Federal Court



Cour fédérale

Date: 20150311

Docket: T-2280-12

Citation: 2015 FC 306

Ottawa, Ontario, March 11, 2015

PRESENT: The Honourable Madam Justice Strickland

BETWEEN:

TEVA CANADA LIMITED

Plaintiff (Defendant by Counterclaim)

and

PFIZER CANADA INC., PFIZER INC. AND PFIZER IRELAND PHARMACEUTICALS

Defendants (Pfizer Canada Inc., Plaintiff by Counterclaim)

and

PFIZER PRODUCTS INC.

(Plaintiff by Counterclaim)

ORDER AND REASONS

UPON MOTION by Teva Canada Limited ("Teva"), the Plaintiff (Defendant by Counterclaim), pursuant to Rule 51 of the *Federal Courts Rules*, SOR/98-106 ("*Federal Courts Rules*"), for:

- 1. An order setting aside the Order of Prothonotary Aronovitch dated August 12, 2014 (the "Order") and:
 - a. striking the following paragraphs from the Defendants' Statement of Defence and Counterclaim:
 - i. paragraphs 29 to 38, pertaining to Canadian Patent No. 2,044,748;
 - ii. paragraphs 39 to 45, pertaining to the industrial design;
 - iii. paragraphs 46 to 49, pertaining to passing off;
 - b. striking the counterclaim (paragraphs 50 to 68), or ordering that it proceed as a separate action;
 - c. granting Teva the costs of this motion and the motion below; and
- 2. Such further relief as counsel may advise and this Honourable Court may deem just.

AND UPON considering the written submissions of Teva and of Pfizer Canada Inc., Pfizer Inc. and Pfizer Ireland Pharmaceuticals, Defendants (Plaintiffs by Counterclaim); and Pfizer Products Inc., Plaintiff by Counterclaim (all collectively, "Pfizer");

AND UPON hearing the submission of the parties at Ottawa on February 16, 2015;

AND UPON considering:

Procedural History

- [1] The relevant procedural history leading to this motion was summarized in the Order of the Prothonotary, which I have substantively adopted below.
- [2] Pfizer Canada is the Canadian licensee of Canadian Patent No. 2,044,748 ("748 Patent") and has marketed sildenafil citrate tablets under the brand name VIAGRA.
- [3] Apotex and Teva (formerly Novopharm but referred to as Teva throughout) each sought to obtain a Notice of Compliance ("NOC") from the Minister for their respective generic tablets containing sildenafil. Each served Pfizer with a Notice of Allegation ("NOA") alleging invalidity of the 748 Patent.
- [4] Pfizer initiated separate proceedings in this court, first against Apotex and then Teva, seeking orders under s. 6 of the *Patent Medicines (Notice of Compliance)*Regulations, SOR/93-133 ("NOC Regulations"), prohibiting the Minister from issuing NOCs to both Apotex and Teva.
- [5] Pfizer was ultimately unsuccessful in both proceedings.
- [6] In the first proceedings between Pfizer and Apotex, the Federal Court found that Pfizer had not met its burden to establish Apotex's allegations of patent invalidity were unjustified (*Pfizer Canada Inc v Apotex Inc*, 2007 FC 26 at para 65, 59 CPR (4th) 183

[*Pfizer 1*]). The Federal Court of Appeal dismissed Pfizer's appeal. Leave to the Supreme Court of Canada ("SCC") was refused (*Pfizer Canada Inc v Apotex Inc*, 2007 FCA 195, 60 CPR (4th) 177 [*Apotex*]; *Pfizer Canada Inc v Apotex Inc*, [2007] SCCA No 371).

