

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

|                              |   |                                  |
|------------------------------|---|----------------------------------|
| _____                        | ) |                                  |
| ARIAD PHARMACEUTICALS, INC., | ) |                                  |
| MASSACHUSETTS INSTITUTE OF   | ) |                                  |
| TECHNOLOGY, THE WHITEHEAD    | ) |                                  |
| INSTITUTE FOR BIOMEDICAL     | ) | Civil Action No. 02 CV 11280 RWZ |
| RESEARCH, and THE PRESIDENT  | ) |                                  |
| AND FELLOWS OF HARVARD       | ) |                                  |
| COLLEGE,                     | ) | U.S. District Judge              |
|                              | ) | Rya W. Zobel                     |
| Plaintiffs,                  | ) |                                  |
| v.                           | ) |                                  |
|                              | ) |                                  |
| ELI LILLY AND COMPANY,       | ) |                                  |
|                              | ) |                                  |
| Defendant.                   | ) |                                  |
| _____                        | ) |                                  |

**LILLY’S MOTION TO SUPPLEMENT PTX 2 IN ORDER TO COMPLETE THE PTO PROSECUTION FILE OF U.S. PATENT NO. 6,410,516**

Lilly submits this motion to supplement PTX 2 so that the complete the PTO prosecution history file of U.S. Application No. 08/464,364, which issued as the '516 patent, will be in evidence. Ariad produced an incomplete and inaccurate copy of the patent prosecution file (PTX 2). As it now stands, PTX 2 is missing over 200 pages consisting of, for example, pages from PTO Office Actions, references cited by Ariad during prosecution, and other official PTO documents.<sup>1</sup> Without the complete '516 patent prosecution file, the Court’s decisions on the issues presented in the upcoming bench trial will be based on a deficient evidentiary record. And moreover, the Federal Circuit will have an incomplete record on appeal.

The prosecution history of a patent “consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent.” *Phillips v.*

<sup>1</sup> For the Court’s convenience, Lilly has attached Table 1 (Exh. A) identifying the documents missing from PTX 2.

*AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). It is “created by the patentee in attempting to explain and obtain the patent,” and “provides evidence of how the PTO and the inventor understood the patent.” *Id.* Here, Ariad is attempting to exclude essential portions of the very record it created—many critical to evidentiary, factual, and legal issues this Court must decide. Indeed, the Federal Circuit has observed:

Under normal circumstances, we would expect the prosecution history to play a critical role in proving that a patentee defrauded the PTO. The prosecution history is, after all, the record of all correspondence between the patentee and the PTO, and therefore provides the best *direct* evidence of every representation that the patentee made.

*Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1359 n. 6 (Fed. Cir. 2004) (emphasis in original), *rev'd on grounds unrelated to the prosecution history*, 126 S. Ct. 980 (2006). Given the Federal Circuit's emphasis on the prosecution history as the best direct evidence of the patentee's representations, Ariad cannot possibly argue that the Court should render its decisions on an incomplete and inaccurate copy of the '516 patent prosecution file.

In particular, during the April 7, 2006 pre-trial conference, the Court specifically stated that an issue requiring decision is “whether these reexamination documents are properly part of the prosecution file . . . .” (Exh. 4 to D.I. 357.) Ariad recently filed a motion to exclude the reexamination files from evidence in an attempt to prevent this Court from considering this highly relevant evidence bearing on the issue of inequitable conduct and materiality. (D.I. 357.) A page missing from the complete copy of PTX 2 (but present in DTX 2) answers the Court's question, Paper No. 46, which states “[t]his Notice incorporates by reference into the patent file, all papers entered into the reexamination file.” (Exh. B, Paper 46 (underline in original, emphasis added).) Without a complete and accurate copy of the '516 patent prosecution file, the Court would search in vain for this answer.

Another issue this Court must decide is whether Ariad committed inequitable conduct by failing to notify the PTO of the errors associated with Fig. 43 in the '516 patent. The '516 patent states that "Fig. 43 *is* the nucleotide sequence and the amino acid sequence of *IκB-α*." ('516 Patent, col. 10, lines 16-17.) In contrast, the patent mentions MAD-3 and pp40 and states that they are "IκB-like" proteins. (*Id.* at col. 32, lines 34-38.) Consistent with the specification of the '516 patent, Ariad discussed two references in an Information Disclosure Statement (IDS) filed on May 5, 1992, but missing from PTX 2. (Exh. C.) In its IDS, Ariad characterized Haskill, *et al.* as disclosing MAD-3 as an "IκB-like protein" and Davis, *et al.*, as disclosing pp40 as a "Rel-associated protein . . . which is functionally related to the NF-κB inhibitor IκB." (Exh. C at ADL 0000438.5 and 000438.18.) Thus, throughout the prosecution of the '516 patent, and in the patent itself, Ariad consistently took the position that MAD-3 and pp40 were "IκB-like." In an about-face, Ariad now argues in its Supplemental Trial Brief that MAD-3 and pp40 are IκB-α instead of merely "IκB-like." (D.I. 360 at 14.) The missing IDS from the '516 prosecution file highlights the inconsistent position Ariad now takes and exclusion of this document from PTX 2 may significantly hinder Lilly's ability to expose this conflict at trial.

Lilly also contends that Ariad committed inequitable conduct for failing to provide the PTO with copies of the inventors' own publications, which show their knowledge that well-known prior art compounds had been reported to inhibit NF-κB. Ariad contends that "It Is Unlikely during the '516 Prosecution That a Reasonable Examiner Would Have Considered Lilly's References Important to Patentability" (D.I. 360 at 9) because the PTO withdrew its inherent anticipation argument. Ariad is correct that the PTO withdrew its inherent anticipation rejections, but there is no explicit indication in PTX 2 as to the reason why. This is because PTX 2 is missing the last two pages of a July 1998 Office Action, which shows that PTO withdrew its

inherent anticipation rejection because Ariad amended its claims to require use of an “agent” that acted inside the cell—not because the PTO’s rejection was meritless. (Exh. D “The rejection of claim 57 under 35 U.S.C. 102(b) as being anticipated by Wall et al. is withdrawn in view of the amendment to the claim.”)

Finally, contained within the pages missing from the ’516 prosecution file are copies of references Ariad submitted to the PTO. In this litigation, Ariad relies on some of these references, such as Siebenlist et al., in rebuttal to Lilly’s inequitable conduct argument. (See D.I. 360 at 14.) PTX 2, however, is missing a page from this reference. (Exh. E.) Again, without supplementation of PTX 2, the ’516 patent prosecution file would be missing pages from documents that Ariad itself relies on.

These are but a few examples of the issues affected by the pages missing from the ’516 patent prosecution file. Accordingly, Lilly respectfully requests the Court permit supplementation of PTX 2.

Respectfully submitted,

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/s/ Charles E. Lipsey

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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 August 3, 2006.

/s/ Charles E. Lipsey