Federal Court  Cour fédérale

Date: 20231003

Docket: T-1178-23

Citation: 2023 FC 1325

Toronto, Ontario, October 3, 2023

PRESENT: The Honourable Madam Justice Furlanetto

BETWEEN:

BAYER INC. AND REGENERON PHARMACEUTICALS, INC.

Applicants

and

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

Respondents

JUDGMENT AND REASONS

I. Overview

[1] This is an application for judicial review of a May 26, 2023 decision [Decision] of the Minister of Health [Minister], issued through the Office of Submissions and Intellectual Property [OSIP]. In the Decision, the Minister found that through a transfer of ownership, the Respondent Biosimilar Collaborations Ireland Limited [BCIL], as the successor second person on a New

Drug Submission [NDS] could adopt the Notice of Allegation [NOA] of the predecessor second person, BGP Pharma ULC dba Viatris Canada [Viatris]. The Minister found that with the transfer, BCIL obtained the benefits of section 5 of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*Regulations*], including prior service of the NOA under subsection 5(3).

[2] While the Applicants argue that the Decision runs contrary to the *Regulations* and that BCIL must serve a new NOA to comply with subsection 5(3) of the *Regulations*, for the reasons that follow, I find that there is no reviewable error and that the application for judicial review should be dismissed.

II. Background

[3] The NOA at issue in the Decision was the precursor to a proceeding under subsection 6(1) of the *Regulations* involving two Canadian patents that are listed on the Patent Register in association with the medicine aflibercept and its related drug product EYLEA®. Regeneron Pharmaceuticals, Inc. [Regeneron] is the patentee of the listed patents and Bayer Inc [Bayer] is the market authorization holder for EYLEA® and the first person for the purpose of the proceedings under the *Regulations*.

[4] On March 16, 2022, Viatris filed a NDS seeking a notice of compliance [NOC] for an EYLEA® biosimilar known as YESAFILI.

[5] On May 3, 2022, Viatris served Bayer with an NOA alleging non-infringement and invalidity of the two listed patents for EYLEA®. Bayer commenced the subsection 6(1) action (Court File No. T-1241-22) on June 15, 2022, naming Viatris as defendant.

[6] Ownership of the NDS for YESAFILI was subsequently transferred to BCIL in early 2023. Following the transfer, the Minister wrote to the Respondents Viatris and BCIL advising that BCIL was now the second person and asked for confirmation under subsection 7(7) of the *Regulations* that BCIL had been added as the defendant to T-1241-22.

[7] On March 20, 2023, counsel for the Respondents wrote to the Minister and provided information establishing that it had notified the Applicants of the transfer. The letter authorized the Minister to communicate to the Applicants their position that BCIL should be named as a party defendant in T-1241-22 and in other section 8.2 actions that had been commenced in respect of the NDS for YESAFILI.

[8] On March 23, 2023, the Minister wrote to counsel for the Applicants and counsel for the Respondents in relation to the change in manufacturer for YESAFILI. The letter asserted that BCIL was now the second person under section 5 of the *Regulations* and that "[i]n order for the OSIP to be able to administer subsection 7(1) of the *Patented Medicines (Notice of Compliance) Regulations*", BCIL should be made a defendant in T-1241-22. In a response, on the same date, counsel for the Applicants advised that they disagreed with the Minister's advice and that they had instead commenced a separate action under subsection 6(1) of the *Regulations* against BCIL (which is Court File No. T-581-23).

[9] Following subsequent correspondence from counsel for the Respondents and counsel for the Applicants, on April 11, 2023 the Minister issued a preliminary decision responding to a request from counsel for the Applicants that "the OSIP confirm in writing that it has made no determination that BCIL can adopt the steps previously taken by BGP Pharma ULC to comply with the requirements of section 5 of the [Regulations] ... including the service of the [NOA]". In the letter, the Minister confirmed its view that BCIL should be made a defendant in T-1241-22 so that the Minister would be able to administer subsection 7(1) of the *Regulations.* The Minister further stated that to arrive at this position it had preliminarily determined that BCIL could adopt the steps previously taken by Viatris to comply with section 5 of the *Regulations*, including service of the NOA in respect of the listed patents. The Minister invited the parties to provide further representations in response to the preliminary decision.

