Federal Court  Cour fédérale

Date: 20171026

Docket: T-2280-12

Citation: 2017 FC 957

Ottawa, Ontario, October 26, 2017

PRESENT: The Honourable Mr. Justice Zinn

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

[1] Before the Court are two motions: (1) a motion brought by the Defendants [Pfizer] for an Order granting them leave to amend their Statement of Defence and Counterclaim, and (2) a motion brought by the Plaintiff [Teva] for an Order that portions of Pfizer's motion record and paragraphs 28B (c) to (e) of the Amended Statement of Defence and Counterclaim be redacted in the Court's public file.

[2] My view of these motions is captured best in the line spoken by Mercutio as he lay dying: "A plague o' both your houses!" (*Romeo and Juliet*, Act III, Scene 1).

[3] Pfizer's motion was unnecessary when it was filed because Teva, without condition, had consented to the proposed Amended Statement of Defence and Counterclaim (attached hereto). Notwithstanding having the consent in hand, Pfizer, for reasons that appear to be in the nature of some tactical advantage, filed its motion.

[4] Teva, having given its unqualified consent to the amendment, attempted to retract its unconditional consent after Pfizer advised that it would be filing its motion record with the Court. Teva also brought its own cross-motion seeking a confidentiality Order relating to Pfizer's motion record and an Order redacting parts of the Amended Statement of Defence and Counterclaim.

[5] Pfizer's threat to file and the subsequent filing resulted in the Court holding an urgent 25 minute case management conference, Teva bringing its cross-motion, and the setting aside of 3

hours to hear these motions. Each of these appearances occupied the time of four counsel, a Court Registrar, and this Judge.

[6] Had Pfizer not acted as it has, then it would now have its amended pleading, and none of the wasteful steps outlined above would have occupied this Court's time or consumed its limited resources.

[7] Given my findings and disposition of these motions, it is valuable, in my view, to provide the following timeline and recitation of the statements and positions of the parties.

[8] This action relates to Pfizer's Viagra (sildenafil citrate) pharmaceutical. Pursuant to section 8 of the *Patented Medicines (Notice of Compliance) Regulations* SOR/2006-242, Teva seeks compensation for damages it alleges it suffered from being unable to market its sildenafil tablets.

[9] Pfizer asserted at paragraph 28(c) of its Statement of Defence and Counterclaim that if it was found that Teva was entitled to claim damages, then any assessment must take into account "the propriety of any rebates and professional allowances (whether cash payments, free goods or reduced prices) rendered in association with the Teva Tablets."

[10] In its Reply, Teva responded that this allegation regarding its rebating practices was "without any factual basis" and it reserved its right to seek to have these paragraphs struck pursuant to Rule 221 of the *Federal Courts Rules*. In its Reply to Defence to Counterclaim,

Pfizer provided particulars regarding its allegation that Teva's impropriety in failing to comply with Provincial legislation.

[11] Examinations for Discovery were held. Teva produced as its representative, Scott Sherwood, Associate Director of Business Finance. Pfizer asked a number of questions relating to Teva's rebate and professional allowance practices. Pfizer, believing it had obtained significant admissions regarding the propriety of these practices, advised Teva that it would be amending its Statement of Defence and Counterclaim to particularize these allegedly improper practices. By letter dated July 20, 2017, counsel for Pfizer wrote to counsel for Teva, as follows:

> We write to advise you that Pfizer will be bringing a motion to amend its Statement of Defence and Counterclaim. We enclose an electronic copy of Pfizer's Motion Record, in both its public and confidential form, which is hereby served upon you in accordance with the parties [*sic*] agreement to accept electronic service and the *Federal Court Rules* [*sic*]. Hard copies will follow by overnight courier.

[12] Counsel for Teva responded providing his client's consent to the proposed amendment, advising that Teva would be "providing corrected responses" to the answers given at Discovery, and stating that as Pfizer had Teva's consent, no motion was required. In correspondence dated July 27, 2017, counsel for Teva wrote to counsel for Pfizer, as follows:

> I write in response to your letter of July 20, 2017 wherein you advised that Pfizer seeks to amend its Statement of Defence and Counterclaim. I have received instructions from Teva to consent to the proposed amendments.
>
> As a first point, much of the testimony which Pfizer seeks to rely upon is inaccurate and, in accordance with rule 245 of the *Federal Courts Rules*, we will be providing corrected responses shortly.
>
> Moreover, Teva takes issue with the manner in which you have prepared the material for the public version of the motion record

