion on Winston's efforts to secure regulatory approval for the Product.

Under the license agreement, it was Winston's responsibility to obtain regulatory approval for the Product, which triggered Sanofi's commercialization obligation. Winston's first attempt to obtain regulatory approval for the Product ended in a notice of non-compliance from Health Canada; in other words, the Product was rejected. At that point, with some assistance from Sanofi, Winston reapplied and successfully obtained regulatory approval under a more limited indication; namely, Sanofi was approved for use only for less than three months and only as an adjunctive treatment by patients who were using NSAIDs or COX-2 inhibitors.

While the Product was still awaiting Health Canada's approval, during the pendency of the Lundbeck opposition proceeding described above in Part III.B of this Memorandum Opinion and Order, the parties decided to seek a new name for the Product, but they did not immediately agree on one. According to Sanofi, Dr. Joel Bernstein, Winston's chief executive officer, insisted on the name "Rheumoderm," although Sanofi believed that Health Canada was unlikely to approve that name, considering that the Product is a treatment for osteoarthritis, not rheumatoid arthritis. Nevertheless, Dr. Bernstein persisted in pressing the application for the name "Rheumoderm" before Health Canada, which ultimately rejected the name. Elorac's theory, as described above in Part III.B, is that Sanofi never believed that there was ever anything wrong with the Product's original "Civanex" name and only pretended otherwise so that it could stall the launch of the Product while it sought a sublicensee.

Elorac points to passages of Mr. Buckingham's deposition testimony in which he suggests that (1) after Winston's own missteps during the application process initially prevented

it from obtaining regulatory approval for the Product, Sanofi generously stepped in to assist Winston with the process, although Sanofi had no obligation to do so under the license agreement, and (2) Dr. Bernstein's unprofessional conduct in pressing the "Rheumoderm" name before Health Canada may have contributed to the delay in obtaining a final decision from Health Canada on the matter. Elorac contends that Mr. Buckingham should be barred from offering this testimony because it is irrelevant and outside the scope of the allegations of the complaint. In its Second Amended Complaint, Elorac alleges that Sanofi's misconduct in failing to commercialize the Product began in May 2010, when the Health Canada application process was complete and the Product was on the verge of obtaining regulatory approval; any expert testimony concerning actions the parties took during the regulatory approval process prior to May 2010, Elorac argues, is irrelevant. As for the Rheumoderm issue, although Dr. Bernstein's efforts continued after May 2010, Elorac argues that any suggestion that Dr. Bernstein's actions had any negative impact on Health Canada's decisions or the Product's fortunes is speculative and irrelevant.

The Court agrees with Elorac that it is clear from the allegations of the Second Amended Complaint that the misconduct Elorac alleges against Sanofi began in May 2010. The Court fails to see how Dr. Buckingham's testimony concerning Sanofi's actions during the regulatory approval process long before that date will assist the trier of fact, especially considering that, in making this motion, Elorac has conceded that those actions do not form the basis for its breach of contract claim, which is based on later events. However, the Court disagrees with Elorac concerning the Rheumoderm issue. Elorac appears to intend to press its theory that it was merely to stall for time to find a sublicensee, not because of the threat represented by the Product's trademark issues, that Sanofi delayed the launch to find a new name for the Product. If

that is Elorac's theory, then it is fair for Sanofi to attempt to prove that Winston contributed to the delay in launching the Product by prolonging or undermining the process of applying for a new name. Elorac's motion is granted in part and denied in part as to this issue.

3. Lack of expertise

Elorac seeks to exclude Mr. Buckingham's testimony to the extent he will render an opinion on subjects on which he has no expertise, such as trademark law or global economics. In particular, Elorac argues that Mr. Buckingham should not be permitted to testify that Sanofi's actions with respect to the commercialization of the Product were commercially reasonable in light of either the threat of trademark litigation or the lingering effects of the global recession that still affected the market in 2010.

Elorac mischaracterizes the basis of this testimony. Although Elorac is correct that Mr. Buckingham is not an expert in trademark law or global economics, Sanofi is not offering his opinion on those matters, *per se*; Sanofi is offering his opinion on how issues of trademark law or global economics might have reasonably impacted the decisions Sanofi's managers and executives—who were also not experts in trademark law or economics—made with respect to the commercialization of the Product. As the Court suggested above in Part III.B. of this Memorandum Opinion and Order with respect to the proposed testimony of Paula Clancy, the professional opinion of an expert in trademark law would probably be less helpful to the jury in determining the commercial reasonableness of Sanofi's handling of the Product's trademark law issues than the opinion of someone familiar with how pharmaceutical companies weigh risks related to the launch of a new pharmaceutical product, including the risk of potential trademark litigation (and in particular, how that risk might stack up against other risks, including the risk of delaying a launch to choose a new product name). The same goes for the risk of soft sales due to

a weak economy. Mr. Buckingham is in a position to understand how pharmaceutical companies might assess and weigh these risks, and it is for this reason that his testimony will assist the trier of fact. Elorac's motion is denied as to this issue.

