Federal Court  Cour fédérale

Date: 20170502

Docket: T-944-15

Citation: 2017 FC 437

Ottawa, Ontario, May 2, 2017

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

TEVA CANADA LIMITED

Plaintiff

and

JANSSEN INC. AND MILLENNIUM PHARMACEUTICALS, INC.

Defendants

AND BETWEEN:

MILLENNIUM PHARMACEUTICALS INC., JANSSEN INC., CILAG GMBH INTERNATIONAL, CILAG AG AND JANSSEN PHARMACEUTICA NV

Plaintiffs By Counterclaim

and

THE UNITED STATES OF AMERICA REPRESENTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Patentee

and

TEVA CANADA LIMITED

Defendant by Counterclaim

ORDER AND REASONS

I. Overview

[1] Teva, after both parties had improperly filed materials under seal, brought a belated motion for a confidentiality order in respect of its information. The relief requested overreached, and greatly exceeded the scope of the evidence filed to support it. Given an opportunity to adjust its ask or provide appropriate support, Teva filed what can only be characterized as inaccurate and misleading evidence, bringing into question and irrevocably tainting the credibility and reliability of all the evidence adduced in support of its motion. As a result, the Court cannot be satisfied that the materials at issue should be treated as confidential notwithstanding the public interest in open and accessible court proceedings.

[2] For these reasons, more fully explained below, Teva's motion is dismissed, and the material filed by the parties under seal will be placed on the open court record. The parties' request to remove certain parts of the record is however granted, and these portions will be removed before the remaining parts of the records are unsealed.

II. General Principles

[3] The open court principle is of crucial importance in a democratic society, as recognized in *CBC v Québec (Procureur général)*, 2011 SCC 2. It ensures that citizens have access to the courts and can comment on how courts operate and on proceedings that take place in them. Courts are publicly funded. Citizens, whose tax dollars pay for the courts' operations, are entitled to expect that judicial resources are allocated fairly and judiciously amongst many competing demands; they have the right to know how these resources are being used.

[4] Confidentiality orders inherently compromise these fundamental principles and important rights. Private parties to high-stakes pharmaceutical litigation may prefer that the details of their disputes remain shielded from the public view; however their counsel, as officers of the court, have a duty to uphold the independence and authority of the Court. They must assist the Court in upholding the fundamental principles of justice, including the public interest in public and accessible court proceedings. It is not open to counsel, acting as advocates for their clients' private interests, to put aside their duty to the Court and choose to put before the Court incomplete or misleading information, to wilfully blind themselves to the availability of important and relevant information and to fail to fairly put all relevant facts before the Court, whether or not they support their position.

[5] The requirements for the Court to make a confidentiality order, as set out in Rule 151 of the *Federal Courts Rules* SOR/98-106 and as further explained and refined by the Supreme Court of Canada in *Sierra Club of Canada v Canada (Minister of Finance)*, 2002 SCC 41, is not

merely that a party assert or believe that information is confidential or should be treated confidentially, but that the Court be satisfied that it is so. The onus is a heavy one. It is not satisfied by consent or by bald assertions *(Bah v Canada (Ministre de la citoyenneté et de l'immigration)*, 2014 FC 693; *Canada (AG) v Amalki*, 2010 FC 733).

[6] One of the conditions to be satisfied is that the confidentiality order be necessary to prevent a serious risk of harm to an important interest. It may be a trite observation, but for this condition to be met, the moving party must necessarily establish that the information is actually confidential. A party cannot hope to satisfy the Court that a prejudice might be suffered should the information become public, or that a confidentiality order is necessary to prevent that prejudice, if the information is already publicly available and beyond the reach of the Court's protection.

III. The Circumstances of the Case

[7] This is an action brought by Teva Canada Limited to recover from Janssen Inc. and others damages it claims to have suffered as a result of being delayed entry into the Canadian market for bortezomib, pursuant to section 8 of the *Patented Medicine (Notice of Compliance) Regulations* SOR/93-133, as amended.

