UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN, INC. Plaintiff, v. F. HOFFMAN-LA ROCHE LTD., a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company, and HOFFMAN-LA ROCHE INC., a New Jersey Corporation Defendants.	C.A. No. 05-12237-WGY

MEMORANDUM OF LAW IN SUPPORT OF AMGEN'S MOTION TO EXCLUDE THE EXPERT TESTIMONY OF LAUREN J. STIROH

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I. INTRODUCTION

The testimony of Roche's proposed antitrust damages expert, Lauren J. Stiroh, amounts to nothing more than junk science unsupported by evidence or economic analysis.[1] The Court should exclude this testimony for three reasons.

First, Dr. Stiroh's lost profits calculations rested upon the assumption that Roche would obtain FDA approval for peg-EPO on May 18, 2007. When Roche failed to get such approval, Dr. Stiroh admits that, for ten days after learning of the FDA decision, she believed that Roche would no longer have any claim for lost profits, since it would now neither obtain approval nor launch peg-EPO until after the conclusion of the September 4, 2007, trial in this matter. On May 30, 2007, however, the day before Dr. Stiroh's deposition, Roche's lawyers, in a desperate attempt to salvage Roche's primary damages claims, instructed Dr. Stiroh to change this key assumption so that her damages calculations would not be obsolete. The facially untenable theory that the lawyers concocted to justify the continued validity of Dr. Stiroh's calculations is that, following a jury verdict in Roche's favor, the Court would delay enjoining Amgen's anticompetitive behavior for months, beyond the projected start of peg-EPO's sales in December 2007. Thus—solely because of this Court's scheduling—there would still be a period of time in which Roche's participation in the market and Amgen's anticompetitive acts coexisted, and Roche would suffer lost sales. According to the lawyers, this period of post-trial coexistence could last for three months or longer, which would allow Dr. Stiroh's damages calculation to remain unchanged.

Second, Dr. Stiroh fails to analyze the possibility of alternative causation for the damages she asserts. Specifically, she does not segregate damages attributable to the alleged

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[1] See generally Ex. 1 ¶¶ 274-318 (explaining why "Dr. Stiroh's analysis is essentially an exercise in speculation and arithmetic that is devoid of foundation and support, or the application of any economic analysis").

anticompetitive conduct from lost sales and additional expenditures attributable to wholly lawful activities. As numerous courts have recognized, such failure is fatal to an expert's testimony.

Third, Dr. Stiroh failed to perform any economic analysis to derive her damages figures arising from the alleged threats and this litigation. Instead, she adopts those figures directly from Roche witnesses or documents, without applying any analysis at all. Dr. Stiroh's testimony on these points thus is no more useful than that of a lay witness, and the Court should exclude it.

II. FACTUAL BACKGROUND[2]

Dr. Stiroh assessed damages in the following amounts, for the reasons noted below:

- $14.45 million in lost profits due to Amgen's alleged conduct reducing Roche's sales between the time Roche begins sales and the conclusion of trial;
- $90.37 million in lost profits suffered after all anticompetitive acts have stopped, because of the "lingering effects" that those acts will cause for two-and-a-half years following entry of an injunction;
- $13 million in lost sales prior to trial that Roche estimates will result from the "launch proximity to litigation," i.e., physicians' desire to wait until the conclusion of trial before trying peg-EPO;
- $1.79 million in additional marketing expenses that Roche claims it already incurred to counteract Amgen's activities; and
- $5.5 million in litigation expenses that Roche incurred in the defense of this action and claims as Walker Process damages.

Dr. Stiroh traced the $14.45 million and $90.37 million figures entirely to (1) lost sales to Fresenius (the largest of the two large dialysis organizations, "LDOs") because of Amgen's long-term contract with Fresenius, and (2) lost sales to hospitals because of Amgen's hospital discounting practices. Ex. 2 ¶¶ 67, 73, 81, 85. She attributed the need for the $1.79 million in additional spending and at least part of the $13 million in lost sales as being caused by statements

[2] See the Memorandum of Law in Support of Amgen's Motion for Summary Judgment on Roche's Antitrust and State Law Counterclaims (hereinafter "Amgen's Summary Judgment Memorandum") for more details on the factual background of the case.

that Amgen's head of sales, Leslie Mirani, made to two or three individuals who work for small dialysis organizations ("SDOs"). Id. ¶¶ 52-54, 67, 80, 85-87, 89. Ms. Mirani's statements concerned the potential consequences if customers switched to peg-EPO and then Amgen was successful in the trial of this matter. Id. ¶¶ 51-54. Roche calls these statements "threats."

A. Dr. Stiroh Based Her Lost Profits Damages on the FDA Approving Peg-EPO in May 2007.

On April 6, 2007, Dr. Stiroh submitted her report. Ex. 2. She assumed that the FDA would approve peg-EPO in May 2007, and that Roche accordingly would launch the product in July 2007. Ex. 2 ¶ 21. Three of the five damages categories she asserted depended for their existence on this assumption: the $14.45 million, the $90.37 million, and the $13 million.