[10] After further submissions from both the Applicants and the Respondents, on May 26, 2023 the Minister issued the Decision reaffirming its preliminary opinion that BCIL could adopt the steps previously taken by Viatris to comply with section 5 of the *Regulations*, including service of the NOA and that BCIL should be added as a defendant in T-1241-22 for the purpose of the Minister's administration of section 7 of the *Regulations*. The Minister also advised of its view that the stay under subsection 7(1)(d) of the *Regulations* continued to apply and that BCIL was bound by the outcome of T-1241-22.

[11] On June 6, 2023, the Applicants commenced the present application in which they seek an order quashing and setting aside the Decision, a declaration that BCIL cannot adopt the steps previously taken by Viatris to comply with section 5 of the *Regulations*, and a declaration that

prior to May 23, 2023 when BCIL served a further NOA identical to the NOA served by Viatris (causing Bayer to initiate a third action, which is Court File No. T-1228-23), BCIL had not complied with the requirements of section 5 of the *Regulations*.

III. Issues

[12] There are three issues raised by this application:

A. What is the appropriate standard of review?

B. Is the Minister's Decision that a successor second person can adopt an NOA served under subsection 5(3) of the *Regulations* by its predecessor unreasonable or incorrect, as the case may be?

C. If it is unreasonable or incorrect, what is the appropriate remedy?

IV. Analysis

A. *What is the appropriate standard of review?*

[13] The standard of review for all administrative decisions, including those where the administrative decision-maker is interpreting their home statute or statutes closely connected to its function, begins with a presumption of reasonableness: *Canada (Citizenship and Immigration) v Vavilov*, 2019 SCC 65 [*Vavilov*] at paras 16 and 25. The presumption can be rebutted in two types of situations: first, where the legislature has indicated that it intends a different standard of review to apply; and second, where the rule of law requires that the standard of correctness be applied: *Vavilov* at para 17; confirmed recently in *Mason v Canada (Citizenship and Immigration)*, 2023 SCC 21 at para 39. The parties do not dispute that these two situations and the five recognized categories of correctness review that are identified in *Vavilov* as arising therefrom do not apply.

[14] In *Society of Composers, Authors and Music Publishers of Canada v Entertainment Software Association*, 2022 SCC 30 at paragraph 28, the Supreme Court confirmed with reference to *Rogers Communications Inc v Society of Composers, Authors and Music Publishers of Canada*, 2012 SCC 35 [*Rogers*] a sixth category of correctness review where the court and administrative body have concurrent first instance jurisdiction over a legal issue in a statute. It is this further category that the Applicants assert applies here.

[15] The Applicants assert that the issues raise matters of concurrent jurisdiction and that correctness should apply. The Respondents argue that the underlying issues fall squarely within the Minister's jurisdiction and as such that the presumption of reasonableness governs.

[16] In the Decision, the Minister states:

> 2. Having carefully considered the representations provided by Bayer and Regeneron, and by BCIL and BGP Pharma, the OSIP is of the position that BCIL can adopt the steps previously taken by BGP Pharma to comply with the requirements of section 5 of the *Patented Medicines (Notice of Compliance) Regulations* ("*PM(NOC) Regulations*") for New Drug Submission ("NDS") 259183 for YESAFILI (aflibercept), including the service of the Notice of Allegation dated May 2, 2022 in relation to the above-noted patents. As a result, the OSIP is also of the view that BCIL should be a defendant in the action under subsection 6(1) of the *PM(NOC) Regulations* in federal Court No. T-1241-22, for the purposes of the OSIP's administration of section 7 of the *PM(NOC) Regulations.*
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> 3. There is currently a stay under paragraph 7(1)(d) of the *PM(NOC) Regulations* to the issuance of a Notice of Compliance ("NOC") in respect of NDS 259183. The OSIP is of the view that the stay continues to apply in relation to NDS 259183. BCIL has assumed the role of second person for NDS 259183 under the *PM(NOC) Regulations*, and is bound by the outcome in Federal Court File No. T-1241-22, despite not yet being named as a defendant.

[17] The fundamental debate between the parties relates to the characterization of the findings in the Decision and the issues under review. The Applicants argue that dissecting the Decision into discrete section 5 and section 6 issues is artificial because the sole reason the Minister became involved was to effect change in the subsection 6(1) defendants. The Respondents contend that the Applicants conflate the findings of the Minister and the nature of the Decision.