> you served on July 20. The transcripts have been marked "Confidential" in their entirety and it is not within your client's purview to unilaterally ignore that designation, as it has done. If the motion record were to be filed, Teva would insist that the transcripts be redacted in their entirety.
>
> That said, as Teva has consented to the amendments, there is no reason to file the motion record and Teva expects that it will not be filed. If this is not so, please advise immediately so that Teva can bring a motion to protect its confidential information.
>
> [emphasis added]

[13] On July 28, 2017, counsel for Pfizer wrote to express serious concerns about Teva's "unexplained delay in its intent to correct its evidence" stating: "Conveniently, it was only after Pfizer served its motion to amend on Teva based on Sherwood's evidence that Teva now seeks to correct Sherwood's evidence. Teva's actions are telling."

[14] Counsel for Pfizer also responded on July 31, 2017, to the inquiry as to whether Pfizer, in the face of Teva's consent, would proceed to file its motion: "Pfizer will be filing the public version of its motion record, which it has a right to do" [emphasis added]. That resulted in a response from Teva, and an email from Teva to the Court seeking an urgent case management conference.

[15] Teva's letter to Pfizer dated July 31, 2017, reads as follows:

> I write in response to your letter of July 31, 2017 wherein you advised that Pfizer continues to intend to file a motion for leave to amend its Statement of Defence and Counterclaim notwithstanding that you will receive Teva's consent to the proposed amendments.
>
> Obviously, Pfizer's motion is unnecessary, as leave is not required. That of course, shines a bright light on Pfizer's real motivation to nevertheless publicly file material that it neither required nor

> necessary in light of Teva's consent. It also raises the spectre of improper disclosure and a potential breach of the implied undertaking of confidentiality. Public disclosure of compelled (and inaccurate) material cannot be permissible where it is entirely unnecessary.
>
> In addition, of course, requiring Teva to bring a motion where none is required places an entirely unnecessary burden on the Court and on Teva particularly in circumstances where Teva reasonably believed that providing consent to the pleading amendments would obviate the need for a confidentiality motion.
>
> As you know, we have requested an immediate Case Management Conference before Justice Zinn, at which we will bring your client's conduct to his attention.
>
> [emphasis added]

[16] At 4:51 p.m. on July 31, 2017, counsel for Teva emailed the Court alerting it and Pfizer that Teva would now be seeking redactions in the Amended Statement of Defence and Counterclaim:

> Teva will be making submissions on the treatment of the proposed amended statement of defence and counterclaim on tomorrow's Case Management Call. Until that has taken place we respectfully ask that the draft pleadings not be placed onto the Court file. [emphasis added]

[17] In the case management conference which commenced at 10:30 a.m. on August 1, 2017, counsel for Teva, informed the Court and Pfizer that he was instructed to bring a motion seeking an order sealing potions of the motions materials filed by Pfizer, which Teva asserted to contain confidential information and redacting paragraphs 28B (c) to (e) of the Amended Statement of Defence and Counterclaim.

[18] The Court determined that Pfizer's motion to amend and Teva's confidentiality motion would be heard in Toronto on October 5, 2017, and that all materials would be sealed in the Court file pending the determination of the motions.

[19] When these motions came on for hearing, the Court, in light of Rule 200 of the *Federal Courts Rules*, asked counsel for Pfizer why its motion for leave to amend had been filed. Rule 200 provides as follows:

> Notwithstanding rules 75 and 76, a party may, without leave, amend any of its pleadings at any time before another party has pleaded thereto or on the filing of the written consent of the other party. [emphasis added]

[20] Notwithstanding numerous valiant attempts by Mr. Pasparakis, no response satisfactory to the Court was provided; because, in my view, there is none. Just because a party has a "right" to do something, as Pfizer asserts, does not mean that it should do so when the Rules provide for and less expensive and less time-consuming way to obtain the result requested. The motion for leave to amend was and is unnecessary in light of Teva's consent. Pfizer's filing of its motion, as I expressed at the hearing, was abusive of this Court's processes and procedures, and unnecessary.

[21] The consequence of Pfizer filing the motion was that Teva had time to attempt to resile from its previous unequivocal and unconditional consent to the amendment.

[22] At the hearing, counsel for Teva conceded that if the Discovery transcripts could be read to reflect the allegations set out in paragraphs 28B (c) to (e) of the Amended Statement of

Defence and Counterclaim, then there was no basis warranting their redaction. In my assessment, that test has been met. Teva acknowledged as much given that it now seeks to "correct" the responses given at Discovery.