First, Dr. Stiroh calculated $14.45 million in lost profits on LDO and hospital sales between July 2007, Roche's anticipated launch date given May 2007 FDA approval, and the September 2007 trial date. Ex. 2 ¶ 79. Dr. Stiroh's calculation of the $14.45 million, which she described as "[l]ost profits due to hindered entry," was predicated on her assumption that Amgen's alleged anticompetitive acts against Roche would occur from the time that Roche launched peg-EPO and would continue until October 1, 2007, when she assumed the trial in this case would result in a verdict in favor of Roche on the antitrust counts and stop the injury-causing behavior. Ex. 2 ¶ 90; see id. ¶ 60 ("My damages calculations specifically assume that any of Amgen's actions deemed to be unlawful by this Court will be halted at the close of trial.").

Second, Dr. Stiroh calculated $90.37 million in lost profits on LDO and hospital sales due to the post-trial "lingering effects" of Amgen's pre-trial anticompetitive behavior:

> Post trial, lost profits stem from lingering effects of actions prior to trial because it will take some time for Roche to be restored to the position it would have been in had these actions never occurred. These lingering future damages assume no unlawful Amgen actions after the trial has concluded.

Ex. 2 ¶¶ 60, 84. Dr. Stiroh explained that these future damages will exist because

> even if Amgen's anticompetitive contracting practices and related actions are halted at the time of trial, it will take some time for Roche to be restored to the position it would have been in had it been free to compete for all sales from July 2007.

Id. ¶ 81. According to Dr. Stiroh's figures, these "[l]ost profits due to lingering effects of impeded entry" would not end until after the first quarter of 2010. Id. ¶¶ 83-84, 90. Thus, Dr. Stiroh assumes that less than three months of alleged anticompetitive behavior would cause lost sales for two-and-a-half years after the behavior ended.

Third, Dr. Stiroh adopted in her report an additional $13 million in lost sales that Roche estimated would result from the proximity of the July 2007 product launch to the September 2007 trial in this matter:

> According to Roche's 2007 MIRCERA Business Plan, the "[p]roximity of launch to trial causes physicians to wait until trial completion to try MIRCERA." This is estimated to result in lost sales of $13 million. A part of these estimated lost sales is associated with customer threats.

Ex. 2 ¶ 80 (footnotes omitted). This $13 million in asserted damages thus results from lost sales between July 2007 and September 2007, when Roche believed that uncertainty over the trial's outcome would dissuade customers from trying peg-EPO.

Before Dr. Stiroh submitted her report, attorneys for Roche read a number of drafts of the report, and Dr. Stiroh and the attorneys extensively discussed the contents of her draft and final reports. Ex. 3 at 34:13-23, 36:2-38:11. During the course of this extensive review and discussion, Roche's attorneys never told Dr. Stiroh that her assumption that Amgen's anticompetitive acts would end at the conclusion of trial was incorrect. Id. at 34:24-35:25, 38:12-39:3.

B. Roche Attempted to Resurrect Dr. Stiroh's Damages Figures When Roche Failed to Obtain FDA Approval.

On May 18, 2007, the FDA declined to approve peg-EPO, instead issuing an "approvable" letter and postponing any possible approval of peg-EPO until the fall. Ex. 4. Dr. Stiroh read Roche's press release about the FDA decision on May 20. Ex. 3 at 219:13-17. Between May 21

and May 30, 2007, she had a number of conversations with attorneys and one conversation with a business person employed by Roche regarding the impact of the FDA's decision. Id. at 17:6-26:10, 217:2-220:21. During these conversations, Dr. Stiroh learned that Roche now expects to obtain final FDA approval "as early as October" 2007. Id. at 19:8-17. Roche's new anticipated launch date to begin sales of peg-EPO is no earlier than December 1, 2007—two months after the expected conclusion of the trial in this matter. Id. at 21:14-22:9.

Between May 20 and May 30, Dr. Stiroh believed that the failure of her assumptions about peg-EPO's approval and launch dates meant that Roche would experience no lost sales to LDOs or hospitals as a result of Amgen's conduct:

> Q. . . . . If all of your assumptions held true, then between May 18[3] and just prior to your conversations yesterday, you were of the opinion that there were no lost sales in the hospital or LDO channels? Just yes or no, please.
>
> A. I think that's right, yes.

Ex. 3 at 75:13-76:11. This meant her entire calculation of $82.4 million in lost LDO profits and $22.4 million in lost hospital profits (together amounting to $104.8 million in pre- and post-trial lost profits) was incorrect, and would have been reduced to nothing. See Ex. 2 ¶¶ 73, 84.

On May 30, 2007, the day before her deposition, Dr. Stiroh again spoke with attorneys for Roche. Ex. 3 at 28:23-29:6. In that conversation, the attorneys instructed her that instead of keeping her initial assumption that any anticompetitive conduct would end at the conclusion of trial, it would be better to assume that any anticompetitive conduct would not end until the conclusion of an injunction hearing, which they informed her, as a "conservative" estimate, would not be scheduled until at least three months after peg-EPO's December 2007 launch date:

> Q. What are you changing?

[3] Dr. Stiroh initially testified that she learned of the FDA decision on May 18; she later changed her answer and stated that she did not read the press release until May 20. Ex. 3 at 218:25-220:7.

