Federal Court  Cour fédérale

Date: 20140812

Docket: T-2280-12

Ottawa, Ontario, August 12, 2014

PRESENT: Madam Prothonotary Roza Aronovitch

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

UPON MOTION by the Plaintiff, Teva Canada Limited, for:

1. An Order striking the portion of the Statement of Defence and Counterclaim dated March 31, 2014 that is based upon Canadian Patent 2,044,748 (the 748 Patent);

2. An Order striking the portion of the Statement of Defence and Counterclaim that is based upon allegations of passing off in relation to the Defendants' trade-mark rights;

3. An Order striking the portion of the Statement of Defence and Counterclaim that is based on the Defendant's industrial design;

4. An Order striking Pfizer Products Inc. as a plaintiff by counterclaim;

5. An Order striking the counterclaim or ordering that it be tried as a separate action; and

6. Costs of this motion on a solicitor-and-client basis payable forthwith.

UPON the written submissions of the defendants ("Pfizer");

AND UPON hearing the parties' submissions;

Pfizer Canada is the Canadian licensee of Canadian Patent No. 2,044,748 ("the '748 Patent") and has marketed sildenafil citrate tablets under the band name VIAGRA.

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.

Pfizer initiated separate proceedings in this court; first against Apotex and then Teva, seeking orders under section 6 of the *PMNOC Regulations* ("*Regulations*") prohibiting the Minister from issuing NOCs to both Apotex and Teva.

Pfizer was ultimately unsuccessful in both proceedings.

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 ("*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; *Pfizer Canada Inc. v. Apotex Inc.*, [2007] S.C.C.A. No. 371).

In the second proceedings between Pfizer and Teva, Teva moved to dismiss Pfizer's section 6 application in relation to the '748 Patent on the basis that it was an abuse of process to now assert it against Teva and was successful on that basis (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 ("*Pfizer 2*")).

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 the evidence could have been before the Court in *Pfizer 1* had they appreciated such evidence was required.

Relying on *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163 ("*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. Canadian Union of Public Employees (C.U.P.E.)*, Local 79, 2003 SCC 63 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 section 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).

Teva now brings an action under section 8 of the *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 section 6 application (*Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60).

In its defence to Teva's underlying section 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.

Teva brings this motion to strike the above noted portions of Pfizer's defence and counterclaim and to sever the counterclaim and order that it proceed as a separate action.

Pfizer's defence that Teva's sale of sildenafil tablets would have infringed Pfizer's '748 Patent

As I have noted, Pfizer has pled in defence that the manufacture, use, and sale of Teva tablets during the relevant period would have infringed the '748 Patent and that Teva is accordingly not entitled to any damages for sales that would have infringed the patent while it remained extant.

Teva argues that Pfizer's allegation of infringement should be struck as an abuse of process in that Pfizer is impermissibly attempting to relitigate the validity of the '748 Patent, notwithstanding that Pfizer's previous attempt to do so was held to be an abuse of this Court's process. The *Regulations* have been held to be a complete code in respect of matters arising from the *Regulations*. Relying on *Sanofi,* at para 49, Teva argues that Pfizer's defence based on the '748 Patent is impermissible in that the previous determinations of invalidity of the '748 Patent are binding within the context of the *Regulations* pursuant to which this section 8 action is brought.

To succeed in this motion, Teva must establish, in essence, that the Courts' earlier findings pertaining to the '748 Patent in the section 6 proceedings render it plain and obvious that Pfizer's patent infringement defence amounts to an impermissible relitigation and abuse of process for the purposes of this section 8 action, that the defence can not be relevant to the assessment of damages in the circumstances and therefore has no reasonable chance of success.

In my view, Teva has not met this burden.

It is now commonplace for the first person to raise infringement defences in a section 8 proceeding. In at least two cases, the Court has determined section 8 cases invoking *ex turpi causa* defences based on patent infringement where the "first person" in a section 6 proceeding had been unsuccessful in asserting its patent, or the Court had already rejected the argument in the section 6 proceeding. (*Apotex Inc. v. Merck & Co.*, 2012 FC 620 ("*Lovastatin*"); *Apotex Inc. v. Pfizer Canada Inc.*, 2013 FC 493 ("*Azithromycin*").)