[23] Teva, having consented without condition to the filing of the Amended Statement of Defence and Counterclaim, should not have sought, only three days later, to resile from that consent. It too has abused the Court processes.

[24] Pfizer is principally at fault for the wasted judicial resources that these events have caused. The proximate cause was Pfizer's decision, notwithstanding having in hand Teva's consent to the amendment it sought, to file a motion for leave to amend its pleading.

[25] There may be some confidential and proprietary information in the materials that have been filed. Teva asserts that there is. Given that none of the materials filed on these motions ought to have been filed in the first place; I find that any further consideration by the Court as to what, if any materials ought to be redacted or sealed would be an additional waste of judicial resources. Accordingly, I will direct the Registry to remove all of the filed materials from the Court record and return them to the filing party, save and except any Judge's copies which are to be shredded.

[26] In my view, neither party is entitled to costs: Pfizer ought never to have brought this motion, and Teva ought not have played tit-for-tat and withdrawn its unconditional consent. I only regret that I am unable to order both parties to compensate the Court for its losses.

ORDER IN T-2280-12

THIS COURT ORDERS that:

1. The Registry is directed to accept for filing the Amended Statement of Defence and Counterclaim attached hereto; and

2. The Registry is directed to remove from the Court files, both public and sealed, and to return to the party filing the materials (save for the Judge's copies which shall be destroyed), all documents filed by either of the parties hereto relating to Pfizer's motion for leave to amend its pleading, and Teva's cross-motion for a confidentiality order and redaction of the materials filed on these motions.

"Russel W. Zinn"
Judge

11

Court File No. T-2280-12

FEDERAL COURT

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)

AMENDED STATEMENT OF DEFENCE AND COUNTERCLAIM

TO THE DEFENDANT TO THE COUNTERCLAIM:

A LEGAL PROCEEDING has been commenced against you by way of a counterclaim in an action in this Court. The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS COUNTERCLAIM, you or a solicitor acting for you must prepare a defence to counterclaim in Form 171F prescribed by the *Federal Courts Rules*, serve it on the plaintiff by counterclaim's solicitor, or where the plaintiff by counterclaim is self-represented, serve it on the plaintiff by counterclaim, and file it, with proof of service, WITHIN 30 DAYS after this statement of defence and counterclaim is served on you.
If you are not already a party to the main action and you are served in the United States of America, the period for serving and filing your statement of defence is 40 days. If you are served outside Canada and the United States of America, the period for serving and filing your statement of defence is 60 days.

Copies of the *Federal Courts Rules,* information concerning the local offices of the Court and

other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO DEFEND THIS COUNTERCLAIM, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

March 31, 2014

Amended ●, 2017

Issued by:_____
(Registry Officer)

Address of
local office: 180 Queen Street
Suite 200
Toronto, Ontario
M5V 3L6

TO: **AITKEN KLEE LLP**
Suite 2404, 160 Elgin Street
Ottawa, Ontario, K2P 2P7

David W. Aitken
Marcus Klee
Bryan Norrie

Tel: 613.695.5858
Fax: 613.695.5854

Solicitors for the Plaintiff and Defendant by Counterclaim

TO: **PFIZER PRODUCTS INC.**
C/O NORTON ROSE FULBRIGHT CANADA LLP
Suite 3800, P.O. Box 84
Royal Bank Plaza, South Tower
200 Bay Street
Toronto, ON M5J 2Z4

Orestes Pasparakis
Allyson Whyte Nowak
Kristin Wall

Tel: +1 416.216.4000
Fax: +1 416.216.3930

Solicitors for the Plaintiff by Counterclaim, Pfizer Products Inc.

STATEMENT OF DEFENCE

1. Except as admitted, Pfizer Canada Inc. ("**Pfizer Canada**"), Pfizer Inc. ("**Pfizer U.S.**") and Pfizer Ireland Pharmaceuticals ("**Pfizer Ireland**") (collectively, the "**Pfizer Defendants**") deny each and every allegation contained in the Second Amended Statement of Claim.

THE PARTIES

2. Pfizer Canada is a pharmaceutical company authorized to sell sildenafil citrate tablets in Canada under the brand-name VIAGRA® ("**Viagra Tablets**").

3. Pfizer U.S. and Pfizer Ireland are affiliates of Pfizer Canada. Neither Pfizer U.S. nor Pfizer Ireland are "first persons" under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, as amended, (the "***Regulations***") and are not proper parties to this action.

