

Ex. B

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON D.C.**

**Before the Honorable Paul J. Luckern
Administrative Law Judge**

In the Matter of

CERTAIN PRODUCTS and
PHARMACEUTICAL COMPOSITIONS
CONTAINING RECOMBINANT HUMAN
ERYTHROPOIETIN

Investigation No. 337-TA-568

**MEMORANDUM IN SUPPORT OF COMPLAINANT AMGEN INC.'S MOTION
TO DECLARE NO CONFLICT OF INTEREST AND THAT MCDERMOTT
WILL & EMERY LLP IS QUALIFIED AS COUNSEL OF RECORD TO THIS
INVESTIGATION**

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I. INTRODUCTION

In 2004, McDermott Will & Emery LLP (“McDermott”) recognized that its concurrent representation of Amgen and Hoffman-LaRoche, Inc. (“Roche”) was likely to lead to significant conflicts. McDermott approached the issue by discussing with each entity the fact of its representation of the other, and seeking a prospective waiver from Roche on Amgen matters, including “litigation,” that were adverse to Roche. This request received the highest attention and independent review within Roche, with the General Counsel himself of Roche executing the waiver letter. ABA Model Rule of Professional Conduct 1.7 recognizes the enforceability of such waivers where, as here, the client is sophisticated and had independent legal advice.

Amgen subsequently engaged McDermott to represent it in connection with potential patent infringement litigation over Roche’s CERA product. On November 8, 2005, Amgen filed suit against three Roche entities in the Massachusetts District Court on the same patents asserted in this Investigation. McDermott appeared as counsel of record. Despite significant law and motion practice there, at no point in time did Roche object to McDermott’s representation of Amgen in that suit.

During the subsequent six months, this Investigation was commenced and Roche filed its Motion for Summary Determination of No Violation of Section 337 under 35 U.S.C. § 271(e)(1), engendering significant and expedited discovery. Like other counsel on both sides hereto, McDermott then appeared and agreed to be bound by the Protective Order. Roche then raised conclusory allegations that McDermott had a conflict of interest despite the waiver letter. Specifically, Roche alleged that McDermott’s tax work

for Roche was effectively the same matter as the dispute at issue in this patent infringement investigation on Roche's CERA product since discovery may make undefined agreements relevant. Currently, Roche is refusing McDermott lawyers access to confidential information under the Protective Order, at times refusing to even engage with McDermott lawyers on issues, therefore hindering McDermott's knowledge it would obtain through discovery, and is threatening further actions due to possible taint of McDermott's co-counsel.

Roche's contentions are insufficient to meet its burden of demonstrating that McDermott should be disqualified in the face of the waiver letter. McDermott is not representing Roche before this Court on the same matter within the meaning of Model Rule 1.7(b). Roche never engaged McDermott to advise it on this patent infringement lawsuit, and certainly, McDermott is not appearing on both sides of this Investigation. The McDermott tax advice related to corporate issues cannot fairly be characterized as the same patent infringement matter at issue in this Investigation. Even if certain Roche company agreements arising out of corporate tax advice McDermott rendered is discoverable in this Investigation, such discovery cannot support disqualification. Further, the McDermott lawyers working on this matter in McDermott's Silicon Valley Office have no knowledge of any Roche confidential information maintained in other McDermott Offices, and the screen in place ensures that remains so.

Roche's recent actions are contrary to the clear and knowing waiver. Amgen requests that the Court declare that McDermott does not have a conflict of interest and

that McDermott's appearance and access to information under the Protective Order be affirmed.

II. FACTUAL BACKGROUND

A. THE PARTIES ARE SOPHISTICATED GLOBAL PLAYERS IN THE BIOTECHNOLOGY INDUSTRY

Amgen Inc. is a global biotechnology company based in Thousand Oaks, California. Founded in 1980, Amgen is a pioneer in the discovery, development and delivery of innovative therapeutic products based on advances in molecular biology, recombinant DNA technology and chemistry. For over a decade, Amgen's products have been improving the lives of millions of patients over a broad range of treatment indications. Amgen's success as a biotechnology company is attributable in part to the inventions of one of its original scientists, Dr. Fu-Kuen Lin, relating to recombinant human EPO, and the subsequent success of its EPO business that Roche's CERA product (a pegylated or "PEG" EPO) misappropriates.

The Roche Group is one of the world's largest pharmaceutical companies, operating around the globe through numerous entities. Its pharmaceutical operations in the United States are run by Hoffman-LaRoche, Inc., ("Roche"), based in Nutley, New Jersey. Roche filed on April 19, 2006 with the Food and Drug Administration its Biologic License Application to seek regulatory approval to sell commercially in the United States the CERA product that is the subject of this Investigation.

