UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMANN-LA ROCHE INC. Defendants.	CIVIL ACTION No.: 05-CV-12237WGY

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

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INTRODUCTION AND STATEMENT OF FACTS[1]

When all of Amgen's *ad hominem* attacks on Dr. Stiroh and Roche's attorneys are stripped away, what is left is a narrow motion grounded on misstatements of fact and law. Thus, Amgen's motion assumes (as it must for a motion directed solely to damages) that the jury finds that Amgen violated the antitrust laws and injured Roche as a result – *viz* that Amgen anticompetitively maintained a two-decade monopoly in the ESRD ESA market by locking-up the largest ESA purchaser (Fresenius) in a long-term exclusive deal and by threatening its own customers, and achieved a dangerous probability of monopolizing the non-ESRD ESA market through anticompetitive hospital contracts.

Faced with this necessary foundation for its motion, and unable to challenge either Dr. Stiroh's qualifications – a Harvard Ph.D. in Economics with vast consulting and testifying experience on antitrust and damages issues – or her damages model's analytical rigor, Amgen is left to (a) quarrel with three factual assumptions on which part (not all) of Dr. Stiroh's damages analysis is based – one of which Amgen *agrees* with, all of which are supported, and none of which Amgen controverts with evidence; (b) misstate the facts to argue, incorrectly, that Dr. Stiroh failed to take into account the impact of factors other than Amgen's illegal conduct; and (c) contend incorrectly that Dr. Stiroh would not help the jury determine certain categories of damages, damages Amgen wrongly contends to be based solely on Roche representations.

In so doing, Amgen (to use its own over-wrought word) "amazingly" (Mem. 13) ignores the governing Supreme Court and First Circuit case law as to causation and

[1] Amgen's memorandum of law in support of its motion is cited as "Mem." Exhibits to Amgen's motion are cited as "Amgen Ex." Exhibits that accompany this memorandum (which are exhibits to the Mayell Declaration) are cited as "Ex."; and Amgen's memorandum of law in support of its summary judgment motion is cited as "Amgen SJ Mem."

damages. Amgen's misguided criticisms are matters that, at best, go to the weight of Dr. Stiroh's testimony, not to its admissibility. As the Supreme Court emphasized in *Daubert*, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking" expert testimony. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993). The weight of Dr. Stiroh's testimony is to be resolved at trial, not in motion practice.

A. Dr. Lauren J. Stiroh

Dr. Stiroh, who earned a Ph.D. in Economics from Harvard University, is a Senior Vice President of NERA Economic Consulting. She has provided economic consulting services and testimony regarding antitrust and economic damages with respect to numerous industries, including pharmaceuticals, biotechnology and medical devices, as well as regarding a range of conduct, including allegations of monopolization, unlawful tie-ins, business interference, and patent infringement. Ex. 23 at ¶¶ 1-3 & Ex. 1 (Stiroh Rep.).[2]

B. Dr. Stiroh's Expert Opinion and Damages Model

Dr. Stiroh, as Amgen recognizes (Mem. 2), calculated distinct damages associated with various anticompetitive Amgen acts, damages that include both lost profits and out-of-pocket costs. Because Amgen's exclusionary agreements with Fresenius and hospitals

[2] Amgen (Mem. 15 n.17) alleges that Dr. Stiroh previously "offered a baseless and contrived 'expert' opinion to serve her client" in *United Asset Coverage, Inc. v. Avaya Inc.*, 409 F. Supp. 2d 1008 (N.D. Ill. 2006), and that she "may have blindly relied on data that lacked credibility" in *LaPoint v. AmerisourceBergen Corp.*, 2007 Del.Ch. LEXIS 55 (Del. Ch. May 3, 2007). But Dr. Stiroh testified that the *United Asset* judge misunderstood her testimony and that, "[u]ltimately, I think he and I were saying the same thing." Ex. 41 at 245:10-248:20 (Stiroh Dep.). As for *LaPoint*, when Dr. Stiroh learned that "industry data" were not constructed as she had been informed, she told the attorneys that "the opinions that I would have offered at trial would have been different from [those in her] report," and they withdrew her report. Ex. 41 at 250:8-11, 251:22-253:2 (Stiroh Dep.). Amgen is free to cross-examine Dr. Stiroh on these matters, just as Roche can cross-examine Amgen's Professor Teece on the cases in which his opinions were excluded. *See* Ex. 43 at 20:3-20:13 (Teece Dep.).

impede Mircera's entry, Dr. Stiroh calculated lost profits as Roche's damages for those agreements. Ex. 23 at ¶¶ 6, 61-73, 77-85 (Stiroh Rep.). By contrast, Amgen's anticompetitive and tortious customer threats gave rise to two distinct categories of damages: lost profits from chilled sales and out-of-pocket expenses Roche incurred, and incurred solely, to combat the unlawful threats. Ex. 23 at ¶¶ 6, 86-87, 89 (Stiroh Rep.). Finally, Dr. Stiroh identified as damages for Roche's *Walker Process* claims some portion of lost profits and legal fees expended combating Amgen's fraudulent patent suit, which are still accruing. Ex. 23 at ¶¶ 6, 88 (Stiroh Rep.).

