

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 BENCH MEMORANDUM REGARDING ADMISSIBILITY OF
POST-FILING EVIDENCE OF FUNCTIONAL AND STRUCTURAL DIFFERENCES
TO REBUT ROCHE'S INVALIDITY ALLEGATIONS

A central issue concerning Roche's invalidity proof is whether recombinant EPO purified
from mammalian cells grown in culture is identical to Goldwasser's urinary EPO.1 Amgen
respectfully submits that Dr. Strickland's proffered laboratory notebooks, as well as Catlin's
experiments and other scientific literature, although dated after the patent application filing date,
are nonetheless relevant and should be admitted into evidence because:

- They show that Goldwasser's urinary EPO is not identical to the characteristics
of the claimed inventions.2
• The legal principle which Roche invoked to secure the admission of post filing
evidence should be equally available to Amgen to allow of the admission of its
post-filing rebuttal evidence.

1 9/12/07 Trial Tr. 870:18-871:25 ("the factual dispute here is whether it's a new product . . .
The jury is going to have to resolve whether the prior art, which I have let in, all right, the so-
called prior art, is in fact the same product. If it is, the source limitation won't save them. If it's
not, the source limitation is part of the limitation.").

2 See Amgen's Motion to Streamline and Expedite the Testimony of Dr. Thomas Strickland,
(Docket No. 1219).

The relevance of such post-filing evidence of structural differences is particularly important in the context of the claims at issue here, which included source and process limitations in part because the precise structural attributes that distinguish the product from those in the prior art were not susceptible to more particular definition at the time of the invention.<sup>3</sup> Given the unavailability of pre-filing date evidence of structural differences between the claimed invention and the prior art, it follows that evidence of structural differences between the prior art and embodiments of the claimed invention that post-dates the filing date of the application must be relevant.

Because the molecular structures of Goldwasser's urinary EPO and EPO produced from mammalian cells grown in culture are "universal" scientific facts that do not change over time, evidence as to the structure and function of a particular molecule is relevant regardless of whether that evidence arose before or after the date of the patent application.<sup>4</sup> In weighing evidence as to anticipation and obviousness, it is permissible to consider "later knowledge about

---

<sup>3</sup> *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) ("The purpose of product-by-process claims is to allow inventors to claim 'an otherwise patentable product that resists definition by other than the process by which it is made.' Thus, an inventor will not be foreclosed from the benefits of the patent system simply because a product is difficult to describe in words, or its structure is insufficiently understood.") (internal citations omitted); see also *In re Luck*, 476 F.2d 650, 653 (C.C.P.A. 1973); *In re Moeller*, 117 F.2d 565, 568 (C.C.P.A. 1941) ("[T]he rule is well established that where one has produced an article in which invention rests over prior art articles, and where it is not possible to define the characteristics which make it inventive except by referring to the process by which the article is made, he is permitted to so claim his article . . .").

<sup>4</sup> *In re Wilson*, 311 F.2d 266, 268-269 (C.C.P.A. 1962) ("The board considered that the publication was properly cited to show a state of fact. After reading the entire publication, so do we. It clearly is a discussion of the properties of polyurethane foam products generally, products made by the processes of the prior art of record in this case . . . . As evidence of the characteristics of prior art foam products, however, we know of no reason in law why it is not acceptable."); *In re Langer*, 503 F.2d 1380, 1391 (C.C.P.A. 1974) ("the references relied on by the examiner and the board are not cited as 'prior art' references. Indeed, the effective date, for prior art purposes, of many of these references is subsequent to appellant's earliest filing date. Rather, these references are properly cited for the purpose of showing a fact under the principle of *In re Wilson* . . ."); *Ex Parte Raychem Corp.* 1992 WL 409256, \*10 (B.P.A.I. 1992) ("While Gale is not prior art to the claims on appeal, it is proper to consider this reference in determining the patentability of the claims on appeal under 35 USC § 103. Gale is relevant evidence as to (1) characteristics of prior art products . . . and (2) the knowledge possessed by and the level of skill

