Court File No. A-27-24

FEDERAL COURT OF APPEAL

BETWEEN:

BIOGEN INC., BIOGEN MA INC. and BIOGEN CANADA INC.

Appellants

-and-

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CANADA INC.

Respondents

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellants. The relief claimed by the appellant appears below.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellant. The appellant requests that this appeal be heard at (*place where Federal Court of Appeal (or Federal Court) ordinarily sits*).

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341A prescribed by the *Federal Courts Rules* and serve it on the appellant's solicitor or, if the appellant is self-represented, on the appellant, WITHIN 10 DAYS after being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341B prescribed by the *Federal Courts Rules* instead of serving and filing a notice of appearance.

Copies of the *Federal Courts Rules*, information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

Date: January 22, 2024

Issued by: Alexie Quesnel

Registry Officer

Address of local office:

90 Sparks Street, Ottawa, K1A 0H9

TO: **Riches, McKenzie & Herbert LLP**
Suite 1800, 2 Bloor Street East
Toronto ON M4W 3J5

Michael Adams (michael.adams@patents-toronto.com)
Michael Schwartz (mike.schwartz@patents-toronto.com)

Tel: 416-961-5000
Fax: 416-961-5081

Solicitors of the Respondents

AND TO: **Osler, Hoskin & Harcourt LLP**
100 King Street West
1 First Canadian Place
Suite 6200, P.O. Box 50
Toronto ON M5X 1B8

J. Bradley White (bwhite@osler.com)
Dan Hnatchuk (dhnatchuk@osler.com)
Matt Diskin (mdiskin@osler.com)

Tel: 416-362-2111
Fax: 416-862-6666

Solicitors for Samsung Bioepis Co., Ltd.

APPEAL

THE APPELLANTS APPEAL to the Federal Court of Appeal from the Judgment of Madam Justice Pallotta (the "Application Judge") dated January 12, 2024 in Docket No. T-1664-22 (the "Judgment"). The Judgment allowed (in part) the Application of Novartis AG and Novartis Pharmaceuticals Canada Inc. (collectively, "Novartis", the Respondents herein) and ordered:

(a) A permanent injunction as against Biogen Inc., Biogen MA Inc., Biogen Canada Inc., (collectively, the "Appellants" or "Biogen") and Samsung Bioepis Co., Ltd. ("Samsung") prohibiting them from using the BYOOVIZ trademark in association with pharmaceutical preparations for use in ophthalmology or pharmaceutical preparations for prevention and treatment of ocular disorders and diseases, or any other trademark or trade name that is confusingly similar to the registered BEOVU trademark;

(b) That Biogen, Samsung and their licensees deliver-up to Novartis, or destroy under oath, or alter, any goods, packaging, labels, and advertising materials in their possession, power or control that are or would be contrary to the injunction above;

(c) Damages in favour of Novartis in the amount of $20,000; and

(d) Costs in an amount that remains to be determined.

THE APPELLANTS ASK that this Court to:

(a) Grant an urgent interim stay of the Judgment retroactive to January 12, 2024, pending the disposition of a motion for stay of the Judgment.

(b) Grant an interlocutory stay of the Judgment pending the later of a final determination of this appeal or alternatively, one year from the date of a final disposition of all appeals.

(a) Allow this appeal and set aside the Judgment;

(b) Grant the Appellants costs in this Court and the Court below; and

(c) Order such further and other relief as this Honourable Court may find just.

THE GROUNDS OF APPEAL are as follows:

A. Introduction

1. The BYOOVIZ biosimilar ophthalmologic drug is approved for sale in Canada using the brand name and trademark BYOOVIZ. Novartis claims that the Appellants' use of the BYOOVIZ trademark violates Novartis' rights in the registered trademark BEOVU (TMA1,072,372), contrary to subsection 7(b) and sections 19, 20 and 22 of the *Trademarks Act,* R.S.C. 1985, c. T-13, ("Trademarks Act").

2. The Application Judge held that Biogen and Samsung's use of the BYOOVIZ trademark infringed Novartis' rights in the BEOVU trademark, contrary to sections 7(b) and 20 of the *Trademarks Act*.