1. To calculate Roche's lost profits, Dr. Stiroh modeled ESRD and non-ESRD ESA markets comparing the actual world, in which Roche is impeded by Amgen's bundled contracts with hospitals and its long-term exclusive contract with Fresenius, and the "but-for" world where Roche can compete on the merits. Ex. 23 at ¶¶ 58-59, 62 (Stiroh Rep.); Ex. 41 at 41:5-9 (Stiroh Dep.). Dr. Stiroh based the estimated sales and penetration rates in the actual and but for worlds on Amgen's and Roche's ordinary-course-of-business forecasts. Ex. 23 at ¶¶ 63-73 (Stiroh Rep.); Ex. 41 at 86:10-87:2 (Stiroh Dep.). These projections, which are based on the companies' rich knowledge of the ESA markets, reflect the expected impact of both Amgen's illegal conduct and other factors. Ex. 41 at 110:17-111:3, 124:15-125:13, 314:8-15 (Stiroh Dep.).[3] Dr. Stiroh

[3] Amgen asserts that the Amgen projections (Ex. 42 at AM44 1951333) were only a draft. (Mem. 10). But the head of Amgen's U.S. Contingency Counter Launch Team and Amgen's 30(b)(6) designee for "forecasts of Mircera sales" was aware of no more recent forecast by Amgen of penetration rates in ESA distribution channels and Amgen produced none. Ex. 26 at 9:25-10:3, 30:20-23, 51:19-24, 71:12-17 (Azelby Dep.). Moreover, Dr. Stiroh conservatively relied where possible on the Amgen projections' lower penetration rates as compared to those in the Roche projections. (Ex. 23 at ¶¶ 67, 70, 82 (Stiroh Rep.); Ex. 41 at 415:17-416:6 (Stiroh Dep.). Amgen's expert, too, relies on draft Roche documents for forecasts. Ex. 21 at ¶¶ 129, 132, 218 (Bernheim Rep.).

further adjusted the forecasts to isolate factors other than Amgen's conduct that could impact Roche's sales. (*See* p. 7 n.9, *infra*). The estimated price of Mircera was based on Roche's strategic pricing model, which has been the basis for pre-launch price-related planning for Mircera.[4] Finally, the estimated profit rate was based on Roche's OPAC statements, which Amgen's expert agreed "appear to be the best evidence of Roche's expected sales levels, costs and profitability associated with the U.S. launch of [Mircera]." Ex. 23 at ¶¶ 77-78 (Stiroh Rep.); Ex. 24 at ¶ 111 (Teece Rep.). As both sides' economic experts testified, such business documents are "a standard source used in antitrust economics." Ex. 41 at 171:5-19 (Stiroh Dep.); Ex. 43 at 115:13-17 (Teece Dep.); Ex. 30 at 107:5-6 (Elhauge Dep.). That is because, as Dr. Stiroh testified, economists assume that business "actors are economically rational" and that they "take into account the best [available] information. Ex. 30 at 74:9-10, 74:23-75:5 (Elhauge Dep.); Ex. 43 at 114:19-22, 115:23-116:1 (Teece Dep.); Ex. 41 at 171:5-19, 189:15-20, 314:8-15 (Stiroh Dep.). Indeed, Amgen's experts rely on many of the same company documents. Ex. 43 at 114:16-116:1 (Teece Dep.); Ex. 24 at ¶¶ 110-11, 300 (Teece Rep.); Ex. 21 at ¶ 121 (Bernheim Rep.); *see* Ex. 23 at ¶¶ 63-65, 69-72, 77, 82, 84 (Stiroh Rep.).[5]

2. To calculate Roche's out-of-pocket-damages (increased marketing expenses; legal fees), Dr. Stiroh relied on Roche documents and interviews with Roche personnel to determine expenses caused by Amgen's anticompetitive acts. Ex. 23 at ¶¶

[4] Ex. 27 at 9:23-11:10, 12:10-22, 27:17-29:11, 48:11-14, 74:18-75:20 (Beimfohr Dep.); *see also* Ex. 41 at 86:20-87:2 (Stiroh Dep.).

[5] Contrary to Amgen's assertion (Mem. 10), Dr. Stiroh did not blindly use the companies' projections and documents. She, *inter alia*, compared them for consistency, took into account the dates and authors of the documents and the witnesses' deposition testimony, and relied on only those documents that, based on her economics expertise, contain estimates and assumptions she judged to be reasonable. Ex. 41 at 86:10-87:2, 171:14-19, 188:3-13, 189:10-15, 211:2-6 (Stiroh Dep.).

86-89 (Stiroh Rep.); Ex. 41 at 342:24-345:20, 437:14-25 (Stiroh Dep.). In performing this task, Dr. Stiroh employed her specialized training and expertise to assess which expenditures would *not* have been made absent Amgen's anticompetitive conduct and to ensure that no "double counting" of damages occurred, for some of Roche's distinct claims could seek the same items of damages. Ex. 23 at ¶¶ 86-89 (Stiroh Rep.); Ex. 41 at 342:10-345:20, 439:24-441:19 (Stiroh Dep.).

C. The Assumptions as to FDA Approval, the Start of Sales and the Cessation of Amgen's Illegal Conduct

With respect to lost profits (only), Dr. Stiroh's damages model calculates damages for the period between the launch of Mircera and when the lingering effects of Amgen's anticompetitive actions end and Roche is restored to the position it would have been in but for Amgen's conduct. Ex. 23 at ¶¶ 58-61 (Stiroh Rep.); Ex. 41 at 22:20-23:8, 32:9-14 (Stiroh Dep.).[6] In her April 6, 2007, Report, Dr. Stiroh assumed that Mircera would be approved by the FDA in May 2007, that Roche immediately would begin taking orders and would start delivering product two months later, and that Amgen would halt its illegal conduct at the close of a September 2007 trial. Ex. 23 at ¶¶ 21, 58-61 (Stiroh Rep.); Ex. 41 at 26:15-27:3 (Stiroh Dep.). The first two inputs were based on the best information then available; ***e.g.***, the testimony of Roche executives. Ex. 23 at ¶¶ 21 nn. 42-43, 61 n.147 (Stiroh Rep.); Ex. 25 at 7:13-20, 42:1-20 (Abercrombie Dep.); Ex. 31 at 7:3-6, 141:9-12 (Hinson Dep.); Ex. 29 at 4:20-5:10, 101:12-24, 183:9-10 (Duncan Dep.); ***see*** Ex. 38 at 49:15-20 (Schupbach Dep.). On May 18, 2007, the FDA issued an

