Federal Court Cour fédérale

Date: 20180416

Docket: T-1658-17

Citation: 2018 FC 407

Ottawa, Ontario, April 16, 2018

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

JANSSEN INC.

Applicant

and

APOTEX INC. AND
THE MINISTER OF HEALTH

Respondents

and

JANSSEN SCIENCES IRELAND UC

Respondent Patentee

ORDER AND REASONS

[1] In the context of this application for a prohibition order, brought pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (as they existed prior to their repeal

by SOR/2017-166), the Applicant and Respondent Patentee Janssen Inc. and Janssen Sciences Ireland UC bring this motion, pursuant to s. 6(7) of the *Regulations*, for an order compelling the Respondent, Apotex Inc., to provide non-redacted and additional portions of the Abbreviated New Drug Submissions and of the Drug Master File related to Apotex's proposed Apo-darunavir product.

[2] Apotex has already voluntarily produced portions of its ANDS, but in redacted form. It submits that what it has produced is sufficient for the determination of the issues in this application. Apotex also asserts that it does not have access to the DMF for the active pharmaceutical ingredient used to make Apo-darunavir, and that, even if the information contained therein were relevant and important, it has already used its best efforts to secure access to the DMF, and may not be ordered to do more.

[3] There is little controversy between the parties as to the legal test to be applied on a motion for production under s. 6(7) of the *Regulations*. Both parties are *ad idem* that the moving party bears the burden of establishing that the information it seeks is relevant and that an order for disclosure is "important" or "necessary" to the disposition of the issues in the proceeding.

[4] The patent at issue in this application, Canadian Patent No. 2,485,834, covers certain crystalline forms, called pseudopolymorphs, of the anti-HIV drug darunavir. Apotex's Notice of Allegation alleges that its proposed darunavir product will not infringe the patent because none of the claimed forms of darunavir will be made or used in the process of manufacturing the API, because none is present in the API itself or in the final Apo-darunavir product and because none

of the darunavir utilized or produced will convert over time into a claimed form of darunavir. The NOA also alleges that even if an infringing form of darunavir was made during the process, it would merely be "a trivial part of the process" and thus, non-infringing.

[5] For the purposes of this motion only, however, Apotex concedes that information may be considered relevant if it would help Janssen establish that even one molecule of the claimed forms of darunavir is produced in the course of manufacture, is contained in the API or drug product, or is created by conversion over time. The issue of whether *de minimis* quantities should be considered infringing will be a matter for the judge on the merits.

I. Unexplained Redactions

[6] Apotex has voluntarily produced certain sections of its ANDS, but in heavily redacted form. In most cases, it appears that all the pages of a section have been produced, albeit with redactions. In a few cases, however, only a few selected pages of a section have been produced. Some redactions cover entire pages, others only cover certain parts of a page, of a paragraph or of a table.

[7] With the exception of one set of redactions which are addressed separately below, Apotex has not provided Janssen or the Court with any description of the nature or subject matter of the redacted information. No explanation or justification has been provided for the redactions that were made, beyond the general position Apotex has taken to the effect that the information it has already produced is sufficient to permit a determination of the issues and that Janssen bears, and has not discharged, the burden of showing that further information is relevant and necessary to

the determination of the issues. Apotex further relies on evidence generally asserting that ANDS information contains sensitive and confidential information, which could be used to Apotex's prejudice if it became known to its competitors.

[8] Apotex's submissions with respect to redactions fail to address the issue of whether it has the right, without providing a justification, to alter the documents it has produced by making redactions.

[9] The following general principles, applicable to productions made on discovery, were developed in *Eli Lilly Canada Inc. et al v Sandoz Canada Inc.* 2009 FC 345, cited with approval in *Teva Canada Limited v Eli Lilly Canada Inc. et al.* 2016 FC 1131: where a document contains relevant information, it should in principle be produced in its entirety and unredacted. The receiving party is not, however, entitled in all cases to production of the entire, unredacted document. Rather, partial production or redactions may be made, but in accordance with the following principles:

> The redacted portion should be clearly irrelevant to the issues in dispute and would clearly not assist in properly understanding those parts of the documents which are relevant. Redactions should also only be resorted to where important confidentiality concerns exist. In circumstances such as the present action, where enhanced confidentiality protection is afforded to certain types of information, the case for redactions is weaker. Where a redaction is nevertheless made and its propriety is contested, mechanisms should be provided for outside counsel for the receiving party to view the unredacted document to ascertain the basis for the redactions.
>
> (*Eli Lilly Canada Inc. v Sandoz Canada Inc.* at para 14).