[8] The parties sought and obtained from the Court on consent a protective order setting out the terms under which information exchanged between them was to be treated. The order provided that:

> "(…) this Protective Order applies only to govern the manner in which the Parties deal with information exchanged in the course of this litigation and does not entitle any party to file confidentially in this Court information designated as Confidential Information pursuant to this Protective Order in the absence of a separate, specific Confidentiality Order (…)"

[9] A confidentiality order was also issued, allowing the parties to file supporting materials under seal, but only for the purpose of motions to compel.

[10] Notwithstanding these terms, both parties purported to file, pursuant to these orders, sealed materials in the context of a motion brought by Janssen for leave to amend its statement of defence and counterclaim. Such misuse of the terms of protective and confidentiality orders is, alas, all too common in pharmaceutical patent litigation. It is symptomatic of a careless attitude towards the principle of open and accessible court proceedings and of a disregard of counsel's duties as officers of the court to uphold the authority of the Court and respect its orders.

[11] On noticing the parties' improper filing, the Court issued a direction requiring them to show cause why the sealed material should not be opened and placed on the record or removed from the record. The parties agreed that some of Janssen's information and of Teva's information could be removed from the record. Teva agreed that other parts of its information could be placed on the open record. However, Teva also made a motion to allow substantial portions of its information to remain under seal.

[12] Two types of information were at issue in Teva's motion for a confidentiality order: the supply contract between Teva and the supplier of its bortezomib product, including all of the

information contained therein and all documents that refer to that information, and excerpts of Teva's ANDS for its bortezomib product, including the portions of the discovery transcript and written representations that refer to it.

[13] Janssen had included and referred to the supply contract in its motion record because some of the amendments it sought to make alleged that Teva is not the "Second Person" entitled to claim section 8 damages because under the terms and conditions of the supply contract, the supplier had complete control over Teva's activities and should therefore be considered to be the Second Person. Teva filed the ANDS information to show that it was the person who applied for and was named as applicant in the ANDS and therefore, properly the Second Person.

[14] The identity of the supplier and the terms of the supply agreement are accordingly key to the proposed amendments and to the determination of whether they disclose a reasonable defence and should be allowed. Indeed, the particulars of the proposed amendments recite the terms of the supply agreement. The ANDS, for its part, is only relevant insofar as it identifies Teva, and not the supplier, as the applicant.

[15] Teva filed the affidavit of Glenn Ikeda in support of its motion for a confidentiality order. The parts of that affidavit relating to the confidentiality of the supply contract read as follows:

> "3. Teva Production 0074 is a License, Supply and Distribution Agreement between Teva and its related supplier. This document refers to the royalty rate, pricing structure and payment terms as between Teva and its supplier, and for that reason, has been designated as "Confidential – Financial Information." This document contains a confidentiality clause in paragraph 12 which requires Teva and its supplier to maintain any information disclosed pursuant to this agreement as confidential, except to

> consultants, affiliates and employees who need or are entitled to know the confidential information for the purposes of carrying out the objectives of the agreement. The agreement contains sensitive commercial information (Teva's costs and information regarding Teva's supply chain) that could be used by competitors to Teva's disadvantage in a competitive bidding process.
>
> 4. Teva considers this document to be confidential and treats it as such, as this agreement sets out the pricing arrangement for bortezomib as between Teva and its supplier, and this information is not publicly disclosed or shared with parties external to Teva."
>
> [Emphasis added.]

[16] Even though that paragraph refers to "information regarding Teva's supply chain", the emphasis is on the financial aspects of the agreement, and not on the identity of the supplier. Paragraph 3 even acknowledges that the supplier is related to Teva.

[17] Given the importance of the supply terms to the issues on the motion to amend and the lack of evidentiary support for their confidential nature or for the prejudice Teva might suffer from public disclosure of these terms, the Court was not satisfied that a confidentiality order was justified in respect of any element other than the financial aspects of the agreement. With respect to the ANDS, the affidavit only spoke to the confidentiality of the scientific information it contained.

[18] The confidentiality designations sought by Teva greatly exceeded these parameters. They sought to seal the entirety of the supply agreement and of the ANDS and any reference to their content. The designations even included the particulars of the proposed pleadings. The Court accordingly called the parties to a hearing, to give Teva an opportunity to explain the extent of the proposed confidentiality order or suggest a more tailored approach.