[6] Dr. Stiroh's analysis is "conservative" because she "did not calculate lost sales beyond LDOs and hospitals, even though there is evidence that Amgen's anticompetitive threats and anticompetitive litigation are having, and will continue to have, adverse consequences for Roche's anticipated MIRCERA sales." Ex. 23 at ¶¶ 67, 80, 85 (Stiroh Rep.).

'approvable' letter for Mircera. Ex. 41 at 18:23-19:7 (Stiroh Dep.); Amgen Ex. 4. Dr. Stiroh then spoke with Roche's Vice President of Regulatory Affairs, who informed her that FDA approval was expected as early as October 2007, an estimate Amgen does not contest. Ex. 41 at 19:8-20:10, 25:9-14, 26:21-24 (Stiroh Dep.); Amgen SJ Mem. 19-20. That Mircera sales would begin upon approval and product delivery two months later remained unchanged. Ex. 41 at. 19:8-20:10, 26:21-24 (Stiroh Dep.).

At about the time that she spoke with Roche's Vice President of Regulatory Affairs, Dr. Stiroh spoke to Roche's lawyers regarding when Amgen would cease its illegal conduct. She was informed that the prior assumption – that Amgen would immediately cease its illegal conduct upon the return of an adverse jury verdict – was too conservative, and that it would take at least four months for post-trial briefing, an injunction hearing and briefing, and Amgen's seeking of a stay on appeal to be concluded.[7] Ex. 41 at 28:10-22, 30:9-31:12 (Stiroh Dep.). Dr. Stiroh explained that relying on Roche's lawyers is reasonable because they have expertise on these issues and because Amgen has never stated that "if there is a finding of liability, we will stop this [illegal conduct] on the day of trial." Ex. 41 at 31:4-12, 229:12-230:2 (Stiroh Dep.).[8] Amgen, strikingly, has neither submitted *any* evidence on this point nor represented that it would immediately terminate its illegal conduct upon return of the jury's verdict. Indeed, Amgen's

[7] Amgen misleadingly asserts that Dr. Stiroh "stated that . . . 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 trial before the conduct ended" (Mem. 6); this was the first case where it was relevant for Dr. Stiroh to assume a date when a party would cease its illegal conduct. Ex. 41 at 32:21-33:14 (Stiroh Dep.).

[8] The assumption that it will take at least four months to halt Amgen's conduct is amply supported by prior Amgen litigation. In Amgen's suit against Hoechst, it took 4 months between the end of trial and this Court's ruling, another 23 months until the Federal Circuit ruled on the appeal, 11 months between the second trial and this Court's ruling, and another 22 months until the Federal Circuit's ruling. (Ex. 3).

expert could state neither whether "Amgen will voluntarily cease its conduct" nor whether "Amgen would seek a stay of any injunction pending appeal." Ex. 43 at 43:16-45:12 (Teece Dep.).

D. Dr. Stiroh's Damages Model Accounts for Other Factors

Dr. Stiroh testified that her lost profits model *does* account for factors other than Amgen's illegal conduct that could impact Mircera sales.[9] Amgen nonetheless contends that she failed to consider five specific factors that "could have an impact on Roche's ability to make sales." (Mem. 9). Amgen is wrong.

1. Fresenius. Amgen asserts that Dr. Stiroh failed to consider Fresenius' purported belief that Epogen is superior to Mircera and thus (Amgen says) that Fresenius would not purchase Mircera regardless of the exclusivity commitment to Amgen. (Mem. 9). Amgen ignores that what Fresenius did and did not believe, and what Fresenius might or might not do absent exclusivity, is a jury issue. The record provides ample factual basis for Dr. Stiroh's prediction that, absent the long-term exclusive commitment to Amgen, Roche had a substantial chance of securing Fresenius business. Ex. 23 at ¶ 68 (Stiroh Rep.). Amgen documents evidence great concern that Roche could secure both LDOs and that Amgen sought exclusivity as part of a plan to block Mircera.[10] If

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[9] *See, e.g.*, pp. 3-5, *supra;* Ex. 23 at ¶¶ 64-65, 72 (excluding oncology sales from the estimated market size and for Roche's hospital penetration rates to account for lack of an oncology indication), ¶ 78 (adjusting Roche's expected profit margin to account for differences in the expected profitability for each segment) (Stiroh Rep.); Ex. 41 at 110:5-111:3, 124:8-125:13, 277:11-279:16, 379:6-23 (explaining that LDOs' ESA preferences are reflected in forecasts and accounting for the impact of J&J's bundled contracts) (Stiroh Dep.).