A. That I understand that there would be an injunction hearing or an injunctive hearing, whatever the appropriate term is, and that that is not part of the September trial, and that the conduct would not be resolved or a decision on how the conduct would be resolved would not take place until the injunctive hearing. That's – for my purposes, that's a pure assumption information that I've learned from counsel. It's not a conclusion that I've drawn.

. . . .

Q. What date do you assume this injunction hearing will take place?

A. I don't have a firm date for it. I understand that it would be a conservative assumption to say that it would be at least a quarter after the trial or at least a quarter again after launch, which is essentially the same window of time.

It's not to say I assume that the injunction hearing would be held in February, but if I were to make that assumption in my damage analysis and say there is a quarter period of time where Roche's product is on the market and the conduct is ongoing, that that is a conservative assumption and that the actual expectation would be longer than that.

Q. And what is the basis for your assumption that it will take at least three months for the court to schedule an injunction hearing?

A. That – just discussions with lawyers. That it's essentially a legal expertise, not economic expertise, and it's an input into the damage analysis.

Q. Okay. So you have no opinion of your own as to when this injunction hearing will be; is that correct?

A. That's correct.

Q. And you've conducted no analysis of your own to determine when that injunction hearing would take place; is that correct?

A. That's correct.

Ex. 3 at 26:15-31:22; see also id. at 395:24-398:3 (explaining that the "conservative assumption" of anticompetitive conduct ending a quarter after launch—or in February 2008—provides for an "identical time frame" for damages as what is in her report). Dr. Stiroh stated that, in the approximately 30 antitrust cases in which she has served as an expert, this is the first case in which she has found it "appropriate" to assume that there would be at least three months after the conclusion of the trial before the conduct ended. Id. at 32:21-33:14.

Based on the May 30 conversation, Dr. Stiroh changed the key assumption she had made in her report that Amgen's allegedly anticompetitive conduct would end at the conclusion of the trial. Ex. 3 at 28:23-29:6; see also id. at 31:23-32:20 ("[Roche's lawyers and I] discussed what the timing would be, and I said that the damages that I've calculated depend on when sales start and when the conduct ends. And if there's a window of time where there are sales and the conduct is ongoing, then that's what calibrates the – the damage period."). Dr. Stiroh emphatically testified that this change was based on information from Roche's lawyers, rather than on any conclusion she herself had drawn:

> A. That is a pure assumption that I've made. The basis of it is only discussions with counsel. . . . So the only information I have right now on that is coming from Roche's counsel. . . .

Ex. 3 at 229:6-230:10; see id. at 31:4-12. She also stated that she performed no analysis to verify this new assumption that she got from Roche's lawyers. Id. at 230:19-24; see id. at 31:13-22.

Based solely on this new assumption, at her deposition Dr. Stiroh changed her theory and testified that the lack of Roche entry prior to trial would not be fatal to Roche's damages claims. Dr. Stiroh specifically testified that, absent the new assumption about the date of an injunction, the lost profits that she "calculated from impeded launch," i.e., the $14.45 million and the $90.37 million, "do not apply." Ex. 3 at 40:2-9; see also id. at 41:23-43:17 (agreeing that, if the conduct ended prior to December 1, 2007, Roche would experience no lost sales resulting from Amgen's Fresenius contract or Amgen's hospital contracts).

With regard to the $13 million figure from "launch proximity to trial," Dr. Stiroh testified that some undefined portion of the $13 million could still survive if this Court delayed the trial until after peg-EPO's launch:

> A. And so one example would be if the trial were to move, so launch is still in proximity to the trial date, then I think the 13 million is still part of the damage calculation.

. . . .

Q. . . . . The Roche documents say that there will be a $13 million drop in sales between July and September over uncertainty about trial. Are you now saying that any part of that 13 million is still a damage to Roche?

A. Yes.

Q. How much?

A. I don't know.

Q. Okay. And have you made any attempt to try to calculate how much of that 13 million is still a damage to Roche?

A. No.

Q. And you have no number you can give us; is that correct?

A. I could give you a number by making an assumption of when the – if the trial were to move, then I would say it is still at 13 million. If we're assuming that the trial will – that the infringement hearing will be concluded in September, then, no, I cannot give you a number.

Ex. 3 at 46:6-49:7 50:12. Specifically, she testified that if the Court delayed the trial until February, the full $13 million would apply as damages, but if any other scenario occurred, she had no basis to testify how much, if any, of the $13 million would survive. See id.; id. at 49:8-50:12.

On May 31, 2007, Amgen deposed Dr. Stiroh. She did not change any of her damages figures in any way as a result of the five-month delay in FDA approval.[4] Instead, her testimony, as discussed above, was that the three months of pre-trial damages that she calculated (from July through September) could simply be transferred directly to three months of post-trial, pre-injunction damages (from December through February), assuming that the Court would not enjoin Amgen's conduct (or that the conduct would not otherwise end) until several months after the

[4] Dr. Stiroh did, on the morning of her deposition, submit one change in response to Dr. Teece's criticism of her report: she reduced the $13,000,000 figure to $11,431,034 to convert that figure from a "lost sales" figure to a "lost profits" figure. Ex. 5.

conclusion of the trial. Dr. Stiroh also testified to no change in the "lingering effects" damages that she alleged would be caused by this three-month period of impeded entry.

