

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Taro Pharmaceuticals U.S.A., Inc.
Petitioner,

v.

Apotex Technologies, Inc.
Patent Owner

Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

Inter Partes Review No. IPR2017-01446

PETITIONER'S REPLY

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I. INTRODUCTION

Cardiac health was of central importance to doctors treating blood-transfusion-dependent patients. Cardiac disease was the main cause of death for these patients prior to the introduction of chelation therapy; it was a concern when patients were treated with the original iron chelator, deferoxamine, and continued to be a concern with deferiprone. Doctors understood that cardiac iron was the culprit, and the prior art studied this issue. For example, the '328 patent cites Dr. Olivieri's early work, which recognized that "deferiprone induced reduction of iron in the liver and the heart." (Ex. 1001, 7:47–54.) Doctors, including Dr. Olivieri and Dr. Hoffbrand, administered deferiprone to blood-transfusion-dependent patients in order to reduce iron overload, which they understood would reduce their cardiac iron, which would in turn improve heart function and treat cardiac disease.

Patent Owner ("PO") defends its patent by claiming that the named inventors came up with a "new use" for the admittedly old drug deferiprone. But the prior art not only taught the administration of 75 mg/kg/day deferiprone to blood-transfusion-dependent patients, it also taught administering that amount of deferiprone to such patients (i) with cardiac iron overload and (ii) with iron-induced cardiac disease, (iii) with positive results. "Newly discovered results of known processes directed to the same purpose are not patentable, because such

results are inherent.” *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368,1376 (Fed. Cir. 2001). Because the claimed methods of treatment are directed to the same patient populations with the same drug in the same amount as in the prior art, the Board should find that the claims are unpatentable and cancel the challenged claims.

II. CLAIM CONSTRUCTION

All of the claims are directed to treating blood-transfusion-dependent patients by administering a therapeutically effective amount of deferiprone. The preambles identify the method and the type of patient; the independent claims (and claim 19) each recite an intended result:

Claim	Method of	Type of Patient	Intended Result
1	treating iron induced cardiac disease	experiencing an iron overload condition of the heart	to stabilize/reduce iron accumulation in the heart
2	treating iron loading in the heart	experiencing an iron overload condition of the heart	to reduce further iron overload in the heart
4	stabilizing iron induced heart disease	having iron overload	to treat the iron burden in the heart
5	reducing the iron burden in the heart	having iron overload	to reduce the iron burden of the heart

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