Federal Court of Appeal | Cour d'appel fédérale

Date: 20191004

Docket: A-24-19

Citation: 2019 FCA 249

CORAM: **NADON J.A.**
PELLETIER J.A.
DE MONTIGNY J.A.

BETWEEN:

PFIZER CANADA INC.

Appellant

and

AMGEN INC. AND AMGEN CANADA INC.

Respondents

Heard at Montréal, Quebec, on April 1, 2019.

Judgment delivered at Ottawa, Ontario, on October 4, 2019.

REASONS FOR JUDGMENT BY: NADON J.A.

CONCURRED IN BY: PELLETIER J.A.
DE MONTIGNY J.A.

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REASONS FOR JUDGMENT

NADON J.A.

I. Introduction

[1] This is an appeal by Pfizer Canada Inc. (Pfizer) of a decision rendered by Prothonotary Milczynski (the Prothonotary) on October 25, 2018 (T-741-18) pursuant to which she dismissed a motion brought by Pfizer seeking the dismissal of an action commenced in the Federal Court by the respondents Amgen Inc. and Amgen Canada Inc. (Amgen). More particularly, by its motion, Pfizer argued that Amgen's action was redundant, scandalous, frivolous or vexatious or

was otherwise an abuse of process in accordance with section 6.08 of the *Patented Medicines (Notice of Compliance) Regulations*, S.O.R./93-133 (the Amended Regulations).

[2] In the Prothonotary's view, Amgen's action was not scandalous, frivolous, vexatious or an abuse of the Court's process.

[3] For the reasons that follow, I would dismiss Pfizer's appeal.

II. Facts

[4] Amgen sells two biologic drugs, namely Neupogen, a filgrastim, and Neulasta, a pegfilgrastim. It has listed Canadian Patent No. 1,341,537 (the '537 Patent) in connection with these products on the Patent Register. Amgen applied for the '537 Patent in 1986 and it was granted in 2007.

[5] Pfizer intends to market a biosimilar drug to Neupogen called Nivestym. Hence, Pfizer filed a new drug submission w the Minister of Health (the Minister) seeking a Notice of Compliance (NOC) for its product. Since the '537 Patent is listed on the Patent Register, the Amended Regulations also required Pfizer to serve Amgen with a Notice of Allegation (NOA).

[6] Pfizer's NOA was served on Amgen on March 7, 2018. In response, on April 20, 2018, Amgen commenced an action against Pfizer under section 6(1) of the Amended Regulations. This led Pfizer to file its motion for the dismissal of Amgen's action on the grounds of, *inter*

alia, abuse of process. Following the Prothonotary's decision dismissing its motion, Pfizer filed an appeal to this Court on January 9, 2019.

III. The Regulatory Regime

[7] The Regulations, which came into force in 1993, were recently amended in September 2017, and these proceedings have been brought under the Amended Regulations. Under the Regulations prior to the coming into force of the Amended Regulations (the Former Regulations), once a first person (in this case Amgen) lost a section 6 proceeding against a second person (in this case Apotex), the first person effectively lost the right to use section 6 in respect of all subsequent market entrances. This was the result of this Court's decision in *Sanofi-Aventis Canada v. Novopharm Ltd.*, 2007 FCA 163, [2008] 1 F.C.R. 174 [*Sanofi*].

[8] Pursuant to the Amended Regulations, the remedy provided under section 6 has been converted from an application to prohibit the Minister from issuing a NOC into an action for patent infringement, with procedural safeguards of examination for discovery and oral evidence as well as determinations on substantive patent validity and infringement. Under the Former Regulations, section 6 proceedings only served to determine whether the second person's allegations of non-infringement were justified so as to allow the Minister to issue a NOC to that second person.

[9] In this appeal, the issue is whether this change (*i.e.* an action instead of an application) allows a first person to commence a section 6 proceeding under the Amended Regulations notwithstanding a previously unsuccessful section 6 proceeding under the Former Regulations.

IV. Prior proceedings under the Former Regulations pertaining to Amgen's drugs Neupogen and Neulasta

[10] In Court file T-2072-12, Amgen asserted its '537 Patent against Apotex Inc. (Apotex), which sought a NOC from the Minister in respect of its drug Grastofil, a biosimilar to Neupogen. Following receipt of Apotex's NOA, Amgen commenced an application under section 6 of the Former Regulations seeking an order from the Court prohibiting the Minister from issuing a NOC to Apotex until after the expiry of its patent.

[11] By a decision rendered on November 10, 2015 (the Hughes Decision), Hughes J. of the Federal Court found that Apotex's allegations of invalidity of the '537 Patent were justified on the grounds of obviousness and thus dismissed Amgen's application. Hence, Apotex received a NOC from the Minister for Grastofil.

[12] In Court file T-1710-15, prior to the release of the Hughes Decision, Amgen also asserted its '537 Patent against Apotex in relation to a different dosage strength of Grastrofil. On October 9, 2015, Amgen commenced an application under section 6 of the Former Regulations seeking an order prohibiting the Minister from issuing a NOC to Apotex for this second form of Grastofil until the expiry of the '537 Patent.

[13] Notwithstanding the Hughes Decision, Amgen continued its second application, leading Apotex to file a motion for dismissal of the application pursuant to paragraph 6(5)(*b*) of the Former Regulations, on the ground that it was redundant, scandalous, frivolous or vexatious or otherwise an abuse of process.

[14] On October 4, 2016, Prothonotary Milczynski of the Federal Court dismissed Amgen's application as constituting an abuse of process. As a result, the Minister issued the NOC sought by Apotex, which then brought this form of Grastofil to market in Canada as well.