4. Credibility

Elorac moves to exclude Mr. Buckingham's testimony because, Elorac argues, he makes determinations of the credibility of witnesses or their state of mind. In particular, he assumes at one point where the testimony of Sanofi's Manon Decelles and Elorac's Dr. Bernstein was in conflict about when Ms. Decelles first told Dr. Bernstein that Sanofi would sublicense the Product to Valeant, that Ms. Decelles's account was the correct one.

The Court fails to see any basis for excluding Mr. Buckingham's testimony merely because he assumed that Ms. Decelles rather than Dr. Bernstein was correct about when certain conversations between them took place. The timing of this conversation is not an ultimate factual issue that the jury will have to resolve. In accepting Ms. Decelles's version of the story over Dr. Bernstein's, Mr. Buckingham simply makes an assumption on which his opinion is partially based. Elorac is welcome to explore this and all assumptions on which Mr. Buckingham relied on cross-examination, but the mere fact that he made some assumptions provides no reason for excluding his testimony. *See, e.g., Richman*, 415 F. Supp. 2d at 942 ("Experts routinely base their opinions on assumptions that are necessarily at odds with their adversary's view of the evidence. That does not mean that the expert has made impermissible credibility determinations that preclude him from testifying. If an expert could not base his opinion on assumptions—which in turn are based on testimony—there could be little meaningful and informative expert testimony in any case in which there was a divergence of testimony.") (internal citations omitted).

5. State of mind

Elorac moves to exclude Mr. Buckingham's testimony because, Elorac argues, he offers opinions on the state of mind of Sanofi and its personnel. In particular, according to Elorac, he opines on the state of mind of Sanofi personnel who assisted Elorac with obtaining regulatory approval for the Product and who were involved in the process of seeking approval for the "Rheumoderm" name.

The Court has already explained in Part IV.A.2 of this Memorandum Opinion and Order that any assistance Sanofi may have offered to assist Winston in obtaining regulatory approval prior to May 2010 is irrelevant to Elorac's claims in this case. Thus, any testimony Mr. Buckingham proposes to offer on that topic is excluded, regardless of whether Mr. Buckingham intends to testify to a witness's state of mind. The Court has also already explained in Part IV.A.2, in contrast, that evidence related to the application for approval of the Rhuemoderm name is relevant to the extent Elorac alleges or argues that Sanofi used that process as a stall tactic, but Elorac is correct that Mr. Buckingham may not offer an expert opinion on a person's state of mind, which is a factual determination he is no better qualified to make than the jury. See Salas v. Carpenter, 980 F.2d 299, 305 (5th Cir. 1992). In response to one of counsel's questions at his deposition, Mr. Buckingham seemed to opine on what Sanofi's motivation actually was in proceeding with the Rheumoderm name, and the Court agrees with Elorac that such testimony is inadmissible. If he testifies at trial, Mr. Buckingham must confine his testimony to what was commercially reasonable; he may not testify about the state of mind of Sanofi personnel.

6. Failure to explain prior experience based on confidentiality agreements

Elorac argues that the Court should exclude Mr. Buckingham's testimony because, at his deposition, he claimed that confidentiality agreements with his former employers prevented him from divulging details of two pharmaceutical product launches he had helped to execute while he was with the pharmaceutical companies Optimer and Ipsen. According to Elorac, because Mr. Buckingham relied on this experience in formulating his expert opinions, he is required to describe it in detail, or his testimony must be barred.

But Sanofi's burden under the rules of evidence is not so high. Sanofi has the burden of demonstrating that Mr. Buckingham is sufficiently qualified by his training and experience to opine on the commercial reasonableness of its actions, and to the extent he relies on his experience, he must connect that experience to his testimony. The Court does not agree that he failed to do that merely because he refused to divulge every detail of every product launch with which he had been involved. Mr. Buckingham is qualified by long experience in the industry to give the opinions he is offering, and Elorac does not genuinely dispute his qualifications, nor does Elorac argue with any conviction that it cannot determine whether he is qualified without additional details about his experience at Optimer or Ipsen. The fact that he was bound by confidentiality agreements to refuse to answer certain of Elorac's questions about some aspects of his prior experience, and that this prior experience formed some undefined part of the "background knowledge," see Allstate Ins. Co. v. Electrolux Home Prod., Inc., 840 F. Supp. 2d 1072, 1081 (N.D. Ill. 2012), that informed his opinion, does not undo those qualifications.

For the foregoing reasons, Elorac's motion to exclude the testimony of John Buckingham is granted in part and denied in part. The motion is granted with respect to opinions concerning

pre-May 2010 events related to the process of applying for regulatory approval and with respect to opinions on the state of mind of Sanofi personnel, but it is denied in all other respects.

