

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

**ROCHE’S OPPOSITION TO AMGEN’S MOTION TO CORRECT THE FILE
HISTORY OF THE ‘868 PATENT BY ADDING A DOCUMENT THAT WAS MISSING
(D.N. 1311)**

Amgen offered absolutely no proof that the document admitted as TRX 2012A was ever received by the Patent Office and, therefore, it is not part of the file history of the ‘868 patent.¹ Instead, admission of this irrelevant paper serves only to confuse the jury and prejudice Roche’s case (Fed. R. Evid. 402, 403) because the facts demonstrate that the document was not received or considered by the Patent Office:

- TRX 2012A is from Amgen’s internal files, not the PTO’s files
- Mr. Odre’s declaration (D.N. 1312) expressly admits that the PTO did not receive the document when purportedly submitted by Amgen as Exhibit E to a Second Preliminary Amendment (D.N. 1312, ¶¶4-6)

¹ The Court admitted exhibit 2012A into evidence on October 4, 2007 without limitation and before Roche had received and responded to Amgen’s motion. (Daily Transcript of hearing In Re Obviousness-Type Double Patenting, Vol. 2, Tr. 153:9-17). The Court expressly stated that Roche could respond to the motion and that the Court was willing to revisit its ruling. (*Id.* at 153:21-154:6). In addition, Amgen is aware that Roche reserved its right to object to any additional prosecution-related documents that Amgen may try to introduce separate from the file histories agreed-to by the parties and put on the numbered exhibit list. Roche, therefore, submits this opposition as a motion for reconsideration.

- There is no return postcard pursuant to MPEP §503 demonstrating that the PTO subsequently received a copy of the document as Amgen now contends
- To Roche's knowledge none of the PTO certified file histories produced by Amgen in this litigation includes the "missing" document
- To Roche's knowledge no version of the file history of the '868 patent previously admitted as an exhibit in the *Amgen v. TKT* litigation includes the "missing" document
- The face of the '868 patent does not list the relevant documents as "References Cited"

The "missing" document that Amgen contends is part of the file history of the '868 patent, TRX 2012A, was found in a file maintained by Amgen's counsel, not the files maintained by the PTO. (D.N. 1312, ¶7). However, it is the file history as it exists in the PTO -- not the applicant's internal files -- that constitutes the official file history and reflects the information before the PTO during prosecution. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2006) (the prosecution history is the complete record of the proceedings before the PTO); *Vitronics Corp. v. Conception, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (same). Thus, any document found in Amgen's internal files but not shared with the PTO does not constitute part of the file history of the '868 patent and is irrelevant.

As Amgen readily admits, after it first purported to submit the prior art search designated as TRX 2012A, the Patent Examiner expressly stated that the document then cited as Exhibit E to a Second Preliminary Amendment was not received. (D.N. 1312, ¶¶4-6, *see also* TRX 2012 at 2012.446). The affidavit submitted by Mr. Odre here merely states that -- 19 years after the fact -- he now recalls resubmitting the document to the Patent Office with a subsequent paper. (D.N. 1313, ¶¶8-9). However, there is no documentary proof to corroborate his current memory or to prove that the PTO in fact received the document which was found in Amgen's counsel's files.

The Patent Office recognizes that a disagreement may arise regarding whether an applicant has actually submitted a paper to the examiner and, therefore, has specific safeguards in place to combat revisionist history. M.P.E.P. §503 sets forth the long-standing practice by which an applicant obtains a stamped return postcard from the PTO as documentary evidence that specific papers were submitted to and received by the Patent Office. M.P.E.P. §503, 500-4 (5th ed., Aug. 1983) and 500-23 (8th ed. Rev. 6, Aug. 2006) (“A postcard receipt which itemizes and properly identifies the items which are being filed serves as *prima facie* evidence of receipt in the USPTO of all the items listed thereon on the date stamped thereon by the USPTO.”)² A quick review of the admitted file history of the ‘868 patent (TRX 2012) shows that Amgen availed itself of this provision and used return postcards as evidence of filings (*see* TRX 2012 at 21012.1166, 2012. 1438-1439); however, Amgen has proffered no stamped postcard showing that the “missing” document was ever received by the PTO.³ Here, the last word from the Patent Office is that the paper was never received.