[15] Following Apotex's entry into the market with its drug Grastofil, Amgen commenced an action against Apotex in the Federal Court pursuant to section 55 of the *Patent Act*, R.S.C. 1985, c. P-4 (the Patent Act) for infringement of its '537 Patent. In due course, Amgen's action and Apotex's counterclaim of invalidity were discontinued.

[16] Finally, on January 30, 2017, in Court file T-145-17, Amgen commenced an application for an order prohibiting the Minister from issuing a NOC to BGP Pharma ULC dba Mylan EPD (Mylan) in respect of the drug Fulphila, a biosimilar to Neulasta, until after the expiry of the '537 Patent.

[17] Following Mylan's advice to Amgen that it would be seeking the dismissal of its application on the ground of abuse of process pursuant to paragraph 6(5)(*b*) of the Former Regulations, Amgen discontinued its application on March 13, 2017.

V. The proceedings now before this Court

[18] In the present matter, Pfizer's NOA puts forward the same allegations of obviousness that the Hughes Decision found to be justified.

[19] In response to Pfizer's NOA, Amgen has commenced, pursuant to subsection 6(1) of the Amended Regulations, an action against Pfizer for a declaration that the making, constructing, using or selling of its drug Nivestym would infringe a number of claims of the '537 Patent. Pfizer, by its statement of defence and counterclaim to Amgen's action has alleged, *inter alia*, that the '537 Patent is invalid and void.

VI. Relevant Statutory Provisions

[20] The relevant provisions of the Amended Regulations are the following:

Amended Regulations	**Règles révisées**
6(1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any patent or certificate of supplementary protection that is the subject of an allegation set out in that notice.	**6(1)** La première personne ou le propriétaire d'un brevet qui reçoit un avis d'allégation en application de l'alinéa 5(3)a) peut, au plus tard quarante-cinq jours après la date à laquelle la première personne a reçu signification de l'avis, intenter une action contre la seconde personne devant la Cour fédérale afin d'obtenir une déclaration portant que la fabrication, la construction, l'exploitation ou la vente d'une drogue, conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), contreferait tout brevet ou tout certificat de protection supplémentaire visé par une allégation faite dans cet avis.
…	[…]
6(3) The second person may bring a counterclaim for a declaration	**6(3)** La seconde personne peut faire une demande reconventionnelle afin d'obtenir une déclaration :
(*a*) under subsection 60(1) or (2) of the Patent Act in respect of any patent claim asserted in the action	***a*)** soit au titre des paragraphes 60(1) ou (2) de la Loi sur les brevets à l'égard de toute revendication se

brought under subsection (1); or

rapportant à un brevet faite dans le cadre de l'action intentée en vertu du paragraphe (1) ;

(*b*) under 125(1) or (2) of that Act in respect of any claim, asserted in the action brought under subsection (1), in the patent set out in the certificate of supplementary protection in question in that action.

***b*)** soit au titre des paragraphes 125(1) ou (2) de la même loi, à l'égard de toute revendication, faite dans le cadre de l'action intentée en vertu du paragraphe (1), se rapportant au brevet mentionné dans le certificat de protection supplémentaire en cause dans cette action.

6(4) If the Federal Court makes a declaration referred to in subsection (1), it may order any other remedy that is available under the Patent Act, or at law or in equity, in respect of infringement of a patent or a certificate of supplementary protection.

6(4) Si la Cour fédérale fait la déclaration visée au paragraphe (1), elle peut ordonner toute autre réparation sous le régime de la Loi sur les brevets, ou en vertu de toute autre règle de droit, relativement à la contrefaçon d'un brevet ou d'un certificat de protection supplémentaire.

6.01 No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(a) in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) unless the first person or the owner of the patent did not, within the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection.

6.01 Aucune autre action qu'une action intentée en vertu du paragraphe 6(1) ne peut être intentée contre la seconde personne pour la contrefaçon d'un brevet ou d'un certificat de protection supplémentaire visé par un avis d'allégation signifié en application de l'alinéa 5(3)a) relativement à la fabrication, à la construction, à l'exploitation ou à la vente d'une drogue conformément à la présentation ou au supplément visé aux paragraphes 5(1) ou (2), sauf si la première personne ou le propriétaire du brevet n'avait pas, dans la période de quarante-cinq jours prévue au paragraphe 6(1), de motifs raisonnables pour intenter une action en vertu de ce paragraphe.

…

[…]

6.08 An action brought under

6.08 Toute action intentée en vertu du

subsection 6(1) may, on the motion of a second person, be dismissed, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection.	paragraphe 6(1) peut, sur requête de la seconde personne, être rejetée en tout ou en partie au motif qu'elle est inutile, scandaleuse, frivole ou vexatoire ou qu'elle constitue par ailleurs un abus de procédure à l'égard d'un ou de plusieurs brevets ou certificats de protection supplémentaire.
7.1 The Minister shall not issue a notice of compliance to a second person before the latest of	**7(1)** Le ministre ne peut délivrer d'avis de conformité à la seconde personne avant le dernier en date des jours suivants :
…	[…]
(*d*) the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1);	***d*)** le lendemain du dernier jour de la période de vingt-quatre mois qui commence à la date à laquelle une action a été intentée en vertu du paragraphe 6(1);

[21] The relevant provisions of the Former Regulations are the following :

