Federal Court  Cour fédérale

**Date: 20190311**

**Docket: T-1969-17**
**T-1970-17**
**T-1971-17**

**Citation: 2019 FC 293**

**Ottawa, Ontario, March 11, 2019**

**PRESENT: Case Management Judge Mandy Aylen**

**BETWEEN:**

**GENENTECH, INC. AND HOFFMANN-LA ROCHE LIMITED**

**Plaintiffs/**
**Defendants by Counterclaim**

**and**

**CELLTRION HEALTHCARE CO., LTD.**

**Defendant/**
**Plaintiff by Counterclaim**

## ORDER

[1] The Plaintiffs/Defendants by Counterclaim, Genentech, Inc. and Hoffmann-La Roche Limited [Plaintiffs], seek leave to join Teva Pharmaceuticals International GmbH, Teva Canada Ltd., Teva Canada Innovation and Celltrion, Inc. [Additional Defendants] as defendants to the actions in each of T-1969-17, T-1970-17 and T-1971-17 and for leave to amend their Statement of Claim in each action to:

A. Plead additional facts concerning bringing HERZUMA to market in Canada, as set out in paragraphs 5-6, 8, 13A-13F, 44-48, 55-56, 57A-69, 71-76, 78-89, 92, 94 and 96 of each of the proposed amended pleadings;

B. To implead the Additional Defendants as parties and seek relief against them, as set out in the style of cause and paragraphs 1-3 of each of the proposed amended pleadings; and

C. To remove the 596 Patent from the action on consent, as set out in paragraphs 1(a), 2(a), 5-6, 8, 10, 12, 21, 28, 30-32, 49-54, 76(a), 78-79, 81, 84, 88, 94 and 96 of each of the proposed amended pleadings.

[2] As Celltrion consents to the proposed amendments to remove the 596 Patent, the Plaintiffs are entitled, pursuant to Rule 200 of the *Federal Courts Rules*, to amend their pleadings as of right as set out in paragraph 1(c) above.

[3] Celltrion opposes leave being granted to the Plaintiffs to join the Additional Defendants and to make the majority of the balance of the proposed amendments to the Plaintiffs' pleadings.

## Analysis

### (a) Leave to Join the Additional Defendants and Make Related Amendments

[4] Motions for leave to amend pleadings are governed by Rule 75 of the *Federal Courts Rules*. As a threshold issue, the Plaintiffs must satisfy the Court that the proposed amendment has a reasonable prospect of success, as it would be a waste of resources to allow an amendment that is doomed to fail [*Bauer Hockey Corp v Sport Maska Inc (Reebok-CCM Hockey)*, 2014 FCA 158 at para 13; *Teva Canada Limited v Gilead Sciences Inc*, 2016 FCA 176 at paras 29-31]. If

the threshold issue is satisfied, the Court then considers other factors such as whether allowing the amendment would (i) result in an injustice to the other party not capable of being compensated by an award of costs, and (ii) serve the interests of justice [*Canderel Ltd v Canada*, [1994] 1 FC 3 (CA) at para 10; *Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2014 FCA 65 at para 13]. Ultimately, it boils down to a consideration of simple fairness, common sense and the interest that the courts have that justice be done [*Merck & Co Inc v Apotex Inc*, 2003 FCA 488 at para 30; *Janssen Inc v Abbvie Corporation*, 2014 FCA 242 at para 3]. In considering whether or not to grant leave to amend, the Court must assume that the facts pleaded in the proposed amendments are true [*VISX Inc v Nidek Co*, [1996] FCJ No 1721 at para 16].

[5] Rule 104 of the *Federal Courts Rules* provides that the Court may order that a person whose presence before the Court is necessary to ensure that all matters in dispute in the proceeding may be effectually and completely determined be added as a party.

[6] However, the circumstances of these actions are unique, in that the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 [*Regulations*] create a statutory override to the test set out in Rule 104. As such, the issue before the Court is whether the *Regulations* permit the claims against the Additional Defendants, as articulated in the proposed pleadings, to be brought in these actions.