4. Teva Canada Limited ("**Teva**") is a generic pharmaceutical company that is manufacturing and selling sildenafil citrate tablets in Canada ("**Teva Tablets**"). Teva is the successor to Novopharm Limited ("**Novopharm**") and ratiopharm Inc. ("**ratiopharm**") by virtue of an amalgamation (the "**Amalgamation**") effective August 10, 2010.

5. Teva is governed by the *Canada Business Corporations Act*, R.S.C. 1985, c. C-44 ("***CBCA***").

VIAGRA TABLETS

6. Pfizer Canada obtained a notice of compliance ("**NOC**") for Viagra Tablets on March 8, 1999 and has marketed Viagra Tablets in Canada since on or about that time.

7. Pfizer Canada markets blue and diamond-shaped Viagra Tablets in dosages of 25 mg, 50 mg and 100 mg (the "**Viagra Tablet Get-up**").

8. Pfizer Canada has sought to protect its intellectual property in the Viagra Tablets by, *inter alia*:

a) causing patents to be added to the Patent Register in respect of Viagra Tablets, including Canadian Patent No. 2,044,748 (the "**'748 Patent**") and Canadian Patent No. 2,163,446 (the "**'446 Patent**");

b) obtaining an industrial design registration in respect of the design of the Viagra Tablets, which was issued on February 4, 2000; and

c) seeking a trade-mark registration for the Viagra Tablet Get-up, which process is still ongoing.

THE NOVOPHARM APPLICATION

9. On or about July 6, 2007, Pfizer Canada received a notice of allegation from Novopharm making various allegations of non-infringement and/or invalidity with respect to the '748 and '446 Patents, *inter alia* (the "**Novopharm Notice of Allegation**"). This was the first notice that the Pfizer Defendants had of Novopharm's intention to market a sildenafil product in Canada.

10. In response to the Novopharm Notice of Allegation, Pfizer Canada brought an application (T-1566-07) for an order to prohibit Novopharm from receiving an NOC from Health Canada (the "**Novopharm Application**"). Pfizer U.S. and Pfizer Ireland were named as parties to the Novopharm Application pursuant to section 6(4) of the *Regulations*.

11. The Novopharm Application was dismissed, in part, with respect to the '748 Patent by Order dated April 18, 2008 pursuant to section 6(5)(b) of the *Regulations*.

12. The Novopharm Application was granted on June 18, 2009 with respect to the '446 Patent and upheld unanimously by the Federal Court of Appeal.

13. On November 8, 2012, the Supreme Court of Canada allowed Teva's appeal.

THE RATIOPHARM APPLICATION

14. On or about December 4, 2008, Pfizer Canada received a notice of allegation from ratiopharm making various allegations of non-infringement and/or invalidity with respect to the '748 and '446 Patents, *inter alia* (the "**ratiopharm Notice of Allegation**").

15. In response to the ratiopharm Notice of Allegation, Pfizer Canada brought an application (T-1935-08) for an order to prohibit ratiopharm from receiving an NOC from Health Canada (the "**ratiopharm Application**"). Pfizer U.S. and Pfizer Ireland were named as parties to the ratiopharm Application pursuant to section 6(4) of the *Regulations*.

TEVA TABLETS

16. On November 8, 2012, Teva received an NOC for Ratio-Sildenafil 25 mg (DIN: 02319640), 50 mg (DIN: 02319659), and 100 mg (DIN: 02319667) tablets.

17. On November 8, 2012, Novopharm received an NOC for Novo-Sildenafil 25 mg (DIN: 02308738), 50 mg (DIN: 02308746), 100 mg (DIN: 02308754) tablets. On December 18, 2012, the Minister of Health ("**Minister**") issued a second NOC to reflect a product name change from Novo-Sildenafil to Teva-Sildenafil. The drug identification numbers ("DIN") assigned remained unchanged.

18. The Teva Tablets sold in Canada are blue and diamond-shaped tablets.

19. The Teva Tablets copy the Viagra Tablet Get-up and industrial design.

~~**WAIVER OF DAMAGES**~~

~~20. The parties expressly agreed to Teva's waiver of all damages in relation to patents listed in connection with Viagra. Teva is therefore estopped and precluded from making the claim herein.~~

~~21. The Pfizer Defendants plead and rely upon section 186(e) of the *CBCA*.~~

NOT A "FIRST PERSON"

22. There is no basis in fact or law for the claim that Pfizer U.S. and Pfizer Ireland are "first persons" under the *Regulations*. Teva's decision to name Pfizer U.S. and Pfizer Ireland in this action is vexatious and such claim should be dismissed with full indemnity costs.

