Paper No. ____
Filed: May 10, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED.,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Case IPR2016-00712
Patent No. 8,927,592

PETITIONER MYLAN'S BRIEF ADDRESSING THE EFFECT OF CAFC DECISION ON PATENT OWNER'S MOTION TO AMEND PURSUANT TO PAPER NO. 108

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I. Introduction

In its February 5, 2019 opinion, the Federal Circuit vacated the Board's denial of Patent Owner's motion to amend in light of *Aqua Products* and the Board's construction of the proposed claims, instructing the Board on remand to treat the preamble as an additional limitation of proposed claim 31. However, the Federal Circuit left undisturbed the Board's conclusion that claims 1-5 and 7-30 of the '592 patent (the "original claims") are all unpatentable. As a result, the underlying issues the Board decided in reaching its unpatentability conclusion are now settled and preclusive. Further, the evidentiary record—identical to that which was before the Board when it entered its final written decision ("FWD," Paper 99)—establishes that the proposed claims are unpatentable even in light of *Aqua Products* and applying the Federal Circuit's claim construction.

II. Decided Issues Supporting the Board's Original Unpatentability Determination Are Now Preclusive and Support Denial of the Motion.

Issues decided in a trial proceeding and thus "within the scope of the judgment appealed from" are only open to reconsideration on remand if "explicitly reserved or remanded by the [appellate] court," all other issues "are foreclosed from further consideration." *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed. Cir. 1999); *see also Tronzo v. Biomet, Inc.*, 236 F.3d 1342, 1349 (Fed. Cir. 2001) ("Because Biomet failed to [appeal punitive damages], clearly implicated in the initial decision of the district court, our mandate in *Tronzo I* acted

to prevent Biomet from raising this issue on remand or in any future proceedings in this litigation."). This doctrine is part of the mandate rule. As a result of this doctrine, the Board's conclusion that claims 1-5 and 7-30 are unpatentable and every issue the Board decided in reaching that conclusion are final and preclusive.

In deciding that the original claims were unpatentable, the Board decided issues of fact and law that support a finding that the proposed claims are likewise unpatentable. In light of the Federal Circuit's mandate, the Board should consider them to be conclusively settled. The settled issues of fact and law include the following:

A. Settled Issues 1-4: The Example 1 Protocol Is In the Prior Art

1. As of the priority date[1], the prior art references Winquist and the TROPIC Listing together disclosed the same treatment protocol being used in the same clinical trial for treating the same patient population as that described in Example 1 of the '592 patent. FWD, 16-19, 42.

2. In 2008, a POSA would have known that Winquist and the TROPIC Listing disclosed the same treatment regimen being used in the same ongoing phase III trial—the TROPIC Study—and would have read them together. FWD, 23-24.

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[1] The priority date asserted by Patent Owner for the proposed claims is January 11, 2010. Paper 22 at 2.

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