- In the second proceedings between Pfizer and Teva, Teva successfully moved to dismiss Pfizer's s. 6 application in relation to the 748 Patent on the basis that it was an abuse of process to now assert it against Teva (Order of Prothonotary Tabib dated April 18, 2008, Court File No. T-1566-07). On appeal from that Order, the Court noted that the parties agreed that Teva's NOA contained all the same allegations of invalidity regarding the 748 Patent as were contained in Apotex's NOA, which Pfizer had failed to establish were unjustified (*Pfizer Canada Inc v Novopharm Ltd*, 2008 FC 674, 67 CPR (4th) 203 [*Pfizer 2*]).
- [8] In that proceeding, Pfizer had claimed that the Court was not bound by its prior determination because Pfizer intended to file additional evidence against Teva that had not been before the court in *Pfizer 1*. Pfizer explained that the evidence could have been before the Court in *Pfizer 1*, had they appreciated such evidence was required.
- [9] Relying on Sanofi-Aventis Canada Inc v Novopharm Ltd, 2007 FCA 163, 282 DLR (4th) 476 [Sanofi], the Court rejected those submissions and held that Pfizer was required to bring forward all evidence on each ground of invalidity raised in Apotex's NOA in the first proceedings. Moreover, the Court found that none of the discretionary factors in Toronto (City) v CUPE, Local 79, 2003 SCC 63, [2003] 3 SCR 77 [CUPE], that would

allow the Court to exercise its discretion to not dismiss duplicitous proceedings, applied in that case. The Court confirmed, therefore, that Pfizer's attempt to seek an Order of Prohibition from the Minister was an abuse of process as it related to the 748 Patent and dismissed the part of Pfizer's s. 6 application that pertained to it. The Federal Court of Appeal later dismissed Pfizer's appeal from that decision (*Pfizer Canada Inc v Novopharm Ltd*, 2008 FCA 263, 74 CPR (4th) 329).

- [10] Teva then brought an action under s. 8 of the NOC Regulations seeking compensation for its losses suffered as a result of being prohibited from selling its generic version of VIAGRA during the relevant period, namely, beginning April 25, 2008, the date certified by the Minister, and ending November 8, 2012, the date of the Supreme Court judgment ultimately dismissing Pfizer's s. 6 application (*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60, [2012] 3 SCR 625).
- In its defence to Teva's underlying s. 8 action, Pfizer pleads *ex turpi causa* and denies that Teva is entitled to any damages or lost sales, as these sales would allegedly have been made unlawfully. Pfizer has defended and counterclaimed on several grounds, including that the manufacture and sale of the Teva tablets during the relevant period would infringe the 748 Patent, infringe Pfizer's industrial design rights and constitute passing off.
- [12] Teva brought a motion to strike the portions of Pfizer's defence and counterclaim and to sever the counterclaim and order that it proceed as a separate action.

[13] By her Order of August 12, 2014, the Prothonotary denied Teva's motion. She found that abuse of process was not available to strike out Pfizer's defence and that Teva had not met its burden to justify that Pfizer's defences of passing off under the *Trade-Marks Act*, RSC 1985, c T-13, or an infringement of industrial design should be struck. In addition, she declined to exercise her discretion to sever the counterclaim. Teva now appeals against the Prothonotary's Order.

Issues

- [14] The issues may be framed as follows:
 - a) What is the standard of review?
 - i. Has Teva raised a vital issue?
 - ii. Was the Order clearly wrong?
 - b) Should Pfizer's defence based on the alleged infringement of the 748 Patent be struck out as an abuse of process?
 - c) Should Pfizer's defence based on alleged passing off and violation of its industrial design be struck out?
 - d) Should Pfizer's counterclaim be struck out or tried separately from the main action?

Standard of Review

- [15] The standard of review for decisions of prothonotaries was described by the Federal Court of Appeal in *Merck & Co, Inc v Apotex Inc*, 2003 FCA 488 at para 19:
 - [19] ...a judge should logically determine first whether the questions are vital to the final issue: it is only when they are not that the judge effectively needs to engage in the process of determining whether the orders are clearly wrong. The test would

now read: "Discretionary orders of prothonotaries ought not be disturbed on appeal to a judge unless: (a) the questions raised in the motion are vital to the final issue of the case, or (b) the orders are clearly wrong, in the sense that the exercise of discretion by the prothonotary was based upon a wrong principle or upon a misapprehension of the facts."

i) Has Teva raised a vital issue?

