UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

GLYCOBIOSCIENCES, INC.,

Plaintiff,

v. CASE NO. 1:12-CV-01901-RDM

INNOCUTIS HOLDINGS, LLC,

and

DARA BIOSCIENCES, INC.

Defendants.
_____/

SECOND DECLARATION OF ANDREW C. KOLBERT, Ph.D., M.T.M.

1. My name is Andrew C. Kolbert. I have been retained as an expert by Glycobiosciences, Inc.
2. My fee is $650 per hour and is not dependent upon the outcome of this lawsuit.
3. I am Sr. Vice-President, Technical Services of Avomeen Analytical Services, (Avomeen) an independent certified testing laboratory located in Ann Arbor, Michigan.

4. Avomeen has previously conducted tests for Glycobiosciences. Whether or not we perform additional tests for Glycobiosciences is not dependent upon my signing this Declaration and is not dependent upon the outcome of this lawsuit
5. A copy of my resume (curriculum vitae) has previously been submitted to the Court.
6. I have read and understand, from a technical standpoint, U.S. Patent No. 6,387,407, a copy of which is attached as Exhibit 2.
7. I am providing information from a technical standpoint as the patent would be understood by someone of ordinary skill in polymer chemistry and pharmaceuticals. I have been told to explain things as of the 1995 to 1997 time frame.
8. As noted in greater detail in my C.V., I have specific prior experience in both polymer chemistry and in pharmaceuticals. The '407 patent involves both of these technologies.
9. In my experience, the ordinary worker in the field of polymer chemistry and pharmaceuticals would have a Ph.D. degree and some years of practical experience or the equivalent. Examples of "the equivalent" would be a lesser degree coupled with a substantial number of years of experience. I cannot put a number on the "years of experience" that may be required as that would depend on the precise nature of the experience.

Ionic and non-ionic polymers

10. I have been given a copy of a chart or slide presentation (14 pages, 27 individual slides or charts) and been informed that Defendants' presented this chart to the Court during a hearing on June 10, 2015. I shall refer to the presentation by "slide" number, the small number on each slide, rather than the larger number on each page.

11. The '407 patent refers to a gel composition including hyaluronate sodium salt and a non-ionic polymer. I will now address the issue of the non-ionic polymer and how Defendant's proposed definition in the charts is incorrect and internally inaccurate.

12. Defendants' proposed definition for nonionic polymer, "**polymers**, such as hydroxyethyl cellulose **that do not contain ionizable 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**," is incorrect in the scope of the '407 patent. (slide 4).

13. Plaintiffs proposed original definition, "a polymer that does not contain ionic bonds," is accurate within the scope of the '407 patent. (slide 4).

14. Not all polymers that have ionizable groups are ionic.

15. Acids are referred to as proton donors and have ionizable functional groups such as carboxyl groups, illustrated as "(-COOH)".

16. Bases are referred to as proton acceptors and have ionizable functional groups such as hydroxyl groups, illustrated as "-OH".

17. Notice that acids and bases involve the transfer of protons, not electrons.

18. Defendants' definition fails to take into account the ionizable functional groups of bases, and a person of ordinary skill in the art would consider the functional groups of both acids and bases when considering "ionizable groups."

19. A polymer having functional groups that ionize does not accurately define the polymer as ionic.

20. For example, hydroxyethyl cellulose contains hydroxyl groups. (Slides 7, 13, 14). The letter "R" in the diagram means that as one option, hydrogen (H) appears in the diagram in place of the R. The hydrogen bonds with the oxygen to form OH, a hydroxyl group.

21. Hydroxyl groups are ionizable groups. The pKa of the group is very high and it may be difficult to ionize it, but it can be ionized under certain conditions. Thus hydroxyethyl cellulose contains ionizable groups. However, hydroxyethyl cellulose is a nonionic polymer as described in the patent and as Defendants agree on slides 13 and 14.

22. **This demonstrates an inherent inconsistency, inaccuracy, and major flaw in Defendants' definition: accordingly to Defendants' definition, hydroxyethyl cellulose would be incorrectly categorized as an ionic polymer because it contains ionizable groups, namely the hydroxyl**

groups, even though Defendants (and the '407 patent itself) list hydroxyethyl cellulose as nonionic.

23. Defendants incorrectly create their definition and distinction with reference to hyaluronic acid rather than the salt form known as sodium hyaluronate, (which is the sodium salt form of hyaluronic acid); but the salt form is claimed in the '407 patent. Hyaluronic acid and sodium hyaluronate, although similar, are not the same.

24. Sodium is classified as an alkali metal. Hyaluronic acid does not contain an ionic bond with an alkali metal because it does not even contain any alkali metal. On the other hand, sodium hyaluronate does contain sodium and does form an ionic bond with that sodium.

25. In sodium hyaluronate, a sodium atom and an oxygen atom donate and accept electrons, respectively, (also referred to as electron transfer), to form an ionic bond. Electron transfer is different from proton transfer described above.

26. Thus sodium hyaluronate (which is claimed) is an ionic polymer because it contains an ionic bond.

27. In hyaluronic acid, no alkali metal is present, and no ionic bond is formed.

28. The strong negative charge of the sodium hyaluronate comes from the presence of the sodium. Defendants incorrectly state that hyaluronic acid has a strong negative charge due to the presence of a carboxyl group.

29. Hyaluronic acid does not have a **strong** negative charge. Carboxyl groups do not have a **strong** negative charge.

30. Defendants incorrectly use functional groups of acids (such as carboxyl) to define whether a polymer is nonionic. However, in doing so, Defendants merely define an acid, not an ionic or nonionic polymer. (Slide 11). Furthermore, the comment in the '407 patent to "strong negative charge" (column 3, lines 7-10) does not mention hyaluronic acid although Defendants make this statement in Slide 11.

31. Not all polymers that contain a carboxyl group are ionic.

32. All polymers that contain an ionic bond are ionic.

33. Polyacrylic acid (Carbomer 980) does not contain any ionic bonds even though some functional groups can be ionized.

34. Plaintiff and Defendants agree that sodium hyaluronate is ionic and hydroxyethyl cellulose is nonionic.

35. Sodium hyaluronate contains an ionic bond, and hydroxylethyl cellulose does not contain an ionic bond.

36. Therefore, ionic polymers are the polymers that contain ionic bonds, and non-ionic polymers are polymers that do not contain ionic bonds. This is independent of whether the polymer is ionizable.

Further Declarant sayeth not:

Signed at Ann Arbor, Michigan,
under penalty of perjury this
18 day of June, 2015.

Andrew C. Kolbert, Ph.D. M.T.M.