[7] Canadian patent law is statutory and accordingly, any cause of action must be grounded in the *Patent Act* and/or the *Regulations* [*Apotex v Sanofi-Synthelabo Canada Inc*, [2008] 3 SCR 265 at para 12]. In this case, Celltrion Healthcare Co, Ltd [CTHC] filed a number of new drug submissions [NDSs] seeking regulatory approval for its drug HERZUMA and served corresponding notices of allegations on Roche Canada. Section 55.2(1) of the *Patent Act*

provides that activities in pursuit of regulatory approval are exempt from a claim of patent infringement. However, the *Regulations* create a statutory cause of action – namely, an action pursuant to section 6(1) of the *Regulations* - that may be brought by first persons and patent holders while a drug is awaiting regulatory approval from Health Canada.

[8] Each of these actions are actions brought pursuant to section 6(1) of the *Regulations*, which provides:

> 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 submissions 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.
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> 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.

[9] The *Regulations* define a "second person" in section 2(1) thereof as "the person referred to in subsection 5(1) or (2) who files a submission or supplement referred to in those subsections". Section 5(1) provides:

> If a second person files a submission for a notice of compliance in respect of a drug
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> Dans le cas où la seconde personne dépose une présentation pour un avis de

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| and the submission directly or indirectly compares the drug with, or make reference to, another drug marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the submission the required statements or allegations set out in subsection (2.1). | conformité à l'égard d'une drogue, laquelle présentation, directement ou indirectement, compare celle-ci à une autre drogue commercialisée sur le marché canadien aux termes d'un avis de conformité délivré à la première personne et à l'égard de laquelle une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne inclut dans sa présentation les déclarations ou allégations visées au paragraphe (2.1). |

[10] Section 5(2) provides:

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| If a second person files a supplement to a submission referred to in subsection (1) seeking a notice of compliance for a change in formulation, a change in dosage form or a change in use of the medicinal ingredient and the supplement directly or indirectly compares the drug for which the supplement is filed with, or makes reference to, another drug that has been marketed in Canada under a notice of compliance issued to a first person and in respect of which a patent list has been submitted, the second person shall include in the supplement the required statements or allegations set out in subsection (2.1). | Dans le cas où la seconde personne dépose un supplément à la présentation visée au paragraphe (1), en vue d'obtenir un avis de conformité à l'égard d'une modification de la formulation, d'une modification de la forme posologique ou d'une modification de l'utilisation de l'ingrédient médicinal, lequel supplément, directement ou indirectement, compare la drogue pour laquelle le supplément est déposé à une autre drogue commercialisée sur le marché canadien aux termes de l'avis de conformité délivré à la première personne et à l'égard duquel une liste de brevets a été présentée — ou y fait renvoi —, cette seconde personne inclut dans son supplément les déclarations ou allégations visées au paragraphe (2.1). |

[11] The Plaintiffs assert the *Regulations* do not preclude the joinder of the Additional Defendants, arguing that:

A. Section 6(1) merely provides that a second person must be named as a defendant to an action. Once that "box is checked", there is no prohibition on adding other parties as defendants beyond the second person.

B. In the alternative, the Additional Defendants can be viewed as falling within the meaning of second person as:

    a. The definition of second person is not merely the person named in the submission, it is the person who files a submission. As the Additional Defendants have been involved in the regulatory process, including the filing of the submissions, each of them could be said to be a second person; and

    b. The definition of second person is flexible enough to include the Additional Defendants by virtue of the common law concepts of agency, corporate control, inducement and common design.

[12] The Plaintiffs further assert that if there is any doubt, the issue of whether a section 6(1) action can be brought against non-second persons and the issue of whether the Additional Defendants are second persons should be left to be determined by the trial judge.

[13] CTHC asserts that a proper interpretation of the *Regulations*, grounded in a consideration of the purpose of the *Regulations* and taking into consideration the various rights and obligations imposed by the *Regulations*, renders it clear that a section 6(1) action can only be brought

against a second person and that there is no right of action against any other person. Moreover, CTHC asserts that the Additional Defendants cannot, as pleaded, be considered second persons within the meaning of the *Regulations*.

[14] The first issue for determination is whether the *Regulations* permit a section 6(1) action to be brought against a non-second person.