Roche identifies itself as a major player in biotechnology. This major player is an experienced litigant. A LEXIS Report reveals many different law firms – including large

firms such as Covington & Burling, Kirkland & Ellis, Kaye Scholer and Arnold & Porter – representing Roche in many litigations across the country. (Morgan Decl., Ex. 7.) Martindale-Hubbell lists over 20 in-house Roche lawyers. (Morgan Decl., Ex. 8.)

B. MCDERMOTT'S TAX AND EMPLOYMENT BENEFITS REPRESENTATION OF ROCHE

Starting some years ago, Roche engaged McDermott to advise it on the structuring of its affairs from a tax perspective to comply with relevant tax laws. McDermott's work for Roche has not focused on any specific product, as Roche's attorneys concede, but instead has focused on general inter-company transfers of Roche products overall and how to structure such affairs from a tax compliance issue. (Gaede Decl., Exs. C and R.) The work has been handled primarily by McDermott's Washington, D.C. Tax Group. McDermott has not advised Roche as to patent infringement generally, CERA's infringement of the asserted Amgen patents, and/or validity or enforceability of those patents. (Riedy Decl., ¶ 5.)

C. MCDERMOTT'S REPRESENTATION OF AMGEN

McDermott has a long-standing relationship with Amgen beginning back in July 1995. (Gaede Decl., ¶ 5.) McDermott attorneys further have enjoyed a long standing relationship with Amgen's General Counsel stretching back to his days as General Counsel of Medtronic Inc. (*Id.*) By early 2004, Amgen increasingly turned to McDermott for legal advice on its affairs. (Gaede Decl., ¶ 5.)

D. WAIVER BY ROCHE OF ADVERSE MATTERS

With McDermott performing increasing amounts of work for Amgen, it became increasingly clear that Roche and Amgen could, indeed inevitably would, in the future, be in conflict with each other. McDermott addressed the issue in 2004 by contacting Roche to discuss the concept of a prospective waiver that would permit McDermott to be free to act for Amgen on matters actually or potentially adverse to Roche. (See Riedy Decl., Ex. A.) Indeed, McDermott stated that it was prepared to disengage from its relationship with Roche (in an orderly fashion and pursuant to the rules) if Roche was not willing to grant a broad prospective waiver to McDermott. (*Id.*) Discussions ensued with Karen Nagle of Roche. (*Id.*) These conversations culminated in an informed consent, broad waiver letter that was signed by F.C. Kentz, III, General Counsel of Roche. (Riedy Decl., ¶ 6, Ex. A.)

The letter commenced by identifying the structural conflict that existed in the pharmaceutical industry, and specifically identified Amgen as the client for which McDermott sought the waiver. After providing some further background, the letter stated:

More specifically, by this letter we seek your waiver of conflicts arising from our engagement on behalf of Amgen in matters that are or might be adverse to Hoffmann-La Roche including litigation, and including matters that actually or arguably are substantially related to the subject matter of services that we provided to you or are providing to you, providing that we establish and maintain an ethical wall between those attorneys providing tax, regulatory, employment or other advice to Hoffmann-La Roche and those attorneys engaged by Amgen to provide any services which are or may be adverse to Hoffmann-La Roche.

(Riedy Decl., Ex. A.) The waiver letter further provides that “wherever practicable, [McDermott] will seek to staff the adverse engagements from offices different from those engaged to provide services on behalf of Hoffmann-La Roche.” (*Id.*) Mr. Kentz “agreed to and accepted” the terms of the waiver on December 23, 2004. (*Id.*)

Roche executed the December 2004 waiver against its public recognition that patent litigation with Amgen regarding Roche’s CERA product was likely inevitable. Roche’s Global Pharmaceutical’s Head William Burns publicly stated in 2003 to analysts in Zurich:

Knowing Amgen from having worked with them over the years and having observed them over the years, I think that we should expect that they will take us to court [over CERA].

(Gaede Decl., Ex. B.) The potential dispute between Amgen and Roche over CERA’s infringement of Amgen’s EPO patents was also reported on by analysts and commented on by Amgen officers in 2003 and 2004. (Gaede Decl., Exs. C and D.)

E. MR. GAEDE JOINS MWE IN FEBRUARY 2005 AND MCDERMOTT IS ENGAGED TO REPRESENT AMGEN IN THIS DISPUTE

Mr. William Gaede joined McDermott in February 2005. Formerly, he was a partner of Cooley Godward LLP. Mr. Gaede had represented Amgen since early 1997 when he defended a patent infringement suit brought by Genentech against Amgen. (Gaede Decl., ¶ 2.) Lead counsel for Roche in this matter, Leora Ben-Ami of Kaye, Scholer LLP, represented Genentech in that hard-fought patent litigation suit. (*Id.*)

In the Spring of 2004, Amgen engaged Cooley Godward to represent it in connection with possible patent litigation against Roche over CERA. (Gaede Decl., ¶ 3.)