B. Steve Arthur Blitzer

Elorac moves to exclude the testimony of Steve Arthur Blitzer, a Canadian pain physician. Dr. Blitzer treats chronic pain problems and performs medical assessments of patients with pain conditions as a consultant for insurance companies, law firms, and the Workplace Safety and Insurance Board of Ontario (formerly the Worker's Compensation Board). In his report, Dr. Blitzer explains that, in his opinion, there are a number of different factors that influence what sort of treatment a physician prescribes, including efficacy, cost, and insurance coverage. (See Pl.'s Mem. in Supp. of Mot. to Exclude Testimony of Dr. Steve Arthur Blitzer, Ex. 1, Raver Affidavit, Ex. A, Blitzer Report at 5-6, ECF No. 242-1.) Next, Blitzer reviews the "mixture" of options for treating chronic pain associated with osteoarthritis, discusses their relative advantages and disadvantages, and opines on how physicians typically choose among them. (Id. at 6-9.) Finally, he describes his experience with the Product, including his interactions with Valeant salespeople promoting it, the results he has seen in his patients when he has prescribed the Product, and the factors he believes make the Product an unappealing treatment option, particularly given that it is an adjunctive therapy that is only approved to be prescribed for a three-month time period. (*Id.* at 9-14.)

Elorac argues that Dr. Blitzer's expert testimony should be excluded because his first-hand knowledge of the Product is limited and unreliable; his knowledge of the treating and prescribing practices of other physicians is limited and unreliable; and his opinion on his interactions with Valeant salespeople is not opinion testimony at all but untimely-disclosed fact testimony.

1. Opinions on effectiveness of Product based on experience prescribing it and on range of treatment options for osteoarthritis

Elorac argues that Dr. Blitzer's limited first-hand experience with prescribing the Product is an insufficiently reliable basis for his opinions about the Product's effectiveness and how it fits into the range of treatment options for osteoarthritis, especially considering that Dr. Blitzer admitted that he has not prescribed the Product often.

The Court agrees with Elorac that Dr. Blitzer's personal experience is not a sufficient basis for a scientifically reliable opinion on the clinical effectiveness of the Product and whether it is typically a useful or attractive option to patients. Sanofi itself has argued in this round of *Daubert* motions that the Seventh Circuit requires an expert to make use of the "empirical toolkit of the social sciences" where possible, or show that "some problem blocked the use of . . . statistical tools." *See Zenith*, 395 F.3d at 419. But Dr. Blitzer has made no effort to use statistical tools, and it is obvious that nothing "blocked" the use of the scientific "toolkit" to analyze whether the Product is an effective treatment for osteoarthritis; the record of this case is rife with examples of studies of the performance of pharmaceutical products. Dr. Blitzer's opinion on the effectiveness of the Product is barred.

It is not clear whether Elorac similarly seeks to bar Dr. Blitzer from testifying generally on the range of treatment options for osteoarthritis available to Canadian patients (*see, e.g.,* Blitzer Report at 6-9, ECF No. 242-1), or if Sanofi would call him to offer any such testimony even if he were barred from opining on the Product's effectiveness. But to the extent Elorac seeks to bar this testimony as well, it stretches its arguments too far. Dr. Blitzer is a practicing physician who treats patients with osteoarthritis in Canada, *i.e.*, patients who have the ailment the Product was intended to treat in the market where the parties intended to launch it. He is qualified by his experience to describe the landscape of treatment options available to

osteoarthritis patients in Canada and how he helps his patients weigh their options, and this testimony would likely assist the trier of fact in assessing what sort of promotional activity was commercially reasonable under the circumstances. His testimony on that issue is therefore admissible.

2. Opinion on prescribing practices

Elorac argues that Dr. Blitzer is not qualified to opine on the prescribing practices of Canadian physicians generally and his opinion is not based on scientifically reliable methodology in that regard. According to his report, Dr. Blitzer's opinion on physicians' general prescribing practices is based on his own experience as a physician, his conversations with other physicians, and his review of medical records in connection with the medical assessment and consulting work he sometimes performs. (*See id.* at 4-6.) According to Elorac, Dr. Blitzer "conducted no independent systematic research and relied upon no research, studies or surveys of any kind to support his opinions." (Pl.'s Mem. at 12, ECF No. 242.)

The Court agrees with Elorac that this opinion does not satisfy the standard set by Daubert and the Federal Rules of Evidence because it is based on anecdotal evidence consisting of Dr. Blitzer's own observations as a member of the medical community in Canada. While it is not inappropriate per se for an expert to rely on his own personal experience, this particular subject appears to be one that could be illuminated by a scientific analysis making use of the "empirical toolkit of the social sciences." See Zenith, 395 F.3d at 419. But again, Dr. Blitzer has not provided any such analysis, nor has Sanofi shown that "some problem blocked the use of . . . statistical tools." Id. To the contrary, it appears that it would have been feasible to perform some sort of systematic review of medical records or other data that might have provided a

scientifically reliable basis for an opinion on physicians' general prescribing practices. Dr. Blitzer did not do so, so his testimony on this point is barred.

3. Opinion on Valeant promotional effort

Elorac argues that Dr. Blitzer should not be permitted to offer testimony on Valeant's efforts to promote the Product. According to Elorac, such testimony is not expert opinion testimony but prejudicial and untimely-disclosed fact testimony based on nothing more than Dr. Blitzer's own observations as a target of Valeant salespeople. The Court agrees with Elorac. Allowing Dr. Blitzer to offer fact testimony in the midst of expert testimony could confuse and mislead the jury and cause prejudice to Elorac. His testimony on Valeant's marketing efforts will be barred.

