

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and
AMGEN MANUFACTURING, LIMITED,

Plaintiffs,

vs.

HOSPIRA, INC.,

Defendant.

C.A. No. 15-839 (RGA)

~~MEMORANDUM~~ ORDER ON CLAIM CONSTRUCTION

This 23 day of January, 2017, the Court, consistent with the findings and conclusions set forth in the Memorandum Opinion dated November 30, 2016 (D.I. 162) and the Memorandum Opinion dated January 12, 2017 (D.I. 177),

IT IS HEREBY ORDERED:

1. With respect to the '298 patent:
 - a. The term "an isoform" means "a group of molecules that has a single isoelectric focusing point and a specific number of sialic acids per molecule, and appears as a single band on an isoelectric focusing gel (an example of which is shown in Figure 1 of the '298 patent)" (D.I. 162, p. 6, line 22 to p. 7, line 3; D.I. 177 p. 4, lines 10-12.)
 - b. The term "an isolated . . . isoform" in Claim 1 means "one and only one isoform, that is, a group of erythropoietin molecules all with the same isoelectric focusing point and the same number of sialic acids per molecule and which appear as a single band on an isoelectric focusing gel, separated from erythropoietin


- molecules having a different isoelectric focusing point and number of sialic acids per molecule.” (D.I. 177, p. 4, lines 13-18.)
- c. Claim 8 is invalid under 35 U.S.C. Section § 112, ¶ 4 for failure to properly narrow the scope of claim 1, from which it depends.
 - d. The term “consisting essentially of” in Claim 13 means “the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” (D.I. 177, p. 8, lines 4-7.)
 - e. The term “erythropoietin consisting essentially of erythropoietin molecules having a single specific number of sialic acids per molecule” in Claim 13 means “erythropoietin consisting essentially of one and only one isoform.” (D.I. 177, p. 8, lines 2-4.)
 - f. Claim 19 is invalid under 35 U.S.C. Section § 112, ¶ 4 for failure to properly narrow the scope of claim 13, from which it depends.
 - g. The term “erythropoietin molecules having a predetermined number of sialic acids per molecule selected from the group consisting of 1-14” in Claim 24 essentially describes “an isoform,” (D.I. 177, p. 5, lines 14-21), and Claim 24 claims “methods of preparing one or more erythropoietin isoforms.” (D.I. 177, p. 7, lines 9-10.)
 - h. Claim 27 is an independent claim (D.I. 177, p. 10, lines 6-7), and the term “mixture of two or more erythropoietin isoforms of Claim 1” in Claim 27 means “a mixture of two or more of the isolated erythropoietin isoforms of Claim 1.”

2. With respect to the '349 patent:

- a. The term "DNA sequences which control transcription" means "DNA sequences that initiate and may regulate the processes of transcription."
- b. The term "transcription control DNA sequences" means "DNA sequences that initiate and may regulate the processes of transcription."

Dated:

January 23, 2017


The Honorable Richard G. Andrews