[10] For example: (i) as early as 2003, Amgen considered using long-term exclusive contracts "at a strategic point of time" to block Roche competition (Ex. 6 at AM44 0011409, 411; Ex. 7 at AM44 0094998); Ex. 34 at 70:20-71:9, 88:15-89:16 (Lyons Dep.)); (ii) months before Amgen claims *Fresenius* approached *Amgen* about exclusivity, Amgen

Fresenius purchasing Mircera were *not* a realistic threat, why would Amgen, in its documents' words, "spend[] $300 million to buy insurance against potential ~$2.5 B sales loss"?[11] Moreover, there is extensive evidence that the exclusivity provision, and the purported justifications for exclusivity, were included at Amgen's, not Fresenius' insistence.[12] Tellingly, Fresenius initially objected to including statements about product efficacy in the contract (Ex. 35 at 40:2-23 (McGorty Dep.); Ex. 19 at FMCNA 002516-17), supporting an inference that Amgen's massive payment for exclusivity, not a genuine evaluation of not-yet-approved Mircera, explain the long-term agreement.[13]

2. <u>The LDO Document</u>. Amgen alleges that Dr. Stiroh did not account for an unidentified Roche document predicting, in Amgen's words, that "even with a July 2007 launch date, Roche could not . . . penetrate an LDO until 2008." (Mem. 9). Amgen fails to note that the document purportedly was created when Roche expected to be fore-

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developed a "hedging strategy," under which *Amgen* would "*[a]pproach LDOs*/SDOs with a one-time opportunity in advance of [Mircera's] patent resolution with more attractive rebate terms *in exchange for an exclusive contract*" (Ex. 5 at AM44 0007897) (emphasis added); (iii) in February 2006, Amgen's senior management approved a series of tactics to block Mircera's entry, including efforts to retain at least one LDO, supported by a plan to communicate "operational and legal risks" to LDO management, among others (*see* Ex. 4 at AM44 0007137; Ex. 44 at 300:13-20 (Torley Dep.)); and (iv) Amgen's Vice President of Sales implemented this strategy by meeting with Fresenius and DaVita management (Ex. 44 at 123:13-124:7 (Torley Dep.); Ex. 32 at 54:19-55:4 (Kogod Dep.); Ex. 36 at 30:9-31:8 (Mirani Dep.), Ex. 8 at AM44 0231764).

[11] Ex. 11 at AM44 1516870; *see* Ex. 12 at AM44 1934907; Ex. 13 at AM44 1934908 (recognizing that without "revised" long-term contracts Amgen would lose $5 ***billion*** due to Mircera's sustained market entry).

[12] Amgen documents show discussions with Fresenius about long term exclusivity by April 2006 (Ex. 37 at 79:20-80:1 (Morrow Dep.); Ex. 10 at AM44 1027895; Ex. 44 at 195:23-196:2, 330:22-334:11, 354:23-355:15 (Torley Dep.), and about a "co-exclusive worldwide" arrangement by May 4, 2006 (Ex 10 at AM44 1027895). This all preceded the May 26, 2006, Fresenius letter requesting an exclusive agreement.

[13] *See also* Ex. 44 at 350:3-351:16 (Torley Dep.); Ex. 11 at AM44 1516870; Ex. 13 at AM44 1934908; Ex. 44 at 204:6-206:1 (Torley Dep.); Ex. 9 at AM44 0392147; Ex. 14 at AM44 1951163; Ex. 39 at 79:21-80:4 (Sharer Dep.); Ex. 40 at 3; Ex. 20 at FMCNA 002859.

closed from the LDO segment until expiration of Amgen's two-year contracts with ***both*** DaVita and Fresenius, which contained switching-impeding terms. Ex. 23 at ¶ 68 (Stiroh Rep.). It was not until late March 2007, ***after*** the document allegedly was written, that Amgen eased those terms for DaVita. Ex. 33 at DVA-Roche 0002000; Ex. 32 at 17:7-22, 64:4-23 (Kogod Dep.). In any event, Dr. Stiroh relied on a January 24, 2007, ***Amgen*** projection for her estimate that Roche would penetrate the LDO segment in the third quarter of 2007. Ex. 23 at ¶ 69 (Stiroh Rep.); Ex. 42 at AM44 1951333.

3. **Hospitals as Cost Minimizers.** Amgen is simply wrong in asserting that the projections on which Dr. Stiroh relies did not take into account that hospitals, depending on their in- and out-patient mix, can be cost minimizers. Dr. Stiroh's model is based on projections and Roche's pricing model which account for this factor. Ex. 23 at ¶ 72 nn.167-68 (Stiroh Rep.); Ex. 41 at 376:10-19 (Stiroh Dep.); Ex. 27 at 149: 6-150:22 (Beimfohr Dep.).

4. **The Black Box Warning.** Shortly before Dr. Stiroh's Report was finalized, the FDA ordered Amgen to place a "black box" warning on Epogen and Aranesp to warn against overdosing. Dr. Stiroh stated in her Report that "there has been insufficient information to determine whether this will have a material impact on the expected size of the market for ESA products." Ex. 23 at ¶ 62 n.148 (Stiroh Rep.). Thereafter, she reviewed Amgen's own documents, including its most recent quarterly filing with the SEC which states that the black box warning "did not significantly impact EPOGEN sales" and that that "the impact on product sales has been primarily observed in oncology." Ex. 16 at pp. 13, 21; Ex. 15 at AM44 2024361; Ex. 41 at 80:5-82:5, 277:11-278:8 (Stiroh Dep.). Should new information become available before trial about the warning's

likely impact, Dr. Stiroh will "adjust [her] calculations accordingly." Ex. 23 at ¶ 62 n.148 (Stiroh Rep.); Ex. 41 at 81:23-82:5, 277:24-278:8 (Stiroh Dep.).[14]

5. J and Q Codes. Amgen asserts that Mircera's potential lack of J and Q codes for Medicare reimbursement "will interfere with providers obtaining Medicare reimbursement." (Mem. 9). But, as Dr. Stiroh testified, to the extent that this could impact sales, the relied-upon projections reflect it. Ex. 41 at 323:13-324:4 (Stiroh Dep.).