Former Regulations	**Règles avant révision**
6(1) A first person may, within 45 days after being served with a notice of allegation under paragraph 5(3)(a), apply to a court for an order prohibiting the Minister from issuing a notice of compliance until after the expiration of a patent that is the subject of the notice of allegation.	**6(1)** La première personne peut, au plus tard quarante-cinq jours après avoir reçu signification d'un avis d'allégation aux termes de l'alinéa 5(3)a), demander au tribunal de rendre une ordonnance interdisant au ministre de délivrer l'avis de conformité avant l'expiration du brevet en cause.
6(2) The court shall make an order pursuant to subsection (1) in respect of a patent that is the subject of one or more allegations if it finds that none of those allegations is justified.	**6(2)** Le tribunal rend une ordonnance en vertu du paragraphe (1) à l'égard du brevet visé par une ou plusieurs allégations si elle conclut qu'aucune des allégations n'est fondée.
6(3) The first person shall, within the 45 days referred to in subsection (1), serve the Minister with proof that an	**6(3)** La première personne signifie au ministre, dans la période de 45 jours visée au paragraphe (1), la preuve que

application referred to in that subsection has been made.	la demande visée à ce paragraphe a été faite.
…	[…]
6(5) Subject to subsection (5.1), in a proceeding in respect of an application under subsection (1), the court may, on the motion of a second person, dismiss the application in whole or in part	**6(5)** Sous réserve du paragraphe (5.1), lors de l'instance relative à la demande visée au paragraphe (1), le tribunal peut, sur requête de la seconde personne, rejeter tout ou partie de la demande si, selon le cas :
(*a*) in respect of those patents that are not eligible for inclusion on the register; or	***a*)** les brevets en cause ne sont pas admissibles à l'inscription au registre ;
(*b*) on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents.	***b*)** il conclut qu'elle est inutile, scandaleuse, frivole ou vexatoire ou constitue autrement, à l'égard d'un ou plusieurs brevets, un abus de procédure.

VII. The Prothonotary's decision

[22] The Prothonotary dismissed Pfizer's motion because of her view that Amgen's action did not constitute an abuse of process. Her rationale for that conclusion is set out below.

[23] After a brief review of the facts and of Pfizer's submissions in support of its motion, the Prothonotary turned to the Amended Regulations. At paragraph 13 of her reasons, she discusses some of the circumstances that necessitated amendments be made to the Former Regulations:

> The current *Regulations* (revised *Regulations*) came into force on September 21, 2017, replacing summary prohibition applications with full actions to determine with finality, the substantive issues of patent infringement and invalidity. The Regulatory Impact Analysis Statement published in Canada Gazette, Part I, Vol. 151 No. 28 on July 15, 2017 (RIAS) confirmed that the revisions addressed the inadequacies of the old *Regulations*, among them that:

- placed constraints on procedure for obtaining and adducing evidence – parties were required to rely on a "paper record" without full discovery or viva voce witness testimony;

- denied effective rights of appeal due to the "mootness" problem once a NOC was issued; and

- required patent holders/assignees to commence subsequent actions to assert their patent rights – applications under the old Regulations did not determine patent infringement or invalidity, only whether an NOA's allegations in that regard were "justified".

[24] She then indicated that section 6.08 of the Amended Regulations, which pertains to actions that constitute an abuse of process, is, in essence, a provision identical to paragraph 6(5)(*b*) of the Former Regulations, which addressed abusive applications under the old regime.

[25] The Prothonotary then turned to Pfizer's submission that, by reason of this Court's decision in *Sanofi*, this action constituted an abuse of process. Pfizer argued Amgen's action was the fourth proceeding brought by Amgen under both the Former and Amended Regulations pertaining to the same issues. According to Pfizer, it was therefore abusive for Amgen to once again institute proceedings and thereby obtain the injunctive relief of up to 24 months provided in paragraph 7(1)(*d*) of the Amended Regulations.

[26] The Prothonotary could not subscribe to Pfizer's arguments. In her view, the Hughes Decision could not "simply be grafted on the within action", since the regime now provided under the Amended Regulations is quite distinct from the regime under the Former Regulations (Prothonotary's reasons at paragraph 17). For her, a key distinguishing factor was that, following the Hughes Decision, it had been open to Amgen, under the Former Regulations, to commence a patent infringement action in regard to the '537 Patent. Citing this Court's decision in *Apotex*

Inc. v. Pfizer Ireland Pharmaceutical, 2011 FCA 77, 419 N.R. 189 [*Pfizer Ireland*], the Prothonotary pointed out that the Hughes Decision did not conclusively determine the issues of patent validity and infringement.

[27] The Prothonotary also considered the fact that, under the Former Regulations, appeals taken from Federal Court decisions concerning applications were often found to be moot by this Court because the Minister had issued a NOC to the generic (the second person) prior to the hearing of the appeal. She explained that, under the Former Regulations, a patentee's recourse was therefore to an infringement action under the Patent Act, while a generic was entitled to file a counterclaim regarding the validity of the patent at issue.

[28] The Prothonotary then indicated that, with regard to the '537 Patent, there had not yet been a final disposition of any action or counterclaim. The Hughes Decision, in her view, did not and could not determine what is in issue in Amgen's action filed under the Amended Regulations, namely, the validity of the '537 Patent and, if valid, whether Pfizer's Nivestym infringed any of the claims of the '537 Patent.

[29] Then, at paragraph 23 of her reasons, the Prothonotary made the following remarks concerning the change brought about by subsection 6(1) of the Amended Regulations:

> Thus the revised *Regulations* not only instituted the more fulsome adjudicative process of an action with its procedural safeguards of examinations for discovery and *viva voce* evidence, the issues to be decided are different as between the revised and old *Regulations* – substantive patent validity and infringement is now determined, not simply whether allegations are justified. Amgen is not pursuing a "second chance". The within action is effectively its first and only chance.