In conclusion, Dr. Blitzer will be barred from testifying as to the clinical effectiveness or usefulness of the Product or the general prescribing practices of physicians, but he will be permitted to testify as to the range of options available to Canadian patients suffering from osteoarthritis, including the Product. Elorac's motion to exclude the expert testimony of Dr. Blitzer is granted in part and denied in part.

C. Simon Alexander

Elorac moves to exclude the testimony of Simon Alexander. For over twenty years, Mr. Alexander worked in regulatory affairs for a number of pharmaceutical companies, ultimately serving as Director of Drug Regulatory Affairs for Novartis Pharmaceuticals Canada, Inc. For the last five years, he has worked as a consultant in pharmaceutical regulatory affairs for clients throughout the health care industry.

Mr. Alexander proposes to describe and critique the parties' efforts to obtain regulatory approval to market the Product in Canada. Mr. Alexander explains in his report that Winston's

efforts in that regard were initially unsuccessful, which prompted Sanofi to become involved in the process, ultimately resulting in the Product's approval under a modified indication in July 2010. (*See* Pl.'s Mem. in Supp. of Mot. to Exclude Testimony of Simon Alexander, Ex. 1, Raver Affidavit, Ex. A, Alexander Report at 1-14, ECF No. 238-1 at 7-21.) He also briefly discusses the effort to change the name of the Product to Rheumoderm and the 2012 application to Health Canada to broaden the Product's approved indication. (*See id.* at 15-17.)

Elorac argues that any opinions Mr. Alexander might offer on regulatory proceedings taking place prior to the Product's approval in 2010 are irrelevant because Elorac has not alleged any wrongdoing against Sanofi prior to May 2010. The Court agrees. As the Court has already explained in Part IV.A.2 of this Memorandum Opinion and Order, it is clear from the allegations of the complaint that the misconduct Elorac alleges against Sanofi began in May 2010, and testimony concerning the parties' actions during the regulatory approval process long before that date will not assist the trier of fact. This is especially true considering that, in briefing this motion as well as the motion to exclude John Buckingham's testimony, Elorac has expressly conceded that actions before May 2010 do not form the basis for its breach of contract claim, which is based on later events. Thus, Mr. Alexander's testimony on pre-May 2010 events is irrelevant, will not assist the trier of fact, and is therefore inadmissible.

Although Elorac argues for excluding any testimony concerning the Rheumoderm issue, the Court has already explained in Part IV.A.2 above that this evidence is relevant to rebut Elorac's theory that the delay in launching the Product until approximately a year after it received regulatory approval was attributable to Sanofi's stalling for time to find a sublicensee. Similarly, Mr. Alexander's discussion of the attempt to broaden the Product's indication in 2012 so that it could be prescribed more widely is relevant to the extent it sheds

light on whether Sanofi made reasonable, good-faith efforts to commercialize the Product after it received regulatory approval in 2010. Mr. Alexander's testimony on these issues is relevant and admissible.

Elorac also argues that Mr. Alexander impermissibly offers opinions on the state of mind and credibility of certain of the parties' employees. For example, he opines that a Health Canada employee with whom Dr. Bernstein tangled during the Rheumoderm episode was not a "low-down employee," as Dr. Bernstein had said, but an "experienced and well-respected individual." The Court agrees with Sanofi that Elorac "exaggerates" by characterizing these remarks as testimony on state of mind or credibility. (*See* Sanofi Resp. Br. (Alexander) at 13-14, ECF No. 304.) Mr. Alexander is simply providing his opinion based on "reasonable conclusions an expert can draw from the evidence" of the interactions among Winston, Sanofi and Health Canada. (*See id.* at 14.) These conclusions do not cross the line between analysis of the reasonableness of certain behavior and opinions on state of mind or credibility.

Finally, Elorac argues that Mr. Alexander should be barred from testifying on certain matters with which he lacks sufficient expertise. He proposes to testify that Health Canada's rejection of the Rheumoderm name is "not surprising," based on the relevant regulations, and that Winston had "no basis for contacting the regulator" during the Rheumoderm process, when it was not the legal owner of the Product's drug identification number (Alexander Report at 15, ECF No. 238-1 at 21)—but, Elorac argues, Mr. Alexander is not a regulatory lawyer and is unqualified to give these opinions. Further, he proposes to testify that Health Canada's approval of the Product was unlikely to influence American and European regulatory authorities—but, Elorac argues, he has no expertise with pharmaceutical regulation in those countries. However, these criticisms go to weight rather than admissibility. Mr. Alexander is qualified as an expert in

pharmaceutical regulatory affairs based on a decades-long career working in that field for major pharmaceutical companies. Even if his direct experience has been limited to Canada, he worked for companies with global reach and has "co-led many international project teams" (*id.* at 1, ECF No. 238-1 at 7); he certainly has some familiarity with how other regulatory regimes in other countries might interpret and use decisions by Health Canada. In Part III.A of this Memorandum Opinion and Order, this Court rejected Sanofi's argument that the fact that most of Mr. Baldini's experience has been outside Canada should bar him from testifying, concluding instead that his decades of experience in the global pharmaceutical industry qualify him as an expert, and the weight his opinion should receive, given his lesser familiarity with the Canadian market, is an issue for Sanofi to explore on cross-examination. The Court now rejects Elorac's similar argument for similar reasons.

