UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMGEN INC.,)
Plaintiff and Counterclaim-Defendant, v.)) Civil Action No. 05-12237 WGY
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC., Defendants and Counterclaim-Plaintiffs.)))))

DECLARATION OF SUSAN GRAF IN SUPPORT OF ROCHE'S OPPOSITION TO AMGEN'S MOTION FOR SUMMARY JUDGMENT ON ROCHE'S ANTITRUST AND STATE LAW COUNTERCLAIMS

- I, Susan Graf, declare as follows:
- 1. I am a Product Director on the MIRCERA[™] brand team at Roche. I make this declaration in support of Roche's opposition to Amgen's motion for summary judgment on Roche's Antitrust and State Law Counterclaims. This declaration is based on my personal knowledge. MIRCERA[™] is an erythropoeisis-stimulating agent ("ESA") that Roche has developed and submitted to the Food and Drug Administration ("FDA") for approval.

Increased Marketing Costs Because of Amgen's Anticompetitive Conduct

2. As a result of our membership in the MIRCERATM brand team, both myself and other members of the brand team have been aware that during the latter part of 2006 Amgen communicated messages to potential MIRCERATM customers to dissuade them from considering the purchase of MIRCERATM. As described below, these messages included threats that Amgen

would impose financial penalties on customers that purchased MIRCERATM and later wished to purchase Amgen ESAs, threats that Amgen would consider suing customers who purchased MIRCERATM for patent infringement, and messages designed to create doubt among the purchasers as to whether MIRCERATM will enter the markets for ESAs.

- 3. First, I and the brand team members understood that during the latter part of 2006 Amgen threatened customers with unfavorable contract terms if they purchased MIRCERATM and later decided to purchase ESAs from Amgen. Amgen's threats were communicated to thought leaders among potential MIRCERATM customers, giving the threats widespread impact among MIRCERATM's potential customer base. These threats, we also believed, will dissuade some customers from purchasing MIRCERATM who otherwise would have purchased the product once it receives FDA approval. These threats also created fear, uncertainty and doubt among potential customers of Roche's commitment to the anemia markets and Roche's ability to successfully introduce MIRCERATM once it is approved.
- 4. Second, I and the brand team understood that during the second half of 2006 Amgen also threatened ESA purchasers that if they purchased MIRCERA™ they could be named as defendants in lawsuits by Amgen as infringers. To the MIRCERA™ brand team, these threats increased the fear, uncertainties and doubts among potential customers about Roche's commitment to the anemia markets and about Roche's ability to successfully introduce MIRCERA™ once it is approved. In addition, I and the brand team understood that these threats will dissuade some customers from purchasing MIRCERA™ who otherwise would have purchased the product once it receives FDA approval.
- 5. Third, I and the brand team understood that in the latter part of 2006, Amgen publicized to potential MIRCERATM customers that its patent infringement lawsuit against

Roche would result in MIRCERATM being withdrawn from the market. As a result, I and the brand team understood that potential MIRCERATM customers questioned Roche's commitment to the anemia markets, and that some potential customers were dissuaded from purchasing MIRCERATM who otherwise would have purchased the product once it receives FDA approval.

- 6. As a direct result of the Amgen conduct described above, I and the brand team during the latter half of 2006 decided to increase Roche's marketing spending over its budgeted amounts in three targeted areas. The amount ultimately spent in these areas in 2006 exceeded the planned spending in these areas approved through Roche's budgeting process. The increased spending in these areas was intended to further establish Roche as a committed player in the anemia markets to counter the above-described Amgen conduct, as further detailed below. I and the brand team expect that the increased spending will prevent the loss to Roche of some, but not all, of the potential customers that would not have purchased MIRCERA™ because of the Amgen threats described above. However, we believe that there will remain customers that will not purchase MIRCERA™ because of Amgen's threats.
- 7. First, I and the brand team decided to increase spending in the category of Journal Advertising resulting in actual increased spending of about \$934,000 due to Amgen's conduct described above. Specifically, the MIRCERATM marketing spending for Journal Advertising increased from the budgeted amount of about \$900,000 for 2006 to actual spending of \$1.834 million as a result of the expansion of a Roche campaign entitled the "New Blood" campaign, which consisted of print ads that emphasized Roche's commitment to anemia treatment. To counter the doubts and fears among potential MIRCERATM customers caused by the Amgen conduct described above, Roche expanded the New Blood campaign to place airport displays and additional advertisements. The increased spending of about \$934,000 incurred up to the end of

2006 consisted of the costs of placing the ads in selected medical journals and newspapers during that time, and for an airport display in the San Diego airport related to the November 2006 American Society of Nephrology meeting.

