Attachment Part 1 of 4

Obviousness-Type Double Patenting

Roche Presentation

October 4th, 2007

AMGEN INC.,
Plaintiff,

v.

F. HOFFMANN-LA ROCHE, LTD
ROCHE DIAGNOSTICS GmbH
and HOFFMANN-LA ROCHE INC.
Defendants.

CIVIL ACTION No.: 05-CV-12237WGY

Theory No. 3 Obviousness Type Double Patenting

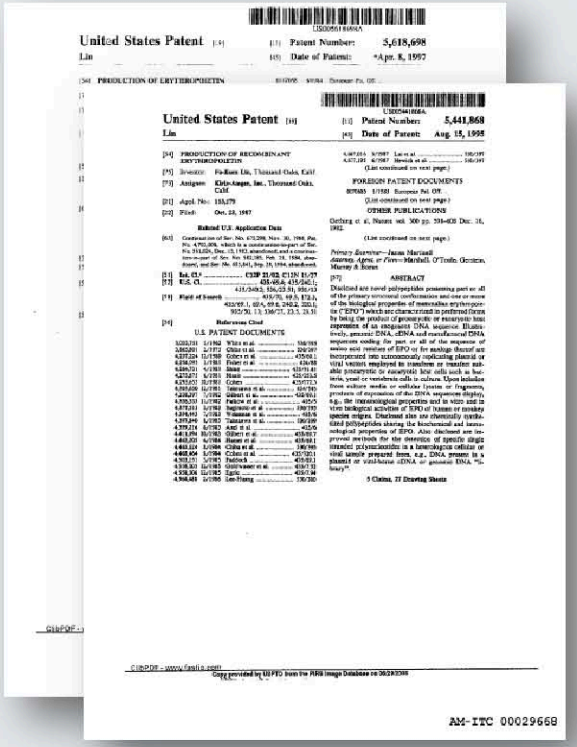
Claims of the ‘008 patent render the asserted claims of the ‘868 and ‘698 patent invalid

United States Patent [19]
Lin

[11] Patent Number: 4,703,008
[45] Date of Patent: Oct. 27, 1987

AM-ITC 00456126

‘008 Patent, TRX 7, Expired in 2004



United States Patent [19]
Lin

[11] Patent Number: 5,618,698
[45] Date of Patent: *Apr. 8, 1997

United States Patent [19]
Lin

[11] Patent Number: 5,441,868
[45] Date of Patent: Aug. 15, 1995

AM-ITC 00029668

‘868 and ‘698 Patents, TRX 2 and 3, Both Expire in 2012

Obviousness Type Double Patenting

- Judge created doctrine grounded in fairness and public policy;
- To prevent the unjustified and improper timewise extension of the right to exclude granted by a patent;
- Applicants should not be allowed to extend their patent rights for inventions that are merely obvious variations of prior expired inventions.

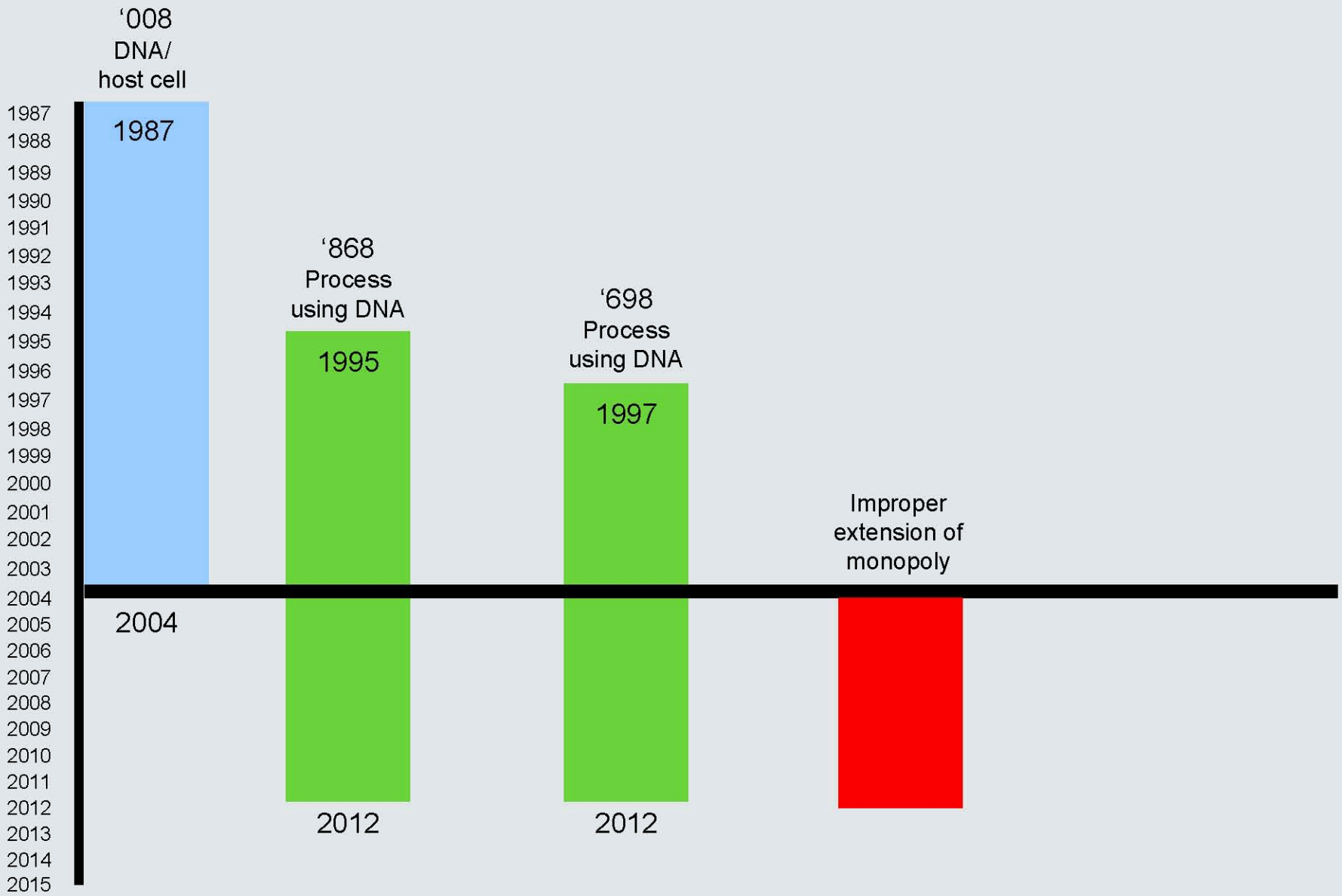
In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Obviousness Type Double Patenting – What It Is Not