[18] In my view, the crux of the Decision concerns a second person's obligations under section 5 of the *Regulations* following a transfer of ownership of an NDS. While the Minister indicates that it is their view that BCIL should be a named defendant in the T-1241-22 action, they do so from the stand-point of their administration of section 7 of the *Regulations*. The Minister does not make a legal determination as to the parties in T-1241-22. Its analysis is restricted to an analysis of section 5 of the *Regulations* only.

[19] As stated by the Minister in the body of the Decision: "[t]he specific question at issue in th[e] decision is whether a successor person can adopt (and benefit from) a notice of allegation served on the first person under subsection 5(3) of the *PM(NOC) Regulations*". This is a question relating to the effect of the transfer of the NDS on the obligations of the second person under subsection 5(3) the *Regulations*.

[20] In *Teva Canada Ltd v Pfizer Canada Inc*, 2016 FCA 248 [*Teva*], in the context of a proceeding involving subsection 5(1) of the *Regulations*, the Federal Court of Appeal [FCA] found that *Rogers* had no application and that the Minister had exclusive jurisdiction to decide whether a drug submission filed by a second person made a comparison with a Canadian reference product so as to require the second person to address a patent listed on the Patent

Register. The FCA found that the Court's role as first instance decision-maker arises only under section 6, after a proceeding under the *Regulations* is initiated:

> [56] Aside from the Court's potential role on an application for judicial review of a ministerial decision made under section 5, the PMNOC Regulations provide a role for the Court as a first instance decision maker only under section 6: where a first person has initiated an application for prohibition it is for the Court to determine whether the allegations contained in a second person's notice of allegation are justified. On an application for prohibition, the Court does not consider whether section 5 ought to have been triggered in the first place. It follows that in a prohibition application there is no possibility of conflicting interpretations between the Minister and the Court with respect to whether section 5 was triggered.

[21] This principle from *Teva* was recently applied in *Abbvie Corporation v Canada (Minister of Health),* 2022 FC 1209 [*Abbvie*] and in my view, applies equally well to paragraph 5(3)(a) as it did to subsection 5(1).

[22] As noted in *Abbvie*, and reflected in the Minister's detailed analysis, the *Regulations* are closely connected with the Minister's functions. The Minister has great expertise in their application and interpretation: *Abbvie* at para 73; *Elanco v Canada (Attorney General)*, 2019 FC 5 at para 43. The Minister is responsible for administering drug submissions and for determining whether a manufacturer has satisfied all criteria necessary for an NOC to be issued in respect of a drug submission (subsections C.08.002(1), C.08.004, C.08.004.01 *Food and Drug Regulations*, CRC, c 870 [*FDR*]; subsection 7(1) *Regulations*). This includes determining whether subsection 5(1) of the *Regulations* has been engaged (*Teva*) and accordingly whether the second person has met their obligations under subsection 5(3). Indeed, pursuant to paragraph 5(3)(e) of the *Regulations*, the second person must provide the Minister with proof of service of the

documents referred to in paragraphs 5(3)(a) and (b), along with a copy of the NOA in order for subsection 5(3) to be satisfied. As set out in subsection 5(3):

(3) A second person who makes an allegation referred to in paragraph (2.1)(c) shall	(3) La seconde personne qui inclut une allégation visée à l'alinéa (2.1)c) est tenue de prendre les mesures suivantes :
(a) serve on the first person a notice of allegation relating to the submission or supplement filed under subsection (1) or (2) on or after its date of filing;	a) signifier à la première personne un avis de l'allégation à l'égard de la présentation ou du supplément déposé en vertu des paragraphes (1) ou (2), à la date de son dépôt ou à toute date postérieure;
(b) include in the notice of allegation	b) insérer dans l'avis de l'allégation :
(i) a description of the medicinal ingredient, dosage form, strength, route of administration and use of the drug in respect of which the submission or supplement has been filed, and	(i) une description de l'ingrédient médicinal, de la forme posologique, de la concentration, de la voie d'administration et de l'utilisation de la drogue visée par la présentation ou le supplément,
(ii) a statement of the legal and factual basis for the allegation, which statement must be detailed in the case of an allegation that the patent or certificate of supplementary protection is invalid or void;	(ii) un énoncé du fondement juridique et factuel de l'allégation, lequel énoncé est détaillé dans le cas d'une allégation portant que le brevet ou le certificat de protection supplémentaire est invalide ou nul.
[…]	[…]
(e) provide to the Minister proof of service of the	e) transmettre au ministre la preuve de la

documents referred to in paragraphs (a) and (b), along with a copy of the notice of allegation	signification des documents visés aux alinéas a) et b), ainsi qu'une copie de l'avis d'allégation.