- 8. Second, I and the brand team decided to increase spending in the category of Conventions resulting in actual increased spending of at least \$192,000 due to Amgen's conduct described above. Specifically, the MIRCERA™ marketing spending for Conventions increased by at least \$192,000 to pay for higher level sponsorships at conventions of organizations involved in anemia treatment than the planned sponsorship level. By spending more as a sponsor, Roche had more prominent placement at the convention in terms of banner advertisements and booths. The conventions at which Roche increased its sponsorship spending included the American Nephrology Nurses Association meeting in Boston in September 2006, the National Renal Administrator's Association meeting in Philadelphia in October 2006, and the American Society of Nephrologists Renal Week meeting in San Diego in November 2006. The total increased spend for Conventions over budget was about \$730,000, at least \$192,000 of which I have verified was for the higher-level sponsorships in response to the Amgen conduct described above.
- 9. Third, after the MIRCERA™ brand team learned of Amgen's threats to customers in 2006, I and the brand team decided to attempt to counter these threats, in part, by creating print materials highlighting key messages from the "Discover Roche" campaign for the field force to leave with customers to emphasize Roche's corporate commitment to the treatment of anemia. The materials described Roche's corporate commitment to anemia markets to counter the doubts Amgen created about Roche's staying power in the area. This increase in spending, of about

\$10,000, was in the category of Sales Promotion and was distinct from the Amgen conduct described above as part of the Public Policy and Public Affairs cost category within the budget.

- 10. I had previously informed outside experts for Roche that the increased spend for the development and printing costs of the "Discover Roche" materials for use by the field sales force was reflected in the Field Communications category of budgeted expenses. After further inquiry undertaken to respond to Amgen's summary judgment motion, I have since learned that the increased costs for developing and printing those materials was reflected in the Sales Promotion category, not the Field Communications category, and amounted to about \$10,000.
- 11. Attached hereto as Exhibit A is a true and correct copy of an email and attachment dated January 4, 2007 of the 2006 marketing budget for MIRCERA™ that includes the increased spending in Journal Advertising, Conventions and Sales Promotions described above.

Marketing Costs Are Designed to Increase MIRCERA™ Sales and Vary with Those Sales

- 12. As part of its budgeting process, Roche has created a cost category related to Marketing and Distribution costs for a brand ("M&D"). M&D costs include the following subcategories: M1, Field Force Direct Cost, Field Force Indirect Cost and Other M&D. I have read the declaration of Steven Platt, dated June 18, 2007 ("Platt Declaration"), describing Roche's financial planning process and the categories of M&D costs. The MIRCERA™ brand team prepares budgets based on the categories as described in the Platt Declaration.
- 13. M1 expenses for MIRCERA™ include costs related to promotions, professional programs, medical affairs, product support and other costs. In 2006 Roche's M1 expenditures were over \$60 million. Roche has a process for creating a budget for M1 expenses for a given calendar year. As part of that process, funds are allocated to various M1 cost categories in order to maximize sales.

