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Paper 10
Entered: April 14, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EVERGREEN THERAGNOSTICS, INC.,
Petitioner,

v.

ADVANCED ACCELERATOR APPLICATIONS SA,
Patent Owner.

PGR2021-00003
Patent 10,596,276 B2

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 325(d)

I. INTRODUCTION

Evergreen Theragnostics, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting a post-grant review of claims 1–24 of U.S. Patent No. 10,596,276 B2 (Ex. 1001, "the '276 patent"). Advanced Accelerator Applications SA ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). With our authorization, Petitioner filed a Reply (Paper 7, "Reply"), and Patent Owner filed a Sur-Reply (Paper 9, "PO Sur-Reply").

Under 35 U.S.C. § 324(a), a post-grant review may not be instituted "unless . . . the information presented in the petition . . . , if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable." Upon considering the arguments and evidence, we exercise our discretion to deny institution of post-grant review under 35 U.S.C. § 325(d).

II. BACKGROUND

A. Real Parties-in-Interest

Petitioner identifies Evergreen Theragnostics, Inc. as the real party-in-interest. Pet. 86. Patent Owner states that "Advanced Accelerator Applications SA is the assignee of [the '276 patent]" and that "Novartis AG and other Novartis subsidiaries may also have an interest." Paper 4, 2.

B. Related Proceedings

The parties indicate that Petitioner has filed two petitions for post-grant review for a related patent in the following proceedings: PGR2021-00001 (U.S. Patent No. 10,586,278) ("the '278 patent"); and PGR2021-00002 (the '278 patent). *See* Pet. 86–87; Paper 4, 2.

The parties also identify the following pending applications and patents that claim priority to the same patent application as the '276 patent:

Application No. 16/140,962; Application No. 16/045,484; Application No. 16/175,239, now the '278 patent; and Application No. 16/827,606. Pet. 86; Paper 4, 2.

C. The '276 Patent

The '276 patent relates to "radionuclide complex solutions of high concentration and of high chemical stability, [which] allows their use as drug product for diagnostic and/or therapeutic purposes." Ex. 1001, code (57).

The targeted drug delivery concept has been used in radiomedicine to deliver radionuclides selectively to target cells for diagnostic or therapeutic purposes. Ex. 1001, 1:35–37. In a radiomedicine application, a target cell receptor binding moiety is linked to a chelating agent that is able to form a strong complex with the metal ions of a radionuclide. *Id.* at 1:38–41. When the radiopharmaceutical drug is delivered, the decay of the radionuclide affects only the target cells. *Id.* at 1:41–44.

The '276 patent explains that

> [o]ne technical problem with those radiopharmaceutical drug products is that the decay of the radionuclide occurs constantly, e.g. also during the manufacturing and during storage of the drug product, and the released high energy emissions induce the cleavage of the chemical bonds of the molecules which form part of the drug product. This is often referred to as radiolysis or radiolytic degradation. The radiolytic degradation of the receptor binding moiety of the drug may lead to a decrease in its efficacy to act as a diagnostic and/or therapeutic.

Ex. 1001, 1:45–54.

The '276 patent states that, before its invention, the usage of radiopharmaceutical drugs was limited due to their poor stability and the

lack of any significant shelf-life. Ex. 1001, 1:55–2:8. The '276 patent further states that, although the prior art taught various ways to reduce radiolysis and improve stability of radiopharmaceutical drugs, each of those strategies has its own drawbacks. *Id.* at 2:9–39.

According to the '276 patent,

> [i]t remains therefore a challenge to design a ready-to-use radiopharmaceutical drug product which can be produced at commercial scale and delivered as a sufficiently stable and sterile solution in a high concentration which leads to a convenient small infusion volume for patients and which has a composition of high physiological tolerability (e.g. a composition which does not contain ethanol).

Ex. 1001, 2:40–47.

The '276 patent states that its inventors "found a way to design and produce a highly concentrated radionuclide complex solution which is chemically and radiochemically very stable even if stored at ambient or short term elevated temperatures so that it can be produced on commercial scale and supplied as ready-to-use radiopharmaceutical product." Ex. 1001, 2:50–55. The '276 patent also states that the use of two stabilizers — one during complex formation and another after complex formation — was found to be particularly advantageous for shelf-life. *Id.* at 3:67–4:6.

D. Illustrative Claim

Petitioner challenges claims 1–24 of the '276 patent. Claim 1, which is the only independent claim of the '276 patent, is illustrative of the challenged claims, and is reproduced below:

> 1. A process for manufacturing a pharmaceutical aqueous solution, comprising:
>
> providing a solution comprising a complex of the radionuclide ^{177}Lu (Lutetium-177) and a somatostatin receptor binding

peptide linked to the chelating agent DOTA; a first stabilizer against radiolytic degradation, and optionally a second stabilizer against radiolytic degradation different from the first stabilizer; and diluting the solution comprising the complex with an aqueous dilution solution comprising at least one stabilizer against radiolytic degradation to obtain the pharmaceutical aqueous solution;

wherein if the solution comprising the complex comprises only the first stabilizer as an stabilizer against radiolytic degradation and not the second stabilizer, then the aqueous dilution solution comprises at least one stabilizer against radiolytic degradation that is different from the first stabilizer, and in the obtained pharmaceutical aqueous solution, the radionuclide ^{177}Lu is present in a concentration that it provides a volumetric radioactivity of from 250 to 500 MBq/mL and the stabilizers are present in a total concentration of from 1.0 to 5.0 mg/mL, and ethanol is present in a concentration of less than 1%.

Ex. 1001, 37:18–41. Challenged claims 2–24 depend from claim 1, either directly or indirectly.

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