C. Dr. Stiroh Failed to Analyze Alternative Causation.

As Dr. Stiroh herself recognizes, even a finding that Amgen has engaged in anticompetitive conduct does not mean that all sales that Roche failed to make were lost sales caused by that anticompetitive conduct. Ex. 3 at 196:21-197:5. For all of her damages figures except the legal expenses, Dr. Stiroh failed to conduct any analysis to account for potential causes for Roche's injuries other than the alleged anticompetitive conduct. Specifically, Dr. Stiroh acknowledged at her deposition that the following factors could have an impact on Roche's ability to make sales:

- Fresenius and Roche documents indicate Fresenius had concerns with peg-EPO's safety; thought Epogen® was a superior product in terms of clinical, safety, and economic concerns; and would not have bought peg-EPO even if it did not sign the long-term contract with Amgen;
- Fresenius thought a shorter-acting ESA such as Epogen® offers a significant patient benefit over peg-EPO because it allows the physician to avoid over- or under-dosing;
- A Roche document predicts that, even with a July 2007 launch date, Roche could not hope to penetrate an LDO until 2008;
- Hospitals are cost-minimizers that are less likely to buy the more expensive product (peg-EPO), which Roche recognizes will impede its sales to hospitals;
- In March 2007 the FDA issued a black box warning that will affect labeling requirements and dosages for ESAs; and
- Peg-EPO lacks J and Q codes for Medicare reimbursement, which will interfere with providers obtaining Medicare reimbursement.[5]

Roche's lack of FDA approval also, of course, is a cause for Roche's inability to make sales.

[5] Ex. 3 at 79:4-8, 80:19-81:6, 122:18-123:18, 137:11-139:12, 151:16-152:15, 185:4-22, 276:13-278:8, 281:10-282:18, 319:3-17, 322:6-325:8, 371:7-373:25.

Dr. Stiroh's response to all of these factors was that she did not need to consider such alternative causation because she obtained all of her numbers from Roche and Amgen forecasts, and she assumed that the people who created these projections had full information about all of these factors and took them into account in their projections:

> I think for the projections to have value, they have to take into account the economic factors affecting competition. And I assume that the parties that are creating these forecasts are able to do that because they are parties to the market.

Ex. 3 at 314:8-15.[6] She admitted, however, that she did nothing to verify whether the people who created the forecasts either had all relevant information or used that information in making their predictions.[7] She also relied on figures contained in at least one document that was a draft, rather than a final document. Ex. 3 at 326:18-334:19, 337:15-338:25, 413:17-416:6.

As far as the $13 million, Dr. Stiroh made a feeble reference to the fact that any portion of the $13 million attributable to nephrologists waiting for trial would be eliminated now that trial will occur before peg-EPO's launch, but she failed even to posit how much of that damages figure is now invalid for that reason:

> Q. So your only opinion is it's something less than 13 million, but you don't know how much less; is that correct?
>
> A. Yes. I think that the 13 million was – included the lost sales from, at least in part, nephrologists waiting to hear the outcome of the trial. That will have occurred prior – if indeed it does occur, prior to December 1st. Any part of that 13

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[6] See also, e.g., Ex. 3 at 110:5-111:3, 114:2-23, 121:17-122:7, 124:8-19, 135:18-136:12, 144:21-145:7, 147:5-15, 152:5-15, 168:21-169:5, 186:9-187:4.

[7] E.g., Ex. 3 at 82:6-83:3 (explaining she did nothing to verify that February sales forecast upon which she relied took account of FDA's March "black box warning"), 114:24-115:7 (stating she did not know whether "Roche was aware of Fresenius' reservations about the longer acting molecule" or whether Roche took those reservations "into account in any of its calculations"), 147:23-148:3 (no steps to determine if Roche and Amgen accurately and reliably factored Fresenius's non-price issues into projections), 152:16-18 (no steps to verify that Amgen and Roche projections took into account "information about the relative benefits of the drugs in the market"), 171:20-172:6 (no evidence to show that the person who made the projections actually knew about Fresenius's concerns and intended to factor them into the projections).

> million that has to do with nephrologists waiting for trial I think goes away. I'm not the person that could tell you what part of it is due to some financial threats that don't go away because they can't be undone.

Ex. 3 at 262:23-263:15. Moreover, Chrys Kokino, the Roche employee who offered the $13 million figure, testified that this entire loss "more than likely . . . would not exist" "if physicians or providers did not have this uncertainty around the outcome of the trial, nor had not [sic] been brought to their attention from [Roche's] competitors." Ex. 6 at 249:18-250:3.

For the $1.79 million, Dr. Stiroh relied solely on the testimony of Roche witnesses to establish that Roche incurred the additional marketing expenditures entirely in response to anticompetitive conduct by Amgen. One of those same witnesses, however, testified at deposition that Roche spent at least some portion of that money to respond to wholly lawful activities by Amgen, including the fact that Amgen was increasing its "share of voice in the market" and was increasing its own advertising expenditures. Ex. 6 at 162:16-165:15. Dr. Stiroh failed to disaggregate these alternative causes of the alleged damages.

