

**Federal Court of Appeal**



**Cour d'appel fédérale**

**Date: 20240213**

**Docket: A-283-23**

**Citation: 2024 FCA 29**

**CORAM: WEBB J.A.  
BOIVIN J.A.  
MONAGHAN J.A.**

**BETWEEN:**

**BAYER INC. and REGENERON PHARMACEUTICALS, INC.**

**Appellants**

**and**

**BGP PHARMA ULC d.b.a. VIATRIS CANADA and  
BIOSIMILAR COLLABORATIONS IRELAND LIMITED**

**Respondents**

Heard at Ottawa, Ontario, on February 13, 2024.  
Judgment delivered from the Bench at Ottawa, Ontario, on February 13, 2024.

**REASONS FOR JUDGMENT OF THE COURT BY:**

**BOIVIN J.A.**

Federal Court of Appeal



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**REASONS FOR JUDGMENT OF THE COURT**  
**(Delivered from the Bench at Ottawa, Ontario, on February 13, 2024).**

**BOIVIN J.A.**

[1] The appellants appeal from the judgment of Furlanetto J. of the Federal Court (the judge) rendered on October 3, 2023 (2023 FC 1325), which dismissed the appellants' application for judicial review of a decision of the Minister of Health (the Minister). The Minister's decision held that the respondent, Biosimilar Collaborations Ireland Limited, should obtain the benefits of section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133

(*Regulations*), in particular, prior service of the Notice of Allegation. The judge found that the Minister's decision should be reviewed under the reasonableness standard and concluded that the decision was reasonable.

[2] When seized of an appeal from an application for judicial review disposed of by the Federal Court, this Court must step into the shoes of the Federal Court and concentrate on the administrative decision in question (*Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at para. 46).

[3] We are all of the view that this appeal cannot succeed.

[4] Firstly, with respect to the standard of review, the judge did not err in refusing to apply the *Society of Composers, Authors and Music Publishers of Canada v. Entertainment Software Association*, 2022 SCC 30, 471 D.L.R. (4th) 391, exception to rebut the presumption of reasonableness. As observed by the judge, our Court in *Teva Canada Limited v. Pfizer Canada Inc.*, 2016 FCA 248, [2017] 3 F.C.R. 80 at paras 56–57 found that this Court's role as first instance decision-maker arises only when a proceeding is initiated under section 6 of the *Regulations* (see also *AbbVie Corporation v. Canada (Health)*, 2022 FC 1209). Hence, contrary to the appellants' contention, there is no concurrent jurisdiction between the Federal Court and the Minister in terms of the administration of section 5 of the *Regulations*: it squarely falls within the purview of the Minister. As such, the standard of review in this case is reasonableness (*Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, [2019] 4 S.C.R. 653 (*Vavilov*)).

[5] Secondly, the appellants have submitted a number of arguments alleging that the Minister's decision is both incorrect and unreasonable. However, we see no errors in the Minister's reasoning that would warrant our intervention. The Minister's interpretation is consistent with the purpose and scheme of the *Regulations* (*Janssen Inc. v. Apotex Inc.*, 2023 FCA 253; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533) and his decision is both justifiable and justified and bears the hallmarks of reasonableness as required by *Vavilov*.

[6] As stated above, the judge correctly identified the standard of review and properly applied it. Specifically, the judge's reasons are thorough and we can do no better than to adopt them as our own. Our intervention is not required.

[7] The appeal will be dismissed with costs to the respondents.

"Richard Boivin"

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J.A.

**FEDERAL COURT OF APPEAL**

**NAMES OF COUNSEL AND SOLICITORS OF RECORD**

**DOCKET:** A-283-23

**STYLE OF CAUSE:** BAYER INC. and, REGENERON  
PHARMACEUTICALS, INC. v.  
BGP PHARMA ULC d.b.a.  
VIATRIS CANADA and,  
BIOSIMILAR  
COLLABORATIONS IRELAND  
LIMITED

**PLACE OF HEARING:** OTTAWA, ONTARIO

**DATE OF HEARING:** FEBRUARY 13, 2024

**REASONS FOR JUDGMENT OF THE COURT  
BY:** WEBB J.A.  
BOIVIN J.A.  
MONAGHAN J.A.

**DELIVERED FROM THE BENCH BY:** BOIVIN J.A.

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