UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

ROCHE'S OPPOSITION TO AMGEN'S MOTION *IN LIMINE* NO. 18: PRECLUDE ROCHE FROM REFERRING TO GOVERNMENT FUNDING OF DR. GOLDWASSER'S RESEARCH AND FROM ARGUING THAT DR. GOLDWASSER'S RESEARCH SHOULD NOT HAVE BEEN SHARED WITH AMGEN

Three Courts, including this one, have ruled that Dr. Goldwasser's National Institutes of Health-funded research relating to erythropoietin ("EPO") is relevant in adjudicating various claims and defenses relating to the patents in suit.[1] In no case did any of those courts preclude inquiry into the source of Dr. Goldwasser's funding or his dealings with Amgen. Here, the jury will be evaluating the same patents and will hear testimony from Dr. Goldwasser, whose credibility will be under scrutiny. The evidence that Amgen seeks to preclude -- the source of Dr. Goldwasser's funding, the obligations that funding may have imposed on him, and his work with Amgen -- pervades the factual

[1] *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1296 (Fed. Cir. 2006); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 325 (D. Mass. 2004); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1352 (Fed. Cir. 2003); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 111-13 (D. Mass. 2001); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991); *Amgen, Inc. v. Chugai Pharm. Co.*, 1989 WL 169006, *12, *14-15 (D. Mass. 1989).

record of this case and is critical to the jury's assessment of Dr. Goldwasser's testimony. Moreover, the fact of public financing of Dr. Goldwasser's work is inextricably intertwined with the work itself, and impacts Dr. Goldwasser's relationship with Amgen. Not surprisingly, Amgen cites no legal authority to support its attempt to exclude such evidence; there is, in fact, no legal basis to bar inquiry into this evidence.

I. DR. GOLDWASSER'S NIH-FUNDED RESEARCH IS RELEVANT TO ROCHE'S DEFENSES

Roche will show that the various asserted claims of the patents-in-suit are invalid for obviousness under 35 U.S.C. § 103. Dr. Goldwasser's NIH-funded work with urinary EPO is critically important prior art, and is detailed in his NIH grant applications. Amgen has put its dealings with Dr. Goldwasser foursquare at the center of this case, which, as this Court has previously found, goes to the heart of several invalidity arguments including anticipation and obviousness. *See e.g., Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp.2d 69, 111-13 (D. Mass. 2001). As the Amgen-Goldwasser relationship is at the heart of this case, the jury should not be precluded from all evidence concerning that relationship, including the impact public financing had on Dr. Goldwasser's work.

Dr. Goldwasser's NIH affiliation is also highly relevant to Roche's argument that the patents-in-suit are invalid under 35 U.S.C. §§ 102(f)/103, which "bars issuance of a valid patent to a person or persons who derive the conception of the invention from any other source or person." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1381 (Fed. Cir. 2000). Derivation under section 102(f) is a question of fact. *Brand v. Miller*, 487 F.3d 862 (Fed. Cir. 2007). In order to resolve this fact question, courts have recognized that the fact finder should know the source from whom, and the circumstances under

which, the invention was derived. *See O2 Micro Int'l. Ltd. v. Monolithic Power Sys., Inc.*, 476 F.3d 1355 (Fed. Cir. 2006) (citing the disclosure requirements codified in Rule 3-1 of the Local Rules of Practice for Patent Cases before the United States District Court for the Northern District of California). Under the facts of the present case, Dr. Goldwasser's work for and affiliation with the NIH is critical for this factual determination.

That Dr. Goldwasser's research was publicly funded is also relevant to Roche's anticipation defense. His research resulted in an important FDA-sanctioned human clinical trial conducted in 1979-80 utilizing a pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin, which, as Amgen documents acknowledge, anticipates asserted claims of the '422 and '933 patents. The human EPO obtained under a NIH grant awarded specifically for that purpose was used by Dr. Goldwasser and Dr. Baron in their clinical trial.[2] Dr. Goldwasser also relied on positive results of the trial to support later NIH renewal applications.[3] In these documents, Dr. Goldwasser acknowledged that the clinical trial obtained positive results -- a proposition Amgen now contests. The evidence presented to the jury will show that Amgen received and considered the design and results of this clinical trial when planning to conduct its own clinical trials with recombinant human erythropoietin.