Teva acknowledges *Lovastatin* and *Azithromycin* but says that neither case is binding authority in the present case because in those cases the court had not previously determined patent invalidity or made findings of abuse of process.

In my view, abuse of process is not available to strike out Pfizer's defence and *Sanofi* cannot be relied on for that purpose. The Court found in that case that determinations in section 6 proceedings on allegations of patent invalidity made in one NOA can be grounds for dismissing subsequent section 6 applications for abuse of process where the allegations and factual basis underlying those allegations are the same. However, the Court did not state that those findings extended beyond section 6 proceedings to include section 8 actions and the scope of the decision, in my view, cannot be extended as Teva suggests. The Court's interpretation of the application of abuse of process doctrine to *NOC* proceedings were made with regard to the language in paragraph 6(5)(b), which itself is limited to section 6 proceedings (at para 27 and 48). Moreover, as noted below, the Court of Appeal reiterated in *Sanofi* that findings in prohibition proceedings under the *Regulations* have no bearing on patent infringement actions or declarations of patent invalidity (at para 36 and 40).

Teva's contention that the patent has been held invalid in other proceedings under the *Regulations*, as Pfizer points out, misses the fact that the '748 Patent was never invalidated *in rem* in the section 6 proceedings. Indeed, Pfizer's right to assert its patent and defend on the basis of infringement, despite being unsuccessful in the section 6 proceeding, is acknowledged in the very judgment that confirmed the finding that Pfizer's notice of prohibition with respect to the '748 Patent constituted an abuse of process (*Pfizer 2*, at para 44 to 45). Having regard to the unfairness wrought by Pfizer's inability to lead further evidence in the context of the section 6 proceeding, the Court in that case quoted the Federal Court of Appeal in *Sanofi* as follows:

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> [40] [...] Prohibition 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.

In sum, it is not plain and obvious that the assertion of the '748 Patent to allege infringement is prohibited in the circumstances of this case.

Indeed, I see no basis to distinguish *Lovastatin* and *Azithromycin* as it relates to Pfizer's defences. Pfizer, in this case, has the same footing and right to assert the '748 Patent and raise infringement in defence as in *Lovastatin* and *Azithromycin* where in circumstances similar to the case at bar the "first person" was unsuccessful in asserting its patent in the section 6 proceeding and the Court nevertheless entertained arguments on the patent in the section 8 action on the basis that it was relevant for consideration by the Court under subsection 8(5).

Teva has not pointed to any authority to the contrary. It has not brought to the attention of the Court any decision to the effect that a determination under section 6 is a bar to a section 8 action, or a bar to infringement being invoked by a first person in Pfizer's circumstances.

It may be that the Court, on the merits, will be persuaded that Pfizer may not advance particular arguments or adopt a particular position inconsistent with the position held during the section 6 proceedings. That, however, is a matter for trial (*Azithromycin*; *AstraZeneca Canada Inc v. Apotex Inc.*, 2014 FC 638 at para 38 to 48). It is not a basis to disallow the defence which has been found to be available for consideration under subsection 8(5) of the *Regulations*. It will be for the trial judge, on the evidence, to determine its availability and effect in this case.

Pfizer's defence that Teva's sale of sildenafil tablets would have infringed Pfizer's industrial design and amounted to passing off under the *Trade-Marks Act*

Having taken issue in its written submissions with Pfizer Canada's standing as licensee rather than owner of the mark, Teva advised at the hearing of the motion that it would not be pursuing its challenge to Pfizer Canada's standing to assert a defence on passing off under the *Trade-marks Act*.

Teva maintains, however, 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 section 6 proceeding and as such are not relevant to the assessment of damages under section 8. Teva's point being that section 8 does not create a free-standing right of action but is limited by the issues put in play in the section 6 proceeding.