Elorac's motion to bar Mr. Alexander's testimony is granted in part and denied in part. The motion is granted as to any testimony concerning the Product's regulatory record prior to May 2010. The motion is denied as to any testimony concerning regulatory proceedings occurring after May 2010.

D. Tamar D. Howson

Elorac moves to bar the testimony of Tamar D. Howson. Ms. Howson has worked in the pharmaceutical industry for approximately three decades, serving as an executive of global pharmaceutical companies and, more recently, a pharmaceutical industry consultant. Her particular area of expertise is in business development, *i.e.* negotiating licensing deals among pharmaceutical and biotechnology companies. She opines that Sanofi's commercialization efforts were reasonable because the Product had limited potential, which would not have been enhanced by conducting a more aggressive marketing campaign, and because the sublicensing

deal with Valeant was more advantageous to Elorac than terminating the license agreement with Winston/Elorac outright.

Elorac argues that Ms. Howson's testimony should be excluded because (1) she impermissibly makes legal conclusions on ultimate issues, (2) her opinions are not relevant, to the extent she proposes to testify on efforts to obtain regulatory approval, (3) her opinions on granular issues of sales and marketing and on regulatory issues exceed her expertise, given her higher-level experience, (4) she offers opinions on the state of mind and credibility of party employees such as Dr. Joel Bernstein and Dr. Jeffrey Bernstein, President and Chief Executive Officer of Elorac.

1. Legal conclusions on ultimate issues

Elorac argues that Ms. Howson's opinions include a number of inadmissible legal conclusions.

First, Elorac argues that Ms. Howson's opinion that Sanofi fulfilled its obligations under the license agreement by making reasonable efforts to commercialize the Product is an impermissible legal conclusion on an ultimate issue. Elorac made a similar argument in support of its motion to exclude the testimony of John Buckingham, and the Court rejected it, explaining in Part IV.A.1 of this Memorandum Opinion and Order that what is "commercially reasonable" in a particular commercial context is a proper subject for expert testimony under *Daubert* and the Federal Rules of Evidence. The same principle applies here, and Ms. Howson will be permitted to provide her opinion on whether Sanofi's efforts to commercialize the Product were commercially reasonable. (*See, e.g.*, Def.'s Mem. in Opp., Ex. A, Howson Report at 7, ECF No. 312-1 ("Sanofi Canada's efforts to prepare a launch and commercialization strategy for the Product were comparable to those efforts employed in support of a product of similar potential as

determined based on information available prior to receiving regulatory approval. However, its decision to modify that strategy in light of the Product's limited indication was also commercially reasonable.").)

However, in portions of her report and deposition testimony, Ms. Howson reviews the meaning of specific contract language in section 1.9 of the license agreement, the section that defines "commercially reasonable efforts," and these portions of her proposed testimony cross the line between helpful opinion testimony and testimony that invades the province of the court by instructing the jury as to the meaning of a contract. (See, e.g., id. ("The language in Section 1.9 of the License Agreement is customary in the pharmaceutical industry and aims to reflect the parties' agreement that the licensee, in this case, Sanofi Canada, has the flexibility and discretion in determining when, how, and to what extent, it will commercialize the Product."); see generally Pl.'s Mem. in Supp. of Mot. to Exclude Expert Testimony of Tamar D. Howson, Ex. 1, Raver Affidavit, Ex. A, Howson Dep. at 36:21-39:17, ECF No. 254-1; Howson Report at 6-8.) In these passages, Ms. Howson is doing something more than simply opining on whether, based on her experience in the industry, a particular party's performance under a contract was "commercially reasonable," as the contract required, in a particular commercial context, cf. Metavante, 619 F.3d at 761-63; she takes the additional step of opining on the specific meaning of contract terms.

The Court recognizes that Ms. Howson's interpretation hews closely to the plain language of the contract, and it might be obvious to the jury; when asked at her deposition how she reached certain of her conclusions about the contract language, she answered simply, "it's written in English." (Howson Dep. at 39:22.) Still, *Daubert* and the Federal Rules of Evidence do not permit her to opine on the meaning of specific contract language because to do so would

be to offer a legal conclusion that might "allow[] the jury to infer that it could look to that witness for legal guidance[,] and . . . impermissibly tilt[] the balance of power between the parties." *See Cont'l Bank Corp.*, 922 F.2d at 366. Ms. Howson will be barred from opining on the meaning of specific contract language.

Second, Elorac argues that Ms. Howson also offered legal conclusions at her deposition when she addressed the Lundbeck trademark opposition. The Court has already explained in Part IV.A.3 of this Memorandum Opinion and Order, in which it addressed Elorac's similar argument for excluding the testimony of John Buckingham, that the opinion of someone familiar with how pharmaceutical companies weigh risks related to the launch of a new pharmaceutical product, including the risk of potential trademark litigation, is relevant and would be helpful to the trier of fact. That is precisely the sort of opinion Ms. Howson offers. Elorac's motion to exclude her testimony will be denied on this ground.