[23] While the Applicants note that subsection 6(1) of the *Regulations* specifies that an action can only be brought against a second person who has served a NOA under paragraph 5(3)(a), this does not confer first instance jurisdiction on the Court to determine a successor second person's obligations under paragraph 5(3)(a) upon transfer of an NDS.

[24] I agree with the Respondents, the Minister is responsible for administratively determining the section 5 obligations of predecessor and successor second persons in the context of an NDS transfer. The Court retains full carriage over the subsection 6(1) action, including deciding the proper parties and the basis upon which they are named, as informed by the underlying administrative determinations of the Minister as it relates to section 5.

[25] In my view, the decision reported at *Genentech, Inc v Celltrion Healthcare Co, Ltd*, 2019 FC 293 [*Genentech*] is not inconsistent with these principles. *Genentech* was a pleadings motion that dealt with whether additional parties could be added as defendants to a subsection 6(1) action. While the Court in *Genentech* suggested that for the purpose of subsection 6(1) it could consider whether a second person included someone other than the person who filed the NDS, the issues before the Court did not involve a determination of the rights and obligations of a successor second person and I do not view *Genentech* as standing for the proposition that the Court has first instance jurisdiction to determine these issues.

[26] The standard of review is reasonableness and the focus of the analysis must be on the decision actually made and whether the underlying rationale is transparent, intelligible, and justified in relation to the facts and law that constrain the decision maker: *Vavilov* at paras 83-86, 91-95, and 99-100.

[27] As aptly summarized in *Abbvie* at paragraph 46, when conducting reasonableness review:

> [46] Courts must pay respectful attention to the decision maker's reasons, acknowledging the specialized expertise of administrative decision makers, and must be cautious not to substitute their own views of the proper outcome (*Vavilov* at para 75, 83). When conducting reasonableness review of a decision maker's interpretation of a statute or regulation, the Court does not undertake a *de novo* analysis. Rather, courts are to assume that those who interpret the law, whether courts or administrative decision makers, will do so in a manner consistent with the modern principles of statutory interpretation (*Vavilov* at paras 116-118).

B. *Is the Minister's decision that a successor second person can adopt an NOA served under subsection 5(3) of the Regulations by its predecessor unreasonable?*

[28] The Applicants assert that the Decision is unreasonable because: 1) it falls outside the *Regulations* and is not supported by the principles of statutory interpretation; 2) it contemplates premature issuance of an NOC to the successor second person; and 3) it frustrates the Applicants' express right to be able to renounce the 24-month stay. They further contend that the Respondents' fear of prolonging the 24-month stay is not justified and does not support the Decision. In my view, none of these arguments are persuasive for the reasons that follow.

(1) The Scheme and Purpose of the *Regulations*

[29] As recognized by the Minister, the modern approach to statutory interpretation requires that the words of the provisions of the *Regulations* be considered in their entire context, in a

manner that harmonizes their ordinary meaning with the scheme, objects, and intention of the *Regulations*.

[30] The *Regulations* create a patent linkage regime that ties regulatory approval of generic medicines to the protection of patent rights: *Regulatory Impact Analysis Statement*, *Canada Gazette* Part II, Vol 151, extra, pages 32-52 [*2017 RIAS*]. The objective of the *Regulations* is to "balance effective patent enforcement over new and innovative drugs with the timely market entry of their lower priced generic competitors": *2017 RIAS*, p 33; *Abbvie* at para 6; *Fresenius Kabi Canada Ltd v Canada (Health)*, 2020 FC 1013 [*Fresenius*] at para 13.

