

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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AMGEN INC.,)		
)		
Plaintiff,)		
)		
vs.)		
)	CIVIL ACTION No.:	05-CV-12237WGY
F. HOFFMANN-LA ROCHE LTD;)		
ROCHE DIAGNOSTICS GmbH; and)		
HOFFMANN-LA ROCHE INC.)		
)		
Defendants.)		
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**DECLARATION OF MICHAEL SOFOCLEOUS IN SUPPORT OF DEFENDANTS’
MOTION FOR SUMMARY JUDGMENT THAT THE CLAIMS OF PATENTS-IN-SUIT
ARE INVALID FOR DOUBLE PATENTING OVER AMGEN ‘016 PATENT**

I, Michael Sofocleous, declare under penalty of perjury that:

1. I am an expert for Defendants in the above-referenced case. A copy of my Curriculum Vitae is attached hereto as Ex. 1.

2. I make this declaration in support of the Defendants’ Motion for Summary Judgment that the Claims of Patents-In-Suit Are Invalid for Double Patenting Over Amgen ‘016 Patent. The patents-in-suit are U.S. Patent Nos. 5,441,868 (“the ‘868 patent”), 5,618,698 (“the ‘698 patent”), 5,756,349 (“the ‘349 patent”), 5,955,422 (“the ‘422 patent”) and 5,547,933 (“the ‘933 patent”). The claims-in-suit are claims 1 and 2 of the ‘868 patent, claims 4-9 of the ‘698 patent, claim 7 of the ‘349 patent, claim 1 of the ‘422 patent, claims 3, 7, 8, 9, 11, 12 and 14 of the ‘933 patent. Charts showing the relationship of the various patents to each other and to relevant patent applications are attached hereto as Exhibit 2.

3. The doctrine of double patenting seeks to prevent the unjustified extension of exclusivity beyond the term of a patent. If an examiner determines that an applicant’s claimed

invention is identical to (“same invention type double patenting”) or obvious in view of subject matter claimed in an issued patent or another pending application (“obvious-type double patenting”), then the examiner should issue a double-patenting rejection. Manual of Patent Examiner’s Procedure (MPEP) §804-§804.03 (5th ed. Rev. 8, May 1988); MPEP §804-§804.03 (8th ed. Rev. 6, Aug. 2006). The U.S. Patent and Trademark Office (PTO) is required to grant a single patent for a single invention. The purpose of this requirement is to prevent an applicant from extending the right to exclusivity afforded by the patent grant by filing multiple applications (including continuation applications) on the same or similar inventions which issue at different times. PTO policy recognizes that the public should be able to act on the assumption that upon expiration of the patent, the public will be free to use not only the invention claimed in the patent, but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made. The doctrine of obviousness-type double patenting is applied to prevent the issuance of claims that are obvious variations of claims in an earlier patent having a common inventor or owner. MPEP §804 (5th ed. Rev. 8, May 1988); MPEP §804 (8th ed. Rev. 6, Aug. 2006). A rejection for double-patenting is available where the application and reference patent (or application) has a common inventor, assignee or owner. A determination of priority is not required when the two inventions are commonly owned. MPEP §804, §804.03 (5th ed. Rev. 8, May 1988); MPEP §804, §804.03 (8th ed. Rev. 6, Aug. 2006). Obviousness-type double patenting includes rejections based on either a one-way determination of obviousness or a two-way determination of obviousness. If the application at issue is the earlier filed application, a two-way determination of obviousness may be applied to support a double patenting rejection only if: (A) the applicant could not have filed the earlier and later claims in a single application; and (B) the PTO is solely responsible for the delay that

caused the earlier-filed claims to issue after the later-filed claims. *See* MPEP §804 (8th ed. Rev.5, Aug. 2006). When making a two-way obviousness determination where appropriate, it is necessary to apply the obviousness analysis from *Graham v. John Deere*, 383 U.S. 1 (1966), twice, once with the application claims as the claims in issue, and once with the patent claims as the claims in issue. MPEP §804 (8th ed. Rev. 5, Aug. 2006).

4. Amgen could have filed the applications that matured into the patents-in-suit as early as November 30, 1984, before it filed Application Serial Number 06/747,119 (“the ‘119 application”), which is the application that matured into U.S. Patent No. 4,667,016 (“the ‘016 patent”). Instead, Amgen delayed until after the ‘016 patent issued to file the continuation applications that matured into the patents-in-suit. Indeed, each of Amgen’s patents-in-suit matured from an application that Amgen waited to file until after the ‘016 patent issued—in most cases as long as eight years after—even though each of these applications could have been filed at the same time or before the ‘119 application was filed. *See* Ex. 2.

5. There was no legal impediment to Amgen filing the ‘119 application and Application Serial Number 06/675,298 (“the ‘298 application”) together in one application, particularly in view of the Patent Law Amendments Act of 1984, which took effect before either of those applications were filed. Even though these two applications listed different inventors, the 1984 Act specifically provides that “[i]nventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.” 35 U.S.C. §116.

6. Amgen could have filed a continuation-in-part (CIP) application combining the disclosures of the ‘298 application by Lin and the ‘119 application by Lai and Strickland and

named all of the inventors as co-inventors. This CIP application could have claimed priority to the '298 application and the '119 application and could have included all the claims-in-suit as well as the claims of the '016 patent. Alternatively, Amgen could have added the Lin '298 application disclosure to the Lai et al. '119 application at the time of filing the '119 application and included Lin as a co-inventor. Again, all the claims-in-suit as well as the claims of the '016 patent could have been included in this CIP application. In either case, neither Lin nor Lai et al. would have lost his asserted effective filing date because each claim in a CIP application may have different priority dates. Thus, Amgen was not required to file the '016 patent claims in a separate application from the claims-in-suit, but willingly chose to do so.