[19] Teva acknowledged at the hearing that some of the transcripts it had sought to protect did not actually contain any confidential information and that confidentiality may not be justified in respect of portions of the ANDS and of the supply agreement. However, and surprisingly in view of the focus of the affidavit and of the fact that the supplier is a company related to Teva, as already acknowledged in Mr. Ikeda's affidavit, Teva's counsel took the position that the identity of the supplier should remain confidential.

[20] Given the inadequacy of the evidence and counsel's insistence, the Court allowed Teva until the end of the day to verify whether the supplier's identity was truly confidential, and if so, to file further evidence demonstrating the need for confidentiality. The Court at the hearing specifically questioned how disclosure of the identity of the supplier could be prejudicial given that it was a related company and sought assurances that the identity of the product's manufacturer was not already publicly disclosed anywhere else in the world, including in product monographs.

[21] Teva thus filed a second affidavit from Mr. Ikeda. In that affidavit, he makes the following statements:

> "5. Teva Canada and the Teva global group of companies maintain the details of their products supply chains in confidence for commercial competitive reasons. Information relating to the location or identity of the entities that supply Teva's bortezomib products, including the active pharmaceutical ingredient (API) and the finished formulation, is not available to the public. For example, this information is not included on product labels or in product monographs. The supply chain information, including the location, manufacturer information, and details of the processes and materials used are filed with regulatory authorities, including Health Canada. Teva understands and expects that the contents of those filings, including that of bortezomib, are maintained as

> confidential by the regulatory authorities, including Health Canada, and Teva does not disclose such information to third parties in the absence of an agreement or Court order to maintain confidentiality. The identity and location of Teva's suppliers in relation to its bortezomib products are confidential and not known to the public.
>
> 6. Public dissemination of the details of information contained within Teva's regulatory submissions, particularly scientific product information as well as Teva's confidential arrangements with suppliers, including the identity and location of those suppliers (whether external to or within the Teva group of companies), has the potential to harm Teva's commercial interests for a number of reasons."
>
> [Emphasis added.]

[22] These statements seemed at odds with the Court's experience, from previous litigation, in respect of the regulatory regime in Europe. The Court accordingly sought the following clarifications from the parties:

> "From experience in pharmaceutical litigation, it is the Court's understanding that for medicines marketed in European countries, the identity and location of the drug product's manufacturer is required to be disclosed and made available to the public as part of the product's Patient Information Leaflet, or Package Leaflet.
>
> In the interest of ensuring that the Court's decisions are not based on incomplete or misleading information, both parties are asked to provide the Court with evidence setting out their information knowledge or belief as to whether Teva bortezomib is marketed in any European Union countries, and if so, whether the identity of its manufacturer is disclosed in the Package Leaflet(s)."

[23] In response to this direction, Janssen filed a package of six documents it understood were publicly available. One of these documents is a Patient Information Leaflet ("PIL") for Bortezomib Teva from Ireland, which identifies the Marketing Authorization Holder as Teva BV of The Netherlands and lists as "Manufacturer" TEVA Gyogyszergyar Zrt (TEVA

Pharmaceutical Works Private Limited Company) of Hungary, PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.) of Croatia and Teva Operations Poland Sp z.o.o. of Poland. The PIL also states that "this medicinal product is authorized in the Member states of the EEA under the following names". There follows a list of names under which the product is authorized to be sold in 29 countries. The names are variations of Bortezomib Teva, Bortezomib ratiopharm and Bortezomib Pliva.

[24] Also included in the package delivered by Janssen were Summary of Product Characteristics documents for Bortezomib Teva and Bortezomib Actavis, as well as Bortezomib Actavis PILs for the Czech Republic, Hungary and Bulgaria. All these documents appear to disclose the "Manufacturer" of the product; in Actavis' case, it is S. C. Sindan-Pharma S.R.L. of Romania.

[25] Teva filed, as part of the third affidavit from Glenn Ikeda, a PIL for Teva Bortezomib for the UK, showing Teva UK as "Marketing Authorization Holder" and the same three Teva/Pliva entities as "Manufacturer". The affidavit acknowledges that PILs do sometime become publicly available before a product is launched, and that Teva has amalgamated with Actavis so that Actavis branded bortezomib products are currently being sold by Teva in some European countries.