[15] On a plain reading, section 6(1) creates a statutory cause of action against a second person only. Had Parliament intended for that cause of action to extend to other non-second persons, it could certainly have included non-second persons within that provision. It is not open to the Court to read into the plain meaning of this provision a qualification to, or an expansion of, the right of action, which Parliament could have expressly provided if that was the intention [*American Cyanamid Co v Novopharm Ltd*, [1972] F.C. 739 at para 62.].

[16] The regulatory regime created by the *Regulations* is a closed one. All procedural and substantive rights and obligations are granted to a first person, a second person, patent owners and the Minister of Health only. The *Regulations* are not directed at all claims of patent infringement that could arise from the entry of a generic drug into the Canadian market. Rather, they are intended to prevent only infringement by (or infringement induced or procured by) generic drug producers who file NDSs containing a comparison to an existing drug product for which there is a registered patent.

[17] I note that the *Regulations* expressly take into consideration that causes of action for patent infringement under the *Patent Act* and outside of the regulatory regime may arise during

the statutory 24 month stay period. Section 6.02 of the *Regulations* expressly prohibits the joinder of any such actions with a section 6 action, providing:

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| No action may be joined to a given action brought under subsection 6(1) during any period during which the Minister shall not issue a notice of compliance because of paragraph 7(1)(d) other than | Aucune action ne peut être réunie à une action donnée intentée en vertu du paragraphe 6(1) durant la période pendant laquelle le ministre ne peut délivrer d'avis de conformité en raison de l'alinéa 7(1)d), sauf : |
| (a) another action brought under that subsection in relation to the submission or supplement in that given action; and | a) une autre action intentée en vertu de ce paragraphe relativement à la présentation ou au supplément visé dans cette action donnée; |
| (b) an action brought in relation to a certificate of supplementary protection that is added to the register after the filing of the submission or supplement in that given action, if the patent that is set out in that certificate of supplementary protection is at issue in that given action | b) toute action relative à un certificat de protection supplémentaire ajouté au registre après le dépôt de la présentation ou du supplément visé dans cette action donnée, si le brevet mentionné dans ce certificat de protection supplémentaire est en cause dans cette action donnée |

[18] The rationale for the prohibition against joinder is explained as follows in the Regulatory Impact Analysis Statement issued with the amended *Regulations* [Canada Gazette Part I, Vol 151, No 28 at 3321]:

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| The limit on joinder is necessary to restrict the number of issues in dispute to facilitate resolution within 24 months. It is also necessary to avoid further complicating the assessment of damages arising | Les restrictions quant à la réunion d'actions sont nécessaires afin de limiter le nombre de questions en litige et faciliter la résolution de l'affaire dans le délai de 24 mois. Il est aussi nécessaire d'éviter de compliquer |

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| from delayed market entry. | davantage l'évaluation des dommages-intérêts découlant du report de l'entrée sur le marché du produit. |

[19] While the joinder of the Additional Defendants could very well result in efficiencies as the Plaintiffs suggest, the limitation on the claims that may be brought within the context of the *Regulations* is driven by a critical consideration – namely, the speed by which such actions must be determined. To permit section 6 actions to be brought against a potential endless list of defendants who did not file the NDSs but have or will have some role in the making, constructing, using or selling of the generic drug in accordance with the NDS would render it difficult, if not impossible, to complete the actions within the required 24 month period. This was expressly recognized by Parliament in drafting the *Regulations* and limiting the scope of claims (and actions) that could be joined.

[20] However, in doing so, Parliament created a procedure by which the Plaintiffs could broaden the scope of claims asserted in relation to the NDSs and the underlying patents at issue in these actions by, pursuant to section 7(1)(6) of the *Regulations*, permitting the Plaintiffs to opt out of the regime established by the *Regulations* (thereby foregoing the 24-month statutory stay) and commence one global action against CTHC and any other entities against whom they would have a claim for patent infringement under the *Patent Act*.

