

**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 INC.’S RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS
REGARDING NO OBVIOUSNESS-TYPE DOUBLE PATENTING**

The following facts are beyond genuine dispute and compel summary judgment as a matter of law with respect to Amgen Inc.’s motion for summary judgment of no obviousness-type double patenting:¹

1. U.S. Patent Application No. 06/675,298 (“the ‘298 application”) was filed on November 30, 1984 and issued as U.S. Patent No. 4,703,008 on October 27, 1987.

- Ex. H-1 (U.S. Patent Application No. 06/675,298);
- Ex. B (U.S. Patent No. 4,703,008).

2. On July 3, 1986, the United States Patent and Trademark Office imposed a restriction requirement that forced Amgen to select one of six invention groups for continued examination in the ‘298 application.

¹ All referenced exhibits are attached to the accompanying declaration of Mario Moore.

- Ex. H-8 (7/3/86 Office Action), at p.2.

3. In response to the July 3, 1986 restriction requirement, Amgen elected claims from restriction Group II for continued examination in the ‘298 application, and the other, non-elected claims were withdrawn from further consideration in the ‘298 application.

- Ex. H-8 (7/3/86 Office Action), at p.3.

4. As filed on October 23, 1987, U.S. Patent Application No. 07/113,178 (“the ‘178 application”) contained original claims 1-13, 16, 39-41, 47-49, and 55-57 from the parent ‘298 application, which belonged to non-elected Groups I and V of the July 3, 1986 restriction requirement.

- Ex. I (U.S. Patent Application No. 07/113,178), at AM-ITC 00941037-45, AM-ITC 00941076-77;
- Ex. H-8 (7/3/86 Office Action), at p.2.

5. As filed on October 23, 1987, U.S. Patent Application No. 07/113,179 (“the ‘179 application”) contained original claim 1 from the parent ‘298 application, which belonged to non-elected Group I of the July 3, 1986 restriction requirement.

- Ex. J (U.S. Patent Application No. 07/113,179), at AM-ITC 00453982-90, AM-ITC 00454000-01;
- Ex. H-8 (7/3/86 Office Action), at p.2.

6. All claims in U.S. Patent No. 5,547,933 fall within the scope of Group I or Group V, and not Group II, of the July 3, 1986 restriction requirement.

- Declaration of Harvey F. Lodish, Ph.D. in Support of Amgen Inc.’s Motion for Summary Judgment of No Obviousness-Type Double Patenting (“Lodish Declaration”), at ¶¶ 26-28.

7. All claims in U.S. Patent No. 5,756,349 fall within the scope of Group IV, and not Group II, of the July 3, 1986 restriction requirement.

- Lodish Declaration, at ¶¶ 29-30.

8. All claims in U.S. Patent No. 5,955,422 fall within the scope of Group V, and not Group II, of the July 3, 1986 restriction requirement.

- Lodish Declaration, at ¶¶ 31-34.

9. U.S. Patent Application No. 06/747,119 (“the Lai/Strickland ‘119 application”) was filed on June 20, 1985 and issued as U.S. Patent No. 4,667,016 (“the Lai/Strickland ‘016 patent”) on May 19, 1987.

- Ex. K (U.S. Patent Application No. 06/747,119);

- Ex. L (U.S. Patent No. 4,667,016).

10. Although they issued after the Lai/Strickland ‘016 patent, U.S. Patent Nos. 5,547,933, 5,756,349, 5,955,422, 5,441,868, and 5,618,698 (“the patents-in-suit”) all claim priority from applications, including the ‘298 application, that were filed before the June 20, 1985 filing date of the Lai/Strickland ‘119 application.

- Ex. C (U.S. Patent No. 5,547,933);

- Ex. D (U.S. Patent No. 5,756,349);

- Ex. E (U.S. Patent No. 5,955,422);

- Ex. F (U.S. Patent No. 5,441,868);

- Ex. G (U.S. Patent No. 5,618,698).

11. The inventions claimed in the Lai/Strickland ‘016 patent were not conceived as of the November 30, 1984 filing date of the ‘298 application.

- Declaration of Thomas W. Strickland in Support of Amgen Inc.’s Motion for Summary Judgment of No Obviousness-Type Double Patenting, at ¶¶ 11-16 and references cited therein.

12. Amgen did not cause the Lai/Strickland '016 patent to issue before the patents-in-suit by delaying examination of the '298 application during the period from June 20, 1985 to May 19, 1987, when the '298 application and the Lai/Strickland '119 application were co-pending.

- Exs. H-4 to H-16 (prosecution history of '298 application between June 20, 1985 to May 19, 1987).

13. Claim 10 of the Lai/Strickland '016 patent recites a process for purifying recombinant erythropoietin that has already been produced, but does not teach or describe or claim a process for producing that recombinant erythropoietin.

- Ex. L (U.S. Patent No. 4,667,016);
- Lodish Declaration, at ¶¶ 37-38, 44-58.

14. Claim 10 of the Lai/Strickland '016 patent does not teach or describe how to produce an *in vivo* biologically active erythropoietin glycoprotein, glycoprotein product, or pharmaceutical composition prepared from such a product.

- Ex. L (U.S. Patent No. 4,667,016);
- Lodish Declaration, at ¶¶ 37-39.

Respectfully Submitted,
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By its attorneys,

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CERTIFICATE PURSUANT TO LOCAL RULE 7.1

I certify that counsel for the parties have conferred in an attempt to resolve or narrow the issues presented by this motion and no agreement was reached.

_____/s/ Michael R. Gottfried
Michael R. Gottfried

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 the above date.

_____/s/ Michael R. Gottfried
Michael R. Gottfried