

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMGEN, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 05 CV 12237 WGY
)	
F. HOFFMANN-LAROCHE LTD.,)	
a Swiss Company, ROCHE DIAGNOSTICS)	
GMBH, a German Company, and)	
HOFFMANN LAROCHE INC., a New)	
Jersey Corporation,)	
)	
Defendants.)	

**BRIEF IN SUPPORT OF 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**

I. INTRODUCTION

Dr. Goldwasser devoted most of his career to researching erythropoietin (EPO). Among his many achievements, Dr. Goldwasser developed several assays to detect EPO, proved that human EPO was produced by the kidney, and developed methods to purify human EPO from the urine of patients suffering from aplastic anemia. Dr. Goldwasser published most if not all of his successful research results, and provided the urinary EPO that he purified to the scientific community.

Nevertheless, Roche has insinuated that by serving as a consultant to Amgen, and providing urinary EPO to Amgen, Dr. Goldwasser violated some unspecified duty as a recipient of public funding from the U.S. government, specifically the National Institutes of Health (NIH). Amgen anticipates that Roche will make this unsupported allegation part of its obviousness defense, which assumes that Dr. Lin succeeded in cloning the DNA encoding human EPO only because he had access to Dr. Goldwasser's urinary EPO.

Roche's accusations against Dr. Goldwasser are baseless and irrelevant and are likely to mislead and distract the jury by converting the obviousness issue into a sideshow regarding the relationship of public research funding to the ownership of materials produced during that scientific research. Pursuant to FRE 402 and 403, Roche should be precluded from arguing that Dr. Goldwasser's relationship with Amgen was inappropriate or violated some duty to the U.S. government.

Consequently, Amgen requests that Roche be precluded from presenting testimony that: (1) Dr. Goldwasser's work purifying urinary EPO was taxpayer supported through NIH funding; (2) that such public funding created a duty or otherwise prohibited Dr. Goldwasser from providing urinary EPO to Amgen; and (3) that he violated such a duty.

II. FACTUAL BACKGROUND

Roche's patent defense of invalidity, especially its obviousness defense, encompasses Roche's claim that Dr. Lin's successful cloning of the DNA that encodes human EPO was merely the result of his access to the fruits of Dr. Goldwasser's research, including Dr. Goldwasser's supply of urinary EPO. Roche contends that Dr. Lin's inventions were within the routine capabilities of one of ordinary skill in the art in 1983-1984 provided one had access to Dr. Goldwasser's supply of urinary EPO. Roche's experts opine that if anyone of ordinary skill had access to Dr. Goldwasser's supply of urinary EPO in 1983, they too would have cloned the DNA encoding human EPO.

Amgen believes that at trial, Roche may attempt to improperly support its obviousness theory by insinuating that Dr. Goldwasser misused taxpayer money (NIH funding) by providing urinary EPO purified in his lab to Dr. Lin at Amgen. For example, in two expert reports submitted by Dr. Lowe, who Roche has identified as a trial witness, he suggested, without any support in the law or in the rules governing funding of scientific research by the U.S. government, that Dr. Goldwasser had an obligation to share his urinary EPO with everyone who requested it:

Dr. Goldwasser used National Institutes of Health (NIH), i.e., US government, funds to obtain and purify the EPO he sent Amgen. (See Goldwasser Depo. Tr. (2/14/07) at 60, 62, 68, 139-40, 163-64). Despite this fact, Dr. Goldwasser provided pure EPO in amounts sufficient to use for sequencing and therefore cloning to Amgen alone.¹

Despite the fact that Dr. Goldwasser had used NIH grant funds to obtain and purify the EPO he sent to Amgen, he refused to provide any samples of EPO for purposes of cloning to any other company such as Biogen or Schering, which as Dr. Goldwasser admitted, with such material could have cloned the EPO gene or an EPO cDNA.²

¹ Lowe April 6, 2007 Expert Report ¶ 52.

² Lowe May 8, 2007 Second Supplemental Expert Report ¶ 9.

III. ARGUMENT

There is no basis in fact or law to support Roche's argument that the government funding of Dr. Goldwasser's scientific research prohibited him from sharing his supply of urinary EPO with Amgen or required him to distribute his urinary EPO to any and all who asked for it. Allowing Roche to make such arguments to the jury may mislead the jury into believing that Dr. Lin's patents were somehow unfairly granted, leading the jury to an erroneous conclusion of invalidity based upon emotion rather than the law.

There is no evidence that Dr. Goldwasser was obligated to do anything other than conducting the experiments described in his applications for NIH funding of his research. There is no evidence that the NIH placed restrictions on Dr. Goldwasser with regard to how he distributed (or even whether he had to distribute) his purified urinary EPO preparation. And there is no evidence that Dr. Goldwasser was under any duty to provide his urinary EPO freely to the public. Indeed, Dr. Goldwasser testified in his deposition in this case (as he has in previous proceedings) that before he entered into a consulting relationship with Amgen, he sought and received clearance to do so both from the National Institutes of Health and the University of Chicago:

Q. Right. And by virtue of your giving them that government-paid-for protein, that information became secret?

MR. FLOWERS: Objection, argumentative, lacks foundation.

THE WITNESS: As indicated in one of these documents, before I entered into any arrangement with Amgen, I had called someone at NIH to make sure it was all right with them, and I checked with the University authorities to make sure it was all right with them.³

Consequently, any suggestion by Roche that Dr. Goldwasser's relationship with Amgen was somehow improper would be unfounded and irrelevant, and should be excluded under FRE

³ Transcript of February 14, 2007 Deposition of Eugene Goldwasser, Ph.D. at 138:22-139:7.

402.

FRE 403 states that “[e]vidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.”⁴ Roche’s attempt to tarnish Dr. Goldwasser and his relationship with Amgen has no probative value, will unfairly prejudice Amgen, and will likely confuse and mislead the jury regarding the real issue in this case — whether Roche can prove that Dr. Lin’s asserted claims were anticipated or obvious in view of the prior art. To avoid misleading the jury and unfair prejudice to Amgen, Roche should be precluded from arguing in support of its invalidity defense that Dr. Goldwasser’s relationship with Amgen was in any way inappropriate or violated some unidentified duty resulting from the government funding of his research.

IV. CONCLUSION

For the foregoing reasons, Amgen requests that this Court preclude Roche from presenting testimony or arguing that: (1) Dr. Goldwasser’s work purifying urinary EPO was taxpayer supported through NIH funding; (2) that such public funding created a duty or otherwise obliged Dr. Goldwasser to share his supply of urinary EPO with anyone who requested it; and (3) that he violated such a duty.

⁴ FRE 403.

Respectfully Submitted,

Date: August 28, 2007

AMGEN INC.,
By its attorneys,

Of Counsel:

STUART L. WATT
WENDY A. WHITEFORD
MONIQUE L. CORDRAY
DARRELL G. DOTSON
KIMBERLIN L. MORLEY
ERICA S. OLSON
AMGEN INC.
One Amgen Center Drive
Thousand Oaks, CA 91320-1789
(805) 447-5000

/s/ Michael R. Gottfried
D. DENNIS ALLEGRETTI (BBO#545511)
MICHAEL R. GOTTFRIED (BBO#542156)
PATRICIA R. RICH (BBO#640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (857) 488-4200
Facsimile: (857) 488-4201

LLOYD R. DAY, JR. (*pro hac vice*)
DAY CASEBEER
MADRID & BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

WILLIAM GAEDE III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

KEVIN M. FLOWERS (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

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 August 28, 2007.

/s/ Michael R. Gottfried
Michael R. Gottfried