[21] It is also worth noting that the *Regulations* impose a significant set of obligations on the first person, patent owner and/or second person. One of these obligations is detailed in section 6.09 of the *Regulations*, which provides:

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| Every first person, second | Les premières personnes, |

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| 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) or a counterclaim brought under subsection 6(3) to which they are a party. | secondes personnes et propriétaires de brevets sont tenus d'agir avec diligence en remplissant les obligations qui leur incombent au titre du présent règlement et, s'ils sont parties à une action intentée en vertu du paragraphe 6(1) ou à une demande reconventionnelle faite en vertu du paragraphe 6(3), de collaborer de façon raisonnable au règlement expéditif de celle-ci. |

[22] It would be incongruous with section 6.09 to find that section 6(1) authorizes the commencement of actions against non-second persons, as section 6.09 imposes no obligation on non-second persons to cooperate in expediting a section 6 action. For the cooperation obligation to achieve its desired result, all parties to a section 6(1) action would have to be similarly bound.

[23] I agree with CTHC that the right of action against a second person prescribed by section 6(1) is a regulatory exception to a statutory exemption to patent infringement, enacted for the limited purpose of preventing infringement by a person who takes advantage of the early working and stockpiling exemptions [*AstraZeneca Canada Inc v Canada (Minister of Health)*, 2006 SCC 49 at paras 12-16]. It would be improper to construe the scope of the regulatory exception created by section 6(1) more widely than is necessary to fulfill the values which support it [*Air Canada v British Columbia*, [1989] 1 SCR 1161 at 1207-1208]. Enlarging the right of action provided by section 6(1) beyond claims against second persons would clearly go beyond this purpose, as infringement is adequately protected by the statutory regime. In addition to the statutory stay pending the determination of the action, by operation of section 7(1) of the *Regulations*, any NDS that is subject to a declaration of infringement will not be approved until

expiry of the patent that has been declared infringed. As an unapproved NDS cannot be marketed, there is no need to enjoin non-second persons who may have a role to play in bringing the subject generic drug to market.

[24] Accordingly, I find that the plain wording of the *Regulations*, considered as a whole and in light of the purpose of the *Regulations*, makes it apparent that a section 6(1) action may not be brought against non-second persons.

[25] The second issue for determination is whether a proper interpretation of second person could include the Additional Defendants and if so, whether the proposed pleadings advanced by the Plaintiffs are sufficient to bring the Additional Defendants within the Plaintiffs' proposed interpretation of second person.

[26] On the second issue, the Plaintiffs rely on the Federal Court of Appeal's decision in *Apotex Inc v Eli Lilly and Co*, 2004 FCA 358 [*Eli Lilly*], where the Federal Court of Appeal considered whether the definition of "first person" in the context of a section 8 proceeding could include Lilly Canada's US entity, notwithstanding that it was Lilly Canada that had listed the patents at issue pursuant to section 4 of the *Regulations*. Lilly US had brought a motion for summary judgment seeking to have the claim against it dismissed on the basis that only Lilly Canada could be considered a first person. In the action, Apotex had asserted that Lilly Canada was a wholly owned subsidiary of Lilly US and that Lilly US exerted complete control over the operations of Lilly Canada. The motions judge held that the assertion that Lilly US exercised control over Lilly Canada was irrelevant to the determination of the first person issue, as Apotex's motion was based on legislation, rather than the common law.

[27] The Federal Court of Appeal held:

> [11] That common law concepts, such as agency, for example, are never relevant to the interpretation of legislation is a very broad proposition, for which no supporting authority was advanced. Indeed, it is clear from the cases relied upon by Apotex that, in some circumstances at least, whether a wholly owned subsidiary has acted, in effect, as the agent of its shareholder corporation may be relevant in determining the liability of the parent under a taxing statute: see, in particular, *Aluminum Company of Canada Ltd. v. City of Toronto*, [1944] S.C.R. 267 at 271-72.
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> [12] In my opinion, the assertions of complete corporate control in Apotex's pleadings go beyond asserting the kind of relationship between Lilly US and Lilly Canada that inevitably exists between a corporation and its sole shareholder. It might emerge on discovery that the degree of control exercised by Lilly US over Lilly Canada was such as to make Lilly US a "first person".
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> [13] If this were so, actions taken in the name of Lilly Canada, including the submission of a patent list with respect to nizaditine, might be regarded as actions taken by both Lilly Canada and Lilly US. Thus, Lilly US might be a "first person", and therefore a proper defendant to Apotex's claim under section 8, a question that involves issues of law and fact that cannot be determined without a trial. Further, since the *Interpretation Act*, R.S.C. 1985, c.I-21, subsection 33(2), presumes that "words in the singular include the plural", the fact that section 8 speaks of a "first person" does not preclude the possibility that both Lilly US and Lilly Canada could be found to be a "first person" in this context.
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> [14] In my respectful opinion, therefore, the Motions Judge erred in law in the exercise of her discretion when she said that whether Lilly US controlled Lilly Canada as alleged in Apotex's pleadings could not be relevant to whether Lilly US was a "first person" because of the statutory nature of Apotex's cause of action. Whether, for the purpose of section 8, a "first person" includes the corporation who directed the submission of the patent list in the name of its subsidiary is a sufficiently difficult legal question to require a trial.