Teva says that the discretion that the Court has under subsection 8(5) of the *Regulations* to consider all matters it considers relevant is not "all-encompassing" and not so broad as to encompass these allegations. Teva adds that addressing allegations of passing off and infringement of industrial design is complex, and would require a full trial within the section 8 action such as to unduly complicate and delay the calculation of compensation owed to Teva.

In my view Teva has 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.

Justice Hughes' statement at para 179 to 180 of *Apotex Inc. v. AstraZeneca Canada Inc.*, 2012 FC 559 that subsection 8(5) is not so broad as to encompass "any factor that a party chooses", is not determinative of the matters that may be considered and cannot be interpreted to exclude Pfizer's defences that are impugned by Teva.

The Federal Court in *Sanofi-Aventis Canada Inc. v. Teva Canada Ltd.*, 2012 FC 552 at para 115 to 116 specifically rejects Teva's view that section 6 defines the factors that the Court may take into consideration in assessing any damages to which a second person may be entitled pursuant to section 8 and references the "broad discretion" of the Court as to the factors it may consider in assessing compensation.

On appeal from that decision, the Court of Appeal confirms that the purpose of section 8 of the *Regulations* is to provide and ensure compensation for a generic drug manufacturer improperly kept off the market. By the same token, the Court makes clear that the matters to be taken into consideration to calculate compensation under subsection 8(5) are a question of fact for determination by the judge on merits (*Sanofi-Aventis Canada Inc. v. Teva Canada Ltd.*, 2014 FCA 67 at para 26 to 27). It is apparent from that judgment that a broad scope of claims is eligible for consideration, subject to the sufficiency of evidence needed to establish a party's entitlement.

In any case, the matter is not plain and obvious, or beyond doubt. A motion to strike is not the venue to limit or prejudge the discretion of the hearing judge as to the defences and evidence that the hearing judge may take into consideration on the merits in assessing damages under subsection 8(5). Pfizer has asserted novel and arguable defences which, in my view, must be permitted to go to trial (*R. v. Imperial Tobacco Canada Ltd.*, 2011 SCC 42).

Pfizer's Counterclaim

Teva's first objection is that Pfizer Products, the owner of the VIAGRA Tablet Get-Up trade-mark cannot be named as a plaintiff to the counterclaim since it is not a defendant in the main action. Here again, Teva has not met its burden to strike.

I concur with the submissions of Pfizer at para 81 to 89 of its submissions in that regard which I need not repeat. There is no doubt that this action can proceed separately, or that Pfizer Products is a proper plaintiff. There is precedent in allowing a non-party as a plaintiff by counterclaim and no obvious impediment that one can glean from Teva's authorities to the Court exercising its discretion to join the proceedings in this case if called upon to do so.

More to the point, it is fitting and appropriate that the action and counterclaim proceed together such that Pfizer Products, the owner of the mark, may be bound by any findings on liability made by the Court in the main action in respect of its licensee.

Teva proposes to sever the counterclaim from the main action and invokes the Court's discretion to do so under Rule 106, which allows the severance of a claim where the hearing of the main action and counterclaim, in a single proceeding, would cause "undue complication", "delay", or "prejudice".

I decline to exercise my discretion to sever the counterclaim for the following reasons. There is no evidence filed by Teva regarding prejudice. On the face of it, it is 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 noted above in respect of the owner and licensee of the mark.

As for the determination of the sales of sildenafil in the real world, which is the subject matter of the counterclaim and which Teva maintains will unnecessarily prolong the section 8 action, those sales will serve as a facsimile of the sales in the "but for world" that are at issue in the main action, and therefore, are properly tried and determined in the same proceeding.

I am therefore satisfied that proceeding together with the section 8 action and the counterclaim will result in the just, most expeditious, and least expensive determination of these proceedings on the merits.

THIS COURT ORDERS that:

1. The motion is denied in its entirety.

2. By agreement of the parties, costs of the motion are payable by the plaintiff to the defendants, in any event of the cause.

"Roza Aronovitch"
Prothonotary