[31] This dual purpose was noted by the Supreme Court of Canada in *Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 [*Biolyse*] at paragraph 47, as a fair compromise between the important social interests in health (as represented by cheaper generic drugs) and the interests of patentees to protect their patent rights and monopoly. It was also found to be consistent with the limited scope of subsection 55.2(4) of the *Patent Act* which provides for the regulation-making authority underlying the *Regulations* to prevent abuse of the "early working" exception to patent infringement. Pursuant to subsection 55.2(1) of the *Patent Act*, this exception deems non-infringing the use of patented inventions for development and regulatory submissions: *Patent Act*, RSC 1985, c P-4, ss 55.2(1) and 55.2(4); *Biolyse* at para 53; *Fresenius* at para 29.

[32] The dual purpose of the *Regulations* and the balance it seeks to achieve is reflected in its overall scheme. As summarized in the Decision, the scheme of the *Regulations* provides as follows:

> 16. Pursuant to subsection 3(2) of the *PM(NOC) Regulations*, the Minister maintains a Patent Register, which is a list of patents and certificates of supplementary protection associated with approved drugs. A first person – typically a brand name manufacturer – who files an NDS or SNDS may submit, to the OSIP, a patent for listing on the Patent Register in relation to the drugs for which approval is sought in the NDS or SNDS, in accordance with the eligibility requirements, including timing requirements, for listing specified in section 4 of the *PM(NOC) Regulations*. A first person submits a patent for listing on the Patent Register by filing a Form IV: Patent List ("Form IV").
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> 17. [Pursuant to subsection 5(1)] [i]f a second person files a submission for a NOC in respect of a drug and the submission directly or indirectly compares the drug with, or makes reference to, a first person's drug marketed in Canada under an NOC and in respect of which there is a patent and/or certificate of supplementary protection listed on the Patent Register, the second person must address each listed patent and/or certificate of supplementary protection. Only a patent or certificate of supplementary protection that is listed on the Patent Register prior to the date of filing of the second person's drug submission must be addressed.
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> 18. A second person must, in its drug submission, [in compliance with subsection 5(2.1)], declare how it intends to address each patent and/or certificate of supplementary protection, either by stating its acceptance that an NOC will not issue until the patent or certificate of supplementary protection, as the case may be, expires; by indicating it has obtained consent from the owner of the patent to make, construct, use or sell its drug in Canada; or by making an allegation that the patent or certificate of supplementary protection is invalid or would not be infringed by the second person's drug. The second person does so by filing a Form V: Declaration re. Patent List ("Form V"). Each drug submission received by the Minister is assessed by the OSIP to determine if the requirements of section 5 of the *PM(NOC) Regulations* are triggered, and if so, if they are met.
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> 19. A second person who makes an allegation must then serve notice of that allegation on the first person [pursuant to subsection

> 5(3)]. Within 45 days after service, a first person or an owner of a patent who receives the notice of allegation may bring an action [under subsection 6(1)] against the second person in the Federal Court for a declaration that the making, constructing, using or selling of the drug in accordance with the second person's drug submission would infringe any patent or certificate of supplementary protection that is the subject of the notice of allegation.
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> 20. When an action is brought, pursuant to paragraph 7(1)(d), there is a period of 24 months during which the Minister shall not issue an NOC to a second person (otherwise known as the 24-month stay). Overall, the *PM(NOC) Regulations* prevent the Minister from issuing an NOC to a second person before the latest of a number of conditions outlined in subsection 7(1).
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> [footnotes excluded]

[33] As noted by the Respondents, the NOA is not an act of infringement as pre-approval regulatory activities of a second person are exempt from infringement. The right to bring an action under subsection 6(1), where one would otherwise not be available, is intended to serve as interim patent enforcement, wherein there is a stay of the approval of the second person's drug submission until the allegations relating to the patents are resolved. Approval of the submission is thereby directly linked with the action, and the first person notifies the Minister of the commencement of the action and events indicating its resolution or appeal.

[34] The Applicants highlight that there is no express provision in the *Regulations* that allow for a transfer of the NOA and of its service under subsection 5(3) of the *Regulations* when there is a change in ownership of an NDS. The Applicants argue that where there is no express provision, the Minister does not have jurisdiction to read-in such authority. Rather, the authority can only be conferred by necessary implication: Ruth Sullivan, *The Construction of Statutes*, 7th ed at §12.02[5].

[35] However, I agree with the Respondents, the transfer of the NOA is implicit from the scheme of the *Regulations* and its underlying policies, including those relating to the associated review and handling of drug submissions under the *FDR*.