On January 31, 2005, Mr. Gaede gave notice to Cooley Godward that he was leaving the partnership. (*Id.*, ¶ 4.) Consistent with the terms of his partnership agreement, he never solicited Amgen to leave Cooley Godward prior to his departure. (*Id.*) He joined McDermott on February 11, 2005.

On March 28, 2005, Mr. Gaede sent to Amgen an engagement letter for Amgen to engage McDermott Will & Emery LLP in connection with the potential assertion of Amgen's patents against Roche's CERA product. (Gaede Decl., ¶ 5.) Amgen executed and returned the letter on April 22, 2005. (*Id.*) McDermott lawyers in its Silicon Valley Office have performed the work on this patent infringement dispute. (*Id.*, ¶ 6.) Work on tax and other matters for Roche is not performed in the Silicon Valley Office. (Gaede Decl., ¶ 6; Riedy Decl., ¶ 4.) McDermott lawyers working on the Amgen case have had no access to Roche information. The screen has been entirely effective. (Gaede Decl., ¶ 6; Riedy Decl., ¶ 7.)

F. EVENTS LEADING UP TO RESPONDENTS' ALLEGATION OF A CONFLICT

1. McDermott Appears on November 8, 2005 in the Boston District Court Action Without Objection

On November 8, 2005, Amgen filed suit against F. Hoffman-LaRoche, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. for patent infringement of the Asserted Patents in this Investigation in the District of Massachusetts ("Boston Action"). (Gaede Decl., Ex. E.) McDermott appeared as counsel of record for Amgen on that complaint. (*Id.*) The next day, Roche issued a press release acknowledging Amgen's lawsuit. (*Id.*, Ex. F.)

Over the next several months, Roche did not raise an objection to McDermott's representation of Amgen in the Boston Action, despite several opportunities to do so. For example, in early February 2006, Ms. Ben-Ami corresponded with counsel for Amgen about the time for the Roche entities to respond to Amgen's complaint. (Gaede Decl., Exs. F-G.) On April 11, 2006, Roche moved to dismiss the Boston Action for lack of subject matter and personal jurisdiction. (*Id.*, Ex. I.) Not once in its briefing did Roche raise the issue of a conflict of interest as to any Roche entity. (*Id.*) Even in the face of discovery on topics related to transfer of CERA, Roche never raised a conflict. (*Id.*, Ex. U.) Roche has not alleged that McDermott's representation of Amgen in the Boston Action violates any ethical rule. (Gaede Decl., ¶ 11.)

2. The ITC Investigation

On April 11, 2006, Amgen filed its complaint in this Investigation and, on April 27, filed an amended complaint. On May 12, 2006, notice of the Commission's intent to investigate Amgen's claims appeared in the Federal Register. (Gaede Decl., Ex. J.) On May 19, 2006, Roche filed its Motion for Summary Determination of No Violation of Section 337. On May 30, 2006, both McDermott and the law firm of Marshall, Gerstein & Borun LLP formally filed notices of appearance and protective order subscriptions in this Investigation.

On May 31, 2006, having vaguely referenced the issue in preceding telephone calls over the Memorial Day Holiday Weekend, Roche's counsel, Ms. Ben-Ami, sent to Mr. Day of Day Casebeer Madrid & Batchelder LLP and Ms. Gonzalez of Howrey LLP a letter formally objecting to McDermott's and Marshall, Gerstein & Borun's appearance.

(Gaede Decl., Ex. K.) Ms. Ben-Ami's letter acknowledged the December 2004 waiver letter granted to McDermott, but contended vaguely that McDermott "is poised to become adverse to Roche on the very same matters that it currently advises Roche, namely, future products including CERA and the relationships of the various Roche corporate entities." (*Id.* at 1-2.)

Roche's May 31 letter cited ABA Model Rule of Professional Conduct 1.7, specifically relying on subsection (b)(3), which states that concurrent representation is permissible if "the representation does not involve the assertion of a claim by one client against another client represented by the lawyer in the same litigation or other proceeding before a tribunal." (*Id.* at 2.) Despite this plain language, Roche's letter did not contend: (1) that Roche ever engaged McDermott to provide advice on whether Roche's CERA product infringed Amgen's patents; or (2) that McDermott was engaged to represent Roche in any patent infringement proceeding regarding CERA, much less appear on behalf of Roche in this Investigation. (*Id.*)

The next day, Mr. Gaede responded to Ms. Ben-Ami's letter, explaining that McDermott's concurrent representations of Roche and Amgen under the December 2004 waiver letter complied with ABA Model Rule of Professional Conduct 1.7, which permits concurrent representation of clients:

McDermott has never been engaged to advise Roche in connection with this intellectual property dispute. The tax and employee benefits work McDermott performs for Roche are not the same matters, and certainly do not involve the representation of both parties in this Investigation, as that provision prohibits.