[26] This information contradicts the statements made in Mr. Ikeda's earlier affidavit, where, speaking of the Teva global group of companies, he asserted that "Information relating to the location or identity of the entities that supply Teva's bortezomib products (…) is not available to

the public", and "is not included on product labels or on product monographs". It also contradicts the statement that "the location, manufacturer information (…) are filed with regulatory authorities" but that "Teva understands and expects that the contents of these filings (…) are maintained as confidential by the regulatory authorities". It shows that the final, unequivocal statement of paragraph 5 of Mr. Ikeda's affidavit, that "The identity and location of Teva's suppliers in relation to its bortezomib products are confidential and not known to the public" is untrue.

[27] Yet remarkably, and undermining any vestige of credibility his earlier affidavits might still have in light of this new information, Mr. Ikeda doubles down and asserts that these statements are nevertheless accurate. The convoluted argument by which Mr. Ikeda tries to justify himself is that these PILs disclose "the sites that are approved as release sites" for these products, but not the "identity or location of the manufacturer that is used for any specific manufacturing step", because the site or sites "approved to finally release the product" "may be limited in its involvement to quality control work". However, it defies any logic to suggest that the entity that is referred to in regulated patient information as "manufacturer", and is the entity who finally approves and releases to product to be sold, is not "an entity that supplies" the product or "a supplier" of the product.

[28] What Mr. Ikeda swore to in his April 20, 2017 affidavit is not merely that the precise identity of the manufacturer of the API that goes into its Canadian bortezomib product is not publicly known, but, sweepingly, that the Teva global group of companies keeps information "relating to" the location or identities of entities that "supply" their products confidential. That, it

turns out, is patently untrue: Teva does identify, in PILs that it knows are publicly available, the location and identities of the entities that are authorized to supply bortezomib products to members of its global group of companies.

[29] Teva's dive into granularity in an attempt to explain the inexplicable also misses the point of what the original affidavit was meant to establish. The issue here is whether Teva would suffer serious harm if the identity of its supplier, as set out in the supply agreement, were to be disclosed publicly.

[30] The harm described in Mr. Ikeda's April 20, 2017 affidavit is that Teva's competitors or other suppliers could obtain an unfair competitive advantage by combining the "otherwise confidential identity or location" of Teva's suppliers with public information about the supplier and/or issues relating to the location or jurisdiction in which it operates. For example, if this supplier were to experience manufacturing difficulties, other suppliers of Teva could use that knowledge to pressure Teva for higher prices.

[31] This supposed harm was already speculative. Combined with the facts as they now appear, it lacks any air or reality: The supplier under the supply agreement at issue is the same related entity as is publicly identified in European PILs for Teva bortezomib; accordingly, if the hypothetical scenario described were to occur, other suppliers of Teva could use that knowledge to pressure Teva for higher prices, whether or not the specific identity of the Canadian supplier is made public. In any event, like the European PILS, the supply agreement provides no details as to where or by what entities any specific manufacturing steps are to be performed, including the

manufacture of the API. Any prejudice that might befall Teva Canada by the publication of this information would equally befall the Teva entities who publish the same information in Europe; yet publication of supplier information appears to be routinely done in Europe.

[32] In conclusion, I find that that first affidavit of Glenn Ikeda was incomplete and insufficient, and that his second affidavit was, in material respects, untrue and misleading. Combined with his stubborn insistence, in his third affidavit, that the statements of his second affidavit were accurate, despite clear evidence to the contrary, I find that none of the evidence offered by Mr. Ikeda is reliable or worthy of being believed. This means that there is no reliable evidence on record to support a finding that any of the information of Teva should be treated as confidential. Teva's motion for a confidentiality order must accordingly fail.

[33] This finding equally applies to the portions of Teva's ANDS. Mr. Ikeda's affidavit asserts that the portions of the ANDS contain information regarding the materials and processes employed to make Teva's bortezomib product, which could be used by competitors to produce competing products. It adds that it treats this document as confidential and that Health Canada also treats it as confidential.