- This is not statutory double patenting where the law requires strict identity between the claims;
- Just as the name suggests, the test is "Obviousness" and NOT anticipation.
- As with any obviousness analysis, the Court can rely upon the prior art to decide whether the prior claim in combination with the prior art renders the later claim obvious.

In re Longi, 759 F.2d 887, 897 (Fed. Cir. 1985) (later claim rendered obvious over an earlier claim due to the disclosures of four prior art references disclosing nitrogen containing compounds); MPEP 804, ¶¶ 8.36-8.37 ("Claim [1] rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim [2] of U.S. Patent No. [3] in view of [4], [5].")

TERM OF AMGEN EPO PATENTS
(DNA/host cell claims; Process Claims)



Representative claims from 4,703,008

2. **A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin**.

4. A procaryotic or eucaryotic host cell transformed or transfected with a DNA sequence according to claim ... 2 ... 3 in a manner allowing the host cell to express erythropoietin.

7. **A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin** to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

23. A procaryotic or eucaryotic host cell transformed or transfected with **a DNA sequence according to claim 7** ... in a manner allowing the host cell to express said polypeptide.

24. A transformed or transfected host cell according to claim 23 which host cell is capable of glycosylating said polypeptide.

25. A transformed or transfected mammalian host cell according to claim 24.

27. A transformed or transfected CHO cell according to claim 25.

5,441,868

1. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of:
(a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with **an isolated DNA sequence encoding human erythropoietin;** and
(b) isolating said glycosylated erythropoietin polypeptide therefrom.

Representative claims from 4,703,008

2. **A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.**

4. A procaryotic or eucaryotic host cell transformed or transfected with a **DNA sequence according to claim ... 2 ... 3** in a manner allowing the host cell to express erythropoietin.

6. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 5.

7. **A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin** to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

23. A procaryotic or eucaryotic host cell transformed or transfected with a **DNA sequence according to claim 7** ... in a manner allowing the host cell to express said polypeptide.

24. A transformed or transfected host cell according to claim 23 which host cell is capable of glycosylating said polypeptide.

25. A transformed or transfected mammalian host cell according to claim 24.

5,618,698

6. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of:
a) growing, under suitable nutrient conditions, vertebrate cells comprising amplified **DNA encoding the mature erythropoietin amino acid sequence of FIG. 6;** and
b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.

Dr. Lowe Testified That the Differences Between the '008 Claims and The '868 and '698 Claims Would Have Been Obvious To Those of Ordinary Skill as of 1983 and 1984.

- Dr. Lowe properly compared the claims of each of '868 and '698 patents against claims of the '008 patent and determined that the differences between the claims were obvious and would have been well known to those of ordinary skill in the art. Tr. at 314-326

- According to Dr. Lowe, the asserted claims of the '868 patent contain the identical elements set forth in the '008 patent and obvious additions well known to those of skill in the art. Tr. at 314-326