[36] While there is no specific provision of the *FDR* that deals with a change in the name of a manufacturer during the review of a submission, the handling of such change is dealt with as a matter of policy. Section 14.4 of Health Canada's Guidance Document, "The Management of Drug Submissions and Applications" sets out the information that must be provided to the Minister upon a change to the manufacturer during the review of a drug submission where the product does not yet have a Drug Identification Number (DIN).

[37] As noted by the Minister in the Decision, as a matter of policy, and consistent with the administrative nature of an ownership change, a change in the name of a manufacturer during review of an NDS does not change the filing date of the submission, and the successor manufacturer is not required to refile the submission or to address any patents added to the Patent Register between the date the NDS was filed and the date the successor second person assumed ownership of the NDS. The drug submission process continues uninterrupted under the successor manufacturer, regardless of whether the change of name is due to a merger, buyout, or transfer of rights in the drug. This is because there is no substantive change to the drug, including its site of manufacture and the process for manufacture upon which the submission was filed. After the change, the successor manufacturer becomes responsible for the review and it is the successor who receives the NOC, not their predecessor.

[38] Thus, as noted by the Minister, and conceded by the Applicants, upon transfer of ownership of the NDS, the successor manufacturer becomes the second person under the *Regulations* and their predecessor ceases to be a second person. With this, "the successor manufacturer assumes both the benefits and regulatory responsibilities related to the drug submission". This includes the Form Vs that were filed by the predecessor as part of the NDS in fulfillment of the requirements under subsections 5(1) and 5(2.1), and in my view by extension, was reasonably interpreted by the Minister to include the steps taken by the second person in satisfaction of their obligations under paragraph 5(3)(a).

[39] Paragraph 5(3)(a) of the *Regulations*, requires a second person to serve on the first person a NOA relating to the allegations in the submission that are set out in the Form V. The NOA serves as notice of the basis for the allegations made in the Form V with respect to the listed patents. Without the allegations in the Form V, as noted by the Respondents, there is no foundation for an NOA.

[40] As the successor second person assumes control over the submission, including the Form V, it follows that they would also assume control over the NOA prepared from the allegations in the Form V. This is particularly so as the transfer of the NDS does not result in any change to the allegations made in respect of the patents in issue; thus, there is no basis to require further notice of the allegations.

[41] As rationalized by the Minister, allowing a successor second person to adopt the NOA served by its predecessor is consistent with the handling of a change in ownership after review of

an NDS. In that case, an administrative drug submission must be filed to address the change in ownership. However, such administrative submission does not separately engage section 5 of the *Regulations*. Rather, as noted by the Minister, "only the originating submission that directly or indirectly compares the drug with, or makes reference to, another drug marketed in Canada under an NOC issued to a first person will trigger the application of section 5 of the [*Regulations*]". An administrative NDS for a change in name of manufacturer will be subject to the same patent hold as the original submission and can only receive an NOC after the originating drug submission receives an NOC.

[42] The basis for this, as noted by the Minister, was explained by the FCA in *Teva* at paragraph 89: "when characterizing a drug submission the focus should be upon the drug product itself. The question should be whether the changes reflected in the drug submission give rise to a new or different basis for asserting that a particular product is infringing". In that case, an NOC had issued to the second person and there was a subsequent cross-licensing agreement that granted Teva the right to sell the product. This required Teva to obtain its own NOC. Teva's subsequent submission did not include any new data. Instead, it certified that the drug product was identical to the earlier drug except for the name of the manufacturer. While this was under the old regime where a subsequent action could still be taken, the FCA found that as the drug product would be manufactured in the same location with identical specifications and procedures, there was no basis to require a new NOA to be re-served: *Teva* at paras 90-91.

[43] The transfer of rights to BCIL is the result of an administrative change of ownership over the drug product. Like in *Teva*, there has been no change to the drug product itself. There has

been no different early working by BCIL as transferee to ground any new allegations relating to infringement to justify the requirement for a new NOA.

[44] The Applicants assert that even if the allegations are unchanged, there is still a requirement to re-serve an NOA as the Viatris NOA is rendered a legal nullity from the transfer. However, I do not find support for this contention.

[45] Once the successor second person assumes control over the submission, it acquires the rights to the Form V and the benefit of the allegations made. As set out earlier, this includes the steps taken in respect of those allegations under paragraph 5(3)(a).