7. During the course of the prosecution of the patents-in-suit, Amgen sought and received thirteen extensions of time totaling over fifteen months of additional delay. In many instances, Amgen waited until the last possible day to respond to PTO correspondence. Amgen further delayed the issuance of the claims-in-suit by filing multiple continuation applications, many of which were later abandoned. Thus, the PTO was not solely responsible for the claims-in-suit issuing after the claims in the '016 patent.

8. During the prosecution of the '298 application, the application that matured into U.S. Patent No. 4,703,008 ("the '008 patent"), Amgen voluntarily chose to cancel claims directed to processes for the production of polypeptides while pursuing related claims directed to the polypeptides themselves. An examiner's restriction requirement had grouped both sets of these claims together as one invention, the Group II claims elected for prosecution. These cancelled process claims, which were reintroduced in U.S. Patent No. 5,441,868 ("the '868 patent"), could have avoided the interference proceeding that delayed the issuance of these claims had they been prosecuted along with the related Group II claims that issued in the '008

patent. Thus, the PTO was not at all responsible for these claims in the '868 patent issuing after the claims in the '016 patent.

9. During the prosecution of the Application Serial No. 07/113,179 (the "'179 application")—from which the '868, '349, '698 and '422 patents claim priority—the Examiner made an obviousness-type double patenting rejection based on the '016 patent (Lai et al.), appropriately applying the one-way obviousness test. Amgen argued that the two-way test should be used. In withdrawing this obviousness-type double patenting rejection, the Examiner agreed to apply the two-way test, but also noted that the pending claims of the '179 application were indeed obvious over the claims of the '016 patent.

... and while *the instantly claimed method is an obvious variation of the process of Lai et al.* it is considered that applicant is not responsible for the delay in the prosecution of the instant application which resulted in the prior patenting of a later filed application to an invention derived from the instant invention. ...

('179 File History, Paper 34, 2/15/94 Office Action at 2 (emphasis added)). I disagree with the examiner's conclusion that the applicant was not responsible for the delay, because *inter alia* the Applicant did not have to wait until the after the '016 patent issued to file the '179 application and instead could have filed the application much earlier. For the reasons discussed above, the two-way test, which is only rarely applicable, should not have been used in this case, but rather the much more typical one-way test should have been used. This portion of the prosecution history does show, however, that the Examiner found that the pending claims of the '179 application, the application that matured into the '868 patent, were obvious in light of the claims of the '016 patent. I have seen no indication in the prosecution histories that Amgen objected to this finding by the Examiner.

10. Amgen admitted during prosecution of application serial number 07/113,178 (“the ‘178 application”), from which the ‘933 patent claim priority, that

both the starting material and final product of the [‘016 patent] ...are included within (dominated by) the recombinant product claims of the present application.

(‘178 File History, Paper 19, 1/11/90 Amendment at 3 (emphasis added)). If the final product of the ‘016 claim 10 process is included within and dominated by the pending claims in the ‘178 application, then under the one-way test those pending claims should be unpatentable for obviousness-type double patenting.

11. By saying that the ‘178 application claims “dominated” the final product of the ‘016 patent claim 10, Amgen apparently hoped to convince the examiner that the holding of *In re Kaplan*, 789 F.2d 1574, 229 U.S.P.Q. 678 (Fed. Cir. 1986) would prevent the application of obviousness-type double patenting. However, such an argument is wrong and, indeed, such an argument turns *In re Kaplan* backwards. In *In re Kaplan*, the earlier-issued patent dominated the later application; the later application was directed to an improvement over what was claimed in the earlier-issued patent, and that improvement was not obvious over the claims of the earlier patent. The court in *In re Kaplan* found that such a fact scenario did not warrant an obviousness-type double patenting rejection. The situation with Amgen’s patents is the exact opposite: Amgen’s later claims dominate the earlier-issued claims in the ‘016 patent, and accordingly, Amgen’s later claims *must* be obvious and *cannot* be patentably distinct over the claims of the earlier ‘016 patent.

12. Nevertheless, Amgen succeeded in getting the examiner to withdraw this double patenting rejection of the ‘178 application. The Examiner’s explanation for withdrawing the

rejection, however, betrayed a fundamentally flawed misunderstanding of patent law. The Examiner explained (in the '178 File History, Paper 34, 12/29/93 Office Action at 2):

... Because the present invention does not require the methods of Lai, it is not believed that the grant of patent for the claimed invention will have the effect of prolonging the term of exclusivity for the method claims of the prior patent.

There are several mistakes incorporated in this sentence. One mistake, is that the main clause of the sentence does not follow from the initial clause; the claimed invention for rEPO (in the '178 application) could dominate the several different processes for recovering rEPO, but the claimed invention could still prolong the exclusivity of the '016 patent. Another mistake is that Amgen had previously admitted that the claimed invention did indeed "dominate" the '016 patent. The sentence also sets forth a test for obviousness-type double patenting that is stricter than the actual test, which requires that the later claims not be obvious over the earlier-issued claims.

13. Thus, in my opinion, the legal bases for the Examiners' decisions in the '179 and '178 applications to withdraw the obviousness-type double patenting rejections based on the '016 patent were incorrect as a matter of law.

Executed this 7th day of June 2007 at Fairfax, Virginia.

/s/ Michael Sofocleous
Michael Sofocleous

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) and paper copies will be sent to those indicated as non registered participants on June 12, 2007.

/s/ Nicole A. Rizzo

Nicole A. Rizzo

List of Exhibits

Exhibit 1 Curriculum Vitae

Exhibit 2 Charts showing Patent Filings from Amgen's EPO Project of Early 1980's

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