[30] At paragraph 24 of her reasons, the Prothonotary made the point that under the Amended Regulations it was not open to Amgen, whose ‘537 Patent was still on the Patent Register, to commence an action for infringement under the Patent Act in regard to its patent.

[31] She then addressed Pfizer’s arguments that the course of action open to Amgen, following the Hughes Decision, was to delist the ‘537 Patent from the Patent Register and then commence an action under the Patent Act. Having failed to delist its patent prior to being served with Pfizer’s NOA, Pfizer argued that Amgen could only blame itself for being barred from commencing an action under the Patent Act.

[32] The Prothonotary was not persuaded by Pfizer’s arguments. In her view, the purpose of the Amended Regulations was to grant patentees (first persons) the right to have patent issues litigated and determined on a full record with a true right of appeal in a single proceeding. The legislation, she added, left it to the patentee to decide whether to pursue its rights under the Amended Regulations or, if it chose to delist its patent, under the Patent Act. By delisting its patent, the patentee would thus be allowing potential competitors to obtain a NOC without having to serve upon it a NOA. In other words, it was the Prothonotary’s view that there was no obligation on the part of Amgen to delist its patent and to proceed by way of an action under the Patent Act.

[33] The Prothonotary concluded her remarks, at paragraph 28 of her reasons, as follows:

> Accordingly, I am not satisfied beyond doubt that it is plain and obvious that the within action is scandalous, frivolous, vexatious or is otherwise an abuse of the Court’s process. It is neither relitigation nor redundant. Actions commenced under

> the revised [Amended] *Regulations* determine different issues than in applications commenced under the old [Former] *Regulations*."
>
> [My emphasis].

[34] As a result, the Prothonotary dismissed Pfizer's motion with costs in favor of Amgen, in any event of the cause.

VIII. Issue

[35] The only issue before us on this Appeal is whether the Prothonotary erred in dismissing Pfizer's motion for abuse of process.

IX. Standard of Review

[36] In *Hospira Healthcare Corporation v. Kennedy Institute of Rheumatology*, 2016 FCA 215, [2017] 1 F.C.R. 331 this Court held that discretionary decisions of prothonotaries were subject to the standards enunciated by the Supreme Court of Canada in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 23. Consequently, questions of fact and questions of mixed fact and law are reviewable on the basis of the palpable and overriding error standard and questions of law and questions of mixed fact and law, where there is an extricable legal principle at issue, they will be reviewed on the standard of correctness.

[37] While the parties are not in disagreement with respect to the applicable standards, they disagree as to whether the appeal raises a question of law or a question of mixed fact and law. Pfizer says there are two pure questions of law that must be determined on the appeal. Firstly, the Prothonotary's determination that *Sanofi* was no longer good law under the Amended

Regulations, and, second, whether she erred in failing to apply the proper legal test for abuse of process motions.

[38] I agree with Pfizer that the first question is a question of law. However, I ultimately conclude that the Prothonotary's treatment of *Sanofi* was correct and therefore that her conclusion flowing from the application of the law to the facts is to be determined under the palpable and overriding error standard. In addition, while I agree, as I must, that selecting the appropriate legal test is a question of law, I see no error on the part of the Prothonotary with regard to the applicable test and its application, albeit her articulation of the test was not as clear as it should have been.

X. Analysis

A. *The Prothonotary's first error*

[39] I begin with Pfizer's submission that the Prothonotary erred in finding that this Court's decision in *Sanofi* was no longer good law under the Amended Regulations. Pfizer's specific arguments are discussed below.

[40] First, Pfizer makes the point that, on the basis of *Sanofi*, there were no second chances under the Former Regulations. In other words, once a patentee failed on a section 6 proceeding, it was barred from commencing, in respect of similar issues, another application to prevent a different generic from obtaining a NOC and entering the market with its product. Thus, by reason of *Sanofi*, the fate of a second application was its dismissal by the Court on the grounds that the proceeding was an abuse of process under paragraph 6(5)(*b*) of the Former Regulations.

Consequently, the only remedy available in those circumstances, according to Pfizer, was for a patentee to commence a patent infringement action under section 55 of the Patent Act.

[41] This reasoning leads Pfizer to say that, following the Hughes Decision, Amgen could only assert its rights under the ‘537 Patent by way of an action under the Patent Act.

[42] Pfizer then says that because section 6.08 of the Amended Regulations and paragraph 6(5)(*b*) of the Former Regulations are identical provisions, there is no basis for the Court to treat them differently. Treating the provisions differently, Pfizer adds, would lead to the type of inconsistency that the Court cautioned against in *Sanofi*.

[43] With those principles in mind, Pfizer says that the Prothonotary was in error in distinguishing section 6.08 of the Amended Regulations from paragraph 6(5)(*b*) of the Former Regulations, which she did on the grounds that the issues to be determined under the Amended Regulations were not the same as those that were the subject of applications referred to in paragraph 6(5)(*b*) of the Former Regulations. In Pfizer’s view, the principles enunciated in *Sanofi* and the Court’s inherent jurisdiction to prevent abuse of process remain applicable under the Amended Regulations.