- 14. The vast majority of M1 costs change, or can change, depending upon the volume of MIRCERA™ sold, or expected to be sold. For example, the promotion category includes agency fee costs, which are fees paid to advertising agencies to help develop promotional literature that is designed to drive sales. As part of the M1 budgeting process Roche would increase planned expenditures of agency fees if it were expecting greater future sales. Conversely, if Roche anticipates lower future sales it would cut the projected spending of agency fees.
- 15. Other examples of M1 expenses that vary, or can vary, on the volume of MIRCERA™ sales, or expected sales, include direct mail (which includes costs of printing and mailing promotional pieces), conventions (which includes costs of sponsorships by Roche), journal advertising (which includes the costs of placing advertisements), and sales promotional items (which includes the costs of producing marketing tools for use by the field sales force). Roche allocates money in the budget for these costs with the expectation that this spending will result in additional MIRCERA™ sales volume. If the volume of MIRCERA™ sales declines, Roche will spend less on these categories of M1 expenses. Other categories of M1 expenses that vary with the amount of anticipated sales include the costs of reprinting medical articles for use by the field sales force, grants to associations, costs to develop and train speakers, public relations activities, and the costs of field force meetings.
- 16. Roche has the ability to alter its M1 costs as market conditions change. Roche can increase its advertising, promotion and sales force spend in response to opportunities in market segments that may become available to it. Conversely, Roche can also decrease such M1 costs if a certain market opportunity is no longer available to it. For example, were large dialysis organizations not an opportunity available to Roche, Roche would decrease certain promotion expenses, such as production costs of printed pieces and premiums, such as pens and notepads.

- 17. Field Force Direct Costs include the salaries, bonuses, and other costs of the MIRCERA™ field force, which includes the field sales representatives and medical liaisons. Roche's expenditures on its field force are made with the expectation that the spending will generate sales. The amount of spending can also change depending on sales volume -- for example, costs of the field sales force can also increase if sales increase as the field force size increases and/or is paid more in bonuses, and can decline if sales decline as the field force size decreases and/or is paid less in bonuses.
- 18. Roche may also alter Field Force Direct Costs as market conditions change. Roche could increase the number of sales representatives and medical liaisons in response to market opportunities that become available to it. Conversely, Roche could reduce the size of the sales force and medical liaisons if a market segment was no longer available to it.
- 19. Field Force Indirect Costs include various cost categories as outlined in the Platt

 Declaration that are allocated to MIRCERA™ based on headcount. These categories include

 account management, technological support and sales analysis and targeting, among others. The

 activities that result from a number of the Field Force Indirect Costs are intended to drive

 MIRCERA™ sales. For example, the work of account managers, who interact with large

 accounts on a number of Roche products; sales targeting staff, who develop plans to more

 productively deploy sales reps; and sales training personnel, who train the field force to be

 effective, can increase MIRCERA™ sales volume. In addition, a number of these costs vary, or

 can vary, with changes in actual or expected MIRCERA™ sales volume. For example, the total

 amount of spending on certain Field Force Indirect Costs, such as account management,

 technological support, sales administration and field force training, can change if MIRCERA™

sales change because the number of personnel may increase or decrease based on increases or

decreases in MIRCERATM sales.

20. Other M&D costs include other expenses associated with the MIRCERA™ brand

including distribution costs and the costs of internal, non-field based personnel dedicated to

MIRCERATM, such as the MIRCERATM brand team of which I am a member, and medical affairs

personnel. Many of the Other M&D costs vary, or can vary, with actual or expected sales. For

example, distribution costs of MIRCERATM will vary directly with the amount of sales. A

decline or increase in MIRCERATM sales could lead to declines or increases in the personnel

dedicated to the MIRCERATM brand such as the size of the marketing team or number of

dedicated medical affairs personnel that support MIRCERATM.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 29 day of June 2007 at Nutley, New Jersey

<u>/s/ Susan Graf</u> Susan Graf

CERTIFICATE OF SERVICE

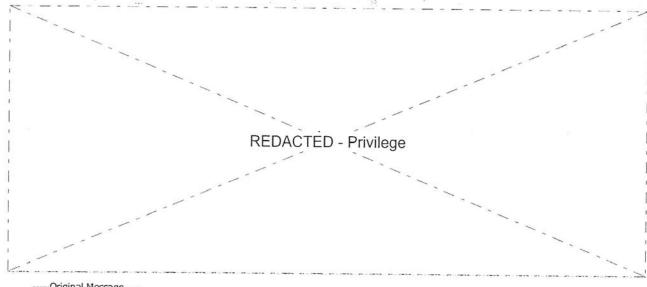
I hereby certify that a redacted version of this document was filed through the ECF system and was sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies were sent to those indicated as non-registered participants on June 29, 2007.