- [16] Teva submits that the issues raised in this motion to strike are vital to the final issue in this action, which is the assessment of Teva's damages under s. 8 of the NOC Regulations. The inclusion or exclusion of Pfizer's defences to reduce or negate Teva's damages goes to the heart of that matter. Conversely, Pfizer submits that vitality does not arise in these circumstances.
- [17] Whether the striking of pleadings is vital to the case or not must be determined on a case by case basis (*Multi Formulations Ltd v Allmax Nutrition Inc*, 2009 FC 896 at para 8).
- [18] As stated by this Court in *Apotex Inc v Astrazeneca Canada Inc*, 2009 FC 120 at para 23, referencing *Peter G White Management Ltd v Canada*, 2007 FC 686 at para 2, the mere fact that what was sought before the prothonotary might have been determinative of the final issues in the case does not result in the judge's hearing the matter *de novo*. The jurisprudence makes it clear that it is not what was sought, but what was ordered by the prothonotary which must be determinative of the final issues in order for the reviewing judge to undertake a *de novo* review.

- [19] In that regard, it has been determined that where a prothonotary has struck out a proceeding, such a decision is vital to the final issue of the case. Conversely, where a prothonotary has not struck out the proceeding, that decision is not finally determinative of any issue vital to the case (also see *Chrysler Canada Inc v Canada*, 2008 FC 1049 at para 4; *Teva Canada Limited v Pfizer Canada Inc*, 2013 FC 1066 at para 10, aff'd 2014 FCA 244).
- [20] Therefore, in this case as the Prothonotary declined to strike out the assailed paragraphs of Pfizer's Statement of Defence or its counterclaim, her decision is not finally determinative, and review *de novo* of her decision does not arise because the main action will proceed in any event, at which time the subject defences and counterclaim will be addressed.
- [21] Accordingly, the decision will only be set aside if the learned Prothonotary's decision is found to be clearly wrong.

ii) Was the Order clearly wrong?

Teva submits that the Prothonotary's Order was clearly wrong as it was based on wrong legal principles regarding the scope of s. 8 and the interpretation of the NOC Regulations. Further, that the principle of proportionality as set out by the Supreme Court of Canada in *Hryniak v Mauldin*, 2014 SCC 7 [*Hryniak*], applies to a motion to strike as the issues on this appeal are pure questions of statutory interpretation and should be resolved at this stage of the proceedings.

- [23] Pfizer submits that Teva's burden on the motion to strike was to show a readily apparent radical defect in Pfizer's pleadings that rendered it certain to fail (Rule 221, Federal Courts Rules; Hunt v Carey Canada Inc, [1990] 2 SCR 959 at p 980 [Hunt]; R v Imperial Tobacco Canada Ltd, 2011 SCC 42 at para 17, [2011] 3 SCR 45 [Imperial Tobacco]; Edell v Canada (Revenue Agency), 2010 FCA 26 at para 5, 399 NR 115). The burden was particularly high given that s. 8(5) of the NOC Regulations expressly provides the trial judge with discretion to take into account all matters that he or she considers relevant to the assessment of damages. Further, Hryniak does not serve to lower the threshold on a motion to strike. Finally, Teva's submissions do not demonstrate that it was plain and obvious that Pfizer's pleading was defective and that the Prothonotary's decision was clearly wrong.
- [24] In my view, the Prothonotary clearly recognized and applied the correct test on a motion to strike in her decision and found that Teva had not met its burden. She did not base her decision on a wrong principle or upon a misapprehension of the facts.

 Accordingly, I decline to set aside her decision. My reasons for this are as follows:

Pfizer's defence based on infringement and abuse of process

Teva's Position

[25] Teva asserts that the Prothonotary erred in law by failing to recognize that findings from the s. 6 proceeding are binding in this action and by failing to recognize that

Pfizer is precluded from assessing the 748 Patent under s. 8(5) of the NOC Regulations and under the doctrine of *ex turpi causa* to reduce or eliminate Teva's damages.