Finally, Elorac argues that Ms. Howson offers legal conclusions on whether Sanofi violated the terms of the license agreement when it assigned its contract rights to Valeant. (Howson Dep. at 200-04.) The Court agrees that this testimony concerns a pure legal issue that does not directly bear on the commercial reasonableness of Sanofi's actions and would not assist the trier of fact. Ms. Howson will be barred from offering her opinion on this point at trial.

2. Regulatory Approval

Elorac argues that Ms. Howson's testimony concerning the parties' actions during the process of seeking regulatory approval is irrelevant. As the Court has already explained in Parts IV.A.2 and IV.C above, expert testimony concerning the actions the parties took during the regulatory approval process prior to May 2010, particularly Winston's alleged missteps and "Sanofi's allegedly heroic efforts in assisting Elorac in obtaining regulatory approval" (Pl.'s

Mem. at 10, ECF No. 254), is irrelevant and will be barred. ¹⁰ However, expert testimony concerning actions taken after that time, particularly actions taken in connection with the Rheumoderm name-change effort, is relevant and admissible. Elorac's motion is granted in part and denied in part on this issue.

3. Lack of Expertise

Elorac argues that Ms. Howson's testimony should be barred because she lacks direct, personal experience with certain aspects of pharmaceutical sales, marketing and regulation that are critical to this case. For example, she offers opinions on Sanofi's launch and commercialization strategies, but she admitted at her deposition that she has never personally overseen the launch of a pharmaceutical product or the training or performance of a sales force. Similarly, she opines on Sanofi's assessment of the probability of success in applying to Health Canada for a broader indication that would dispense with the three-month use limitation, but she admitted that she is not an expert in regulatory compliance.

Elorac conceives of relevant experience too narrowly. Ms. Howson has decades of experience in business development in the pharmaceutical industry. To negotiate licensing deals effectively, she must understand the particular parties' respective interests and positions, which requires understanding issues such as how products are likely to be promoted and how they might achieve regulatory approval or maintain regulatory compliance. None of the passages of deposition testimony that Elorac cites demonstrates any lack of competence or familiarity with these topics on Ms. Howson's part; to the contrary, she discusses these issues with the

_

¹⁰ In its response brief, Sanofi argues at length that it should be permitted to prove that it entered into the license agreement in the expectation that the Product would receive a broader indication than the one Health Canada ultimately approved. The Court does not understand Elorac to be seeking to bar testimony on this point, and nothing in the Court's ruling should be understood to prevent Sanofi from offering evidence to that effect. What Sanofi is barred from introducing is evidence bearing on the process of seeking and obtaining regulatory approval prior to May 2010, including evidence of specific steps (or missteps) the parties took in order to advance the goal of obtaining regulatory approval prior to May 2010. Sanofi's expectations about what the outcome of the regulatory approval process would be are outside the scope of the Court's present ruling.

confidence befitting someone with such long experience in the industry. On cross-examination Elorac is free to attempt to explore the limits of Ms. Howson's familiarity with these aspects of commercializing pharmaceutical products, but any weakness it discovers goes to the weight the jury should give her testimony rather than its admissibility. Elorac's motion is denied on this ground.

4. Credibility

Elorac argues that Ms. Howson improperly offers opinions on the credibility of Winston and Elorac's Dr. Joel Bernstein and Dr. Jeff Bernstein with respect to certain disputed facts, including when Sanofi notified Winston that it would not market the Product itself and whether Sanofi's CEO promised in December 2012 that Sanofi would submit and pay for an application to change the Product's three-month use limitation. 11 The Court agrees with Elorac that Dr. Howson may not offer her opinion on which of two witnesses is telling the truth on a particular point. See United States v. Benson, 941 F.2d 598, 604 (7th Cir. 1991) ("Credibility is not a proper subject for expert testimony; the jury does not need an expert to tell it whom to believe, and the expert's stamp of approval on a particular witness'[s] testimony may unduly influence the jury.") (internal quotation marks omitted). The Court has explained that experts may make assumptions about disputed facts and give opinions based on them, but they may not simply tell the jury whom to believe on a disputed point. Although Ms. Howson's opinions on the Bernsteins' credibility on a couple of facts represent a very minor aspect of her testimony almost unrelated to the main thrust of her opinion on commercial reasonableness, the Court agrees with Elorac that she should be barred from offering these opinions at trial.

¹¹ Elorac also argues that Ms. Howson improperly speculates as to Sanofi's motivation in assisting Winston with obtaining regulatory approval, but the Court need not address this issue because it has already explained that testimony concerning efforts to secure regulatory approval prior to May 2010 is irrelevant and inadmissible.