[28] The Plaintiffs assert that the *Eli Lilly* case demonstrates that common law concepts such as agency and control may be relevant to the interpretation of "second person" under the

*Regulations* and that the Federal Court of Appeal has left the door open to there being more than one "second person" under the *Regulations*. Applying these principles to the proposed pleadings, the Plaintiffs assert that it is at least arguable that "second person" could include the Additional Defendants by virtue of the common law concepts of agency, corporate control, inducement and common design, which the Plaintiffs assert are implicated in the amendments sought to be made.

[29] At the hearing of the motion, I brought to the attention of the parties additional authorities that had considered the meaning of "first person" for the purpose of a section 8 action and sought their submissions in relation thereto. In *Sanofi-Aventis Canada Inc v Novopharm Limited*, 2010 FC 150 at para 27, Madam Prothonotary Milczynski held:

> Whether a "first person" under the *Regulations* may include persons other than the person who filed the NDS and patent list (or cannot include them without amendment to the *Regulations*) has not yet been fully canvassed at trial, and has yet to be finally determined. Thus, it is clear that this issue ought not to be decided on a motion to strike, where sufficient material facts have otherwise been pleaded to support the claim. Novopharm has done so in respect of Sanofi Germany. However, even if Novopharm's broader interpretation of "first person" is accepted, the allegations as against Schering fail to meet the requirement of pleading sufficient material facts that if proven, would enable a Court to make a finding that Sanofi Canada was an agent, acting as nominal first person, directed and controlled by Schering. Schering and Sanofi Canada are unrelated parties. Novopharm has not pleaded that Schering is a "first person" that exercises "complete control" over Sanofi Canada. I am satisfied that in any event of the disposition of the first person issue, it is plain and obvious that Novopharm's claim for section 8 damages against Schering is clearly doomed to fail.

[30] In *Teva Canada Ltd v Pfizer Canada Inc*, 2014 FC 69, Justice de Montigny found that the decision in *Eli Lilly* left the door open for other considerations that are potentially relevant to determining whether each applicant for a prohibition order was also a first person.

[31] In *Actavis Pharma Co v Alcon Canada Inc*, [2016] OJ No 5965, Justice Akbarali of the Ontario Superior Court of Justice considered a motion to strike on the basis that the defendant at issue could not be considered a first person within the meaning of the *Regulations* and held:

> [25] The law as to who can be a first person is thus unsettled. However, where allegations of complete control of a first person have been levied against a party who is also pleaded to be a first person, the claims have been allowed to proceed. Neither party here could point me to a case that dealt squarely with an alleged controlling first person from a different corporate family. As I have already noted, the *Sanofi-Aventis* case is closest to the point but the pleading against Schering was deficient.
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> [26] At its essence the question is whether "control" for the purposes of being a first person under s.8 of the PMNOC can only mean "control" in the traditional sense of corporate structure, or whether "control" can have a broader meaning in this context. In other words, if a corporation controls a corporation that is a first person by reason of something other than their corporate structures, is it frivolous to plead that the controlling corporation is also a first person?
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> [27] In its pleading, the plaintiff has alleged that Kyowa exercised complete control over Alcon Canada in that it controlled a number of matters relating to the marketing and sale of drug products, the listing of products on the patent list, and the proceedings that are or may be taken under the PMNOC. The allegations made by the plaintiff are strikingly similar to those made in *Apotex Inc. v. Eli Lilly and Company and Eli Lilly Canada Inc.*: 2004 FCA 358 at para. 9. Lilly US's motion for summary judgment was dismissed and the allegations against it allowed to proceed. While there, the allegations of control were made against a related company, there is nothing before me to suggest that complete control can only occur when companies are related.
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> [28] Certainly where corporations are related, complete control may be easier to make out, but this is not a trial on the merits. I am not prepared to find, at this early stage, in the face of the pleading that Kyowa exerted complete control over Alcon Canada in respect of matters relevant to *PMNOC*, that it is frivolous to claim that Kyowa is also a first person.