D. Dr. Stiroh Failed to Perform Economic Analysis to Derive Her Conclusions on Damages Arising from the Alleged Threats and This Litigation.

The $13 million, $1.79 million, and $5.5 million are all figures that Dr. Stiroh adopted from Roche or its attorneys without any economic analysis or validation. Dr. Stiroh adopted the $13 million figure based on Roche's representations and not only failed to perform any calculations of her own but did not even know what calculations, if any, had been used to derive the number. Ex. 3 at 50:13-52:2. In fact, she testified that she could not even say whether Roche used any kind of mathematical calculation to derive the $13 million. Id. at 260:12-18. In adopting Roche's $1.79 million figure for marketing expenditures, Dr. Stiroh relied on statements from Roche employees Chrys Kokino and Susan Graf regarding particular categories of marketing expenses that they increased as a result of Amgen's activities. Ex. 2 ¶¶ 86-87. Dr. Stiroh then performed a simple mathematical calculation to determine the extent to which spending in those categories exceeded

the budgeted amounts for those categories. Ex. 3 at 357:23-361:6. She specifically testified that she accepted Mr. Kokino's and Ms. Graf's representations about the increased spending, including that the increased spending resulted from Amgen's conduct, "at face value." Id. at 362:13-16. As for the $5.5 million, Dr. Stiroh testified "that with respect to the legal bills that the calculation that I have done is something that somebody else can replicate and do." Ex. 3 at 438:22-439:7 (agreeing her work on the legal bills did not involve "a skill that's unique to economists").

III. LEGAL STANDARDS

The proponent of expert testimony has the burden of showing that its expert will assist the trier of fact by sharing scientific, technical, or other specialized knowledge.[8] A court should exclude expert testimony "if it is neither based on realistic assumptions nor 'accompanied by a sufficient factual foundation.'"[9] In other words, expert testimony cannot be speculative or conjectural.[10] Similarly, the court must exclude expert testimony that lacks a reliable methodology.[11]

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[8] United States v. Monteiro, 2005 U.S. Dist. LEXIS 39062, at *3-4 (D. Mass. Nov. 28, 2005) (noting proponent has burden of showing that expert testimony meets the requirements of Fed. R. Civ. P. 702); see Cipollone v. Yale Indus. Prods., 202 F.3d 376, 380 (1st Cir. 2000) ("The ultimate purpose of the [expert evidence] inquiry is to determine whether the testimony of the expert would be helpful to the jury in resolving a fact in issue.").

[9] Flebotte v. Dow Jones & Co., 2000 U.S. Dist. LEXIS 19862, at *4-5 (D. Mass. Dec. 22, 2000) (quoting Boucher v. U.S. Suzuki Motor Corp., 73 F.3d 18, 21, 22 (2d Cir. 1996)); see also Magarian v. Hawkins, 321 F.3d 235, 240 (1st Cir. 2003) ("[C]onclusory allegations, improbable inferences, and unsupported speculation are insufficient to defeat summary judgment. This principle applies with equal force to expert opinions.") (quotation and citation omitted).

[10] Schubert v. Nissan Motor Corp., 148 F.3d 25, 29 (1st Cir. 1998); see also Boucher, 73 F.3d at 21 (expert testimony should be excluded "if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith").

[11] Ed Peters Jewelry Co. v. C&J Jewelry Co., 124 F.3d 252, 261 (1st Cir. 1997) (expert's appraisal properly excluded where "no demonstration that the appraisal rested on a reliable methodological foundation") (alteration and quotation omitted); see SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp., 188 F.3d 11, 25 (1st Cir. 1999) ("Expert opinions . . . are no better than the

(continued…)

IV. ARGUMENT

A. Roche's Eleventh Hour Contrivance Cannot Salvage Dr. Stiroh's Testimony in Support of Lost Profits.

Amazingly, the delay of peg-EPO's launch until two months after trial (at the earliest) had only a temporary impact on Dr. Stiroh's conclusions regarding lost sales. In her report, Dr. Stiroh calculated the July to September lost profits based on the assumption that there would be a three-month pre-trial period of time in which Amgen's Fresenius and hospital contracts would interfere with sales Roche otherwise would be able to make during that time period. See Ex. 2 ¶ 79. Similarly, she based the "lingering effects" calculation on what would be necessary to bring Roche to the same position in which it would have been had Amgen's contracts not impeded Roche's ability to make pre-trial sales. See id. ¶¶ 81-84, 90. Initially, Dr. Stiroh realized that the FDA's delay of approval ended all possibility of Roche suffering any lost profits damages because there would be no anticompetitive conduct during any time while Roche was in the market.