Elorac's motion to bar Ms. Howson's testimony is granted in part and denied in part. The motion is granted with respect to Ms. Howson's opinions on (a) the meaning of specific language in the license agreement, (b) whether Sanofi violated the terms of the license agreement by assigning its rights to Valeant without approval from plaintiff, (c) the parties' actions during the process of seeking regulatory approval prior to May 2010, and (d) the credibility of the Bernsteins concerning certain communications with Sanofi. In all other respects the motion is denied.

E. Rahul Guha

Elorac moves to exclude the testimony of Rahul Guha. Dr. Guha has a Ph.D. in management, with a focus on economics and quantitative marketing, and he works as a Senior Vice President and head of the Antitrust and Competition Practice at Cornerstone Research, an economic consulting firm. From 2007 to 2014, he served as the head of Cornerstone's Pharmaceuticals and Healthcare Practice. He has consulted on a "wide variety of economic issues arising in antitrust and competition, intellectual property, valuation, and contractual matters in the pharmaceutical and healthcare industries." (Def's Mem. in Opp., Ex. A, Guha Report at 1, ECF No. 310-1.)

Dr. Guha opines that Mr. Baldini and Dr. Purohit's conclusions are fundamentally flawed because they fail to account for the fact that the licensing deal between Sanofi and plaintiff gave Sanofi every incentive to use commercially reasonable efforts to promote the Product, and if Sanofi did not make commercially reasonable efforts to promote the Product, it was acting against its own interest in that regard. Additionally, Dr. Guha opines, Elorac's expert's opinions are flawed to the extent they rely on Pennsaid and the Synvisc products as benchmarks because these products are not closely analogous to Civamide Cream and might have had significantly

different sales expectations. In particular, Dr. Guha explains that in his opinion, Dr. Manning's analysis is flawed because he relies on Pennsaid's responsiveness to marketing without analyzing or accounting for the Product's actual responsiveness to marketing after its launch, which, according to Dr. Guha's calculations, was dramatically lower than Pennsaid's. ¹²

Elorac argues that Dr. Guha's testimony should be excluded because it is (1) irrelevant and (2) exceeds Dr. Guha's expertise.

1. Relevance

Elorac argues that Dr. Guha's opinion concerning Sanofi's incentives under the license agreement and the economic irrationality of its alleged misconduct under the license agreement is irrelevant and unhelpful to the trier of fact because it has little bearing on whether Sanofi committed the intentional breach of contract that Elorac has alleged. Dr. Guha's opinion is based on the fact that the licensing arrangement was structured so that if the Product succeeded, both parties benefited financially; this obvious point, Elorac argues, does not bear at all on Elorac's theory that Sanofi unreasonably determined that the Product would not succeed and abandoned its contractual obligation to commercialize it.

The Court agrees with Elorac that Dr. Guha's opinion on the matter of incentives under the license agreement would not assist the trier of fact, at least not enough to justify the risk that the jury would place undue weight on the testimony because it has a "gloss of expertise," *cf. Victory Records*, 2011 WL 382743, at *2; *see also Davis v. Duran*, 277 F.R.D. 362, 369 (N.D. Ill. 2011) (citing *Daubert*, 509 U.S. at 595 ("Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 of the present rules exercises more

56

¹² Dr. Guha also critiques the analysis of Elorac's other damages expert, Dr. Walton, but because the Court has already explained that it will bar Dr. Walton's testimony, it will likewise bar Dr. Guha's critique of it.

control over experts than over lay witnesses.")). The jury has no need to hear from an expert that Sanofi stood to make money under the license agreement if the Product was successful; it is obvious from the terms of the license agreement themselves, and any witness familiar with the terms of the license agreement can provide the same testimony. No expert economic analysis is necessary on that basic point, nor, in truth, did Dr. Guha perform any; his opinion appears to be based simply on his review of the license agreement, not a scientific analysis. True, Dr. Guha possesses expertise on which he could draw in evaluating the agreement, but he has not explained, and the Court does not see, how this expertise added anything to the evaluation that would elevate Dr. Guha's opinion above the opinion a layperson might reach upon review of the license agreement. Dr. Guha's opinion on Sanofi's economic incentives under the license agreement would not be helpful to the trier of fact and is barred.

2. Lack of expertise

Elorac argues that Dr. Guha exceeds his expertise by opining that Elorac's experts have chosen inappropriate benchmarks in Pennsaid and the Synvisc products. According to Elorac, Dr. Guha has no expertise in pharmacology, he has no direct experience within the pharmaceutical industry as a pharmaceutical company employee, he has never personally been involved in plans to launch a pharmaceutical product, and he therefore has no basis for opining that the benchmarks Elorac's experts have used are inappropriate, especially considering that Sanofi and Valeant's own documents show that they viewed

The Court agrees with Elorac that the Court should exclude Dr. Guha's opinion on the appropriateness of the benchmark products used by Elorac's experts, to the extent it is based on Dr. Guha's own comparison of the characteristics of benchmark drugs with those of the Product. Dr. Guha explains that he analyzed the facts of this case "as an economist" might (Pl.'s Mem. in

Supp. of Mot. to Exclude Testimony of Dr. Guha, Ex. 1, Raver Affidavit, Ex. A, Guha Dep. at 130:14-15, ECF No. 250-1), which is the only way in which he is qualified by experience and training to analyze it; but no economic analysis reliably supports his opinion that there are important differences between Civamide Cream and Pennsaid or the Synvisc products that might significantly affect the market potential of the products. It is Dr. Guha's mere *ipse dixit* that connects his opinion to the characteristics of the drugs; he does not adequately explain how either scientific analysis or professional experience led him to his opinion.