[46] This view is further supported by the language of paragraph 5(3)(d) which provides that the second person must provide the first person, without delay, any portion of their submission produced with the NOA under paragraph 5(3)(c)(iii) (*i.e.*, documents that are relevant to infringement) that have changed "on or before the later of the 45th day after the day on which the [NOA] is served and the day of the disposition of any action that has been brought under subsection 6(1)". Thus, the NOA is not declared a nullity, and the second person is not required to serve a new NOA, every time there is a change to the second person's submission. The second person is simply required to provide notice of the changes made.

[47] As noted by the Minister, it would be incongruous with paragraph 5(3)(d) to interpret paragraph 5(3)(a) differently when the change relates to the manufacturer's name. Consistent with paragraph 5(3)(d) of the *Regulations*, section 5.7 of Health Canada's Guidance Document

on the "*Patented Medicines (Notice of Compliance) Regulations*" [PMNOC Guidance] provides that if a NOA has been served on the first person, the new second person need only notify the first person of its new name in order to ensure transparency.

[48] While it would be open to the successor second person to withdraw the NOA served, there is no basis to suggest they must do so or that it no longer has effect. The *Regulations* provide under subsection 5(6) the specific circumstances when a second person must retract an NOA, a change in manufacturer is not one of those circumstances:

(6) A second person who has served a notice of allegation on a first person under paragraph (3)(a) shall retract the notice of allegation and serve notice of the retraction on the first person within 90 days after either of the following dates:	(6) La seconde personne qui a signifié l'avis d'allégation à la première personne en vertu de l'alinéa (3)a) doit retirer celui-ci et signifier un avis du retrait à la première personne dans les quatre-vingt-dix jours qui suivent :
(a) the date on which the Minister notifies the second person under paragraph C.08.004(3)(b) or C.08.004.01(3)(b), as the case may be, of the *Food and Drug Regulations* of their non-compliance with the requirements of section C.08.002, C.08.002.01, C.08.002.1 or C.08.003, as the case may be, or section C.08.005.1 of those Regulations; or	a) soit la date à laquelle le ministre a informé la seconde personne, aux termes de l'alinéa C.08.004(3)b) ou C.08.004.01(3)b), selon le cas, du *Règlement sur les aliments et drogues*, de sa non-conformité aux articles C.08.002, C.08.002.01, C.08.002.1 ou C.08.003, selon le cas, ou à l'article C.08.005.1 du même règlement;
(b) the date of the cancellation by the second person of the submission or supplement to which the allegation relates.	b) soit la date de l'annulation par la seconde personne de sa présentation ou de son

supplément faisant l'objet
de l'allégation.

[49] Further, I agree with the Respondents, an interpretation of the *Regulations* that requires a successor second person to re-serve the same NOA on a first person would be contrary to the objectives of the *Regulations* and the balance set out in *Biolyse*.

[50] Indeed, the Applicants' interpretation, would lead to the necessity for multiple actions involving the same allegations; a consequence that was to be specifically eliminated by the 2017 amendments to the *Regulations*: *2017 RIAS*, p 34.

[51] The Applicants contend that the *Regulations* safeguard against any attempt by the first person to restart the clock through the use of case management and the language under section 6.09 of the *Regulations*, which provides that "[e]very first person, second person and owner of a patent shall act diligently in carrying out their obligations under these Regulations and shall reasonably cooperate in expediting any action brought under subsection 6(1)...". They argue that in a circumstance such as this, they would have a hard time arguing against a new two-year schedule for the subsequent proceedings in T-1228-23.

[52] However, this argument misses the point. Even if subsequent schedules were aligned, it does not change the fact that with every new action, the timeline from which the stay under paragraph 7(1)(d) is calculated is from the date of the new proceeding. The Court's jurisdiction to shorten the stay is not unlimited. Pursuant to subsection 7(8) of the *Regulations*, the Court may shorten or extend the 24-month period under paragraph 7(1)(d) only "if it finds that a party

has not acted diligently in carrying out their obligations under [the] Regulations or has not reasonably cooperated in expediting the action".

[53] Further, it is not sufficient to simply rely on section 8 of the *Regulations* as the Applicants propose. As noted by the Respondents, there is nothing in the Decision or section 8 confirming whether a second person may recover damages for a period that it is not a second person.