art-related *facts existing on the filing date.*”<sup>5</sup>

An experiment to detect particular structural and functional characteristics is relevant regardless of whether that experiment occurred before or after the filing date of the patent application. In *National Semiconductor Corp. v. Ramtron Intern. Corp.*<sup>6</sup> National Semiconductor sought to prevent discovery into tests that occurred after the filing date of the patent at issue. The court held that that because the tests would have produced the same results regardless of whether they were performed before or after the filing date, such tests were relevant to the issue of enablement and discoverable even if performed after the date of filing.<sup>7</sup>

Roche invoked this very same principle in securing the admission of evidence arising after the date of the patent application. In its bench memorandum seeking to present the testimony of Dr. Bertozzi concerning statements made by Amgen scientists in documents dated years after the date of the patent application, Roche argued that such statements are admissible under *In re Wilson* and later decisions citing to *In re Wilson*:

Post-filing admissions that the structure of recombinant erythropoietin (“EPO”) is identical to the [sic] that of prior art urinary EPO are admissible evidence to be considered by the fact-finder. The case law is well-established that “later-issued patents and publications may be used to show the state of the art existing on the date of the application in question.” *In re Koller*, 613 F.2d 819, 824 (C.C.P.A. 1980). As the Federal Circuit’s predecessor court acknowledged, there is “no reason in law why it is not acceptable” to consider post-filing publications to demonstrate the characteristics of known prior art products. *In re Wilson*, 311 F.2d 266, 269 (C.C.P.A. 1962). The Manual of Patent Examining Procedure likewise states that “references cited to show a universal fact need not be available as prior art before applicant’s filing date.” (MPEP §2124 (8<sup>th</sup> ed. Rev. 5, Aug. 2006). Evidence of the identity of the structures of prior art urinary EPO and recombinant EPO is therefore relevant and admissible for Roche’s invalidity case.<sup>8</sup>

---

of the ordinary person in this art), citing *In re Wilson* (other citations omitted).

<sup>5</sup> *In re Hogan*, 559 F.2d 595, 605 (CCPA 1977) (emphasis added), citing *In re Wilson*, 311 F.2d 266, 135 (1962). By contrast, it is not permissible to consider “later knowledge about *later* art-related *facts* . . . which *did not exist on the filing date.*” *In re Hogan*, 559 F.2d at 605.

<sup>6</sup> 265 F. Supp. 2d 71, 75 (D. D.C. 2003).

<sup>7</sup> *Id.*.

<sup>8</sup> Roche’s Bench Memorandum that Later Admissions that the Structure of Recombinant EPO is

The Court permitted Roche to offer the testimony of Dr. Bertozzi, even though she was not one of ordinary skill in the art at the time of the date of the invention.<sup>9</sup> The Court further permitted Dr. Bertozzi to offer invalidity opinions that relied on the publications and statements by Amgen scientists in the documents dated years after the date of the invention and the date of the patent application, and the Court admitted those documents into evidence.<sup>10</sup>

It would be fundamentally unfair to allow Roche to present and rely upon post-filing evidence in support of its invalidity arguments, while denying Amgen the opportunity to rebut Roche's proof with post-filing evidence. Consistent with the case law and admission of Roche's post-filing evidence, the Court should admit into the evidence the laboratory notebooks of Dr. Strickland, as well as Catlin's experiments and other scientific literature as part of Amgen's rebuttal evidence that prior art urinary EPO compounds are not identical to Lin's claimed inventions.

---

Identical to Prior Art Urinary EPO are Relevant and Admissible (Docket No. 1059) at 1-2.

<sup>9</sup> Bertozzi Trial Tr. 1064:12-1065:17.

<sup>10</sup> Bertozzi Trial Tr. 1029:2-5, 1031:16-1034:17, 1036:20-1037:5, 1037:20-1039:9, 1040:8-1042:18, 1044:24-1050:3.

Dated: October 2, 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/ 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  
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