- Teva asserts that because of the recognized close connection between s. 6 and s. 8, the s. 8 action is, in effect, a direct extension and continuation of the underlying s. 6 application. There, the Federal Court of Appeal in *Apotex* affirmed that in the s. 6 NOC application Pfizer could not establish the validity of the 748 Patent. It subsequently affirmed in Teva's s. 6 proceeding, which forms the basis of this s. 8 proceeding, that Pfizer's assertion of the 748 Patent to permit Teva from selling its sildenafil product was an abuse of process and constitutes an attempt to re-litigate issues already decided. Teva asserts that by way of its defence to the s. 8 proceeding Pfizer now again attempts to relitigate the validity of the 748 Patent.
- [27] According to Teva, to do so is an abuse of process, as the prior determination regarding the patent validity is binding "within the context of the NOC Regulations" (*Sanofi* at para 49). Teva disagrees with the Prothonotary's interpretation of *Sanofi* in this regard and asserts that this Court has held that its determinations in the s. 6 proceeding define the scope of the s. 8 proceeding.
- [28] Teva submits that while infringement can be asserted in limited circumstances, this is not such a case. It distinguishes *Apotex Inc v Merck & Co, Inc*, 2011 FCA 364 at paras 4, 14 [*Lovastatin*], which permitted an infringement defence, on the basis that there was no prior finding of invalidity or non-infringement to bind the Court, as there the s. 6

proceeding was dismissed without adjudicating those issues. It distinguishes *Apotex Inc v Pfizer Canada Inc*, 2013 FC 493 at paras 10, 18, 21–22 [*Azithromycin*], aff'd 2014 FCA 54, on the basis that the submission of fresh evidence in that case forms an exception to *res judicata* (*CUPE* at para 52).

- [29] Teva also asserts that the Prothonotary erred in equating actions under s. 8 with infringement actions under the *Patent Act*, RSC 1985, c P-4. While s. 6 proceedings do not bar subsequent litigation under the *Patent Act*, re-litigation under the NOC Regulations is not permitted (*Sanofi* at para 49). Teva submits that infringement under the *Patent Act* concerns whether a party has actually infringed a patent, which is not alleged in this case. Infringement in the context of the NOC Regulations is concerned with whether the patent should prevent the generic from selling its product. The purpose of the NOC Regulations is to balance the need for patent protection with the need for lower cost generic drugs. Generics are tied to their NOA and are not permitted to raise any new allegations of invalidity or non-infringement. On Pfizer's interpretation, generics would have multiple opportunities to establish infringement for the purposes of the NOC Regulations. This would skew the intended balance and would not be an efficient use of judicial resources.
- [30] When appearing before me, Teva asserted that the Federal Court of Appeal appears to have determined that the issue of patent infringement is relevant to s. 8 proceedings only if raised in s. 6 and
 - a) infringement was not previously determined but has since been determined (*Lovastatin*); or

b) if determined in s. 6 but new issues, such as new evidence, arise in which case issue estoppel does not apply.

Pfizer's Position

- [31] Conversely, Pfizer submits that the Court has repeatedly recognized that infringement of a first person's patent rights by a second person is a relevant factor when considering s. 8(5) of the NOC Regulations (*Lovastatin* at para 26; *Azithromycin* at para 78) and that infringement defences are now routinely pleaded in s. 8 proceedings, listing five examples of this, as was recognized by the Prothonotary.
- Here Pfizer has not commenced a separate infringement action or counterclaim with respect to the 748 Patent because Teva only began selling its tablets after the patent's expiry. While Teva did not infringe the patent in fact, it would have done so in connection with any sale of its tablets in the "but for" world. Thus, Pfizer is raising the 748 Patent as a defence only.
- Pfizer submits that Teva's position that findings of invalidity made in the context of a s. 6 proceeding are binding on the subsequent s. 8 proceeding is in error and has been rejected by the Court (*Sanofi-Aventis Canada Inc v Teva Canada Limited*, 2012 FC 552 at para 115 [*Ramipril FC*], aff'd 2014 FCA 69 [*Ramipril FCA*]). Further, Pfizer notes that *Azithromycin* permitted Pfizer to proceed with its infringement defence even though such allegations had been rejected in the underlying s. 6 proceeding (*Azithromycin* at para 23).