TEVA'S CLAIMS

23. The Pfizer Defendants deny that Teva:

    a) is entitled to any compensation for lost sales of Teva Tablets as pled in paragraph 26(a) of the Second Amended Statement of Claim, including that Teva:

        i) would have received an NOC for sildenafil citrate tablets on April 25, 2008;

        ii) would have been able to sell sildenafil citrate tablets throughout the relevant period; and

        iii) would have been able throughout the relevant period to supply sufficient commercial quantities of sildenafil citrate tablets to sustain the losses alleged;

    b) would have secured "a significant competitive advantage" as pled in paragraph 25 of the Second Amended Statement of Claim. Such a claim is unrecoverable in law and without basis in fact; and

    c) suffered the losses claimed at paragraphs 26(b), 26(c), 26(d), 26(e), 26(f), and 26(g) of the Second Amended Statement of Claim which losses are, in any event, not recoverable in law, speculative, and not causally connected to the Pfizer Defendants' commencement of the Novopharm Application.

ASSESSMENT OF COMPENSATION – SUBSECTION 8(5)

24. In response to the allegation at subparagraph 27(a) of the Second Amended Statement of Claim the Pfizer Defendants plead:

a) no Court has found the '446 Patent to be invalid on the grounds of anticipation, inutility, or obviousness;

b) no Court has found the '446 Patent to be invalid under section 53 of the *Patent Act* R.S.C. 1985, c. P-4, as amended ("***Patent Act***") for containing any untrue material allegation or any wilful omission/addition for the purpose of misleading;

c) the validity of the '446 Patent was affirmed in a prohibition proceeding between the Pfizer Defendants and Apotex Inc. in Federal Court File T-1314-05 and on appeal;

d) the equivalent U.S. Patent No. 6,469,012 was found to be valid and infringed in August 2011 in *Pfizer v. Teva*, 10-cv-128, U.S. District Court, Eastern District of Virginia (Norfolk);

e) until the SCC Judgment, each and every judge that had considered the '446 Patent had held its claims to be valid and infringed by Teva; and

f) Teva was aware at all times of the invention disclosed in the '446 Patent such that it was able to develop a generic version of sildenafil citrate and obtain an NOC for said product by comparison with Viagra Tablets.

25. The Pfizer Defendants did not delay the process under the *Regulations* as alleged in paragraph 27(b) and (c) of the Second Amended Statement of Claim or at all. Pfizer Canada exercised its legal right to commence an Application to prevent the infringement of its patents by Teva, as permitted by section 55.2 of the *Patent Act* and the *Regulations*. There was no finding by that Court that Pfizer acted to delay the Novopharm Application.

26. The Pfizer Defendants deny that the approval of Teva Tablets before April 25, 2008, would have increased the sales volume of sildenafil in Canada, as alleged in paragraph 27(e) of the Second Amended Statement of Claim. Rather, the market would not have developed absent the marketing activities of Pfizer Canada. There is no factual basis for the assertion that Teva would have taken steps to expand the market for sildenafil on or after April 25, 2008.

27. With respect to subparagraphs 27(h) and (i), the Pfizer Defendants deny that Teva experienced a "ramp-up" in the real world and further deny that it would be a proper exercise of the Court's discretion not to include "ramp-up" in the relevant period.

APPORTIONMENT OF DAMAGES

28. If this Court determines that Teva is entitled to claim damages from Pfizer Canada, which is denied, any such assessment must take into account:

a) the presence of other generic products in the market (including by Pfizer) and the proportionate market share that would have been earned by those entities;

b) that Pfizer Canada would have lowered the price of Viagra Tablets in order to compete with Teva and other generic manufacturers and retain market share and sales revenue; and

c) the propriety of any rebates and professional allowances (whether cash payments, free goods or reduced prices) rendered in association with the Teva Tablets and the fact that Teva's sales of the Teva Tablets were enabled by its unlawful rebating practices..

NO LIABILITY OR COMPENSATION FOR UNLAWFUL ACTIVITY – *EX TURPI CAUSA*

a) Teva's unlawful rebating practices

28A. Since October 1, 2006, generic drug manufacturers have been prohibited from paying rebates to customers in Ontario under the *Drug Interchangeability and Dispensing Fee Act* (the "***DIDFA***") and the *Ontario Drug Benefit Act* (the "***ODBA***") (together, the "**Ontario Legislation**").