Dr. Guha's calculation of the actual responsiveness to marketing of the Product after its launch, which turned out to be much lower than Pennsaid's, and which Dr. Guha believes supports his opinion that it was not commercially reasonable for Sanofi or its partners to spend more on marketing the Product, stands on different footing. This is the sort of quantitative analysis Dr. Guha is qualified to perform by his experience and training, and excluding his testimony on this point would require the Court to cross the line between assessing the scientific reliability of an expert's opinion, which is the Court's proper function under *Daubert*, and assessing his credibility, which is for the jury to decide.

True, Elorac identifies a potentially serious flaw in this analysis, which is that, in forming his opinion, Dr. Guha did not take into account any strategic or tactical deficiency in the marketing of the Product; he simply assumed that any dollar spent on marketing the Product was as good as any other dollar, no matter how ill-conceived the overall marketing strategy or ill-timed the marketing effort. At his deposition he could not clearly articulate any defense of this assumption. (Guha Dep. at 122-24, 130-133.) But Elorac does not frame this flaw as a failure of Dr. Guha's methodology (perhaps because one of its own experts, Dr. Manning, uses a similar methodology). Rather, it argues that the Product's apparently meager responsiveness to

marketing is not illuminating because its sales record was tainted by the "disastrous launch of the Product." (Pl.'s Mem. at 12, ECF No. 250.) This is essentially an argument that Dr. Guha did not select an appropriate "data set"—but, as the Court explained in rejecting Sanofi's similar argument to exclude the testimony of Dr. Manning, "an expert's reliance on faulty information is a matter to be explored on cross-examination; it does not go to admissibility," provided there is at least a "rational connection between the data and the opinion." *See Manpower*, 732 F.3d at 809 (citing *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 432 (7th Cir. 2013) ("Our system relies on cross-examination to alert the jury to the difference between good data and speculation.")). There is certainly such a "rational connection" here. Elorac will have the chance to confront Dr. Guha with its theory that the Product did not sell because its launch was inadequate, both in terms of investment and execution, and that the inadequacy of the launch corrupted Dr. Guha's analysis, and the jury will decide his credibility; this potential weakness provides no reason to bar his testimony on this point.

Elorac's motion to exclude Dr. Guha's expert testimony is granted, except that Dr. Guha will be allowed to testify that the Product's responsiveness to marketing was small in comparison with Pennsaid's.

CONCLUSION

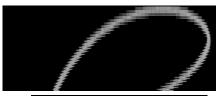
For the reasons set forth above, the Court makes the following rulings:

Sanofi's motion to exclude the testimony of Robert E. Baldini [259] is denied. Sanofi's motion to exclude the testimony of Paula Clancy [263] is granted. Sanofi's motion to exclude the testimony of Ahnal Purohit [267] is denied. Sanofi's motion to exclude the testimony of Richard L. Manning [271] is denied. Sanofi's motion to exclude the testimony of Edward Walton [275] is granted.

Elorac's motion to exclude the testimony of John Buckingham [245, 247] is granted in part and denied in part; the motion is granted with respect to opinions concerning pre-May 2010 events related to the regulatory approval process and opinions concerning the state of mind of Sanofi personnel, but it is denied in all other respects. Elorac's motion to exclude the expert testimony of Dr. Steve Arthur Blitzer [241, 243] is granted in part and denied in part; Dr. Blitzer will be barred from testifying as to the clinical effectiveness or usefulness of the Product or the general prescribing practices of physicians, but he will be permitted to testify as to the range of options available to Canadian patients suffering from osteoarthritis, including the Product. Elorac's motion to exclude the testimony of Simon Alexander [237, 239] is granted in part and denied in part; the motion is granted as to any testimony concerning the Product's regulatory approval proceedings prior to May 2010, but denied as to any testimony concerning regulatory proceedings occurring after May 2010. Elorac's motion to exclude the testimony of Tamar D. Howson [253, 255] is granted in part and denied in part; the motion is granted with respect to Ms. Howson's opinions on (a) the meaning of specific language in the license agreement, (b) whether Sanofi violated the terms of the license agreement by assigning its rights to Valeant without approval from plaintiff, (c) the parties' actions during the process of seeking regulatory approval prior to May 2010, and (d) the credibility of the Bernsteins concerning certain communications with Sanofi, but in all other respects the motion is denied. Elorac's motion to exclude the testimony of Rahul Guha [249, 251] is granted in part and denied in part; Dr. Guha will be allowed to testify that the Product's responsiveness to marketing was small in comparison with Pennsaid's, but in all other respects the motion is granted and his testimony will be barred.

SO ORDERED.

ENTERED: August 21, 2017



HON. JORGE ALONSO United States District Judge