[44] Pfizer further argues, in response to Amgen’s submission that it is entitled to assert the remedy of the action provided in section 6(1) of the Amended Regulations, that because the amendments did not create new rights, Amgen could only assert its rights by way of an action

under the Patent Act. In other words, Pfizer says that Amgen cannot use the amendments to resurrect its section 6 rights that lapsed following the Hughes Decision.

[45] Pfizer's rationale for this proposition is that section 6 confers upon patentees significant and special benefits that are unavailable under the Patent Act. Namely, section 6 requires a second person to serve a NOA on a first person, bestows on patentees the right to commence *quia timet* actions before a second person may enter the market, and entitles a first person bringing an action under section 6 to an automatic 24-month stay before a second person can obtain a NOC.

[46] After pointing out that the above benefits, which existed under the Former Regulations, have not changed under the Amended Regulations, Pfizer says that these benefits are "draconian" and that patentees cannot be allowed, after an unsuccessful attempt under section 6, to again utilize the aforesaid benefits to its advantage.

[47] According to Pfizer, instead of focussing on the fact that the amendments changed the remedy under section 6 from an application to an action, the Prothonotary should have considered whether Amgen once again availing itself of the benefits provided by the Regulations would promote the integrity of the Court's process. In its view, the answer to that question is no.

[48] In Pfizer's view, Amgen's only remedy was an action under the Patent Act and not one under the Amended Regulations. In other words, an action, no different from the one available

under section 6(1), was available to Amgen except that under the Patent Act Amgen could not avail itself of the benefits conferred upon patentees by the Regulations.

[49] In concluding its remarks with regard to the Prothonotary's first purported error, Pfizer says that the principles leading to the Court's final determination in *Sanofi* continue to apply under the Amended Regulations, namely, judicial economy, inconsistency and the integrity of the adjudicative process. Paragraphs 91 and 92 of Pfizer's memorandum of fact and law clearly set out its position:

> This case will not enhance the credibility or effectiveness of the judicial process. To the contrary, the outcome is absurd. Amgen's right to invoke the *Regulations* is resurrected and they are allowed to stop new competitors from entering markets that have been genericized for years. This encourages first persons who have been unsuccessful under the *Regulations* to again assert their patents listed on the Register so that they can take advantage of extraordinary remedies (such as the ability to bring *quia timet* actions and the automatic stay). The inconsistent treatment of competitors is manifestly unfair to Pfizer and plainly threatens the "integrity of the administration of justice".
>
> The safeguard for patentees under the previous *Regulations* was a patent infringement action. That is still a safeguard under the amended *Regulations*. It was not another section 6 proceeding.

[50] Finally, Pfizer takes issue with the Prothonotary's view that, absent an action under section 6(1) of the Amended Regulations, Amgen would be precluded from asserting its rights under the '537 Patent.

[51] In Pfizer's opinion, the Prothonotary's view is misguided. While it is true that under the Amended Regulations, a patentee whose patent remains listed on the Patent Register cannot take an action other than the one set out at section 6(1), it was open to Amgen to delist the '537 patent

from the Patent Register which would have allowed it to commence an action under the Patent Act.

[52] In other words, Pfizer's position is that, following the Hughes Decision, Amgen should have immediately delisted the '537 Patent or, at the very least, should have done so upon the coming into force of the amendments in September 2017.

[53] Having chosen not to delist the '537 Patent and hence elected to continue to use the Patent Register as an obstacle to prevent competitors from entering the market, Amgen is said to no longer be in a position to complain of unfairness. Pfizer says that Amgen must now live by its strategic choice and that its wound is self-inflicted.

[54] Pfizer also takes issue with the Protonothary's view that it was nonsensical to force Amgen to delist its patent and that the Amended Regulations did not intend such an outcome. Pfizer says that the Prothonotary, in coming to that view, ignored the Regulatory Impact Analysis Statement (RIAS), which Pfizer says specifically warned first persons that failure to delist their patents would be fatal to their ability to bring infringement actions under the Patent Act.

[55] In my respectful view, the Prothonotary did not misunderstand *Sanofi* and did not commit a reviewable error. The question, in my view, is not whether *Sanofi* is good law, as it obviously remains good law, but rather whether the action commenced by Amgen, in light of the Amended Regulations, constitutes an abuse of process. In my view, it does not.

[56] To begin with, it will be useful to examine why this Court in *Sanofi* concluded that Sanofi's attempt to relitigate, under section 6(1) of the Former Regulations, issues that had already been dealt with by the Federal Court and this Court in previous proceedings, *i.e.* in *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, 43 CPR (4th) 161 and *Aventis Pharma Inc. v. Apotex Inc.*, 2006 FCA 64, 46 CPR (4th) 401 [*Apotex*], constituted an abuse of process.

[57] In *Sanofi*, at paragraph 35 of his reasons for this Court, Sexton J.A. indicated that "this Court's analysis with respect to abuse of process must now be informed by the principles enunciated by the Supreme Court of Canada in *Toronto (City) v. C.U.P.E., Local 79*, [2003] 3 S.C.R. 77, 2003 SCC 63 ("C.U.P.E.")." Those principles, on which this Court relied in *Sanofi*, may be stated as follows:

i. The doctrine of abuse of process engages the inherent power of the Court to prohibit the misuse of its procedure;

ii. The doctrine of abuse of process is a flexible doctrine unencumbered by the specific requirements of concepts such as issue estoppel;

iii. An example of circumstances where the doctrine of abuse of process has found application is where, though the requirements of issue estoppel are not met, the litigation at issue is, in essence, an attempt to relitigate a claim already determined by the Court, and allowing relitigation would have a negative impact on judicial economy, on consistency, on finality and on the integrity of the administration of justice;

iv. The doctrine of abuse of process concentrates on the integrity of the adjudicative process;

v. Futility of the proceedings at issue (the plain and obvious test) is not the correct test in dealing with motions of abuse of process because proceedings which constitute an abuse of process are not necessarily futile.