28B. During the alleged period of delay, Teva had a business practice of obtaining generic market share through unlawful rebating practices, including, among others, the following practices that have been admitted by Teva (the "**Teva Rebating Practices**"):

a) Teva purposefully attributed higher rebate payments to its customers in the "Rest of Canada" to circumvent the restrictions on rebates under the Ontario Legislation;

b) Teva purposefully attributed higher professional allowances to its products that were not listed as a benefit on the Ontario Formulary (private and cash sales) to circumvent the restrictions on public sales;

c) Teva characterized payments to pharmacies as "education allowances" in circumstances in which those payments did not have anything to do with education;

d) Teva purposefully developed other programs, which were, for all intended purposes, a form of rebate, but were characterized in such a way so that its customers did not have to report the payments as rebates; and

e) Teva purposefully avoided creating documentation on the subject of rebates and/or professional allowances because it knew its activities were improper.

28C. The Teva Rebating Practices were developed to circumvent the Ontario Legislation.

28D. If Teva had sold the Teva Tablets during the alleged period of delay, the Teva Tablets would have been the subject of the Teva Rebating Practices.

28E. In order to be designated as "interchangeable" under the *DIDFA*, Teva would have had to certify to the Ontario Ministry of Health and Long Term Care (the "**Minister of Health**") that it did not provide any unlawful rebates with respect to the Teva Tablets. The Teva Rebating Practices were unlawful. Therefore, Teva would have either made a false certification to the Minister of Health or the Teva Tablets would not have been designated as interchangeable.

28F. Teva is not entitled to any damages in this action:

a) Teva's unlawful rebating practices are a relevant factor the Court must consider under section 8(5) of the *Regulations* in determining whether to award damages to Teva; and/or

b) Had Teva complied with all legal requirements relating to rebates, Teva would not have been able to achieve the same generic market share (i.e. the Teva Tablet sales would have been lower); and/or

c) Had the Teva Tablets not been designated as interchangeable under the *DIDFA*, Teva would have made *de minimis* sales.

(b) Patent Infringement – the '748 Patent

29. The manufacture, use and sale of Teva Tablets in Canada during the alleged period of delay would have infringed the '748 Patent.

30. The '748 Patent entitled "Pyrazolopyrimidinone Antianginal Agents" was issued by the Commissioner of Patents on February 3, 1998 based on an application filed June 17, 1991. A copy of the '748 Patent is attached hereto as **Schedule "A"**.

31. Pfizer U.S. was the owner of the '748 Patent. The '748 Patent was in full force and effect from its date of issue, and was presumed to be valid under section 43(2) of the *Patent Act* until it expired on June 17, 2011. Pfizer Canada was a licensee under the '748 Patent.

32. By reason of the grant of the '748 Patent under section 42 of the *Patent Act*, and prior to its expiry, Pfizer U.S. and Pfizer Canada had the exclusive right, privilege and liberty of making, constructing, importing, exporting, using and selling the invention described in the '748 Patent in Canada. The invention that was the subject of the exclusive right conferred by the '748 Patent and at issue in this Defence is more particularly defined in the disclosure and in claims 1 through 21, as if recited herein at length.

33. The '748 Patent describes the following subject-matter, *inter alia*:

a) The compound of formula (I) and pharmaceutically acceptable salts thereof;

b) A process for making the compound of formula (I);

c) A pharmaceutical composition comprising a compound of formula (I);

d) Uses of the compound of formula (I);

e) A commercial package containing a compound of formula (I); and

f) A process for the manufacture of a medicament for the treatment of various disorders.

34. Sildenafil was included in the group of compounds represented by formula (I) of claim 1 of the '748 Patent.

35. Claim 6 of the '748 Patent claimed the compound of sildenafil by its chemical name 5-[2-ethoxy-5-(4-methylpiperazinyl-sulphony)phenyl]-1-methyl-3-n-propyl-1,6-dihydro-7H-pyrazolo-[4,3-d]pyrimidin-7-one or a pharmaceutically acceptable salt thereof. Sildenafil citrate is a pharmaceutically acceptable salt of sildenafil.

36. Teva has infringed the '748 Patent. At no time in the underlying Application did Teva deny infringement of these claims.

37. If Teva had manufactured, offered for sale, marketed or sold sildenafil citrate tablets during the alleged period of delay, Teva would have unlawfully infringed Pfizer U.S. and Pfizer Canada's exclusive rights under the '748 Patent by virtue of section 55.1 of the *Patent Act* and/or section 39(2) of the *Patent Act*, as it existed prior to the date on which section 55.1 of the *Patent Act* came into force.

