IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GLYCOBIOSCIENCES, INC., Plaintiff, v. INNOCUTIS HOLDINGS, LLC, ET AL., Defendants.	CASE NO. 1:12-CV-01901-RDM

PLAINTIFF'S MOTION TO STRIKE PORTIONS OF DEFENDANTS' CLAIM CONSTRUCTION SUBMISSION
(or for Alternate Relief)

Introduction

The parties submitted two terms for a "claim construction" (Markman ruling) by the Court, the first term being "about 650,000 to about 800,000" relating to molecular weight and the second term being "nonionic polymer."

This Motion relates only to the second term – nonionic polymer.

Procedurally, pursuant to the Court's Scheduling Order, the parties submitted opening claim constructions briefs on February 20, 2015 (DE 48, 49) and responsive claim construction briefs on May 20, 2015 (DE 62, 63).

Defendants then presented a multipage document at the "claim construction" or "Markman" hearing on June 10, 2015.

The schedule for filing briefs as described above did not provide the opportunity to "reply" to a responsive brief and did not provide the opportunity to respond to any submissions at the Markman hearing.

Plaintiff has now discovered that Defendants' submission is inaccurate as will be explained below. Accordingly, Plaintiff submits that Defendants' responsive brief and Markman Hearing submission, as they relate to the term "nonionic polymer," should be stricken.

Attached to this Motion as Exhibit A is the Second Declaration of Dr. Andrew Kolbert. Attached to this Motion as Exhibit B, for the convenience of the Court, is a duplicate copy of Defendants' Markman Hearing submission which contained 27 individual slides on 14 pages. Dr. Kolbert refers to the errors in the slides as summarized below.

Background

This is a suit for infringement of Glycobiosciences, Inc's. ("Glyco's") U.S. Patent No. 6,387,407 ("the '407 patent"). The patent refers to a blended gel matrix containing a negatively charged polymer material namely hyaluronate sodium salt, and a nonionic polymer.

A distinction should be made between hyaluronic acid, which does <u>not</u> appear in the claims of the '407 patent and thus is <u>not</u> claimed, and hyaluronate sodium salt (sodium hyaluronate) which <u>is</u> claimed. This distinction is important because Defendants' claim construction arguments attempt to define nonionic polymers by relying upon features of the former (the acid) rather than that which is actually claimed. The result, as explained below, is that the second component (hydroxyethyl cellulose or HEC) which both parties agree is a nonionic polymer would be incorrectly categorized as "ionic" under Defendants' flawed proposed claim construction.

The errors (or the confusion that led to the errors) may be based on the fact that both "ionic" and "ionizable" begin with "ION". Yet the terms have different meanings not only in the context of the '407 patent, but in the field of chemistry in general.

Argument

Acids including hyaluronic acid

Acids are referred to as proton donors and have what is referred to as ionizable functional groups. One example of such a functional group is a carboxyl group illustrated as (-COOH). (Second Kolbert Declaration, ¶ 15) (Hereafter "Kolbert II")

A. Bases

Bases are referred to as proton acceptors and also have ionizable functional groups. One example of such a functional group is a hydroxyl group illustrated as "-OH". (Kolbert II ¶ 16) Acids and bases involve the transfer of protons, not electrons. (Kolbert II ¶ 17)

B. Ionizable Acids and Bases

A carboxyl group is ionizable. A hydroxyl group is ionizable (Kolbert II ¶ 18, 21)

C. Alkali Metals

The Court heard argument regarding sodium hydroxide. Sodium is classified as an alkali metal. (Kolbert II ¶ 24)

D. Hyaluronic acid does <u>not</u> contain ionic bonds

Hyaluronic acid does <u>not</u> contain an alkali metal and no ionic bond is formed. (Kolbert II ¶¶ 24, 27). Contrary to Defendants' Slide No. 11, hyaluronic acid does <u>not</u> have a strong negative charge, and carboxyl groups do not have a strong negative charge. (Kolbert II ¶¶ 28, 29)

E. Defendants' Flawed Nonionic Polymer Claim Construction

Defendants propose:

> "polymers, such as hydroxyethyl cellulose, that do not contain <u>ionizable</u> groups such as a carboxylic group, and does not refer to

> polymers, such as hyaluronic acid and polyacrylic acid, that do contain ionizable or ionized groups. (Emphasis added)

F. Hyaluronate Sodium Salt is not Hyaluronic Acid

The '407 patent claim is to hyaluronate sodium salt not hyaluronic acid. Defendants incorrectly propose a claim construction (e.g., Slide No. 4) with reference to hyaluronic acid, rather than to the "salt" form known as sodium hyaluronate. (Kolbert II ¶ 23) While hyaluronic acid and sodium hyaluronate are similar, they are not the same. (Ibid.)