[32] At the hearing of the motion, none of the parties were able to point me to a decision where the issue of the scope of "first person" under the *Regulations* was finally determined at trial. As such, it remains an unsettled issue. In light of the aforementioned case law, I find that this Court may well engage in a similar approach to consider whether a "second person", for the purpose of a section 6(1) action, can include someone other than the person who filed the NDS. Therefore, I must leave open the possibility that the Plaintiffs could succeed on their conceptual argument that second person could include another person.

[33] However, whatever the determination might be made as to whether a second person can include another person, I find that, as pleaded, the Plaintiffs' claim against the Additional Defendants is doomed to fail. Each of the proposed pleadings pleads:

- CTHC filed the NDSs and served the notices of allegations at issue in these actions [paras 1, 5, 6, 8, 44, 76, 80, 81, 84, and 88].

- CTHC, Celltrion, Inc. [CT], Teva Pharmaceuticals International GmbH [Teva International], Teva Canada Ltd. [TCL] and Teva Canada Innovation [TCI] "entered into an exclusive partnership to commercialize HERZUMA under a Business Collaboration Agreement [BCA]. TCL and TCI are affiliates of Teva International under the BCA" [para 13F].

- "[CTHC and CT, collectively Celltrion] has entered into a BCA with Teva International, whose Canadian affiliates, TCL and TCI, have been designated as its exclusive commercial partners in Canada. Celltrion has publicly stated that under this agreement, Celltrion has partnered with [Teva International, TCL and TCI, collectively Teva] to

market HERZUMA in Canada. In its statement regarding this agreement, Celltrion positions HERZUMA vis-à-vis HERCEPTIN without limitation to its uses" [para 45].

- "In accordance with the BCA, Celltrion and Teva are responsible for bringing HERZUMA to market in Canada" [para 45A].

- "Celltrion and Teva were both involved in the preparation of the HERZUMA NDS, including the decision to pursue the same indications as HERCEPTIN for HERZUMA. Celltrion and Teva are both involved in negotiations with Health Canada over the HERZUMA label, including the wording of the Product Monograph" [para 45B].

- "Celltrion and Teva were responsible for deciding the indications for each of the HERZUMA NDSs" [para 82].

- "Upon regulatory approval for HERZUMA, Celltrion and Teva will work in concert to manufacture, import and sell HERZUMA in Canada for use in patients. For example: (a) CT will manufacture HERZUMA for use in Canada; (b) CTHC will distribute HERZUMA to TCL; (c) TCL will import HERZUMA to Canada; and (d) TCI will market HERZUMA for use in Canada. The above roles and responsibilities were established to facilitate the common goal of promoting the use of HERZUMA in Canada" [para 45D]

- "Celltrion and Teva are acting in concert in Canada with respect to HERZUMA. Accordingly, in fact and law, Celltrion and Teva are responsible and liable for each other's acts, including any acts which result in the infringement of the [asserted claims of

the various patents], whether directly or indirectly, or by inducement" [paras 57A, 64A and 72A].

