

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN INC., )

Plaintiff, )

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. )

Civil Action No.: 05-12237 WGY

**REBUTTAL EXPERT REPORT OF STEPHEN G. KUNIN**

- Lot 82 uEPO; and
- Alpha Therapeutics uEPO.

439. Moreover, Mr. Sofocleous cites no support in Dr. Bertozzi's report for his conclusion as to whether experimental results conflict.

440. It is my understanding, based on my review of the record, that Applicant did submit declaration evidence to the Patent Office, namely a January 1994 declaration by Dr. Cummings. It is further my understanding, based on my review of the record and described more fully below, that the 1994 Cummings declaration did address glycosylation differences between naturally-occurring EPO and rEPO. (AM-ITC 00460858-84). Moreover, it is my understanding that the literature references discussed by Dr. Cummings disclosed uEPOs purified by techniques developed after Lin's patent filings, *see e.g.*, Yanagi (AM-ITC 00460870), and Storing (AM-ITC 00460864-68). Applicant therefore submitted the information it identified to the Patent Office.

441. In paragraph 375 of his report, Mr. Sofocleous alleges that Applicant did not make known to the Patent Office certain information regarding carbohydrate analysis of CHO rEPO and urinary EPO. Mr. Sofocleous contends that it was necessary to disclose such information in order to correct an error in Example 10 of the '933 patent (col. 28:51-67). The allegation is untrue. I note that these statements were disclosed to the Patent Office in the *Fritsch v. Lin*, Interference No. 102,334 proceeding, and reviewed and considered by the Patent Office examiner during prosecution of the '933 patent. (AM-ITC 00941744; AM-ITC 00902526; AM-ITC 00941412; AM-ITC 00941237-40; AM-ITC 00950983- 91) (*see Fritsch v. Lin* Interference No. 102,334, 21 U.S.P.Q.2d 1739 (BPAI 1991); (*see also* AM-ITC 00947092-119; AM-ITC 01005096-123; AM-ITC 00995155-76; AM-ITC 00993963-81).

442. In fact Judge Young considered and rejected precisely this same issue in

*Amgen Inc. v. HMR*, 126 F.Supp.2d 69, 144-145 (D. Mass. 2001) (citations omitted):

In addition, the erroneous nature of certain carbohydrate constitution values was disclosed through the Interference record to, and presumably considered by, the Patent Office. ... During the Interference, the Board was informed that this carbohydrate data was incorrect [and nonetheless ruled in Applicant's favor] ... The '933 prosecution history reveals that the Examining Division reviewed the Interference Record and the Board's decision ... In addition, the Examiner also had before him the correct carbohydrate data ...

**3. Mr. Sofocleous Fails to Identify Any Material, Non-Cumulative Information That Was Not Before the Patent Office**

443. Mr. Sofocleous further contends that Applicant failed disclose to the Patent

Office the following references:

- “Dr. Egrie’s data” (AM-ITC 01072481; AM-ITC 01072486) (MS Report ¶ 368);
- The Egrie *et al.* 1986 article (MS Report ¶¶ 369-370);
- The Eschbach *et al.* 1987 article (MS Report ¶¶ 369-370);
- The 1984 Egrie presentation (AM-ITC 01073033) (MS Report ¶ 370);
- The Browne article (MS Report ¶¶ 371-372);
- The Vapnek article (MS Report ¶ 373);
- Amgen’s statements to the FDA (MS Report ¶ 374);
- A February 1992 declaration by Dr. Strickland (MS Report ¶ 376).

444. The materials referred to in paragraph 368 are the Egrie Input data<sup>29</sup>

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<sup>29</sup> (AM-ITC 00142244-69; AM-ITC 01005096-123; AM-ITC 00945674-98); (see also AM-ITC 00945663-73) showing that “there were no differences when Lin’s CHO rEPO was compared to Lot 82 and Alpha Therapeutics urinary EPO”, “CHO(2) + Lot 82 same size” (AM-ITC 00142249; AM-ITC 01005103), and “α Therapeutics – is same size as CHO + Lot 82” (AM-ITC

Executed this 11<sup>th</sup> day of May, 2007 at Alexandria, VA.

  
STEPHEN G. KUNIN