E. Lost Profits as a Result of Amgen's Threats

Contrary to Amgen's claim, Dr. Stiroh derived the $13 million in lost sales from the threats not simply from "Roche's representations" (Mem. 11), but also from Roche's 2007 Business Plan. Ex. 23 at ¶ 89 (Stiroh Rep.); Ex. 18 at R-11-0006380007. Moreover, Dr. Stiroh testified that some portion of the $11 million in lost profits from these lost sales can be expected to be suffered notwithstanding the delay in FDA approval. Ex. 41 at 48:8-14 (Stiroh Dep.). Amgen's financial threats cannot be undone (Ex. 41 at 42:18-20 (Stiroh Dep.)); and Amgen's threats to sue customers if they buy Mircera will continue to deter the purchase of Mircera until there is no further risk of an appellate reversal of a jury finding of no Roche infringement, particularly given Amgen's CEO's vow to defend its patent portfolio aggressively (Ex. 39 at 62:5-8, 74:11-16 (Sharer Dep.)).

[14] Amgen's Dr. Bernheim explained that "economists regularly deal with uncertainty; it's unavoidable," and that he, like Amgen's other expert and Dr. Stiroh, all stated in their reports that they "reserve the right to revise [their] opinions if additional information [is] provided to [them]." Ex. 28 at 80:17-18 (Bernheim Dep.); Ex. 21 at ¶ 13 (Bernheim Rep.); Ex. 24 at ¶ 9 (Teece Rep.); Ex. 22 at ¶ 5 (Bernheim Rebuttal Rep.); Ex. 23 at ¶ 7 (Stiroh Rep.).

F. Out-of-Pocket Marketing and Litigation Expense Damages

To calculate Roche's damages from increased out-of-pocket costs, Dr. Stiroh relied upon information provided by Susan Graf, Mircera's product director, as to the amount of Roche's additional expenditures for journal advertisements, convention sponsorships and anemia brochures and for the fact that Amgen's unlawful threats caused Roche to make *all* of the additional expenditures. Ex. 23 at ¶¶ 86-87 (Stiroh Rep.); Ex. 41 at 342:24-345:20 (Stiroh Dep.). Based upon Ms. Graf's further verification (*see* Ex. 2 at ¶¶ 2-11 (Graf Dec.)), Roche now seeks $1.1 million rather than $1.7 million for those damages.[15] Also clear is that Roche spent all of the $5.5 million in legal expenses claimed defending Amgen's fraudulent patent action. Ex. 1 at ¶¶ 2-4 (Rocha Dec.).

Importantly, these already incurred out-of-pocket damages do *not* depend on Amgen terminating its unlawful conduct before Mircera is available for sale. Moreover, although these expenses stand on their own as proof of damages, Dr. Stiroh applied her expertise to confirm that Amgen's unlawful conduct caused them and to ensure that they did not overlap with the lost profits she calculated. Ex. 23 at ¶¶ 86-87 (Stiroh Rep.); Ex. 41 at 342:10-345:20, 437:14-25, 439:24-441:19 (Stiroh Dep.). In short, as review of her Report reveals, and as Dr. Stiroh testified, her work in this case "meet[s] the standards for analytical rigor to qualify for publication in a peer-reviewed economics journal." Ex. 41 at 212:14-19 (Stiroh Dep.).

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[15] As for the ambiguous testimony of Chrys Kokino (who was asked about Amgen's "conduct" and not specifically anticompetitive acts), it does not contradict Ms. Graf's. *See* Amgen Ex. 6 at 161:17-162:15 (describing additional spending in journal advertising); *id.* at 163:14-164:6 (describing expanded presence at conventions); *id.* at 164:7-12 (describing increased spending on anemia brochure) (Kokino Dep.). In contending otherwise (*see* Mem. 19), Amgen strips from its context Mr. Kokino's testimony referring to Roche marketing expenses unrelated to the customer threats. These expenses, however, are *not* part of Roche's damage claim. Ex. 2 at ¶¶ 2-10 (Graf. Dec.).

ARGUMENT

DR. STIROH'S OPINIONS EASILY SATISFY THE STANDARD FOR ADMISSIBILITY UNDER RULE 702 AND *DAUBERT*

Rule 702 was intended to admit a "broader range" of testimony than under the "rigid" and "austere" *Frye* standard, which limited expert testimony to evidence that "is 'sufficiently established to have general acceptance in the field to which it belongs.'" *Daubert*, 509 U.S. at 583, 588-89; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997). Thus, in accord with the "general approach of the Rules . . . to relax traditional barriers to expert testimony," "[t]he presumption under the Rules is that expert testimony is admissible." WEINSTEIN'S FED. EVID. § 702.02[1] (2d ed. 2007).

The *Daubert* inquiry is a "gate-keeping," "flexible inquiry," *not* a fact-finding one. *Cortes-Irizarry v. Corporacion Insular de Seguros*, 111 F.3d 184, 188 (1st Cir. 1997); *Correa v. Cruisers*, 298 F.3d 13, 26 (1st Cir. 2002). "'*Daubert* does not require that the party who proffers expert testimony to carry the burden of proving to the judge that the expert's assessment of the situation is correct"; rather, "[i]t demands only that the proponent of the evidence show that the expert's conclusion has been arrived at in a scientifically sound and methodologically reliable fashion.'" *United States v. Mooney*, 315 F.3d 54, 63 (1st Cir. 2002) (*quoting Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998)). An expert may *not* be excluded because the court views the opposing expert's opinion as "more persuasive" and having "the best provenance." *Cortes-Irizarry*, 111 F.3d at 189 n.5; *Ruiz-Troche*, 161 F.3d at 85. The "battle of the experts" goes to the "weight of the evidence."[16]

[16] *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1105-06 (1st Cir. 1994); *Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005) (reversing summary judgment). *See Monsanto Co. v. McFarling*, 2007 U.S. App. LEXIS 12099, *19 (Fed. Cir. May 24, 2007) (expert

As *Daubert* explains, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 596; *accord Diefenbach v. Sheridan Transp.*, 229 F.3d 27, 31 (1st Cir. 2000). As a result, after *Daubert*, the rejection of expert testimony "is the exception rather than the rule." Notes of Advisory Committee on 2000 Amendment to FED. R. EVID. 702.

