

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN’S OPPOSITION TO ROCHE’S BENCH MEMORANDUM REQUESTING A
JURY INSTRUCTION THAT STATEMENTS IN THE SPECIFICATION ARE
BINDING ADMISSIONS ON AMGEN

Amgen Inc. respectfully requests that the Court reject Roche’s proposed jury instruction that certain statements in Amgen’s patent specification constitute binding admissions. Roche’s “jury instruction” is simply a poorly-disguised request to have certain portions of the specification read in as admissions. However, these statements in the specification do not constitute “admissions” for two key reasons:

- (1) Relevance: many of these statements relate to information about methods and tools for isolating DNA. But under In re Deuel, 51 F.3d 1552 (Fed. Cir. 1995) and related cases, proof of prior art methods of cloning are insufficient as a matter of law to establish obviousness of an isolated DNA. A DNA molecule cannot be obvious if there is no DNA sequence information available, regardless of what “tools” may have existed, and thus these statements are irrelevant to an

obviousness inquiry.

(2) No Admission of Amgen: recitations in the specification recounting statements made in other prior art references do not constitute any endorsement by Amgen of the accuracy of those references.

ARGUMENT

Roche's request to list as "admissions" multiple sections of the patent specification that discuss tools and methods available in the art to isolate DNA should be rejected because these sections are irrelevant to the obviousness inquiry. A *prima facie* showing of obviousness of a claim reciting a DNA sequence requires a prior art compound structurally similar to the recited DNA, and some suggestion, motivation or reason to modify the structurally similar prior art compound to make the recited DNA. The foregoing principle was established in *In re Dillon*, 919 F.2d 688 (Fed Cir. 1990) and *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000). The *Dillon* standard was reaffirmed by the Federal Circuit even after the Supreme Court's decision in *KSR in Takeda Chem. Ind. Ltd v. Alphapharm Pty, Ltd*, 492 F.3d 1350 (Fed. Cir. 2007).

Roche has presented no evidence of a prior art compound that was structurally similar to the EPO DNA. Nor has Roche presented any evidence of any suggestion or motivation to alter any such similar compound to make the claimed EPO DNA sequence. A DNA molecule cannot be obvious if there is no DNA sequence information available in the prior art. Roche's selections from the specification indicating that there was some minimal information available as to the amino acid sequence of the EPO protein are irrelevant. A partial amino acid sequence of the protein does not render obvious the nucleotide sequence of the DNA encoding the protein. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991); *Takeda Chem. Ind., Ltd. v. Alphapharma Pty., Ltd.*, 492

F.3d 1350 (Fed. Cir. 2007) *Regents of the Univ. of Cal. v. Monsanto*, 2005 U.S. Dist. LEXIS 40379, *35 (N.D. Cal. Dec. 16, 2005).

Similarly, Roche's selections from the specification regarding methods and tools that were available in 1983-84 for seeking to isolate DNA are also irrelevant to an obviousness determination. The asserted claims require possession of the DNA sequence itself—they are not claims to a method for obtaining the gene sequence. As a result, cloning methods in the prior art cannot, as a matter of law, render a claim to a DNA sequence obvious. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991).

As the Federal Circuit held in *Amgen v. Chugai*, a research plan for isolating the EPO DNA sequence is insufficient to establish conception of the EPO DNA sequence. In *Amgen* the court held that conception of the EPO DNA sequence could not have occurred until the gene itself was successfully isolated, and for that reason rejected GI's contention that a planned method to clone the gene was sufficient to prove conception.

“What cannot be contemplated or conceived cannot be obvious.”¹ And that is why proof of known methods for cloning genes cannot, as a matter of law, establish a *prima facie* case of obviousness of the DNA sequence. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *Mendenhall v. Cedarapids*, 5 F.3d 1557, 1570-71 (Fed. Cir. 1993); *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993); *Amgen v. Chugai*, 927 F.2d 1200 (Fed. Cir. 1991); *Amgen, Inc. v. F. Hoffman-La Roche Ltd.*, 494 F.Supp.2d 54, 60 (D. Mass. 2007).

In addition, statements in the specification noting what had previously been stated in various prior art references such as Farber, et al. are not “admissions” of Amgen. These are merely recitations of what others had said – not adoption of those positions by Amgen. Such

¹ *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

hearsay is not admissible for the truth of the matter asserted. Indeed, the Court previously allowed testimony contradicting this reference over Roche's objections that the patent specification constituted a binding admission and thus such testimony should not be allowed.² Roche's veiled request for reconsideration of this prior ruling should be denied.

Lastly, Amgen notes that Roche has inexplicably requested that certain statements describing the invention itself be treated as "admissions" relating to obviousness. Any statements in the patent specification after '933 Patent, Col. 10, line 5 are describing Dr. Lin's inventions, not the prior art, and therefore have no place in an obviousness inquiry.

CONCLUSION

For the foregoing reasons, Amgen respectfully requests that Roche's proposed "jury instruction" requesting that statements from the specification be treated as admissions be denied.

Dated: October 10, 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

/s/ Patricia R. Rich
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

² 9/26/07 Trial Tr. at 1558:20-1562:5.

(805) 447-5000

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 on-registered participants.

/s/ Patricia R. Rich
Patricia R. Rich