3. This appeal concerns the proper test for trademark confusion for physician-administered specialized drug products. The central issues are:

    (a) Who is the relevant consumer for drugs that are prescribed and administered by ophthalmologists;

    (b) Application of the "first impression" test when the relevant consumers are highly sophisticated professionals;

    (c) Whether saying a drug name to patients is "use" of a trademark within the meaning of sections 2 and 4 of the *Trademarks Act*; and

    (d) Whether "use" of a trademark within the meaning of sections 2 and 4 of the *Trademarks Act* is required for a consumer to "encounter" a trademark.

B. The Application Judge Erred in Finding Patients are Relevant Consumers

4. The Application Judge made errors of law, or in the alternative, committed a palpable and overriding error of mixed fact and law, by finding that patients are a relevant consumer to be considered in the test for confusion by:

    (a) concluding that the patient is a relevant consumer on the basis that the patient can exercise at least the choice to refuse administration of the treatment they will receive;

(b) discounting the relevance of trademark "use" (within the meaning of sections 2 and 4 of the *Trademarks Act*) in determining the relevant consumers;

(c) interpreting the Supreme Court of Canada's use of the term "encounter" in describing the first impression test to eliminate the requirement of "use" (within the meaning of sections 2 and 4 of the *Trademarks Act*) for a consumer to encounter a trademark;

(d) concluding that the timing of trademark "use" (within the meaning of sections 2 and 4 of the *Trademarks Act*) and the timing of a consumer's confusion upon encountering a trademark may be asynchronous; and

(e) finding that verbal communication of the BYOOVIZ drug name constitutes use of the BYOOVIZ word mark.

C. Application Judge Erred in Applying the First Impression Test

5. The Application Judge made errors of law, or in the alternative, committed a palpable and overriding error of mixed fact and law, in applying the "first impression" test. With respect to ophthalmologists and pharmacists, the Application Judge erred by:

(a) failing to consider the "first impression" in the circumstances in which the ophthalmologists and pharmacists would encounter the BYOOVIZ trademark;

(b) ignoring the familiarity that doctors and pharmacists have with the providers of drugs and that they are closer in the chain to manufacturers in determining the likelihood of confusion; and

(c) failing to account for the level of sophistication of ophthalmologists and pharmacists in the assessment of the first impression test, despite finding that ophthalmologists and pharmacists are likely to have an elevated level of attention.

6. With respect to patients, the Application Judge's errors in applying the first impression test are:

(a) failing to consider the "first impression" in the circumstances in which the patient would encounter the BYOOVIZ trademark;

(b) concluding that the patients first encounter the BYOOVIZ trademark when the ophthalmologists verbally communicate the BYOOVIZ drug name to the patient;

(c) ignoring the role of ophthalmologists in reducing the likelihood of patient confusion; and

(d) failing to incorporate the impact of informed and less-impulsive patients when encountering the trademark in the test of first impression in the confusion analysis, despite finding that patients are likely to have an elevated level of attention.

D. Application Judge Erred in Applying the Test for Confusion

7. The Application Judge made errors of law, or in the alternative, committed a palpable and overriding error of mixed fact and law, in concluding that the BYOOVIZ trademark is confusing with the BEOVU trademark:

(a) with respect to the paragraph 6(5)(a) factor by:

(i) disregarding the inherent distinctiveness of the BYOOVIZ trademark as a coined term; and

(ii) concluding that the distinctiveness of the BEOVU trademark favours Novartis;

(b) with respect to the paragraph 6(5)(c) and 6(5)(d) factors by:

(i) finding that the nature of the goods and trade for the BEOVU and BYOOVIZ drugs are essentially identical;

(ii) ignoring the evidence that ophthalmologists consider and deal with the BEOVU and BYOOVIZ drugs in different ways as a matter of standard practice;

(iii) failing to provide sufficient or any weight to the unique and highly specialized nature of the goods and trade for the BEOVU and BYOOVIZ drugs in the confusion analysis; and

(iv) concluding that the paragraph 6(5)(c) and 6(5)(d) factors favour Novartis;