Dr. Goldwasser's NIH-funded research is therefore highly relevant to this litigation.[4] To grant Amgen's motion would improperly deprive the jury of critical

[2] Depo. Tr. of Eugene Goldwasser, Ph.D., dated Feb. 14, 2007 at 139-40.
[3] *Id.* at 195-200.
[4] Fed. R. Evid. 402.

information necessary to reach an informed decision on the validity of the claims of the patents in suit.

II. THE OBLIGATIONS OF DR. GOLDWASSER'S FUNDING ARE PERTINENT TO THE AMGEN-GOLDWASSER RELATIONSHIP -- THE KEY TO THE CLAIMED INVENTION

With a stockpile of highly purified human EPO from his government-funded research, Dr. Goldwasser became an essential figure in human EPO research. Dr. Goldwasser had the only significant supply of pure human EPO, and Amgen was the exclusive beneficiary of significant quantities of this material. Amgen concedes that this human EPO was integral to the information disclosed in Dr. Lin's patents.[5] The jury should be permitted to consider whether this material, obtained through NIH funding, was instrumental in Amgen's work under §§ 102(f)/103.

Recognizing the significance of Dr. Goldwasser to Amgen's work, Amgen pressured Dr. Goldwasser not to share his purified human EPO with others. As Dr. Goldwasser testified, Amgen "did not want me to consult with anybody else competing with them in the cloning of epo."[6] In fact, Dr. Goldwasser had been contacted by several entities, including researchers from Schering Plough and Biogen, at about the same time as he was approached by Amgen. Yet he categorically denied all non-Amgen requests for samples of his EPO protein from these companies. *See Amgen, Inc. v. Chugai Pharm. Co.*, 1989 WL 169006 (D. Mass. 1989) (finding that "[r]equests made by Biogen to Dr. Goldwasser and the National Institutes of Health in late 1981 and early 1982 for high purity EPO were turned down.").

[5] Depo. Tr. of Eugene Goldwasser, Ph.D., dated Feb. 14, 2007 at 82.
[6] *Id.* at 249.

Dr. Goldwasser clearly understood that the "obligations" created by his receipt of funds from the NIH required that the results of his research be made available to others. At the same time, however, Amgen sought more and more material, information and know-how to suit its private ends. The jury should hear and understand the scope of these competing interests and how this tension manifested itself in Dr. Goldwasser's relationship with Amgen. Dr. Goldwasser in fact told Amgen that the pure EPO he was providing to them was the result of "roughly $230,000 per year (direct costs) in grants from the NIH."[7] Critically, Dr. Goldwasser conceded that

> we operate on public funds, and the public has a right and ***we have a duty*** to make sure that our use of the public funds is public; that is what we do is available for anyone who wants to use it.[8]

This evidence is critical for the jury to evaluate the import of the Dr. Goldwasser's contributions to Amgen and its effect on the validity of Amgen's patents.

III. PRECLUDING ROCHE FROM OFFERING THIS HIGHLY RELEVANT EVIDENCE WILL PREJUDICE ROCHE, NOT AMGEN

Because of Dr. Goldwasser's ambiguous "consultancy" relationship with Amgen, a reasonable jury not informed that Dr. Goldwasser's research was paid for by the NIH could well assume that Dr. Goldwasser's work was sponsored by Amgen, which it was not. Leaving such an impression would be against the facts and completely misleading. Full disclosure to the jury of the facts of Dr. Goldwasser's affiliations is therefore necessary for an informed ruling, and to avoid prejudice to Roche.

[7] *Id.* at 139.
[8] Depo. Tr. of Eugene Goldwasser, Ph.D., dated Feb. 26, 2007 at 430 (emphasis added).

CONCLUSION

Amgen's requested relief will have the effect of denying the jury the ability to consider relevant evidence in evaluating Roche's defenses of invalidity, and other defenses. For the foregoing reasons, Roche respectfully requests that the Court deny Amgen's Motion *in Limine* No. 18.

Dated: September 3, 2007
Boston, Massachusetts

Respectfully submitted,

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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 (NEF) and will be delivered to Amgen's trial counsel by electronic mail in the manner requested in the August 29, 2007, letter of Renee DuBord Brown to Thomas F. Fleming. Paper copies will be sent to those indicated as non registered participants on September 4, 2007.

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