[58] At paragraph 36 of his reasons in *Sanofi*, Sexton J.A. stated that there was no reason to believe that a second attempt under section 6 of the Former Regulations would "lead to a more accurate result than the first [application]." He went on to remark that such a scenario was different from one where the second proceeding is an action for infringement under the Patent Act because, in the latter proceeding, the parties will "have the benefit of a full trial and the attendant procedural safeguards, [and therefore] a more accurate result may arise." This led Sexton J.A. to make the point that decisions under the Former Regulations "are not binding on actions for patent infringement or to declare a patent invalid".

[59] Sexton J.A. also wrote that it was important, in deciding whether proceedings constituted an abuse of process, to ensure that application of the doctrine did not result in unfairness. In his opinion, no unfairness would arise from a finding of abuse of process in the matter before the Court because "[p]rohibition proceedings under the NOC Regulations do not prevent patentees from enforcing their patent rights through actions for patent infringement in accordance with the *Patent Act*. Moreover, the findings from any such prohibition proceedings have no bearing on patent infringement actions." (*Sanofi* at paragraph 40).

[60] With the above principles in mind, I now turn to Pfizer's arguments.

[61] While it is correct to say that under the Former Regulations, by reason of *Sanofi*, a patentee was not entitled to a second attempt under section 6(1) against another generic with regard to the same issues, the question is whether this holds true following the adoption of the Amended Regulations. In my view, considering the nature of a section 6 action under the Amended Regulations and in the light of the principles enunciated in *Sanofi*, Amgen's action cannot be found to be an abuse of process.

[62] First, *Sanofi*, in following *C.U.P.E.*, made it clear that what it considered an abuse of process was the fact that *Sanofi*'s second application could possibly give rise to inconsistent judicial decisions on the same issues in equivalent proceedings, which could jeopardize the credibility of the adjudicative process.

[63] Second, the purpose of a section 6 application under the Former Regulations was not to determine the questions of infringement or validity of the patent, as in a section 55 action under the Patent Act, but rather the question of whether the Minister should be prohibited from issuing a NOC to a generic with respect to a product biosimilar to the patentee's product (see, for example, *Merck Frosst Canada Ltd. v. Canada (Minister of National Health and Welfare)*, [1994] F.C.J. No. 662 (C.A.) at para 25 [*Merck Frosst*]; *David Bull Laboratories (Canada) Inc. v. Pharmacia Inc.* (1994), [1995] 1 F.C. 588 (C.A.) at para 14 [*David Bull*]; *Pfizer Canada Inc. v. Apotex Inc.*, [2001] 11 C.P.R. (4th) 245, 2001 CanLII 22156 (FCA) at para 25 [*Apotex 2001*]; *Novartis AG v. Apotex Inc.*, 2002 FCA 440 at para 9 [*Novartis*]; *Sanofi* at para 36; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359 at para 40; *Pfizer Ireland* at para 19). The proceedings under section 6 of the Former Regulations and those pursued under section 55 of the

Patent Act are therefore not equivalent proceedings as they seek to determine entirely different questions.

[64] Third, because of the foregoing, under the Former Regulations, a patentee could commence proceedings under section 55 of the Patent Act following the dismissal of a section 6 application.

[65] Finally, and crucially, an action commenced under section 6 of the Amended Regulations decides essentially the same issues as a section 55 action under the Patent Act. Consequently, on my understanding of *Sanofi*, Pfizer is wrong to say that under the Amended Regulations, a patentee who failed in respect of an application under the Former Regulations is barred from commencing an action under section 6 of the Amended Regulations because that action constitutes an abuse of process. In my view, it does not. The present scenario is quite different from the one before the Court in *Sanofi*. The issues to be determined in Amgen's section 6 action, namely, whether Pfizer's product will infringe the '537 Patent or whether the '537 Patent is valid, are not issues that were determined by the Hughes Decision and thus remain to be determined. Accordingly, in my respectful opinion, there is nothing abusive about Amgen's section 6 action.

[66] On my understanding of *Sanofi* and the Amended Regulations, it cannot be said that Amgen's action threatens the credibility of the adjudicative process nor that it will have a negative impact on the efficient use of scarce judicial resources.

[67] Before turning to Pfizer's argument that no unfairness would result from the dismissal of Amgen's action, I wish to discuss this Court's decision in *Pfizer Ireland*, which helps clarify the Court's decision in *Sanofi* and which, in my respectful opinion, makes it abundantly clear that Amgen's action under section 6 of the Amended Regulations does not constitute an abuse of process.

[68] The appeal before this Court in *Pfizer Ireland* was in the context of a section 55 Patent Act action in which the generic was seeking a declaration of invalidity of the patent at issue.

[69] Prior to the commencement of the section 55 proceedings, the Federal Court had made an order, under the Former Regulations, that prohibited the Minister from issuing a NOC to the generic until the expiry of the patent. More particularly, the Federal Court had found that the generic's allegation of invalidity was not justified. The generic's appeal of that decision was dismissed by this Court.

[70] In its defence to the generic's action, the patentee asserted, *inter alia*, that by reason of *res judicata*, issue estoppel, collateral estoppel, comity and abuse of process, the generic was precluded from relitigating certain issues which had already been determined in the section 6 application.