(c) with respect to the paragraph 6(5)(e) factor by:

(i) elevating the importance of sound in the resemblance analysis on the basis that the "spoken trademark" is an important way consumers encounter the trademarks in issue, and the predominant way patient consumers encounter the trademarks in issue;

(ii) failing to give sufficient weight to the evidence demonstrating that doctors and pharmacists rely heavily on written records when engaging with drug names on prescriptions and in record keeping in the normal course of trade, and that the goods in issue would rarely be ordered verbally;

(iii) failing to properly account for the high level of sophistication of ophthalmologists and pharmacists in assessing degree of resemblance; and

(iv) concluding that the degree of resemblance factor favours Novartis;

(d) by disregarding relevant surrounding circumstances in the confusion analysis, including that:

(i) ophthalmologists only use a small number of anti-VEGF (anti-vascular endothelial growth factor) drugs, which includes the BEOVU and BYOOVIZ drugs;

(ii) the high level of training, experience and familiarity of ophthalmologists with respect to anti-VEGF drugs, including the BEOVU and BYOOVIZ drugs;

(iii) the rigorous checks and balances in the decision-making process relating to the purchase, handling and administration of the BEOVU and BYOOVIZ drugs; and

(iv) the BYOOVIZ drug has been sold concurrently with the BEOVU drug in the United States since at least as early as July 2022, with no evidence of actual confusion or administration of the wrong drug to patients;

(e) by concluding that the surrounding circumstances favour Novartis because there is no state of the register/state of the marketplace evidence to suggest that the

presence of other "close" third party trademarks should reduce the ambit of protection afforded to the BEOVU trademark;

(f) by the formulaic application of the "casual consumer somewhat in a hurry" test without accounting for the fact that ophthalmologists and pharmacists are highly sophisticated consumers, applying their medical training in a professional context, as acknowledged by the Application Judge;

(g) in finding that Novartis met its burden of establishing a likelihood of confusion for all relevant consumers; and

(h) in concluding that the Appellants' use of the BYOOVIZ trademark infringed Novartis' rights in its BEOVU trademark, contrary to section 20 of the *Trademarks Act*.

E. Application Judge Erred Regarding Expert Evidence

8. The Application Judge erred in ignoring the expert evidence of Dr. Villeneuve, including by finding that Dr. Villeneuve does not have the relevant expertise to provide the Court with expert evidence about the special knowledge of an ophthalmologist or pharmacist, or how they would perceive the marks at issue, which was central to the Application.

F. Application Judge Erred Regarding the Subsection 7(b) Claim

9. The Application Judge made errors in law, or in the alternative, committed a palpable and overriding error of mixed fact and law, in her application of the legal test for Novartis' claim under section 7(b) of the *Trademarks Act*, including:

(a) by finding that the Appellants deceived the public on the basis of there being a likelihood of confusion between the BYOOVIZ trademark and the BEOVU trademark; and

(b) by finding that Novartis suffered actual or potential damage through the Appellants' actions on the basis that Novartis suffered a loss of control of the BEOVU trademark, despite an acknowledgement that the BEOVU trademark has reduced goodwill, minimal market share and the evidence that demonstrates that further damage to the reputation of the BEOVU trademark would be unlikely.

G. Further Grounds

10. The Appellants relies upon:

    (a) Sections 2, 4, 6(5), 7(b) and 20 of the *Trademarks Act,* R.S.C., 1985, c. T-13;

    (b) Section 27 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended; and

    (c) the *Federal Courts Rules*, SOR/98-106, as amended;

11. Such further and other grounds as counsel may advise and this Honourable Court may permit.

January 22, 2024

MBM Intellectual Property Law LLP
275 Slater Street, 14th Floor
Ottawa ON K1P 5H9

Scott Miller (smiller@mbm.com)
Deborah Meltzer (dmeltzer@mbm.com)
Jonathan Roch (jroch@mbm.com)
Tel: 613-567-0762
Fax: 613-563-7671

Solicitors for the Appellants, Biogen Inc., Biogen MA Inc., and Biogen Canada Inc.