/s/ Kregg T. Brooks Kregg T. Brooks

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EXHIBIT A



----Original Message----

From: Besterci, Janet {Comm~Nutley} Sent: Thursday, January 04, 2007 9:54 AM

Graf, Susan E {CERA~Nutley}; Duncan, Suzann B {CERA~Nutley}

Cc: Coviel, Darlene {PLAN~Nutley}

Subject: MIRCERA 2006 Year end M-1 results

The 2006 M-1 for MIRCERA is \$60,106,208.81 versus F3 of \$59,150,002 and a Latest Estimate of \$54,850,000. We need to identify how the variance over the Latest Estimate went up to \$5.3 M. Please let me know what you think were the main drivers of this overspend.

Have a good day!

Janet <<2006 Final M-1 Results.xls>> 2006 Final M-1 Results.xls

Cost Centers: Actual/Plan/Variance
Date: 01/04/2007
Fiscal Year 2006
From period 1
To period 12
Plan version 3
Cost center group 357170 MIRCERA

SCALURING CONTROL OF THE SCALURING CONTROL OF				
Cost elements	Act.costs	Plan costs	Abs. var.	Var.(%)
* Agency Fees	7,192,036.92	7,152,182.00		
* Conventions	1,353,746.86	623,569.00		
* Direct Mail	238,955.50	300,409.00		
 Field Communication 	178,279.82	51,438.00		
* Intra/Internet	865,942.60	1,152,200.00		
 Journal Advertising 	1,835,424.77	901,316.00		
 * Sales Promotion 	4,966,571.80	4,548,143.00		A CONTRACTOR OF THE PARTY OF TH
** Promotions	16,630,958.27	14,729,257.00		The second second
 * Advisory Boards 	447,894.86	467,602.00		
 Medical Director Spon Pro 	1,890,309.91	2,985,648.99		
* Publications	96,621.00	200,000.00	1	
* Seminars/Symposia	500.00	500.00	100,070.00	31.09-
* Speaker Program Developme* Teleconference	748,230.00	750,000.00	1,770.00-	0.24-
** Professional Program	3,183,555.77	4,403,750.99	1,220,195.22-	07.74
Allocation from R&D	41,205.49	4,400,700.00	41,205.49	27.71-
* Roche Sponsored Studies	1,372,861.49	2,741,232.00	1,368,370.51-	40.00
MDMA-MDA	2,182,716.05	2,446,818.40	264,102.35-	
MDMA-Clin Trials	215,775.16	858,700.00	642,924.84-	
Scien. Comm Consitions	938,881.50	1,594,839.39	655,957.89-	
Scien. CommMed Ed	4,334,345.04	5,145,967.99	811,622.95-	41.13-
* Medical Affairs	9,085,784.73	12,787,557.78	3,701,773.05-	
Customer Market Segment	3,198,407.03	2,294,326.00	904,081.03	
IMS Data	898,997.00	898,995.00	2.00	39.41
Market Intelligence	5,052,451.05	3,922,255.00	1,130,196.05	0.00 28.82
Competitive Intelligence	510,043.05	525,002.00	14,958.95-	
Payment Planning	, , , , , ,	50,000.00	50,000.00-	2.85-
Public Affairs	5,895,063.49	3,557,793.00	2,337,270.49	100.00-
Public Policy & Fed Gov't	6,854,017.59	6,450,000.00	404,017.59	65.69
State Govt Affairs	128,197.67	310,829.00	182,631.33-	6.26 58.76-
* Product Support	22,537,176.88	18,009,200.00	4,527,976.88	25.14
* Field	112	500,000.00	500,000.00-	100.00-
* Meetings	6,785,212.39	6,448,000.00	337,212.39	
CT&D	1,883,520.77	2,272,236.00	388,715.23-	5.23
** Debit	60,106,208.81	59,150,001.77	956,207.04	17.11-
** Over/underabsorption	60,106,208.81	59,150,001.77	956,207.04	1.62 1.62