In short, "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 955 (8th Cir. 2007) (internal quotations omitted). As the First Circuit held, with particular relevance here, where an expert "derive[s] his damage estimates by reviewing . . . "business and financial records and through interviews with company personnel," it is "obvious that these are sources of information normally and reasonably relied upon" by an expert. *Int'l Adhesive Coating Co. v. Bolton Emerson Int'l Inc.*, 851 F.2d 540, 545 (1st Cir. 1988).[17] Amgen's economic experts also relied on the parties' documents and interviews with company executives, and the experts agreed that relying on such material is reasonable for economists in forming their opinions. (*See* p. 4, *supra*).

Applying these standards here, it is plain that Dr. Stiroh's opinions easily meet the

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testimony admitted where "the objections [went] . . . 'to whether the jury should believe the witness or credit his opinions, instead of whether the opinions have a reasonable basis and meet the *Daubert* requirements").

[17] Even if an expert's "description of the underlying documentation was sometimes abbreviated and conclusory, . . . that went to the weight of his testimony, not its admissibility." *Id.* Here, Dr. Stiroh's heavily detailed, 90-paragraph 54-page 191-footnote report (plus charts and an extensive Excel spreadsheet damages model), is plainly not abbreviated or conclusory.

standards for admissibility under Rule 702 and *Daubert*.[18]

A. Dr. Stiroh's Lost Profits Analysis Is Well-Founded

Amgen makes two challenges to Dr. Stiroh's lost profits analysis, neither of which has any merit.[19] Her assumptions as to when the FDA will approve Mircera and when Amgen will cease its anticompetitive conduct *are* factually supported and her analysis *does* account for the impact of factors other than Amgen's illegal conduct.

1. Dr. Stiroh's Assumptions Are Well-Founded

a. FDA approval. For her assumption that the FDA will approve Mircera as early as October 2007, Dr. Stiroh relied on a conversation she had with Roche's Vice President for Regulatory Affairs. Amgen not only fails to point to any evidence controverting this Roche executive's representation regarding likely FDA approval, but also does not contend that it was unreasonable for Dr. Stiroh to rely on the representation. On the contrary, Amgen *agrees* with the assumption (Amgen SJ Mem. 19-20: FDA approval may be forthcoming in "four or five months" (*i.e.*, October or November)). This puts the lie to Amgen's assertion (Mem. 14 n.15) that "there is no evidentiary basis" for the approval-date assumption.

b. Date of First Sale. Dr. Stiroh relied, *inter alia*, on the testimony of Roche's CEO and President, its Vice President of Commercial Operations, and its

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[18] "Amazingly" (Mem. 13), Amgen fails to cite *any* of these First Circuit and other authorities except for *Daubert* and *General Electric*.

[19] Amgen makes a conclusory, omnibus attack on Dr. Stiroh's opinion. (Mem. 1 n.1). Professor Teece's criticisms of Dr. Stiroh's opinion present a classic "battle of experts" – a literal "he said she said" – going to the "weight of the evidence," the resolution of which is for the jury, not the court. *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1105-06 (1st Cir. 1994); *Phillips v. Cohen*, 400 F.3d 388, 399 (6th Cir. 2005). Professor Teece's critiques misapprehend Dr. Stiroh's analysis and reach erroneous conclusions based in part on calculation errors, all of which are grist for the mill before the jury.

Product Director Commercial Operations that Roche will start taking orders for Mircera promptly after FDA approval and that Roche will start shipping Mircera two months later. (*See* p. 6, *supra*). Such testimony by knowledgeable executives is clearly reasonable for an expert to rely upon. Tellingly, Amgen cites *no* contrary evidence.

c. Date of Cessation of Unlawful Conduct. Equally reasonable is Dr. Stiroh's reliance on attorneys for her assumption that Amgen likely will not cease its unlawful conduct until 2008. As Amgen concedes, Dr. Stiroh does not have "legal expertise." (Mem. 15). That is why she did not opine on when Amgen will cease its unlawful conduct, but, instead, relied on a "legal judgment" by persons who do have "legal expertise" – Roche's lawyers. (*Id.*).[20] Tellingly, Amgen *does not represent* that it will (1) cease its unlawful conduct when the jury returns its verdict, (2) not move to set aside the jury's verdict or, if it does, it will agree that the hearing on injunctive relief should be held before the hearing on its post-verdict motion, (3) agree to the entry of injunctive relief, and/or (4) if it does not agree to an injunction, not seek a stay of such relief on appeal. Because Amgen, not Roche, has control over cessation of its conduct, Dr. Stiroh's assumption that Amgen will take every measure to propagate its unlawful conduct does not "lack" an "evidentiary foundation." (Mem. 15).