G. Hyaluronate Sodium Salt is Ionic

Both parties agree that the "hyaluronate sodium salt" is claimed as a negatively charged polymer. (E.g., Claim 1 and Slide No. 3) In hyaluronate sodium salt, a sodium atom and an oxygen atom donate and accept electrons, respectively. This is also referred to as electron transfer, and that is different from proton transfer. The electron transfer forms an ionic bond. Thus the claimed hyaluronic sodium salt is an ionic polymer because it contains an ionic bond. (Kolbert II ¶¶ 24 – 26) In fact, all polymers that contain an ionic bond are ionic. (Kolbert II ¶ 32)

H. The nonionic polymer – hydroxyethyl cellulose (HEC)

Both parties agree that hydroxyethyl cellulose (HEC) is described in the '407 patent as an example of a nonionic polymer. But HEC does contain ionizable hydroxyl groups as demonstrated in Defendants' own Slides 7, 13 and 14, where the letter "R" in the diagram indicates that, as one option, hydrogen (H) may be used in place of "R." The hydrogen will bond

with the oxygen to form OH, a hydroxyl group. (Kolbert II ¶ 20) But since hydroxyl groups are ionizable (Kolbert II ¶ 21), the fact that a polymer has an ionizable group is not an accurate way to define the polymer as ionic. (Kolbert II ¶ 19)

I. Defendants' Definition Ignores the "functional" groups of both acids and bases

As noted above, the functional groups of acids (such as the carboxyl group) and the functional groups of bases (such as the hydroxyl group) are ionizable, meaning the functional groups have the propensity to donate or accept protons. But the presence of an ionizable group within a polymer does not properly define that polymer as ionic. (Kolbert II ¶ ¶18, 19)

J. One "error" in Defendants' Claim Construction -- hyaluronic acid.

Defendants seek to construe "nonionic" as "not referring to hyaluronic acid" by arguing that hyaluronic acid is ionic because it does contain an ionizable group. But the presence or absence of an ionizable group in hyaluronic acid is irrelevant because hyaluronic acid is not claimed. Furthermore, the presence or absence of an ionizable group in an acid is not the test for the polymer being "ionic" as noted above. Defendants' argument is flawed.

K. A second "error" in Defendants' Claim Construction– HEC

Defendants' identify HEC as nonionic (and that is correct) but then argue that the HEC does not contain an ionizable group which is incorrect. HEC does contain an ionizable group.[1] Therefore, Defendants' proposed claim construction is inherently inconsistent and flawed.

1 At the Markman Hearing, Dr. Burdick conceded that the phrase "such as" was merely to present an example. Therefore, the phrase "such as a carboxyl group" is merely an example, and the broader phrase "ionizable groups" does not exclude the hydroxyl group found in HEC.

Under Defendants' proposed claim construction, HEC would be (improperly) identified as ionic because it does contain an ionizable group. But both parties agree HEC is nonionic.

L. A third "error" in Defendants' Claim Construction – "Groups"

Defendants' proposed claim construction relies on the presence or absence of ionizable "groups." This is incorrect. (Kolbert II ¶ 36) A polymer is "ionic" (or nonionic) independent of whether it contains ionizable groups. (Kolbert II ¶36)

Conclusion

Plaintiff believes that the error arose because "ionic" and "ionizable", both starting with "ion" are terms with different meanings. Claim construction cannot properly be predicated on the presence or absence of ionizable groups just because of the presence of "ion…" in the word "ionizable". As Dr. Kolbert noted, a polymer is "ionic" (or nonionic) independent of whether it contains ionizable groups. (Kolbert II ¶36)

Based on the foregoing, Plaintiff asks the Court to strike Defendants' Slides 7, 11, 13, 14, the arguments in Defendants' Response Brief corresponding to nonionic polymer, and the corresponding oral argument corresponding to nonionic polymer

Alternate Relief

Should the Court not be willing to grant the primary relief as requested above, Plaintiff asks the Court to accept this Motion and the Second Kolbert Declaration as a claim construction reply.

Dated: June 19, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 19, 2015, the foregoing document was served this day on all counsel of record electronically via CM/ECF as set forth below.

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