- [34] As to abuse of process, as recognized by the Prothonotary, Teva provides no authority in support of its view that a determination under s. 6 is a bar to a s. 8 action, or a bar to infringement being invoked by a first person in Pfizer's circumstances. Pfizer submits that *Lovastatin* and *Azithromycin* expressly allow for infringement claims to be advanced within a s. 8 action and that the Prothonotary properly rejected Teva's efforts to distinguish those cases. Further, while *Sanofi* found that s. 6(5) of the NOC Regulations specifically precludes an innovator from engaging in serial re-litigation in the context of s. 6 proceedings, she properly recognized that those findings were not extended beyond s. 6 proceedings to include s. 8 proceedings as Teva suggests. Pfizer also submits the s. 6 prohibition proceedings are summary in nature and not intended to finally decide issues of invalidity (*Apotex Inc v Pfizer Ireland Pharmaceuticals*, 2011 FCA 77 at paras 12–19 [*Pfizer Ireland*]).
- [35] Further, that contrary to Teva's public policy submissions, Parliament anticipated that the issues canvassed summarily in a prohibition proceeding could be subject to further litigation and a proper trial (*AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638; *David Bull Laboratories (Canada) Inc v Pharmacia Inc* (1994), [1995] 1 FC 588 at 598–600, 58 CPR (3d) 209 (CA)). It would also be inappropriate to address Teva's novel legal arguments on the motion to strike. The purpose of a motion to strike is to weed out cases clearly bereft of merit, it is not the forum to resolve complex issues of statutory interpretation (*Imperial Tobacco* at para 19). The Federal Court of Appeal has also recently reaffirmed that questions concerning proper interpretation of the NOC Regulations should not be determined on motions to strike (*Teva Canada Limited v Pfizer Canada Inc*, 2013 FC

1066 at para 6, aff'd 2014 FCA 244 at para 4). Claims of abuse of process are also ordinarily determined at trial (*Pfizer Ireland* at paras 19, 24–26).

[36] To permit the assertion of defences unrelated to the patent at issue would skew the balance that the NOC Regulations seek to achieve.

Analysis

- [37] The Prothonotary found that it is now commonplace for the first person to raise infringement defences in a s. 8 proceeding. However, at the time of her decision, only two cases had actually considered the issue. In that regard, she referred to *Lovastatin* and *Azithromycin* and did not accept Teva's efforts to distinguish those cases from the matter before her. As to abuse of process she explained, with reasons, that this was not available to strike out Pfizer's defence and that *Sanofi* could not be relied on for that purpose. I see no clear error in the Prothonotary's finding that Teva had failed to establish that the Court's prior finding concerning the 748 Patent in the s. 6 proceedings rendered it plain and obvious that Pfizer's patent infringement defence amounts to an impermissible re-litigation and abuse of process for the purpose of the s. 8 action, or that the defence cannot be relevant to the assessment of damages in the circumstances of the case and, therefore, has no reasonable chance of success.
- [38] Teva has not shown that the Prothonotary's treatment of the case law was clearly wrong. In support of its position, Teva has offered only an interpretation of statute and case law that differs from the Prothonotary's.

- [39] The Prothonotary appropriately applied the test for striking pleadings. Since Canada (Attorney General) v Inuit Tapirisat of Canada, [1980] 2 SCR 735, the courts have consistently held that striking is appropriate only when it is "plain and obvious" (at 740) that the pleading cannot succeed (see also Imperial Tobacco at para 17; Hunt at 980). The Prothonotary reasonably concluded that Teva had failed to prove that Pfizer's pleadings on infringement plainly and obviously could not succeed. Lovastatin and Azithromycin both could support Pfizer's right to allege infringement on defence, and, as the Prothonotary noted, Teva has adduced no authority supporting its distinguishing of those two cases and characterizing them as clear exceptions to a prohibition of a s. 8 infringement defence. Nor has Teva shown that a determination under s. 6 is a ban to infringement being invoked by a first person in Pfizer's particular circumstances.
- [40] In *Lovastatin* the Federal Court of Appeal stated that it was not necessary to read an *ex turpi causa* exception into s. 8(1) of the NOC Regulations in order to prevent patent infringers from unjustly recovering compensation from a first person:
 - [37] This is because subsection 8(5) confers a broad discretion on the court when assessing the amount of compensation that the second person must pay. It provides that the court "shall take into account all matters that it considers relevant to the assessment of the amount," including any conduct by either party that contributed to the delay in the disposition of the first person's application for prohibition. In my view, this provision enables the Court to determine in its discretion whether, and to what extent, a second person's claim for compensation should be reduced, or eliminated.
 - [38] The Court's broad discretion under subsection 8(5) allows it, when considering arguments based on *ex turpi causa*, to have regard to the factual situation in its entirety, including its nuances...