[34] While in their written representations the Plaintiffs have asserted that the definition of second persons is flexible enough to include the Additional Defendants by virtue of the common law concepts of agency, corporate control, inducement and common design, the Plaintiffs have not in fact pleaded that: (i) CTHC acted as agent of the Additional Defendants; (ii) that the corporate structure between CTHC and the Additional Defendants is such that the Additional Defendants control CTHC; or (iii) CTHC was induced by the Additional Defendants to file the NDSs. Rather, the Plaintiffs solely plead that CTHC and the Additional Defendants act in furtherance of a common design to bring HERZUMA to market. However, the existing case law that leaves the door open to a final interpretation of the proper scope of a "first person" under the *Regulations* is premised on the notion that the first person is controlled by the proposed additional first person, whether by virtue of corporate organization or some other means. Here, there is no allegation in the pleading that CTHC was controlled by each of the Additional Defendants, pursuant to the BCA, corporate structures or otherwise. The Plaintiffs do not plead that in carrying out the common design, the Additional Defendants are exerting control over CTHC.

[35] As such, I find that the proposed allegations against the Additional Defendants fail to meet the requirement of pleading sufficient material facts that if proven would enable the Court to make a finding that CTHC was an agent, acting as a nominal second person, directed and controlled by the Additional Defendants.

[36] With respect to the other argument asserted by the Plaintiffs on the second issue – namely, that as the Additional Defendants have been involved in the regulatory process, including the filing of the submissions, each of them could be said to be a second person – I note that the Plaintiffs have not actually pleaded that the Additional Defendants are second persons by virtue of having filed the submissions. There is in fact no reference to the Additional Defendants having "filed" any of the submissions – rather, the proposed pleading is limited to the Additional Defendants being involved in the "preparation" of the submissions. On this basis, I find that this additional argument is also doomed to fail.

[37] Accordingly, the Plaintiffs' motion for leave to amend their pleadings to join the Additional Defendants is dismissed. While at the hearing of the motion the Plaintiffs suggested that it may be possible to make further proposed amendments to address any material fact insufficiencies, I do not have those proposed amendments before me and therefore I make no finding as to whether leave to make any such further proposed amendments should be granted.

**(b) Factual Matrix Amendments**

[38] The Plaintiffs seek to make a number of additional factual amendments to their pleadings concerning the bringing of HERZUMA to market (many of which relate to the Additional Defendants) and seek to plead, as against CTHC, infringement by common design or acting in concert.

[39] The written representations of CTHC do little to assist the Court in understanding its position in relation to these amendments, as they are afforded few remarks (other than in relation to the pleading of infringement by common design). At the hearing of the motion, CTHC

confirmed that it would not oppose a benign factual amendment about CTHC or a new allegation against CTHC, provided it is properly pleaded. In relation to the allegation of acting in concert or by common design, CTHC asserts that that allegation has not been properly pleaded.

[40] This Court has previously held that while the concept of infringement by common design has not been applied in the context of a patent infringement action, its existence under Canadian law has been recognized. In *Bauer Hockey Corp v Easton Sports Canada Inc*, 2010 FC 361, Justice Gauthier stated:

> [205] This case is very different and can be easily distinguished from all those referred to by Easton's counsel. This has nothing to do with one party procuring or inducing another to use a combination by procuring one component of the combination. Here, through Mr. Lafrenière's involvement (as well later as that of Mr. Daniel Chartrand), Easton was actually participating in the making of the skates that are now found to infringe.
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> [206] As such, while it is not necessary to come to a conclusion in the case at bar, it is worth mentioning for future consideration that in England the courts applied the concept of infringement "by common design", a notion that also exists in Canada although it has not been applied in the context of a patent infringement action. In *Unilever plc v. Gillette (UK) Limited*, [1989] R.P.C. 583 (U.K.C.A.), at p. 609, Lord Mustill, then at the Court of Appeal of England, noted:
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> > I use the words "common design" because they are readily to hand, but there are other expressions in the cases, such as "concerted action" or "agreed on common action" which will serve just as well. The words are not to be construed as if they formed part of a statute. They all convey the same idea. This idea does not, as it seems to me, call for any finding that the secondary party has explicitly mapped out a plan with the primary offender. Their tacit agreement will be sufficient. Nor, as it seems to me, is there any need for a common design to infringe. It is enough if the parties combine to secure the doing of acts which in the event prove to be infringements.

[41] In *Hoffmann-La Roche et al v Sandoz Canada Inc* (Order dated November 15, 2018), I held that the use of the phrase "acting in concert" would fall within the concept of infringement by common design, as conceptually they are no different. As the claim was novel, I held that it should not be struck on a pleadings motion.