[34] The Court is aware and recognizes that ANDS filings are treated confidentially by Health Canada and that there are important public policy reasons to maintain the confidentiality of these filings. However, the fact that information is included in an ANDS is not determinative of the confidential nature of the information itself, or of the continued confidentiality of information over time.

[35] For example, the mere fact that a generic has filed an ANDS for a product is treated confidentiality up until the moment an NOC is issued. However, confidentiality is lost if the generic serves a notice of allegation in respect of that ANDS. Confidentiality is also lost when an NOC issues. Likewise, the draft product monograph included in an ANDS in Canada is treated as confidential, as is the information it contains. Yet, once the product is approved and put on the market, the product monograph becomes public and no claim can reasonably made that the information it contains remains confidential.

[36] Similarly, while a pharmaceutical company may assert that the information contained in its ANDS as to the composition and method of manufacture of its product is treated as confidential, this information may lose its confidentiality once the product is publicly sold. The composition of pharmaceutical products can often be determined by analysing a sample of the product; its mode of manufacture can also often be deduced by analysis or may simply be reasonably deduced from publicly available scientific knowledge.

[37] The circumstances of this case also highlight the fact that the regulatory regime in Europe is different from the Canadian regime. Pharmaceutical companies are not required in Canada to disclose information as to a product's supplier, while some of that information is publicly disclosed in Europe. Information as to a product's composition and mode of manufacture might equally be treated differently in Europe.

[38] Mr. Ikeda's evidence as to the confidentiality of the scientific information found in the ANDS relies solely of his assertion that Teva and Health Canada treat the ANDS and the

information it contains as confidential. It addresses none of the ways in which that information might otherwise be publicly available. Given the lack of credibility of Mr. Ikeda's evidence, I am not prepared to accept that the scientific information contained in the portions of the ANDS that was filed as part of Teva's record is not otherwise publicly available, or cannot reasonably be inferred from public information.

[39] Given the general lack of credibility of Mr. Ikeda's evidence, I also do not have reliable or credible evidence that serious harm may be suffered by Teva if the royalty rate, pricing structure or payment terms found in the supply agreement are made public. There is no reliable evidence before me to explain why financial terms agreed to between related companies "might be used by competitors to Teva's disadvantage in a competitive bidding process" as asserted by Mr. Ikeda in his first affidavit.

[40] Finally, I note that among the information sought to be kept confidential are the particulars of certain amendments to Janssen's Statement of Defence to which the parties consented. These allegations are to the effect that Teva would not have been in a position to enter the bortezomib market before March 2015 because its supplier realized, in November 2014, that it was not making the product in accordance with the specifications set out in the ANDS and DMF on file with Health Canada. Although the confidentiality order sought by Teva includes these particulars within the scope of the order sought, none of the evidence filed mentions this information or explains why Teva might suffer harm if it became public. While the particulars touch upon the reaction used in the preparation of the drug product, there is, as mentioned above, no reliable evidence before me to the effect that the use of this reaction is not already a matter of

public knowledge, and that Teva might suffer any kind of harm if the allegations were not protected by a confidentiality order.

ORDER

THIS COURT ORDERS that:

1. The Registry shall remove the following pages from the parties' materials, filed on Janssen's motion to amend:

   - The pages under tab 16 of volume 3 of Janssen's Motion Record.

   - Pages 0124 to 0142, inclusive, of Teva's Motion Record.

2. Teva's motion to maintain the confidentiality of the materials filed under seal is otherwise dismissed, and the Registry shall unseal and place on the public record the remaining portions of the parties' materials.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-944-15
STYLE OF CAUSE:	TEVA CANADA LIMITED v JANSSEN INC. AND MILLENNIUM PHARMACEUTICALS, INC.
AND BETWEEN:	
STYLE OF CAUSE:	MILLENNIUM PHARMACEUTICALS INC., JANSSEN INC., CILAG GMBH INTERNATIONAL, CILAG AG AND JANSSEN PHARMACEUTICA NV v THE UNITED STATES OF AMERICA REPRESENTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TEVA CANADA LIMITED
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	APRIL 20, 2017
ORDER AND REASONS:	PROTHONOTARY MIREILLE TABIB
DATED:	MAY 2, 2017

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