Rather than challenge the basis of Dr. Stiroh's assumption, Amgen criticizes her for changing it. It is, however, not unusual for experts to revise their opinions where, as here, the facts change, and Dr. Stiroh expressly reserved the right to do so. Ex. 23 at ¶ 7

[20] *See Tuf Racing Prods., Inc. v. Am. Suzuki Motor Corp.*, 223 F.3d 585, 591 (7th Cir. 2000) (rejecting *Daubert* challenge to expert's reliance on "assumptions given him by counsel"); *Southwire Co. v. J.P. Morgan Chase & Co.*, 2007 U.S. Dist. LEXIS 30294 *73 (W.D. Wis. Apr. 24, 2007) ("plaintiffs' counsel provided information to limit the scope of the experts' analysis [but] . . . did not formulate the experts' ultimate opinions . . . . [D]efendants remain free to argue that counsel set improper parameters . . . .").

(Stiroh Rep.). Indeed, each of Amgen's economic experts "reserve[d] the right to supplement or revise my analysis based on . . . additional information."[21] In any event, the issue is not, as Amgen would have it, that the assumption changed, but rather whether it is "realistic." (Mem. 12). Here, particularly in light of Amgen's refusal to submit any evidence on the timing of post-trial proceedings, Dr. Stiroh's assumption of continued Amgen misconduct is reasonable. Uncertainty should be resolved against the antitrust violator who controls its own conduct, not the antitrust plaintiff. *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 265 (1946) ("the wrongdoer shall bear the risk of the uncertainty which his own wrong has created"). Indeed, Amgen's expert testified that he could not state whether the amount of time Dr. Stiroh assumed it would take for Amgen to stop its unlawful conduct was "too long or *too short*." Ex. 43 at 44:20-25 (Teece Dep.) (emphasis added).[22]

2. Dr. Stiroh's Analysis *Does* Account for Other Factors

Amgen asserts that Dr. Stiroh's opinion should be excluded because, Amgen says, it fails "to establish that the claimed injury or damages is attributable entirely to the alleged anticompetitive conduct, rather than to legal competition or other factors."

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[21] Ex. 21 at ¶ 13 (Bernheim Rep.); Ex. 24 at ¶ 9 (Teece Rep.); Ex. 22 at ¶ 5 (Bernheim Rebuttal Rep.). *See Newell P.R., Ltd. v. Rubbermaid Inc.*, 20 F.3d 15 (1st Cir. 1994), where the First Circuit affirmed refusal to disqualify an expert who, in an amended damages report four days before trial and in a deposition three days after trial commenced, used "new calculations using a methodology and valuation procedure different" from his original report. *Id.* at 19. The Court reasoned that the defendant "was very familiar with the subject matter upon which [the expert] would render his testimony" and "had ample opportunity to cross-examine" him. *Id.* at 20. This is an *a fortiori* case; Amgen already has deposed Dr. Stiroh, and did so months before trial.

[22] Furthermore, Roche's lost profits attributable to Amgen's exclusionary agreements are not speculative merely because they presuppose continuing exclusionary conduct. *See Pace Indus., Inc. v. Three Phoenix Co.*, 813 F.2d 234, 240 (9th Cir. 1987) (antitrust claim accrued at time of unlawful acts even if damages for unlawful acts required unlawful conduct to continue).

(Mem. 16). Amgen's contention is legally and factually flawed.

1. Amgen wholly ignores the governing Supreme Court and First Circuit case law regarding causation and injury. Reflecting the Supreme Court's acknowledgement in *J. Truett Payne Co. v. Chrysler Motors Corp.*, 451 U.S. 557, 565 (1981), that "our traditional rule excus[es] antitrust plaintiffs from an unduly rigorous standard of proving antitrust injury," the First Circuit has held that an antitrust plaintiff need only prove that the defendant's unlawful conduct was "a material cause" of the plaintiff's injury, not that it was the "sole cause." *Sullivan v. NFL*, 34 F.3d 1091, 1103 (1st Cir. 1994) (*quoting Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 14 (1st Cir. 1979)).

Similarly, Amgen ignores the black letter law that when an antitrust plaintiff "seeks recovery for injuries from a partial or total exclusion," damages "are rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123 (1969). "[J]uries are allowed to act on probable and inferential as well as (upon) direct and positive proof. Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim." *Bigelow*, 327 U.S. at 264 (citations omitted). As explained in *Truett Payne*:

> The vagaries of the marketplace usually deny us sure knowledge of what plaintiff's situation would have been in the absence of the defendant's antitrust violation. But our willingness also rests on the principle articulated in cases such as *Bigelow*, that it does not "come with very good grace" for the wrongdoer to insist upon specific and certain proof of the injury which it has itself inflicted.[23]

[23] 451 U.S. at 566-67 (internal quotations omitted). *Accord, Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931) ("Where the tort itself is of such a nature to preclude the ascertainment of the amount of damages with certainty, it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts.") (rein-

Accordingly, as held in *Haverhill Gazette Co. v. Union Leader Corp.*, 333 F.2d 798, 805 (1st Cir. 1964), it is "wrong" to require proof that the defendant's violation of the Sherman Act was the "'sole or predominant cause' and 'a more substantial cause of harm than any other known cause.'" Rather, the "plaintiff may recover for loss to which defendant's wrongful conduct substantially contributed, notwithstanding other factors contributed." *Id.* at 806. As the Court explained in reversing and remanding for a new damages determination:

> The difference between a "substantial" cause and one "more substantial than any other" is manifest. If the master put a burden on Gazette, as it may well be he did, to eliminate all proper causes for the shifting of advertising from Gazette to the Journal to the extent of affirmatively showing that the illegal causes were the sole or most substantial, we consider this too favorable treatment of a deliberate wrongdoer. (*Id.*).