- [41] In *Azithromycin* the Court held that, given the relationship between s. 6 and s. 8, "entirely new" allegations of non-infringement or invalidity are not "relevant" for the purposes of s. 8. However, that the conclusion that Apotex's allegation of non-infringement was justified, and resultant denial of Pfizer's request for an order prohibiting the Minister from granting Apotex a NOC, did not prevent the issue of infringement from being raised in the s. 8 proceeding in the circumstances before it.
- The Prothonotary correctly noted that in *Sanofi* the Federal Court of Appeal considered the question of whether a holder of a pharmaceutical patent, having failed to establish that an allegation of invalidity made by one generic drug manufacturer was not justified, then abused the NOC process by seeking to re-litigation the same allegation or invalidity when it is made by a second generic company. Under consideration was abuse of proceed pursuant to s. 6(5)(b) of the NOC Regulations.
- [43] I would also note that the Federal Court of Appeal in *Sanofi* did not address s. 8 and the decision contains no suggestion that its finding should be applied more broadly to preclude "re-litigation" under s. 8 by way of pleading infringement as a defence.
- [44] In sum, the case law offers no definitive rule for the use of infringement as a defence. While Teva interprets *Sanofi* differently and so as to extend to s. 8, it does not adduce authority for this interpretation. In any event, in my view, *Sanofi*'s provision for the

striking of duplicative actions that would relitigate settled issues does not plainly extend to the striking of defences, such as Pfizer's, in actions for damages.

Although the Court can decide questions of statutory interpretation of regulation on a motion to strike, complex issues of statutory interpretation should be left for trial, where fact and law can be adduced and argued. This Court so found in *Apotex Inc v Eli Lilly & Co*, 2001 FCT 636 at paras 13–14 [*Lilly*], when seized with the interpretation of s. 8. And, as the Prothonotary explained, Teva's challenges to Pfizer's "novel and arguable defences" are not plainly and obviously correct (also see *Safilo Canada Inc v Contour Optik Inc*, 2004 FC 1534 at paras 2-3). Granting Teva's motion to strike would inappropriately foreclose Pfizer's potentially meritorious defences and would preclude the Court from specifically addressing this unsettled issue.

Defence of Passing Off and Violation of Industrial Design

Teva's Position

[46] Teva asserts that the Prothonotary erred in holding that Pfizer's allegations relating to passing off, the *Trade-Marks Act*, and industrial design infringement are permissible in a s. 8 proceeding. According to Teva, s. 8(5), which provides that in assessing the amount of compensation the Court shall take into account all matters that it considers relevant to the assessment of the amount, does permit the Court broad, though not unlimited, discretion to consider factors under s. 8(5); however, this is not unlimited (*Apotex Inc v Astrazeneca Canada Inc*, 2012 FC 559 at paras 179–80, aff'd 2013 FCA 77

[Omeprazole]). Ex turpi causa can be considered under s. 8(5), but those considerations must be relevant to the adjudication of the parties' rights under the NOC Regulations. The proper interpretation of those regulations would have demonstrated that Pfizer's allegations fall outside the appropriate scope of factors relevant under s. 8(5) in this case.

- [47] Because Pfizer could bring a separate action for passing off and for industrial design infringement, introducing these claims in the s. 8 proceedings is "unnecessary litigation" and is contrary to the legislative intent of the NOC Regulations. It would force producers of generic drugs into lengthy and unnecessary litigation on issues outside the normal purview of the NOC Regulations and the *Patent Act*.
- It is also contrary to the Federal Court of Appeal's confirmation that the NOC Regulations are a comprehensive statutory scheme and a complete code. Parties are not permitted to incorporate claims by reaching outside the language of the NOC Regulations (*Teva Canada Ltd v Pfizer Canada Inc*, 2014 FC 69 at para 31, aff'd 2014 FCA 138 at para 9). Claims for infringement of trademarks and industrial designs, like claims for punitive damages, fall outside the ambit of s. 8 when it is interpreted in accordance with the purpose for which it was enacted.