Amgen misleads the Court by stating that the document was resubmitted with a subsequent Reply which “was stamped received by the Patent Office on September 27, 1988, indicating that it received the Reply with Exhibit E.” (D.N. 1311 at 2; emphasis added). The stamp to which Amgen refers is not proof that the PTO received TRX 2012A with the Reply -- the stamp only shows that the Reply (that is part of the official PTO file history) was received. There is no similar stamp on the front page of TRX 2012A. The facts set forth in Amgen’s motion belie its argument that the stamp on the Reply serves as proof regarding TRX 2012A:

² Rycroft Declaration, Exs. 1 and 2.

³ Normally a copy of the return postcard does not become part of the PTO file history. However, in this case, Amgen requested that some of the return postcards be included in the agreed-to file histories of the patents-in-suit.

Amgen admits that (1) the Second Preliminary Amendment which purportedly first included the document was also “stamped received by the Patent Office” (D.N. 1311 at 2; D.N. 1312, ¶4) yet (2) also admits that the Patent Office stated it never received Exhibit E with that earlier filing. (D.N. 1312, ¶6). Furthermore, as stated above, to prove particular papers missing from a PTO file history were in fact submitted to and received by the PTO a return postcard must clearly and specifically identify the item filed and the number of pages submitted. M.P.E.P. §503. Thus, the stamp on the Reply is proof of nothing other than that the Reply was received.

That the PTO never received TRX 2012A is further demonstrated by the fact that none of the certified PTO file histories produced by Amgen during discovery includes this document as part of the file.⁴ Likewise, the file history of the ‘868 patent admitted into evidence in *Amgen v. TKT* does not contain this document.⁵ Yet, to Roche’s knowledge, Amgen never complained or “corrected” the file history in that litigation to include document TRX 2012A. Indeed, the ‘868 patent itself demonstrates that the document was not received by the PTO. As Mr. Odre explained in his affidavit, relevant references listed in TRX 2012A are marked with an “x” (D.N. 1312, ¶5), yet the “Reference Cited” section on the face of the ‘868 patent does not list all of the “x” references. (TRX 0002 AM-ITC 00029668-82).⁶

⁴ Amgen produced multiple versions of the PTO certified file history for the ‘868 patent. Rycroft Declaration, ¶5. Roche has been unable to locate any version that contains this “missing” document.

⁵ An uncertified version of the PTO file history of the ‘868 patent was admitted into evidence during *Amgen v. TKT* as exhibit 2002, and also submitted in the Appendix to the Federal Circuit on appeal. Rycroft Declaration, ¶5.

⁶ For example, the ‘868 patent does not list Pennica *et al.*, “Human tumour necrosis factor: precursor structure, expression and homology to lymphotoxin”, *Nature*, 312, 724-729 (D.N. 1312-4, TRX 2012A at AM-ITC 00454632); Wicktor *et al.*, “Protection from rabies by a vaccine virus recombinant containing the rabies virus glycoprotein gene”, *PNAS*, 81(22), 7194-98 (D.N. 1312-4, TRX 2012A at AM-ITC 00454633); Kieny *et al.*, “Expression of rabies virus (continued...) ”

For these reasons, Roche opposes the admission of TRX 2012A into evidence and requests that the Court reconsider its initial ruling that the document be admitted into evidence to “correct” the file history of the ‘868 patent. This document is not part of the PTO file history, is irrelevant, prejudicial, and will confuse the issues.

Dated: October 11, 2007
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glycoprotein from a recombinant vaccinia virus”, *Nature*, 312, 163-166 (*Id.*); Devos *et al.*, “Purification of recombinant glycosylated human gamma interferon expressed in transformed Chinese hamster ovary cells”, *J. Interferon Res.*, 4(4), 461-468 (*Id.*); etc.

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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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