

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**AMGEN’S OPPOSITION TO ROCHE’S MOTION FOR RECONSIDERATION OF THE
COURT’S OCTOBER 4, 2007 ORDER REGARDING THE ‘868 FILE HISTORY**

On October 4, 2007 the Court granted Amgen's motion to correct the file history of the '868 patent by adding a document that Amgen submitted to the PTO during prosecution but was missing from the version of the file history admitted into evidence.¹ Now, Roche asks the Court to reconsider its ruling because Roche contends that admission of this document (a prior art search report) will "confuse the jury and prejudice Roche's case,"² an assertion belied by the fact that the validity phase of the case is closed. Roche's claim that this document was never submitted to the PTO is also meritless. Indeed, Roche's motion for reconsideration fails to provide a shred of evidence to rebut the sworn statement from Amgen's prosecuting attorney that he submitted this document to the PTO — a statement that is corroborated in multiple places throughout the '868 file history and on the face of the '868 patent itself. Thus, the Court should deny Roche's motion for reconsideration (Docket Item ("D.I.") 1354).

Roche makes four arguments in support of its claim that this prior art search report (admitted as Trial Exhibit ("TX") 2012A) was never submitted to the PTO. None of these arguments supports Roche's baseless claim. First, Roche asserts that certain references marked with an "x" on TX 2012A were not listed on the face of the '868 patent and therefore TX 2012A must not have been submitted to the PTO. This is demonstrably false. Without exception, every single one of the references that Amgen's counsel marked with an "x" on TX 2012A is listed on the face of the '868 patent³ — including the four references that Roche represented were not listed on the '868 patent.⁴ This is not at all surprising because the file history in evidence shows that Amgen disclosed each of these marked references to the Examiner in an Information

¹ See 10/4/07 ODP Hearing Tr. 153:15-17.

² Roche's Opposition to Amgen's Motion to Correct the File History of the '868 Patent by Adding a Document That Was Missing (D.I. 1354), at 1. (Although Roche styled its filing as an "opposition," Roche concedes that it is really a motion for reconsideration. See *id.* at 1 n.1, 5.)

³ See TX 2, at 3 (AM-ITC 00029670) and 14 (AM-ITC 00029681).

Disclosure Statement that was devoted exclusively to these particular search results and filed in conjunction with Amgen's September 1988 submission of TX 2012A to the Examiner.⁵ The file history in evidence also shows that the Examiner expressly considered each of these references.⁶

Second, Roche contends that TX 2012A is not included in the copy of the '868 file history currently maintained at the PTO and therefore must never have been received by the PTO. Not only does this argument ignore the file history evidence showing that TX 2012A was received by the PTO, but it is illogical. Patent file histories are public records that are frequently checked out for inspection and copying by interested parties,⁷ and it is not uncommon for documents to become misfiled or lost during this process. Indeed, the PTO's copy of the '868 file history expressly notes that papers are missing.⁸ Thus, Roche's assumption that the PTO's current version of the file history is a complete record of every document submitted during prosecution is unwarranted. Roche's argument is particularly disingenuous given that the version of the '868 file history that Roche entered into evidence in this case (TX 2012) contains over 600 pages of documents from the files of Amgen's prosecution counsel that were added by agreement of the parties because they were missing from the PTO's version of the file history.⁹

Third, Roche suggests that by not seeking to add TX 2012A to the version of the '868 file history used in *Amgen v. TKT*, Amgen somehow conceded that TX 2012A was never submitted

⁴ See Roche's Opp. (D.I. 1354), at 4 n.6.

⁵ See TX 2012.500-01.

⁶ See TX 2012.1233-35 (examiner-initialed copy of Information Disclosure Statement).

⁷ This is especially true for the file histories of Dr. Lin's patents-in-suit, which have been the subject of numerous legal proceedings.

⁸ See, e.g., TX 2012.182 (noting that Paper 6 missing from PTO's copy of '868 file history); TX 2012.794 (noting that Papers 25 and 26 missing from PTO's copy of '868 file history). There have even been instances where the PTO was unable to locate entire file histories. See, e.g., *Racine Federated, Inc. v. Lake Monitors, Inc.*, 758 F. Supp. 482 (E.D. Wis. 1991) (PTO could not locate file history of patent-in-suit).

⁹ See, e.g., TX-2012.190-212; TX 2012.235-443; TX 2012.530-741; TX 2012.749-793; TX

to the PTO. But the '868 file history used in Amgen/TKT was never proffered as a complete record of all documents submitted to the PTO during prosecution of the '868 patent. Rather, as in this case, the '868 file history used in Amgen/TKT was a compilation of the PTO's incomplete file history plus specific documents from Amgen's prosecution counsel's files that were relevant to the disputed issues. Unlike in this case, however, in Amgen/TKT there was no need to add TX 2012A to the '868 file history because there were no obviousness-type double patenting or other defenses to which TX 2012A was necessarily pertinent.

Fourth, Roche contends that under MPEP § 503 the absence of a stamped return postcard confirming receipt of TX 2012A is evidence that the document was never submitted to the PTO. There is no legal (or logical) basis for the negative inference that Roche seeks to draw. What Roche fails to inform the Court is that MPEP § 503 concerns an entirely *optional* procedure. While applicants *may* submit a self-addressed postcard that will serve as *prima facie* evidence of receipt by the PTO, they are *not required* to do so.¹⁰ Thus, the absence of a postcard is not evidence of anything, especially in this instance, where Amgen's prosecuting attorney submitted a sworn declaration confirming that he filed TX 2012A with the PTO.

Finally, and most importantly, Roche's motion for reconsideration fails to account for the substantial evidence establishing that TX 2012A was submitted to the PTO: (1) the sworn declaration from the prosecuting attorney, Mr. Odre, confirming that he submitted TX 2012A to the PTO;¹¹ (2) the Examiner-initialed Information Disclosure Statement devoted exclusively to

2012.802-906; TX 2012.1034-1080; TX 2012.1430-1447.

¹⁰ See MPEP § 503 (8th ed. Rev. 5, Aug. 2006) ("If a receipt for any item (e.g., paper of fee) filed in the USPTO is desired, it may be obtained by enclosing with the paper a self-addressed postcard specifically identifying the item.").

¹¹ Declaration of Steven M. Odre In Support of Amgen Inc.'s Motion To Correct the File History of the '868 Patent by Adding a Document That Was Missing (D.I. 1312).

the references marked with an “x” in TX 2012A;¹² (3) the ‘868 patent itself, which lists on its face every one of the references marked in TX 2012A;¹³ and (4) the absence of any subsequent communication from the Examiner indicating that TX 2012A had not been received, which is notable because TX 2012A was referenced in Amgen’s September 27, 1988 and October 7, 1994 submissions to the PTO,¹⁴ and because it was clearly the Examiner’s practice to state when documents could not be found.¹⁵

For the foregoing reasons, the Court was correct to grant Amgen’s motion to admit TX 2012A, and Roche’s motion for reconsideration (D.I. 1354) should be denied.

¹² TX 2012.1233-35; TX 2012.500-01.

¹³ TX 2, at 3 (AM-ITC 00029670) and 14 (AM-ITC 00029681).

¹⁴ *See* TX 2012.496; TX 2012.1030-31; TX 2012.1055-56.

¹⁵ *See* TX 2012.446.

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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 and paper copies will be sent to those indicated as non-registered participants on October 15, 2007.

/s/ Patricia R. Rich
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