In a desperate attempt to avoid summary judgment on Roche's claims for lost profits,[12] Roche's attorneys concocted a theory in the hopes of establishing that speculative post-verdict injury could somehow give Roche a claim. Specifically, Dr. Stiroh's deposition testimony makes clear that, despite her own belief after May 18 that Roche would no longer have any lost profits damages, Roche's attorneys on May 30 convinced her that she could salvage those damages by changing her assumption about when the alleged anticompetitive conduct would end. Instead of

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data and methodology that undergird them . . . ."); see generally Kumho Tire Co. v. Carmichael, 526 U.S. 137, 149 (1999); Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593-95 (1993).

[12] As explained in Amgen's Summary Judgment Memorandum, at 19-20, Amgen is entitled to summary judgment on Roche's claims for lost profits because Roche has not suffered the requisite actual damages. In fact, Dr. Stiroh specifically agreed that, if Amgen terminated its Fresenius contract and its hospital contracts prior to December 1, 2007, Roche would experience no injury from those acts. Ex. 3 at 43:11-17.

assuming the Court would act promptly to end any anticompetitive practices, she assumed just the opposite. Roche's counsel told her to assume that there would be a several month delay between the conclusion of the jury trial and an injunction hearing to enjoin Amgen. Ex. 3 at 26:15-32:20. Dr. Stiroh thus abandoned both her original opinion and the underlying methodology or approach in her report. Such deviation is not permitted and alone is sufficient to exclude her testimony.[13]

Dr. Stiroh's new assumption that any anticompetitive conduct would not end until several months after the trial renders her opinion on lost profits unreliable and, hence, inadmissible. To begin with, Roche obviously contrived this new assumption specifically to deal with the patent obsolescence of Dr. Stiroh's report in the face of the May 18 FDA decision: there is no logical reason why the assumption of conduct ending several months after trial would be any more valid on May 31 than it was on April 6, or prior to April 6, during the attorneys' extensive review of Dr. Stiroh's draft reports. More significantly, acceptance of this assumption and accordingly of Dr. Stiroh's lost profits figures would require layers upon layers of impermissible speculation.[14] For example, it is sheer speculation: that the FDA will approve peg-EPO in October,[15] that Roche accordingly will be ready to launch peg-EPO on December 1, that a jury will find against Amgen on Roche's antitrust counterclaims and specifically find both the Fresenius contract and the hospital contracts to be illegal, that this Court will hold a separate injunction hearing following the jury trial that will occur after December 1 or whatever date peg-EPO ultimately becomes available

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[13] See Ed Peters Jewelry Co., 124 F.3d at 260 (expert testimony warranted "special skepticism" and was properly excluded where expert's valuation had changed in favor of client's position).

[14] See Augustine Med., Inc. v. Mallinckrodt, Inc., 2003 U.S. Dist. LEXIS 6079, at *25-27 (D. Del. Apr. 9, 2003) (granting summary judgment and finding that expert testimony would be excluded under Rule 702 where expert relied on assumptions rather than evidence and "stack[ed] assumption upon assumption to come to his conclusion").

[15] Dr. Stiroh cites a Roche employee's assumption that FDA approval could happen "as early as" October. There is no evidentiary basis, however, for any prediction of when the FDA will act.

for sale, that the hearing will result in an injunction against Amgen enjoining both the Fresenius and hospital contracts, and that Amgen will not voluntarily terminate or limit its contracts after an adverse jury verdict and before peg-EPO's launch date.

Dr. Stiroh's testimony lacks a reliable foundation and/or methodology because of her reliance on these speculative assumptions. She acknowledges that the information about the likely delay in cessation of Amgen's allegedly anticompetitive conduct involves a "pure assumption" based on "legal expertise" rather than "economic expertise." Ex. 3 at 31:4-22, 229:6-230:24. This assumption is not a topic upon which Dr. Stiroh, as an economist, can provide testimony to assist the trier of fact. Roche also has made no showing that a legal judgment by a party's attorneys predicting the likely scheduling of a hearing is the type of information upon which an economist normally relies in calculating economic damages. Dr. Stiroh's testimony has an "'insufficient evidentiary foundation'";[16] in fact, it has no evidentiary foundation, as the existence of any lost profits is based solely on assumptions tailored to engineer a result, rather than on actual facts.

Roche's $13 million "launch proximity" damages likewise cannot survive; it is impossible to imagine that Roche could be harmed by customers deciding "to wait until trial completion to try" peg-EPO when peg-EPO will not even be available to try until—at the earliest—two months after the trial's conclusion. Ex. 2 ¶¶ 80, 89. Dr. Stiroh's only attempt to salvage the $13 million figure was her testimony that some undefined portion of the $13 million could still survive if this Court delayed the trial by several months. Ex. 3 at 43:18-50:12. Again, however, there is no evidence to support such an assumption, and Dr. Stiroh cannot quantify it.[17]

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[16] F & D Tool Co. v. Sloan Valve Co., 2002 U.S. Dist. LEXIS 20049, at *17 (D. Mass. Oct. 17, 2002) (noting "'expert testimony must be predicated on facts legally sufficient to provide a basis for the expert's opinion'") (quoting Damon v. Sun Co., 87 F.3d 1467, 1474 (1st Cir. 1996)).

