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Paper No. 9
Date: January 16, 2024

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MURRAY & POOLE ENTERPRISES LTD.,
Petitioner,

v.

INSTITUT DE CARDIOLOGIE DE MONTREAL,
Patent Owner.

IPR2023-01064
Patent 11,400,063 B2

Before ULRIKE W. JENKS, SHERIDAN K. SNEDDEN, and ZHENYU YANG, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*.

DECISION

Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

On June 16, 2023, Murray & Poole Enterprises Ltd. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–50 ("the challenged claims") of U.S. Patent No. 11,400,063 B2 (Ex. 1001, "the '063 patent"). Paper 1 ("Pet."). On October 18, 2023, Institut de Cardiologie de Montréal ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply to the Preliminary Response (Paper 7, "Reply") on December 6, 2023 and Patent Owner filed a Sur-reply (Paper 8, "Sur-reply") to Petitioner's Reply on December 13, 2023.

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the arguments and evidence presented in the parties' briefs, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–50 of the '063 patent.

A. Real Parties in Interest

Petitioner identifies Murray & Poole Enterprises Ltd., AGEPHA Pharma FZ LLC, AGEPHA Pharma USA, LLC, and UPTTON Limited, as real parties-in-interest. Pet. 72. Patent Owner identifies Institut de Cardiologie de Montréal ("MHI") and Pharmascience Inc. as real parties-in-interest. Paper 5, 2.

B. Related Matters

The parties state that they are not aware of any related matters. Pet. 72; Paper 5, 2.

C. The '063 Patent (Ex. 1001)

The '063 patent is titled "Early Administration of Low-dose Colchicine After Myocardial Infarctions." Ex. 1001, code (54). The '063 patent issued from Application No. 17/097,285 ("the '285 application"), filed November 13, 2020. *Id.* at codes (21), (22). The '063 patent claims priority to Provisional Application No. 63/093,988 ("the '988 provisional application"), filed on October 20, 2020 and Provisional Application No. 62/935,865 ("the '865 provisional application"), filed on November 15, 2019. *Id.* at code (60). The '063 patent relates to "a method of treating a patient after having a myocardial infarction (MI), the method including initiating the administration of colchicine at a daily low dose to the patient within about 3 days of the MI." *Id.* at code (57).

According to the '063 patent, "[i]nflammation appears to play an important role in atherosclerosis . . . and coronary artery disease." *Id.* at 1:9–11. The '063 patent states that "[b]ecause acute coronary syndromes are associated with higher risks of recurrent events and exacerbated inflammation a need exists in the art for new treatment regimens." *Id.* at 1:60–62. The '063 patent explains that "[c]olchicine is an inexpensive, orally administered, potent anti-inflammatory medication" that is indicated for the treatment of gout, familial Mediterranean fever, and pericarditis. *Id.* at 1:28–30, 1:43–47. However, the cardiovascular effects of colchicine have also been evaluated in trials in which participants were administered 0.5 mg

of colchicine once daily. *Id.* at 1:52–2:28. In one such example, trial participants with stable coronary disease were treated with colchicine at a dose of 0.5 mg once daily and had fewer cardiovascular events than those not receiving colchicine. *Id.*

In a second example, patients who had recently suffered an MI were treated with colchicine at a dose of 0.5 mg once daily and had a statistically significant lower risk of ischemic cardiovascular events than placebo; had significantly reduced rates of death from cardiovascular causes, resuscitated cardiac arrest, myocardial infarction, stroke, and urgent hospitalization for angina leading to coronary revascularization compared to placebo; and had reduced morbidity relative to placebo. *Id.* In that study, "colchicine reduced the risk of ischemic cardiovascular ("CV") events by 23% in the post-MI setting. *Id.* at 2:41–43.

In a third example, the time to treatment initiation ("TTI") was evaluated and patients who had recently suffered an MI were treated with colchicine at a dose of 0.5 mg once daily starting on days post-MI from 0–3, 4–7, and 8–30. In that TTI study, initiation of colchicine treatment in days from 0–3 post-MI reduced the risk of the composite primary endpoint by 48%. *Id.* at 2:43–47. The composite primary endpoint consisted of "a composite of CV death, resuscitated cardiac arrest, MI, stroke, or urgent hospitalization for angina requiring coronary revascularization." *Id.* at 8:5–8. The invention claimed in the '063 patent is based on the treatments used in the TTI study.

1. Overview of Provisional Patent Application No. 63/093,988 (Ex. 1003)

The '988 provisional application describes patients with coronary artery disease (CAD) as being at "an increased risk of cardiovascular events including death, myocardial infarction (MI), stroke, and cardiac arrest; a risk that is magnified for each subsequent cardiovascular event." Ex. 1003, 2:3–4 (footnote omitted). "[I]nflammation has emerged as an important therapeutic target in patients with atherosclerosis." *Id.* at 2:12–13 (footnote omitted). The '988 provisional application is directed to a contemporary meta-analysis evaluating randomized control patient trials comparing colchicine to placebo (or no colchicine) for secondary cardiovascular prevention. *Id.* at 7:21–22. "Colchicine has an established safety profile from its centuries of use to treat gout." *Id.* at 10:5.

> The colchicine trials show improvement in patients with CAD.
>
> In patients with CAD, the addition of colchicine to standard medical therapy was associated with a statistically significant reduction in the primary composite endpoint of cardiovascular mortality, MI, ischemic stroke, and urgent coronary revascularization, compared to patients on placebo or no colchicine.

Ex. 1003, 6:8–12. "[A]ll trials showed a decrease in urgent coronary revascularizations among patients randomized to colchicine, [but] only COLCOT[1] detected a reduction in ischemic strokes." *Id.* 8:11–13.

> The '988 provisional application explains that
>
> [t]he anti-inflammatory properties of colchicine work through various mechanisms to inhibit the pathogenesis of CAD, and subsequently reduce the incidence of ischemic cardiovascular

[1] Colchicine Cardiovascular Outcomes Trial (COLCOT) (Ex. 1006).

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