

FEBRUARY 18, 2020



## Gut check: microbiome patent update

By Matthew Kitces and Mark James FitzGerald, PhD

### ***Genome & Company v. The University of Chicago (PGR2019-00002)***

In our [last issue](#), we discussed the arguments of the parties and the questions of the Board in the January 2020 oral hearing in the Post-Grant Review (PGR) proceedings in which Genome & Company, Inc. is challenging the validity of the University of Chicago's U.S. Patent No. 9,855,302 ("the '302 patent"), which has claims drawn to methods of treating cancer via co-administration of immune checkpoint inhibitors and bacteria of the genus *Bifidobacterium*. This challenge is the first of its kind for an issued U.S. patent in the microbiome space. As such, it provides a first look at the arguments that may be raised when patent owners ultimately act to enforce their rights against competitors in infringement litigation, and how those arguments might be received.

The petitioner, Genome & Company challenged the validity of the patent's claims on two primary grounds: a) that the disclosure was not sufficient to support the breadth of the claims, and b) that the claimed invention is obvious in view of the teachings of the prior art.

In the previous issue, we discussed the arguments of the parties on both sides and questions from the Board regarding enablement, i.e., whether or not the claims are supported by a disclosure that enables one of skill in the art to practice the full scope of the claimed invention without undue experimentation.

In this issue, we discuss the arguments of the parties and questions posed by the Board in regard to the alleged obviousness of the claimed invention.

For reference, the only independent claim of the '302 patent is copied below:

- 1. A method of treating cancer in a human subject comprising co-administering to the subject an immune checkpoint inhibitor and a bacterial formulation comprising bacteria of the genus *Bifidobacterium*.

### **Quick summary**

At the January 15, 2020, Post Grant Review oral hearing for *Genome & Company v. The University of Chicago* (PGR2019-00002), both parties argued about the validity of the U.S. Patent No. 9,855,302 before Judges Mitchell, Snedden, and Schneider. Despite strong arguments from both parties, the

hearing seemed to end up benefiting Petitioner's arguments of non-enablement and obviousness regarding all claims of the '302 Patent. A ruling will be issued by April 15, 2020.

### **Pre-hearing background re: obviousness**

In the original petition for Post Grant Review and throughout the written proceedings prior to the oral hearing, Petitioner provided several prior art references that were not examined by the USPTO, which they argue show that checkpoint inhibitors on their own and some species of *Bifidobacterium* on their own are each known to have effects against cancer. Petitioner thus argues that it would have been obvious for a Person of Ordinary Skill in The Art (POSITA) to combine the two known treatments for cancer as a technique for treating cancer.

The Patent Owner argues against the validity of the Petitioner's expert testimony and argues that the prior art relied upon by the Petitioner is being mischaracterized and fails to provide a reasonable expectation of success for the proposed combination.

### **Hearing overview**

On January 15, 2020, the Patent Trial and Appeal Board heard arguments for this case. Lead Judge Susan Mitchell presided over the hearing, along with Administrative Patent Judge Sheridan Snedden and Administrative Patent Judge John Schneider.

Overall, representatives for Petitioner and Patent Owner both seemed well prepared and persuasive. The judges asked good, probative questions of both parties, although there were a good deal more during the Patent Owner's oral argument.

### **Recap of arguments at hearing: obviousness**

Petitioner spent the bulk of its oral argument going through its various obviousness arguments against the '302 patent's claims. The obviousness case primarily centers on combination of the Korman reference, which is used to show teachings of administering checkpoint inhibitors to treat cancer, and the Singh reference, which is used to show teachings of administering *Bifidobacterium* to treat cancer. Since the conclusions of the Singh reference were challenged by the Patent Owner, Petitioner spent time going through several other articles that cite to the Singh reference for the purpose of treating cancer using *Bifidobacterium*. Petitioner acknowledged that the Singh reference did not definitely state a single mechanism of action for its results, but it did outline how administration of the *Bifidobacterium* suggested strong antitumor activity, which was supported by the other references. The key ideas that were repeated several times throughout the arguments included that Singh was a peer-reviewed paper of other peer-reviewed papers, and that the other peer-reviewed papers supported Singh for its teachings of using *Bifidobacterium* to treat cancer.

During Patent Owner's arguments regarding obviousness, Judge Schneider quickly asked about the Patent Owner's response to Singh being cited by so many other papers. Patent Owner responded with an argument that merely citing a paper does not indicate support of a particular position on that paper, but rather acts as an impetus for the reader to go to the cited article to read and verify whether or not the position is valid. Judge Schneider did not seem to agree with this position. The Patent Owner argued that Singh did not explicitly teach administering *Bifidobacterium* to treat cancer because its results were based on a bad cancer model and because it was unable to show causation (i.e., the mechanism of action of the cancer treatment). The Patent Owner argued that without Singh being able to show causation, the reference cannot be used for obviousness purposes.

For other references, the Patent Owner argued that discussion of how certain mechanisms “might” or “may” occur was merely speculation, and not a conclusion, and thus not suitable for an obviousness rejection. Further, Patent Owner argued that several references had bad data or produced irreproducible results. Judge Schneider pressed the Patent Owner about whether all of these suggestions that *Bifidobacterium* could be used to treat cancer would lead one to move forward in the art along those lines. The Patent Owner said yes, but argued that an invitation to experiment is not the same as a reasonable expectation of success. Judge Schneider appeared skeptical.

Petitioner also pointed to a separate paper written by the inventors of the ‘302 patent, which seemed to explicitly support the assertion that *Bifidobacteria* has an immunostimulatory effect. Judge Mitchell asked whether Petitioners introduced this statement as evidence of an admission. Petitioner responded that they had not, but said “you could.” It seemed that Judge Mitchell may have felt this paper by the inventors was important.

The Patent Owner argued that several of the papers relied upon by Petitioner were faulty due to either statistical inconclusiveness or issues with the probative value of the tests themselves. While technically interesting, these arguments did not appear to carry much weight.

Just based on the questions asked and tenor of the conversations, it seemed to this observer that Judge Schneider was leaning toward the Petitioner, Judge Snedden was on the fence but leaning slightly toward the Patent Owner, and Judge Mitchell was slightly leaning toward the Petitioner. While both sides did seem to have valid positions, this observer feels this hearing benefitted the Petitioner more than the Patent Owner.

A ruling must be issued within one year of the institution of the Review proceedings, meaning we will hear from the Board by April 15, 2020. We will keep you posted!!

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

- Matthew Kitces at [mkitces@nixonpeabody.com](mailto:mkitces@nixonpeabody.com) or 202-585-8026
- Mark James FitzGerald, PhD at [mfitzgerald@nixonpeabody.com](mailto:mfitzgerald@nixonpeabody.com) or 617-345-1058
- David S. Resnick at [dresnick@nixonpeabody.com](mailto:dresnick@nixonpeabody.com) or 617-345-6057