Pfizer's Position

[49] Pfizer submits that its passing off and industrial design rights directly impacted Teva's sildenafil tablet sales during the relevant period, it relies on s. 8(5) and the doctrine of *ex turpi causa actio non oritur*. Pfizer submits that the Prothonotary correctly found that

it was entitled to a full hearing with respect to these novel and arguable defences (*Pfizer Ireland*, above, at para 19), as s. 8(5) recognizes that a broad scope of claims are eligible for consideration (*Ramipril FC* above, at paras 115–16; *Lovastatin* at paras 37–38, 226). Pfizer's pleadings that the Teva tablets sold in the "but for" world would have infringed Pfizer's Viagra tablet's industrial design and constituted passing off are directly relevant to the factual situation to be considered under s. 8(5). Contrary to Teva's submissions, *Omeprazole* does not support a narrower interpretation of s. 8(5). As to Teva's floodgates argument, here Pfizer's defences are directly related to the unlawful manufacture and sale of Teva's tablets in the "but for" period.

- Pfizer also submits that the fact that there has been no finding of industrial design infringement or a separate infringement action in the "real world" is not relevant. While Teva did not infringe the industrial design in fact (given that it expired before Teva came to market), any sale of Teva tablets during the relevant "but for" period would have been infringing. As to Teva's policy arguments that s. 8(5) must be interpreted narrowly to maintain the intended balance of the NOC regulations, they ignore the clear language of Parliament as contained in that provision. Further, policy interpretation must be approached with caution in the context of motions to strike.
- [51] While the NOC Regulations constitute a "complete code" with respect to the remedy available to a second person in a s. 8 damages action (*Teva Canada Limited v Pfizer Canada Inc*, 2014 FCA 138 at para 31, aff'd 2014 FCA 138 at para 9; *Ramipril FC* at para

116), this does not support Teva's submission that the Court's s. 8(5) discretion is thereby limited.

Analysis

- The Prothonotary succinctly summarized Teva's position, being that Pfizer's allegations relating to passing off and infringement under the *Trade-Marks Act*, as well as industrial design infringement are new, were not in the s. 6 proceeding and as such are not relevant to the assessment of damages under s. 8. Teva's point being that s. 8 does not create a free-standing right of action but is limited by the issues put in play in the s. 6 proceeding.
- The Prothonotary found that Teva had not met its burden to justify that Pfizer's defences of passing off under the *Trade-Marks Act* or infringement of industrial design should be struck. She found that Justice Hughes's statement in *Omeprazole* at paras 179–80, as relied upon by Teva, that s. 8(5) is not so broad as to encompass "any factor that a party chooses", was not determinative of the matters that may be considered and could not be interpreted to exclude Pfizer's defences. In support of this, she referred to *Ramipril FC*:
 - [115] In this argument, Teva conflates the cause of action with the remedy. In particular, Teva's position overstates the effect of s. 6, which describes a first person's right to apply for a prohibition order. Section 6 does not define the factors that the Court may consider in assessing any damages to which a second person may become entitled under s. 8.
 - [116] Teva's interpretation of s. 8 also ignores the clear words of s. 8(5), which requires that a court assessing a second person's compensation "take into account <u>all</u> matters that it considers relevant to the assessment of the amount" (emphasis added). Competition in the generic market is clearly relevant to a second

person's recovery. While the *Regulations* are, as Teva argues, a "complete code" (*Apotex Inc v Syntex Pharmaceuticals International Ltd*, 2005 FCA 424 (CanLII), [2006] 3 FCR 318 and *Merck Frosst Canada Inc v Apotex Inc*, 1997 CanLII 4806 (FCA), [1997] 2 FC 561, [1997] FCJ No 149 (CA)), the Court of Appeal has held that s. 8(5) gives the Court a "broad discretion" to consider a number of factors in assessing the amount of a second person's compensation (*Apotex Inc v Merck & Co*, 2011 FCA 364 (CanLII) at paras 37-38, [2011] FCJ No 1865). Consideration of the market share that would have been captured by competitors is relevant to a s. 8 claim, much as it is to any damages claim. This follows from general damages principles, which seek to place a successful plaintiff in the position he or she would have occupied but for the defendant's wrong.