[71] This led the generic to file a motion under Rule 221(1)(*a*) of the *Federal Courts Rules*, S.O.R./98-106 for an order striking those paragraphs of the patentee's defence that made reference to the NOC proceedings under the Former Regulations.

[72] Because its motion was dismissed by a prothonotary, the generic sought *de novo* review before a judge of the Federal Court who struck, on consent, the patentee's defence based on *res judicata* but did not interfere with the prothonotary's decision in all other aspects. As a result, the generic appealed the Federal Court's decision to this Court.

[73] After making the point that the generic's motion was to be determined on the "plain and obvious" test, Sexton J.A., writing for the Court, turned to the parties' arguments and to the merits of the motion.

[74] First, he indicated his agreement with the generic's assertions that "this Court has taken a dim view of attempts to prevent relitigation of issues decided in NOC proceedings in subsequent actions" (Pfizer Ireland at paragraph 12). Sexton J.A. considered, in light of this argument, that it would be useful to review the Court's jurisprudence on the issue.

[75] Sexton J.A. examined our decisions in *Merck Frosst*, *David Bull*, *Apotex 2001*, *Novartis*, and, finally, *Sanofi*. In his view, these were decisions which "dealt only with whether decisions as to validity or infringement made in an NOC proceeding were binding in a subsequent action" (*Pfizer Ireland* at paragraph 18) and in which the Court had made it clear that *res judicata* as a defence was not available.

[76] Sexton J.A. then went on to explain that in these cases, the Court meant, by *res judicata*, a doctrine whereby a party could not relitigate a cause of action which had already been dealt with, adding, at paragraph 19 of his reasons, that:

> *Res judicata* in the sense of cause of action estoppel is inapplicable because the subject matter of an infringement or impeachment action is very different from that of an NOC proceeding. The question before a judge in NOC proceedings is simply whether the allegations of invalidity or non-infringement contained in a notice of allegation are justified. … Simply put, the issues of validity and infringement are not before the court in an NOC proceeding.

[77] Thus, Sexton J.A. made it clear that decisions as to whether allegations of invalidity or infringement were justified made in the context of NOC proceedings could not preclude, by res judicata, subsequent actions from determining substantively the issues of validity or infringement. However, he then made the point that it remained open to a trial judge to apply the doctrines of issue estoppel or abuse of process in a section 55 action where a party was attempting to relitigate certain factual and legal issues determined in an earlier proceeding, such as a NOC application, emphasizing that whether issue estoppel and abuse of process apply as bars to relitigation is a matter falling under the discretion of a trial judge. Sexton J.A. makes the point, at paragraph 22 of his reasons, that the principles on which *Sanofi* was decided can, therefore, apply to prevent relitigation in a section 55 action of certain issues previously litigated in a NOC proceeding.

[78] Sexton J.A. stated that determinations by a trial judge on whether to apply the doctrines of issue estoppel or abuse of process in this manner depend on a "wide variety of circumstances" (*Pfizer Ireland* at paragraph 19). Such determinations could not, in his view, in most instances, be made in the context of a pleadings motion like the one before the Court on the appeal.

[79] Sexton J.A. then turned to this Court's decision in *Pfizer Limited v. Ratiopharm*, 2010 FCA 204, 87 C.P.R. (4th) 185, which, in his view, was the only case which had dealt "with

whether subsidiary findings in an NOC proceeding can have binding effect in a subsequent action" (*Pfizer Ireland* at paragraph 23). In that case, the Court had to determine if a factual conclusion made in a NOC proceeding could bind the Court in a subsequent section 55 action. Sexton J.A. referred to paragraphs 25 and 26 of that decision where Layden-Stevenson J.A. wrote:

> This Court has repeatedly stated that what I will refer to as "NOC proceedings" do not operate as res judicata. While Pfizer may be correct that the factual basis in the NOC proceeding is the same as that in this action, it does not follow that the evidentiary basis is the same. Factual findings are derived from the evidence that is before the court in the particular proceeding. The trial judge was aware of the previous NOC proceedings in relation to the '393 Patent and considered them to be instructive (reasons at para. 18). However, he was not and could not be bound by the factual determinations in a prior NOC proceeding. Rather, it was incumbent upon the judge to arrive at his findings on the basis of the evidence that was before him (at paragraphs 25 and 26, emphasis added by Sexton J.A.).

[80] Sexton J.A. then remarked that Layden-Stevenson J.A. had "left open the possibility that issue estoppel or abuse of process could apply to prevent relitigation of the factual issue where the evidentiary record at trial was identical to that of the NOC proceeding. It is also significant that she considered the applicability of those defences after trial and on a full factual record, rather than at a preliminary stage" (*Pfizer Ireland* at paragraph 23).

[81] All of the above led Sexton J.A. to reiterate that proceedings under the Former Regulations were of a different nature than those commenced under section 55 of the Patent Act, but that the doctrines of issue estoppel and abuse of process remained alive in a section 55 action to "prevent the relitigation of subsidiary factual and legal issues in order to preserve judicial resources, promote the integrity of the justice system, prevent inconsistent findings, and prevent abuse." (*Pfizer Ireland* at paragraph 24). In addition, Sexton J.A. said that the distinction

between the two types of proceedings constituted an important consideration for a trial judge in determining whether abuse of process and related doctrines should find application in a section 55 action: "courts should be cognisant of the summary nature of NOC proceedings and the fact that no discoveries or live evidence are permissible" (*Pfizer Ireland* at paragraph 25).