38. Teva is not entitled to any damages for sales that would have infringed the '748 Patent while it remained extant.

(c) Industrial Design Infringement

39. The manufacture, import and sale of Teva Tablets in Canada during the period of delay would have infringed Canadian Industrial Design Registration No. 88762 for Viagra Tablets (the "**Viagra Industrial Design**").

40. The Viagra Industrial Design entitled "*Pharmaceutical Tablet*" was registered on February 4, 2000.

41. Pfizer Ireland Pharmaceuticals was the proprietor of the Viagra Industrial Design. The Viagra Industrial Design was in full force and effect from its date of registration, and was presumed to be valid under section 7(3) of the *Industrial Design Act*, R.S.C. 1985, c. I-9 ("***Industrial Design Act***") until it expired on February 4, 2010. Pfizer Canada was a licensee under the Viagra Industrial Design.

42. By reason of the registration of the Viagra Industrial Design under section 11 of the *Industrial Design Act*, and prior to its expiry, Pfizer Ireland and Pfizer Canada had the exclusive right to make, import and sell Viagra Tablets in Canada according to the design described in the Viagra Industrial Design.

43. Teva markets and sells sildenafil citrate tablets in Canada that do not differ substantially from the Viagra Industrial Design.

44. If Teva had manufactured, offered for sale, marketed or sold sildenafil citrate tablets during the alleged period of delay, Teva would have unlawfully infringed Pfizer Ireland and Pfizer Canada's exclusive rights under the Viagra Industrial Design.

45. Teva is not entitled to any damages for sales that would have infringed the Viagra Industrial Design.

(d) Passing off

46. If Teva had manufactured, offered for sale, marketed or sold the Teva Tablets during the alleged period of delay, said tablets would have unlawfully imitated the Viagra Tablet Get-up. Teva would have directed public attention to its Teva Tablets and business in such a way as to cause or be likely to cause confusion in Canada with Pfizer Canada's business and Viagra Tablets contrary to section 7(b) of the *Trade-marks Act*, as more fully set forth in the Counterclaim.

47. Teva is not entitled to any damages for sales that would have arisen by virtue of its unlawful passing-off.

48. For each of the allegations at paragraphs 28A – 47, the Pfizer Defendants plead and rely on the doctrine of *ex turpi causa non oritur actio* and section 8(5) of the *Regulations*.

49. The Pfizer Defendants propose that the trial of this action be heard in Toronto.

COUNTERCLAIM

50. The Plaintiffs by Counterclaim, Pfizer Products Inc. ("**Pfizer Products**") Pfizer Canada (collectively "**Pfizer**"), claim:

a) A declaration that Pfizer Products is the owner of the Viagra Tablet Get-up trade-mark;

b) A declaration that Teva has directed public attention to its wares or business in such a way as to cause or be likely to cause confusion between its wares or business and the wares or business of Pfizer Canada, contrary to section 7(b) of the *Trade-marks Act*;

c) An order requiring Teva to maintain proper books and records of all revenue of any kind received from the exploitation of, or otherwise in respect of, any Teva Tablet sold in Canada; and all records in respect of the manufacture and distribution by Teva of its Teva Tablets;

d) An order requiring Teva to deliver up to Pfizer Canada, or its nominee, all articles in its possession, power or control that are confusing or misleading with respect to the Viagra Tablet Get-up, whether said articles are Teva Tablets, moulds and/or tablet presses for Teva Tablets, as well as any packaging, marketing, promotional literature or any other materials associated therewith;

e) ~~Damages or~~ an accounting of profits ~~as Pfizer Canada may, after due inquiry, elect~~ as elected by Pfizer as of May 3, 2017;

f) Costs of this action;

g) Pre-judgment and post-judgment interest;

h) Such further and other relief as to this Honourable Court may seem just.

51. Pfizer repeats and relies on the allegations contained in the Statement of Defence.

PARTIES

52. The Plaintiff by Counterclaim, Pfizer Products, is the owner of the trade-mark for the Viagra Tablet Get-up.

53. The Plaintiff by Counterclaim, Pfizer Canada, is the licensee of the trade-mark for the Viagra Tablet Get-up.

54. The Defendant by Counterclaim, Teva, sells Teva Tablets in Canada that imitate the Viagra Tablet Get-up.

PFIZER'S RIGHTS

55. Viagra Tablets revolutionized the treatment of erectile dysfunction ("**ED**") as the first ever safe and effective oral treatment for ED, a disorder that affects millions of men worldwide.