[54] Moreover, the Applicant's interpretation ignores the express balance that the scheme of the *Regulations* is intended to protect as any additional time the subsequent entry version was kept off the market due to the restarted 24-month stay would not be the result of early working but rather, as noted by the Minister, because of administrative change alone.

[55] In my view, the Minister did not err in finding that the scheme of the *Regulations* and the mechanism of handling submissions under the *FDR* supports a view that the NOA and its service would be transferred to BCIL.

(2) There will be no Premature NOC Issuance

[56] I am also not persuaded by the Applicants' further argument that a loophole is created by the Decision. In my view, it was reasonable for the Minister to find that a successor second person would not be issued an NOC in some intervening period before a change is made to the named defendants in the pending action commenced under subsection 6(1) of the *Regulations* in respect of the predecessor's NOA.

[57] Paragraph 7(1)(d) of the *Regulations* provides that once a proceeding under subsection 6(1) has been commenced, the Minister shall not issue a NOC "to a second person" before the day after the expiry of the 24-month period that begins on the day on which the action was brought.

[58] As stated in the Decision, there can only be one second person at any given time. Once an action has been commenced and is pending, the Minister cannot issue a NOC to a second person. The stay continues to apply in relation to the NDS and in respect of the successor second person even if they have not yet been named as a defendant to the action.

[59] I agree with the Respondents, Rules 104 and 117 of the *Federal Courts Rules,* SOR/98-106, provide provisions for allowing the successor second person to be added as defendant to the action. There is no legitimate argument that the successor second person cannot be added to the proceeding and would be likely to receive an NOC, particularly as notice pursuant to the PMNOC Guidance would be provided to the first person as to the change in ownership.

(3) The Applicants' Right to Renounce the Stay

[60] The Applicants argue that allowing NOA adoption in satisfaction of paragraph 5(3)(a) of the *Regulations* would undermine their express right under paragraph 7(5)(b) to renounce the 24-month stay to avoid the risk of section 8 damages. They assert that the Minister's failure to substantively consider this argument was unreasonable.

[61] The Applicants provide certain hypotheticals as to when a first person might choose to renounce, or choose not to renounce, the stay. However, such hypotheticals do not appear to apply any consistent logic. Further, while the Applicants suggest that the identity of the second person is key to a determination under paragraph 7(5)(b) of the *Regulations*, they provide no evidence to support this contention and none was provided to the Minister.

[62] As noted by the Respondents, as renouncement must be decided at the outset of the subsection 6(1) action, there is inherent uncertainty built into the renouncement right. Information on how the market will form and the distribution channels of the second person's product would not be fully known at that time and would be subject to change irrespective of the identity of the second person.

[63] Moreover, even with the knowledge of BCIL as second person, the Applicants did not renounce the stay in subsequent proceedings initiated in response to a new NOA served by BCIL to preserve rights (Court File No. T-1228-23). Thus, the Applicants own actions do not suggest that the identity of the second person had any bearing on their paragraph 7(5)(b) choice.

[64] While I agree that the Minister did not dwell on the issue of renouncement in the Decision, this does not mean that it was not considered. The Minister notes the Applicant's argument but is unpersuaded that any rights of the Applicants would be frustrated. For the reasons already stated, I do not find this position unreasonable. There was no requirement for the Minister to give more substantive reasons: *Abbvie* at para 63.

[65] The Applicants have not established by this argument that a reviewable error was made.

[66] In my view, the Decision was transparent, intelligible, and justified and is consistent with the scheme, objectives, and purpose of the *Regulations*, including the treatment of submissions under the *FDR*. The Minister considered, and was responsive to, the arguments raised by the Applicants. The Applicants have not established that the Decision was unreasonable.

[67] For all of these reasons, the application is dismissed and there is no need for me to go on to consider the third issue of applicable remedy.

V. Costs

[68] The parties agreed that costs should be awarded to the successful party at the top end of column IV of the Tariff. As the Respondents are the successful party on the application, costs shall be awarded accordingly.

JUDGMENT IN T-1178-23

THIS COURT'S JUDGMENT is that:

1. The application for judicial review is dismissed.

2. The costs of the application are awarded to the Respondents at the high end of column IV of the Federal Court's Tariff.

"Angela Furlanetto"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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

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