The defendant is free to "subject [the plaintiffs' expert's testimony] to vigorous cross examination and . . . to introduce countervailing evidence of its own." *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 794 (6th Cir. 2002).[24] Here, having failed to

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stating Sherman Act jury verdict for plaintiff); *Ford Motor Co. v. Webster's Auto Sales, Inc.*, 361 F.2d 874, 887 (1st Cir. 1966) ("Precise computation of damages can rarely be derived from the complexities of antitrust litigation. This court has recognized that older standards requiring 'certainty' of damages have given way to 'proof of losses which border on the speculative, in order to implement the policy of the antitrust laws.'" (*quoting Momand v. Universal Film Exchanges*, 172 F.2d 37, 42 (1st Cir. 1948)); *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 200 (1st Cir. 1996); *Farmington Dowel Prods. Co. v. Forster Mfg. Co.*, 421 F.2d 61, 84 (1st Cir. 1970); *Storage Tech. Corp. v. Custom Hardward Eng'g & Consulting, Ltd.*, 2006 WL 1766434, *21 (D. Mass. June 28, 2006) (upholding even a "shaky" damages analysis).

[24] Ignoring these cases, Amgen (Mem. 16) relies on other cases, none of which is from the First Circuit and in each of which, unlike here, the expert indisputably did not take into account factors both sides agreed – or the jury found – could have caused the plaintiff's damages. *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1056 (8th Cir. 2000) (damages model "failed to account for market events that ***both sides agreed*** were not related to any anticompetitive conduct") (emphasis added); *Isaksen v. Vt. Castings, Inc.*, 825 F.2d 1158, 1165 (7th Cir. 1987) (plaintiff "made no effort to establish how much of the loss was due to [unlawful] activity as distinct from unrelated business

submit *any* alternative measure of damages, Amgen is in no position to complain about the admissibility of Dr. Stiroh's analysis.[25]

Accordingly, whether Amgen's unlawful conduct is a material cause of the damages and whether Dr. Stiroh's analysis adequately accounts for other factors presents an issue for the jury. Amgen, as explained (*see* pp. 7-10, *supra*), is wrong that Dr. Stiroh presented no facts from which the jury could find the requisite causation and adequately accounted for other factors. Nor is there any basis for a challenge to Dr. Stiroh's reliance on Amgen's and Roche's projections, since "[i]n estimating damages, a claimant may rely on reports and projections made by the wrongdoer itself."[26]

2. Amgen's attacks on both the basis for, and the relevance of Dr. Stiroh's analysis to, Roche's out-of-pocket expenses are equally baseless. Ample record facts demonstrate that all of the $1.1 million in marketing expenses and $5.5 millions in legal

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factors" even though "it is apparent that other causal factors are at work"); *Augustine Med., Inc. v. Mallinckrodt, Inc.*, 2003 U.S. Dist. LEXIS 6079, *26-27 (D. Del. Apr. 9, 2003) (same); *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1163 (7th Cir. 1983) ("MCI's lost profits study does not establish any variation in the outcome depending on which [of the 22 alleged] acts of AT&T were held to be legal and which illegal."); *J.B.D.L. Corp. v. Wyeth-Ayerst Labs., Inc.*, 2005 U.S. Dist. LEXIS 11676, *61-62 (D. Ohio June 13, 2005) (expert relied on defendant's document to infer damages but "rejected the idea that *any* of the other critical assumptions contained in the document, such as quality and quantity of marketing, demographic changes, or introduction of new Wyeth products could also affect Premarin pricing") (emphasis by the Court).

[25] *See D&S Redi-Mix v. Sierra Redi-Mix & Contracting Co.*, 692 F.2d 1245, 1249 (9th Cir. 1982) ("Given appellants' refusal to present a reasonable alternative measure, they may not now argue that those used are fatally speculative."); *Taxi Weekly, Inc. v. Metro. Taxicab Bd. of Trade, Inc.*, 539 F.2d 907, 914-15 (2d Cir. 1976) (plaintiff's verdict "should not be overturned, particularly in light of the fact that the fleet owners presented no alternative price/earnings ratio, while the corporation presented expert testimony in support.").

[26] *Sir Speedy, Inc. v. L&P Graphics, Inc.*, 957 F.2d 1033, 1038 (2d Cir. 1992). *Accord, e.g., LePage's Inc. v. 3M*, 324 F.3d 141, 165 (3d Cir. 2003) (*en banc*); *Charlotte Tele-casters, Inc. v. Jefferson-Pilot Corp.*, 546 F.2d 570, 573 (4th Cir. 1976); *Cherokee Labs., Inc. v. Rotary Drilling Servs., Inc.*, 383 F.2d 97, 106 (5th Cir. 1967).

expenses claimed resulted solely from Amgen's illegal customer threats and fraudulent patent suit, respectively. (*See* pp. 11-12, *supra*). Nor is there any basis for Amgen's assertion that Dr. Stiroh's testimony "will not 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" (Mem. 20 *quoting* FED. R. EVID. 702). To be sure, the proof of these expenses stands on its own. Dr. Stiroh, however, applied her expertise in evaluating the increased expenses to confirm that Amgen's unlawful conduct caused them and to ensure that they do not overlap with the lost profits she calculated. This testimony, coupled with her presentation in one place of the total damages Roche suffered, will surely be "helpful to the jury."[27]

CONCLUSION

For the foregoing reasons, Amgen's Motion to Exclude the Expert Testimony of Lauren J. Stiroh should be denied.

[27] Mem. 12 n.8 (*quoting Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) ("The ultimate purpose of the *Daubert* inquiry is to determine whether the testimony of the expert would be helpful to the jury in resolving a fact in issue.").

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Boston, Massachusetts

Respectfully submitted,

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I hereby certify that a redacted version of this document was filed through the ECF system and was sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies were sent to those indicated as non registered participants on the above date.

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