[42] In this case, the Plaintiffs seek to plead that CTHC was acting in concert with the Additional Defendants toward the common goal of bringing HERZUMA to market, with each of CTHC and the Additional Defendants undertaking various steps in furtherance of that common goal, as detailed in the pleading and noted, in part, above.

[43] CTHC takes issue with the sufficiency of the material facts pleaded in the proposed amended pleadings, arguing that the proposed pleadings do not go far enough to particularize what acts each of CTHC and the Additional Defendants will do or have done in furtherance of the common design. I reject this assertion. I am satisfied that by delineating the roles of each of CTHC and the Additional Defendants in bringing HERZUMA to market, the Plaintiffs have pleaded a minimum level of sufficient material facts to support this cause of action against CTHC and so as to enable me to conclude that the proposed allegation is not doomed to fail. In reaching this finding, I am mindful that this allegation is premised, in large part, on acts that have not yet occurred, which is not surprising in an action under the *Regulations*. To require too high of a threshold for sufficient material facts in the circumstances would, in many circumstances, be unfair.

[44] I am also satisfied that the allegation of acting in concert should be permitted to move forward against CTHC notwithstanding that the Additional Defendants have not been joined to

the actions, as there is nothing in the case law relied upon by the parties that suggests that all potential joint tortfeasors must be impleaded to sustain a cause of action against one of them.

[45] I have considered whether the acting in concert pleading would result in any injustice or prejudice to CTHC not capable of being compensation by an award of costs. CTHC's written submissions on the issue of prejudice focused almost entirely on the impact of all requested amendments on the limited trial time. However, to the extent that the addition of an allegation of acting in concert may expand the evidence needed to be called at trial, the Court could, as part of the exercise of its case management powers, lengthen the trial. To the extent that CTHC is of the view that particulars remain lacking in relation to the acting in concert allegation, it remains open to CTHC to further explore the issue on discovery or to seek particulars from the Plaintiffs. Accordingly, I am satisfied that the proposed amendments will not cause any non-compensable prejudice to CTHC.

[46] I am further satisfied that the proposed amendment to include a claim of acting in concert against CTHC will serves the interests of justice.

[47] I find that leave should be granted to the Plaintiff to make the balance of the amendments proposed to paragraphs 5-6, 8, 13A-13F, 44-48, 55-56, 57A-69, 71-76, 78-89, 92, 94 and 96 of the proposed pleadings (subject to any minor amendments thereto to account for the Additional Defendants not being enjoined to these actions) as such amendments would not be subject to being struck, would not cause an injustice to CTHC incapable of being compensated by an award of costs and would serve the interests of justice as they streamline the pleadings and include relevant factual allegations.

**Costs**

[48] As there was divided success on the motion, I decline to exercise my discretion to make an award of costs.

**THIS COURT ORDERS that:**

1. On the consent of the parties, the Plaintiffs are granted leave to amend their Statements of Claim in each of T-1969-17, T-1970-17 and T-1971-17 to remove the 596 Patent from the actions, as set out in paragraphs 1(a), 2(a), 5, 6, 7, 8, 10, 12, 21, 28, 30, 31, 32, 49, 50, 51, 52, 53, 54, 76(a), 78, 79, 81, 84, 88, 94 and 96 of the proposed Amended Statements of Claim.

2. The Plaintiffs are granted leave to amend their Statements of Claim in each of T-1969-17, T-1970-17 and T-1971-17 to plead as against CTHC an allegation of acting in concert and to plead additional facts concerning the bringing of HERZUMA to market in Canada, as set out in paragraphs 5-6, 8, 13A-13F, 44-48, 55-56, 57A-69, 71-76, 78-89, 92, 94 and 96 of each of the proposed amended pleadings, subject to any minor amendments thereto to account for the Additional Defendants not being enjoined to these actions.

3. The balance of the motion is dismissed.

4. There shall be no costs of this motion.

5. The parties shall, within 10 days, provide the Court with a proposed timetable for the delivery of an amended Statement of Claim in each action, as well amended responding pleadings.

"Mandy Aylen"
Case Management Judge