- The Federal Court Appeal upheld that decision, addressed the purpose of s. 8, but also made it clear that matters to be taken into consideration to calculate compensation under s. 8(5) are a question of fact for determination by the trial judge on the merits (*Sanofi-Aventis Canada Inc v Teva Canada Ltd*, 2014 FCA 67 at paras 86–87, 456 NR 241; note that the Prothonotary may have incorrectly referenced paras 26–27 in her decision).
- The Prothonotary concluded that, in any event, the matter did not meet the test under Rule 221, as the issue was not plain and obvious, or beyond doubt. She stated that a motion to strike was not the venue to limit or prejudice the discretion of the hearing judge as to the defences and the evidence that he or she may take into consideration on the merits in assessing damages under s. 8(5). Pfizer asserted novel and arguable defences that must be permitted to go to trial (*Imperial Tobacco*).
- [56] In my view, the Prothonotary was not clearly wrong. On the contrary, she reasonably analysed the law and found that it did not plainly and obviously support Teva's

position. She also reasonably concluded that striking Pfizer's pleadings would hamper the hearing judge's discretion and interfere, prejudicially to Pfizer, with the assessment of damages under s. 8(5).

- [57] The parties take conflicting positions on the availability of Pfizer's defences under s 8(5) and, as is apparent from their submissions, this is an unsettled area of the law. Although the Prothonotary found that the case law appeared to favour Pfizer's view, she appropriately left the question for argument at trial. This conclusion is reasonable on the basis of the complex questions of statutory interpretation should be resolved at trial, not on a motion to strike (*Lilly* at paras 13–14).
- The Prothonotary was also of the view that the issues raised by Teva require assessment at trial. This was within her discretion as Rule 221 allowed, but did not require, her to grant the motion to strike. Rather, she found that there were insufficient grounds for striking. As her discretionary decision was not clearly wrong, I cannot intervene (*Lundbeck Canada Inc v Canada (Minister of Health*), 2008 FCA 265 at paras 2, 7, [2008] FCJ No 1275).

Striking or separating of counterclaim

[59] On the basis that Teva had filed no evidence of prejudice, the Prothonotary found that it was fitting and appropriate that the action and the counterclaim proceed together such that Pfizer Products, the owner of the mark, might be bound by the findings on liability made by the Court in the main action in respect of its licensee. She stated that her reasons

for this were that there was no evidence filed by Teva regarding prejudice. It was also not evident that the joint trial of the claim and counterclaim, which share common parties and a common body of evidence, might entail more delay or greater prejudice to Teva than two separate trials. Also, given the common parties and issues, severing the counterclaim raises the possibility of inconsistent findings, especially, as she had noted, in respect of the owner and licensee of the mark.

Teva does not assert that the Prothonotary erred but merely states that the Court has the discretion under Rule 106 to sever claims. Teva cannot succeed on this basis. The Prothonotary properly exercised her discretion as she was entitled to do. Such a discretionary finding should not, in the absence of clear error, be disturbed (*Canada v Aqua-Gem Investments Ltd*, [1993] 2 FCR 425 at 453, [1993] FCJ No 103 (QL)).

Conclusion

- [61] For the above reasons, I find that Teva has not established that the Prothonotary's decision was clearly wrong in that it was based on a wrong principle or misapprehension of the facts. Accordingly, I need not address the remaining issues, and Teva's appeal is dismissed.
- [62] The parties have agreed that, with respect to Teva's motion, costs in a lump sum of \$2,500.00 are appropriate. Accordingly, Pfizer shall have its costs in that amount.

<u>ORDER</u>

THIS COURT ORDERS that

- The appeal by Teva Canada Limited of the Prothonotary's Order dated August 12,
 2014 is dismissed; and
- 2. Costs of this motion in the lump sum amount of \$2,500.00 are awarded to Pfizer.

"Cecily	Y. Strickland"
Judge	

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:

T-2280-12

STYLE OF CAUSE:

TEVA CANADA LIMITED v PFIZER CANADA INC.,

PFIZER INC. AND PFIZER IRELAND

PHARMACEUTICALS

PLACE OF HEARING:

OTTAWA, ONTARIO

DATE OF HEARING:

FEBRUARY 16, 2015

ORDER AND REASONS:

STRICKLAND J.

DATED:

MARCH 11, 2015

APPEARANCES:

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