UNITED STATES PATENT AND TRADEMARK OFFICE
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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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ARAGEN BIOSCIENCE, INC.,
AND
TRANSPOSAGEN BIOPHARMACEUTICALS, INC.,

Petitioners,

v.

KYOWA HAKKO KIRIN CO., LTD.
Patent Owner

Patent No. 6,946,292
Issued: September 20, 2005
Filed: October 9, 2001
Inventors: Yutaka Kanda, Mitsuo Satoh, Kazuyasu Nakamura, Kazuhisa Uchida,
Toyohide Shinkawa, Naoko Yamane, Emi Hosaka, Kazuya Yamano, Motoo
Yamasaki, Nobuo Hanai
Title: Cells Producing Antibody Compositions with Increased Antibody Dependent
Cytotoxic Activity

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*Inter Partes* Review No.: IPR2017-01252

**PETITIONERS' SUPPLEMENTAL PAPER
REGARDING EXPERT TESTIMONY OF DR. BRIAN VAN NESS**

Petitioners respectfully refer the Board to the below transcript citations from Dr. Brian Van Ness' June 22, 2017 District Court deposition (Ex. 1037).

## I.     TESTIMONY CONCERNING TEACHINGS OF PETITIONERS' CITED REFERENCES[1]

**A.     Testimony Regarding *Rothman* (Ex. 1002):** Ex. 1037 at 185:9-187:24

Q. And do you recall a line of questioning earlier in the day, Mr. Platt asked you to review [*Rothman*] and whether certain words were used in the reference?

A. Correct.

Q. Do you recall Mr. Platt asking you, for instance, whether the words "alpha-1,6-fucosyltransferase" were present in [*Rothman*]?

A. Yes, I remember that.

Q. And whether the words "FUT8" were present in [*Rothman*]?

A. I was asked that as well.

Q. Are there specific words such as "fucosyltransferase activity", "knockout"?

A. I was asked those as well.

Q. Also words "deleting a gene" or "mutating a gene"?

A. I was asked if this paper, those – whether those terms were present as well.

Q.  Whether or not those exact words are set forth explicitly in this reference, does that influence your opinion as to whether or not the claims at issue in this case are obvious?

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[1] To guide the Board's review, Petitioner has quoted herein select language found within the cited transcript excerpts. The quotations omit objections.

A. So let me explain that in the sense of how I came to the conclusion that the claims were obvious. The terms that were asked of me were not in the paper, but one skilled in the art reads multiple papers. And in order to apply the standards of obviousness, the question before me was: If one looked at papers that described FUT8 as a gene for fucosyltransferase, if one looked at the function of fucosyltransferase as an enzyme that puts a fucose on a sugar molecule on an antibody, if one looked at publications that describe the fact that fucose interferes with ADCC function and if you removed that fucose, you can improve ADCC function, all of those papers – in no one paper did all of that information occur in one place, but that information was distributed through papers that one skilled in the art would have been aware of, all of those prior to October of 2000, such that is would have rendered the claims that were being made obvious, in my opinion.

Q. So for instance, the absence of the explicit language "alpha-1,6-fucosyltransferase", that does not impact your overall obviousness analysis, correct?

A. Not at all. Put another way, I can point to lots of papers where those words are not used and it does no impact.

**B.**    **Testimony Regarding *Harris* (Ex. 1003):** Ex. 1037 at 192:24-194:19

Q. And whether or not any of those exact terms are set forth in [*Harris*], does that affect your obviousness analysis?

A. Not at all.

Q. Why not?

A. Because there are other publications where fucosyltransferase is described, its activity is described, its clones and sequence are

described, its impact on ADCC is described. So there are other papers that describe those activities. The choice of these particular papers were -- have no impact on -- on the fact that there is plenty of literature out there that would have made the attempts, the ideas, and methodologies in each of these patents obvious.

Q. So the specific claim language terms – for instance, alpha-1,6-fucosyltransferase, how would -- how would you believe that to be obvious in something like this when it doesn't necessarily explicitly set forth that word?

A. There is, within these manuscripts, approaches and -- and discussion about the impact of sugars on antibody structure and function. So one who is skilled in the art could easily put together the fact that as this paper is discussing the importance of sugars and the like and some of these other papers, that you would start building a repertoire of information that support the obvious conclusion that if I knock out and – and get rid of fucose on an antibody, I will improve ADCC function. So again, I think this is a conglomerate of all of the pieces of these papers put together, despite the fact that these particular papers don't use the words.

C.   **Testimony Regarding *Umaña* (Ex. 1004):** Ex. 1037 at 194:20-196:8

Q. Whether or not the series of specific words that Mr. Platt asked you about, whether or not those are present explicitly in [*Umaña*], does that affect your obviousness analysis?

A. It does not. In fact, in this one, they say things like there are certain generalities that can be made about the importance of sugars, and so this alerts and informs one skilled in the art that these are important

components that can be modified to improve ADCC activity. So it does not effect -- the lack of those terms in this document do not -- does not affect my opinion on obviousness.

**D.** **Testimony Regarding *Malý* (Ex. 1005):** Ex. 1037 at 196:11-197:17

Q. And whether or not any of those exact words that Mr. Platt asked you about, whether or not those are explicitly set forth in [Malý], does that affect your obviousness analysis?

A. It does -- it does not, no.

Q. Why not?

A. Because again, there is sufficient information among many papers about methodologies, about the importance of fucosyltransferase, and specifically alpha-1,6 in other publications that would lead one to understand that the claims that are put forward in the patents were obvious to anyone skilled in the art.

**II.** **TESTIMONY CONCERNING DR. VAN NESS' CREDENTIALS**

Ex. 1037 at 172:6-174:14

*See also* Ex. 1037 at 29:24-30:25, 46:25-49:6, 114:22-121:22, 179:21-181:9

**III.** **PETITIONERS' OBJECTIONS TO THE SCOPE OF QUESTIONING**

Ex. 1037 at 93:14-94:7, 197:18-198:13

*See also* Ex. 1037 at 138:14-21, 155:23-156:2

**IV.** **TESTIMONY CONCERNING CLAIM ELEMENTS**

Ex. 1037 at 58:23-59:17, 122:8-23, 124:19-127:2

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