UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Celltrion, Inc. Petitioner,

v.

Genentech, Inc. Patent Owner

Patent No. 6,407,213

Inter Partes Review No. IPR2017-01373

PETITIONER CELLTRION'S OPPOSITION TO PATENT OWNER'S MOTION TO STRIKE

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I. Introduction

Patent Owner is seeking to strike Exhibit 1193 and the arguments and testimony that rely on this Exhibit¹ from the record because they show that Patent Owner has mischaracterized the prior art relevant to this proceeding. Patent Owner incorrectly proclaims in its Response that the subject matter claimed in the '213 patent is different from the prior art because it includes a human consensus sequence as a framework for humanized antibodies. This is simply incorrect. As noted throughout Petitioner's papers, the prior art shows that others had successfully used a human consensus sequence to humanize antibodies. Petitioner's entry of Exhibit 1193 into the record as additional evidence to show that Patent Owner's position is wrong is not only proper, but is precisely the purpose of reply papers. Patent Owner should not be permitted to mischaracterize the prior art and then seek to strike any evidence that does not fit its narrative.

Exhibit 1193 is a 1989 publication by Dr. Jefferson Foote, a scientist working in the field of antibody humanization prior to, and concurrently with, the alleged development of the subject matter of the challenged claims of the

¹ Patent Owner seeks to strike Exhibit 1193, the first full paragraphs on pages 15 and 21 of Petitioner's Reply, paragraph 30 of Exhibit 1143, and Exhibit 1138 at 176:25-178:23.

'213 patent. Exhibit 1193 describes Dr. Foote's development of a humanized antilysozyme antibody in which he created a light chain framework using a human consensus sequence. (Ex. 1193, 106.) As explained in Dr. Riechmann's deposition, in his humanization of the CAMPATH antibody, Dr. Riechmann used the same light chain framework that Dr. Foote created and used in the antilysozyme antibody. (Ex. 2039 at 118:1-18 .) Dr. Wilson, Patent Owner's expert, also testified at deposition about Exhibit 1193—testimony that Patent Owner now seeks to strike—in response to questions regarding his opinions about whether consensus sequences were known in the prior art. (Ex. 1138 at 176:15-178:23.)

As discussed in more detail below, Petitioner's Reply properly relies on Exhibit 1193 for two arguments in response to Patent Owner's positions: (1) contrary to Patent Owner's argument that the '213 patent's consensus sequence differentiated the claimed antibodies from prior art humanized antibodies, a person of ordinary skill in the art would have known that others in the field had successfully used a human consensus sequence in a humanized antibody, and (2) it would not have been unexpected for a person of ordinary skill in the art to use the same consensus sequence to humanize multiple antibodies.

II. Petitioner's Reply Arguments are Proper

"There is no blanket prohibition against the introduction of new evidence during an inter partes review proceeding." *Anacor Pharm., Inc. v. Iancu*, 889 F.3d

IPR2017-01373 Petitioner's Opposition to Motion to Strike

1372, 1380 (Fed. Cir. 2018). New evidence is "perfectly permissible" if the opposing party has notice of the evidence and an opportunity to respond. *Id*. But the Federal Circuit recently confirmed that this is not the only permissible use of new evidence after the petition:

In addition, the petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner, or if it is used 'to document the knowledge that a skilled artisan would bring to bear in reading the prior art identified as producing obviousness.'

Id. at 1380-81(citing Genzyme Therapeutic Prod. Ltd. P'ship v. Biomarin Pharm.

Inc., 825 F.3d 1360, 1369 (Fed. Cir. 2016)).

In *Anacor*, the petitioner used one of the supposedly untimely references during the deposition of the patent owner's expert, in response to statements made by the expert witness. *Anacor*, 889 F.3d at 1381. The Federal Circuit held that introducing a responsive reference into the record in this manner did not deny Anacor its procedural rights, because the Board did not materially deviate from the obviousness theory set forth in the petition and Anacor had ample notice of the reference. *Id.* at 1382. As in *Anacor*, the Foote reference was used in at the deposition of Dr. Ian Wilson, Patent Owner's expert, in direct response to testimony that the use of consensus sequences was not known in the prior art. (Ex. 1138 at 176:15-178:23.) Patent Owner now seeks to strike this testimony of its own expert.

Here, Petitioner's citation of Exhibit 1193 in its reply was proper not only because Patent Owner had notice of the subject matter of the disputed material, but also because it directly contradicts Patent Owner's arguments in its Response.

A. <u>Petitioner's Reply Does Not Alter the Instituted Grounds of Invalidity</u>

Patent Owner's arguments that Petitioner's invalidity arguments are "new" or "evolving" are wrong. As stated in both the Petition and Reply, the challenged claims of the '213 patent are invalid as obvious in light of the prior art identified in the instituted grounds. (Paper 2 (Petition) at 26-57; Paper 53 (Reply) at 4-18.) As Patent Owner acknowledges, a subset of the challenged claims require the use of a "consensus" sequence, as defined in the '213 patent. (Paper 59 (Motion to Strike) at 2.) The Petition explains that the prior art disclosed, or would have taught a person of ordinary skill in the art to make, a consensus sequence for use in a humanized antibody. Specifically, as of the priority date, Queen 1990 (Ex. 1050) or Queen 1989 (Ex. 1034) in combination with Kabat 1987 (Ex. 1052) and/or the PDB database would have taught a person of ordinary skill in the art to use a human consensus sequence or make substitutions to move towards a more human sequence.

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