[17] This is not the first case in which Dr. Stiroh has offered a baseless and contrived "expert" opinion to serve her client. In United Asset Coverage, Inc. v. Avaya Inc., 409 F. Supp. 2d 1008

(continued…)

B. The Court Should Exclude Dr. Stiroh's Testimony Because It Fails to Disaggregate the Multiple Causes of the Claimed Damages.

In general, expert testimony may be inadmissible if it fails to consider all relevant facts.[18] In particular, courts in antitrust cases have strictly required experts to establish that the claimed injury or damages is attributable entirely to the alleged anticompetitive conduct, rather than to legal competition or other factors. Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1057 (8th Cir. 2000) (holding expert opinion should not have been admitted "because it did not incorporate all aspects of the economic reality of the stern drive engine market and because it did not separate lawful from unlawful conduct"); Isaksen v. Vt. Castings, Inc., 825 F.2d 1158, 1165 (7th Cir. 1987) (Posner, J.) (finding expert testimony on damages irrelevant where "there was no evidence of how much the antitrust violation, as distinct from unrelated market forces, contributed to [plaintiff's] losses"); Augustine Med., 2003 U.S. Dist. LEXIS 6079, at *26-27 (finding expert opinion unreliable where expert "made no effort to segregate the effects of legitimate activities (e.g., the need for FDA approval) from whatever effects there might be in the market from the alleged anticompetitive activities").[19] As the Seventh Circuit has stated, "Post hoc ergo propter hoc is not a valid methodology of damage calculation, especially when it is apparent that other causal factors

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(N.D. Ill. 2006), Dr. Stiroh opined that a separate market existed for maintenance and service of equipment based on her having "concluded" that at the time of purchasing the equipment, owners lacked certain information about the maintenance policies. Judge Shadur of the Northern District of Illinois lambasted Dr. Stiroh's testimony, stating, "That type of analysis – or lack of analysis – borders on the absurd." Id. at 1046. More recently, Dr. Stiroh's report was withdrawn in another case on the eve of trial, after summary judgment motions had been briefed, when it became apparent that Dr. Stiroh may have blindly relied on data that lacked credibility. LaPoint v. AmerisourceBergen Corp., 2007 Del. Ch. LEXIS 55 (Del. Ch. May 3, 2007).

[18] See Kumho Tire Co., 526 U.S. at 154; Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997).

[19] See also, e.g., J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc., 485 F.3d 880, 890 (6th Cir. 2007); MCI Communications Corp. v. AT&T Co., 708 F.2d 1081, 1161-64 (7th Cir. 1982).

are at work."[20] Here, Dr. Stiroh's opinion on both the three categories of lost profits and on the marketing expenses are subject to this failing.

1. Dr. Stiroh Improperly Attributes All Lost Profits to Anticompetitive Conduct Without Considering Other Causes.

Dr. Stiroh's opinion fails to satisfy the critical requirement that she separate which lost profits are attributable to the alleged anticompetitive conduct and which lost profits instead are attributable to other market factors. As numerous courts have emphasized, expert testimony that fails to segregate damages caused by lawful competition or unrelated circumstances from damages actually caused by the anticompetitive conduct is wholly unreliable. Dr. Stiroh apparently contends that she did not have to consider the impact of any other factors as a cause of her predicted lost sales, as she assumed the unidentified Amgen and Roche employees who generated the forecasts must have incorporated these other factors into the predictions upon which she relied. She admits, however, for example, that "Fresenius' view of its own decision making is a better source to make a prediction on than Amgen and Roche's predictions of what Fresenius' decision making will be." Ex. 3 at 122:8-14. Based on her own admissions, the Declaration from Fresenius's President regarding Fresenius's numerous reasons for choosing Amgen over Roche should "have an impact" on Dr. Stiroh's conclusions. Id. at 122:18-123:18. Dr. Stiroh similarly improperly assumes that any future reluctance on the part of hospitals to buy Roche's product will be due to Amgen's contracts, and she does not consider any other causes. Moreover, it seems beyond dispute that Roche's failure to make sales at any time prior to its hypothetical FDA approval "as early as" October and even prior to its anticipated launch date as early as December would be caused solely by such lack of approval rather than by any alleged threats or other conduct by Amgen. The question is not what Dr. Stiroh concludes but, rather, her failure even to consider

[20] Isaksen, 825 F.2d at 1165.

material evidence and market realities. Because Dr. Stiroh's opinion utterly fails to even try to account for the numerous circumstances other than any alleged anticompetitive conduct impacting Roche's failure to make sales, her testimony should be excluded.

2. Dr. Stiroh's Opinion on Marketing Expenses Relies on Witness Testimony that Likewise Fails to Disaggregate Losses Caused by Anticompetitive and Other Conduct.

The $1.79 million marketing expenses figure that Dr. Stiroh adopts from Roche's documents likewise is not based solely on the alleged anticompetitive conduct. Neither Dr. Stiroh nor the witnesses upon whose testimony she bases her opinion adequately distinguish between increased advertising expenditures to respond to Amgen's lawful competitive activities and increased spending to respond to alleged anticompetitive activities.[21] In essence, Roche complains that because Amgen spent more money on marketing, it had to increase its own marketing spend to avoid a competitive disadvantage. But such an increase in marketing expenditures is a normal part of the competitive process, and absent a breakdown of which portion of the increased spending is directly attributable to the alleged anticompetitive conduct, the $1.79 million figure is unreliable, and the Court should excluded both the testimony of Dr. Stiroh and any lay witnesses on this issue.