56. Pfizer Canada has been selling Viagra Tablets in Canada featuring the Viagra Tablet Get-up since the product was first launched in 1999.

57. The Viagra Tablet Get-up was adopted for the purpose of distinguishing Viagra Tablets.

58. By reason of extensive sales, sampling, information distribution, web-site, television, print-media and other promotion, the Viagra Tablet Get-up has developed substantial goodwill and has become well-known to the purchasing public who associate the appearance of Viagra Tablets with a single trade source.

UNLAWFUL ACTIVITIES OF TEVA

59. On or about October 16, 2012, Pfizer put Teva on notice that any use by Teva of the Viagra Tablet Get-up, or any confusingly similar tablet design, would infringe Pfizer's rights and constitute passing off under the *Trade-marks Act* and at common law.

60. On or about November 8, 2012, Teva obtained an NOC from the Minister for Teva Tablets.

61. On or about this time, Teva began promoting and selling Teva Tablets in Canada which feature the same or a confusingly similar appearance to the Viagra Tablet Get-up. In particular, Teva has adopted the same blue colour scheme and diamond-shaped tablet.

62. Teva's decision to adopt the same or a confusingly similar tablet Get-up was intentional and deliberate in order to appropriate the existing goodwill and reputation associated with the Viagra Tablet Get-up.

63. The promotion, distribution and sale by Teva of Teva Tablets that imitate the Viagra Tablet Get-up is a misrepresentation that deceives the public in a manner that leads, or is likely to lead, the public to believe that Teva and Pfizer's sildenafil citrate tablets are manufactured or sold by the same source.

64. Teva is directing public attention to Teva Tablets in such a way as to cause or be likely to cause confusion in Canada with the Viagra Tablet Get-up contrary to section 7(b) of the *Trade-marks Act*.

65. These activities have been without the licence or consent of Pfizer Products or Pfizer Canada.

66. By reason of the foregoing acts, Teva is making a profit and Pfizer is suffering actual loss, including irreparable harm to its goodwill, lost profits and damages. Every tablet sold by Teva that copies the Viagra Tablet Get-up is a sale that rightfully belongs to Pfizer Canada.

67. Pfizer proposes that this action be tried in Toronto, Ontario.

68. Pfizer confirms that the monetary relief sought herein, exclusive of interest and costs, exceeds $50,000.

Dated at Toronto this 31st day of March, 2014

Amended at Toronto this ●st day of ●, 2017

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NORTON ROSE FULBRIGHT CANADA LLP
Suite 3800, Royal Bank Plaza
South Tower, 200 Bay St.,
P.O. Box 84
Toronto, Ontario M5J 2Z4

Orestes Pasparakis
Allyson Whyte Nowak
Kristin Wall

Tel: +1 416.216.4000
Fax: +1 416.216.3930

Solicitors for the Defendants and Plaintiffs by Counterclaim

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Court No. T-2280-12

FEDERAL COURT

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)

AMENDED STATEMENT OF DEFENCE AND COUNTERCLAIM

NORTON ROSE FULBRIGHT CANADA LLP
Suite 3800, P.O. Box 84
Royal Bank Plaza, South Tower
200 Bay Street
Toronto, ON M5J 2Z4

Orestes Pasparakis
Allyson Whyte Nowak
Kristin Wall

Tel: +1 416.216.4000
Fax: +1 416.216.3930

Solicitors for the Defendants and Plaintiffs by Counterclaim

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; AND PFIZER PRODUCTS INC.
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	OCTOBER 5, 2017
ORDER AND REASONS:	ZINN J.
DATED:	OCTOBER 26, 2017

APPEARANCES:

Jonathan Stainsby Scott Beeser	FOR THE PLAINTIFF (DEFENDANT BY COUNTERCLAIM)
Orestes Pasparakis Daniel Daniele	FOR THE DEFENDANTS AND PLAINTIFFS BY COUNTERCLAIM

SOLICITORS OF RECORD:

Aitken Klee LLP Barristers & Solicitors Toronto, Ontario	FOR THE PLAINTIFF (DEFENDANT BY COUNTERCLAIM)
Norton Rose Fulbright Canada LLP Barristers & Solicitors Toronto, Ontario	FOR THE DEFENDANTS AND PLAINTIFFS BY COUNTERCLAIM