[82] Of great relevance to the determination of this appeal are Sexton J.A.'s remarks, found at paragraph 25 of his reasons in *Pfizer Ireland*, that because *res judicata* did not apply to determinations of validity and infringement, made in the context of NOC proceedings, parties were free to commence proceedings seeking the determination of these issues "in other fora."

[83] The Court's decision in *Pfizer Ireland* leaves no doubt, in my respectful opinion, that the commencement of a section 55 action cannot be prevented by reason of a decision made under section 6 of the Former Regulations. Hence, I am satisfied that the same conclusion must be reached in respect of an action commenced under section 6 of the Amended Regulations which, for all intents and purposes, is a proceeding identical to a section 55 action.

[84] Thus, although Pfizer cannot succeed on the motion now before this Court, it remains open to it to raise issue estoppel and abuse of process once Amgen's action goes to trial. Whether or not Pfizer can succeed on those grounds in respect of factual findings and legal determinations made by the Hughes Decision, shall, as Sexton J.A. made clear in *Pfizer Ireland*, depend on the trial judge's assessment of these issues in light of the evidence.

[85] I now turn to Pfizer's argument that Amgen's proper recourse in this situation was not an action under section 6 of the Amended Regulations but rather an action under the Patent Act. Pfizer's argument, put simply, is that Amgen should have delisted the '537 Patent at the earliest possible time and commenced a section 55 action. The purpose of this argument by Pfizer is to satisfy the Court that no unfairness would result from the dismissal of Amgen's action on the ground that it is an abuse of process.

[86] Having concluded that Amgen's action cannot be found to be an abuse of process, there is no necessity to determine Pfizer's argument that Amgen should have delisted its '537 Patent so as to allow it to commence an action under section 55 of the Patent Act. I would, however, make the following comments.

[87] The Amended Regulations are clear that, in the case of a listed patent, a patentee has no option but to commence an action pursuant to the terms of section 6 of the Amended Regulations. Further, there cannot be any doubt, in my view, that a patentee is under no obligation to delist its patent unless it intends to opt out of the Amended Regulations. Clearly, in the present matter, Amgen does not wish to opt out of the Amended Regulations. I am satisfied that the true reason for Pfizer's motion to dismiss Amgen's action for abuse of process is that it objects to Amgen's right to benefit from the 24-month automatic stay provided by paragraph 7(1)(*d*) of the Amended Regulations. In other words, Pfizer has no difficulty with the general proposition that Amgen, like any other patentee, has a right to pursue an infringement action regarding its product but takes the position that it should not and cannot be entitled to benefit from the automatic stay.

[88] Unfortunately for Pfizer, the Amended Regulations do not support its argument. In my respectful view, this is a matter that could have been addressed by Parliament had it felt it necessary to do so. As Parliament did not address the issue, I can only conclude, on the basis of the Amended Regulations as they presently read, that Amgen may benefit from the 24-month automatic stay. There is absolutely nothing in the Amended Regulations which would allow us to reach the conclusion sought by Pfizer.

[89] For these reasons, I cannot find that the Prothonotary erred in her understanding of *Sanofi* or that she misapplied that decision.

B. *The Prothonotary's second error*

[90] I now turn to the second error Pfizer alleges the Prothonotary to have made. Pfizer says that the Prothonotary failed to apply the proper legal test in determining its motion. In my respectful opinion, that submission cannot but fail.

[91] Pfizer points to paragraph 28 of the Prothonotary's reasons and says that the plain and obvious test is clearly the wrong test. In making this argument, Pfizer directs us to *Sanofi* at paragraphs 31, 35 and 36, where the Court explains that, since the doctrine of abuse of process is concerned with the integrity of the judicial process, the plain and obvious test is not the appropriate test. Rather, on a motion such as the one before us in this matter, the Court's role is to make a substantive determination regarding the impact of the proceeding at issue on the integrity of the judicial process. The fact that proceedings are not futile is no bar or defense against a motion for abuse of process.

[92] Pfizer says that in applying the wrong test, the Prothonotary failed to consider the principles animating the abuse of process doctrine. More particularly, Pfizer says that the Prothonotary failed to appreciate that Amgen was attempting to benefit from the automatic stay of 24 months, which, in the circumstances, is manifestly unfair to Pfizer and could bring the administration of justice into disrepute.

[93] In my respectful view, the Prothonotary made no error in respect of the applicable test as, notwithstanding the unfortunate sentence found at paragraph 28 of her reasons, she clearly did not apply the plain and obvious test in determining Pfizer's motion.

[94] My summary of the Prothonotary's decision, at paragraphs [22] to [34] hereinabove, clearly demonstrates that the Prothonotary substantially determined Pfizer's motion. In other words, she addressed each and every one of Pfizer's arguments, explaining why, in her view, such arguments were incorrect. She thoroughly dealt with all of the substantive issues before her, including whether, by reason of the principles enunciated in *Sanofi* and *Pfizer Ireland*, Amgen's action constituted an abuse of process. In her view, Amgen's action, contrary to the appellant's second attempt in *Sanofi* to proceed by way of section 6(1) of the Former Regulations against a different generic on the same issues, did not constitute an abuse of process. It is clearly apparent from her reasons that the plain and obvious test was not the test that she applied in making her determination.

[95] I am therefore satisfied that the Prothonotary did not err in regard to the applicable test.

XI. Conclusion

[96] For these reasons, I would dismiss the appeal with costs.

"M. Nadon"

J.A.

“I agree.
J.D. Denis Pelletier J.A.”

“I agree.
Yves de Montigny J.A.”

FEDERAL COURT OF APPEAL

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