Roche claims the only alleged anticompetitive conduct that caused Roche to spend this additional $1.79 million was the isolated statements that Leslie Mirani made to Tracey Mooney and Maureen Michael.[22] Astonishingly, Mr. Kokino testified at his deposition as to a number of

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[21] Both Dr. Stiroh and Roche's 30(b)(6) witness Chrys Kokino repeatedly testified that the $1.79 million was authorized in response to Amgen's "conduct" or Amgen's "activities." E.g., Ex. 3 at 355:11-15, 359:5-9, 360:12-361:6, 361:16-25, 362:10-16; Ex. 6 at 161:14-162:1, 163:3-9, 164:17-165:15. However, this figure is only an appropriate measure of damages if it was authorized entirely in response to specific anticompetitive acts rather than in response to a mix of challenged and unchallenged behavior. See Augustine Med., 2003 U.S. Dist. LEXIS 6079, at *26-27.

[22] Roche, however, fails even to establish that the alleged expenditures occurred after these conversations, or after Roche learned about them.

causes for the increased marketing expenditures other than the alleged anticompetitive conversations. Most significantly, Mr. Kokino testified that at least some of the increased expenditures resulted from Amgen's decision to increase its own advertising spend:

> Q. And how do you know that that was caused by Amgen's conduct or that you made that expenditure because of Amgen's conduct?
>
> A. Because it's very apparent in the marketplace today that Amgen is increasing its share of voice in the market and making their presence known and in order to not be at a competitive disadvantage, we've had to increase our presence as well.
>
> . . . .
>
> Q. So Amgen is spending more money?
>
> A. Correct.
>
> Q. And that's led you to spend more money?
>
> A. Yes.

Ex. 6 at 162:16-165:15. Obviously, responding to Amgen's increasing "share of voice in the market" and increasing advertising expenditures to match Amgen's increased advertising expenditures is different than undertaking additional expenditures to counteract anticompetitive threats. See also Ex. 3 at 345:21-346:9 (agreeing that company having "increasing voice in the marketplace" is not anticompetitive).

Mr. Kokino also testified to some of the additional marketing spend being used at congresses and symposia "to recognize and appreciate those persons that were treating these patients." Ex. 6 at 163:14-164:1. Dr. Stiroh fails to explain how such expenditures could properly be included in any measure of antitrust damages. Mr. Kokino further testified to some of the increased expenditure being used in Washington, D.C., apparently to counteract lobbying and publicity efforts by Amgen. Ex. 6 at 162:15-163:9 (explaining that "there was a lot of negative press and misinformation that was being disseminated in Washington by the Amgen personnel there"). Of course, any lobbying activities in Washington, D.C., would be protected by the Noerr-

Pennington doctrine and would not constitute anticompetitive conduct. There also is no evidence that Amgen's press or government relations efforts had any relationship to any anticompetitive activity, yet they were the cause of some undetermined portion of the $1.79 million. Roche's response to such conduct cannot be included in any damages figure.

C. Dr. Stiroh's Testimony Based on the Alleged Threats and This Litigation Involves No Specialized Expertise.

Dr. Stiroh's testimony on the $13 million, $1.79 million, and $5.5 million figures involves no application of economic analysis and accordingly will not "assist the trier of fact to understand the evidence or to determine a fact in issue."[23] Dr. Stiroh's mere repetition of figures gleaned from Roche witnesses and documents is not sufficient to give those figures the imprimatur of an expert opinion.[24] Because these figures involve none of the "specialized understanding" of an economist, Dr. Stiroh's testimony on these figures must be excluded.[25]

V. CONCLUSION

For the foregoing reasons, Amgen requests that this Court exclude the testimony of Roche's damages expert Lauren J. Stiroh.

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[23] Fed. R. Evid. 702; see United States v. Shay, 57 F.3d 126, 133 (1st Cir. 1995) ("Unless the witness's opinions are informed by expertise, they are no more helpful than the opinions of a lay witness."); John W. Strong, et al. McCormick on Evidence § 13, at 24 (5th ed. 1999) (stating the question is not whether witness is more qualified than other experts in the field; rather, "the issue is whether the witness is more competent to draw the inferences than the lay jurors and judge").

[24] See Linda S. Simard & William G. Young, Daubert's Gatekeeper: The Role of the District Judge in Admitting Expert Testimony, 68 Tul. L. Rev. 1457, 1459 (1994) (explaining that lay person opinions are generally inadmissible whereas expert opinions are admissible "because the expert is possessed of special or peculiar training, experience, or observation in respect of the subject under investigation") (footnotes and quotation omitted). As noted in Daubert's Gatekeeper, experts have the "appearance of apparent objectivity" and thus carry "undue weight in the eyes of the jury." Id. at 1460-61 (footnotes and quotations omitted).

[25] Shay, 57 F.3d at 133.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on June 28. 2007.

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