[10] The proper application of these principles obviously requires knowledge of the general nature of the redacted information, so that the receiving party may have a fair opportunity to consider whether reasonable grounds exist to contest the propriety of the redactions made and for the Court to determine, if need be, the relevance of the redacted information. The onus of ensuring that the general nature of the redacted information be sufficiently apparent or disclosed to permit this exercise necessarily rests with the producing party, since the information is uniquely in its possession.

[11] The principles developed in *Eli Lilly v Sandoz* were held to be applicable in the context of motions for production pursuant to s 6(7) of the Regulations: *Janssen Inc. v Teva Canada Limited* (July 31, 2015, T-20-15).

[12] Counsel for Apotex argued at the hearing that in applying these principles, the Court must have regard to the particular nature of prohibition proceedings under the Regulations, and how they differ from proceedings in infringement actions. For example, s. 6(7) itself contemplates that only those portions of the submissions that are relevant to the disposition of the issues in the proceeding may be ordered to be produced. The general principle to the effect that documents should presumptively be produced in their entirety is therefore inapplicable to proceedings under the regulations.

[13] I agree that the particular wording of s. 6(7) justifies the partial production of ANDS documents and that the context of prohibition proceedings may also have an influence, to be assessed in the particular circumstances of each case, on the determination of whether redactions

made to those portions of the submissions that are produced are appropriate. However, these considerations in no way diminish the underlying obligation of the party who makes selective redactions to a document to identify the nature of the information it has redacted. To hold otherwise would allow the disclosing party to selectively disclose only what it believes to be to its advantage and hide whatever might weaken, undermine or invite a contrary conclusion, effectively giving it license to manipulate the evidence with impunity.

[14] To put the above in the factual context of this case: Apotex acknowledges that those portions of its ANDS which disclose the process by which its API is made, the characterization of the darunavir contained in its API and final drug product and the physical stability studies for its API and drug product are relevant to its non-infringement allegations. Yet it has blacked out vast areas from the specific sections of the ANDS that disclose this information, without giving Janssen or the Court any means of understanding what information lies under the redactions. Apotex does not even assert that the information it has removed is not relevant to the issues raised in the proceedings: it simply puts Janssen to the proof that this unidentified information is necessary.

[15] The information Apotex has chosen to disclose appears at first glance conclusive of its allegations, and Apotex thus argues that it is up to Janssen to demonstrate to the Court why the information selectively disclosed might not be complete or conclusive, what might be behind the black boxes and how that might be necessary to determine the issues on this application. Without any evidence from Apotex as to what it has redacted from clearly relevant sections of its

submissions and why, the task it has set for Janssen is, by definition, one of speculation and supposition.

[16] It is worth emphasizing that, with the exception of three of the redacted pages, Apotex has not led evidence from a single witness who has seen the un-redacted pages and who might be able to validate that they do not contain information that completes in a relevant way, weakens or even directly contradicts the information that was left visible. Apotex has not even seen fit to hand over to its own expert or to the Court a copy of the un-redacted information.

[17] On the face of the record before me, the following sections and pages of the ANDS and open portion of the DMF that Apotex has voluntarily produced are relevant and necessary to the determination of the issues in this matter:

3.2.S.1.3	General Properties;
3.2.S.2.2	Description of manufacturing process and process controls;
3.2.S.3.1.2.	Elucidation of structure and other characteristics, Polymorphism;
3.2.S.4.2	Analytical Procedure, Darunavir Drug Substance, Identification X-Ray Diffraction;
3.2.S.4	Control of Drug Substance, Batch Analysis;
3.2.S.3.1	Elucidation of Structure and other characteristics 1) IR Spectroscopy;
3.2.S.3.1	Elucidation of Structure and other characteristics 7) Elemental Analysis.

Specification and Certificate of Analysis for various batches;

Comparative Infrared Spectra;

Structure Elucidation Justification;

Structure Elucidation Report; and

Portions of section 3.2.P.2 Polymorphic Stability.

[18] Their title, the content that can be seen and the very fact that Apotex has acknowledged the relevance of the sections by producing them (albeit in a redacted fashion) all support this conclusion and would justify an order of the Court that Apotex produce these sections and pages.

[19] As a matter of basic fairness and respect for the adversarial process of the Court, Apotex cannot take it upon itself to redact any portion of these sections without, at a minimum, explaining the basis for its redactions and providing sufficient information as to the nature of the redacted information to fairly allow Janssen to contest the propriety of the redactions. Apotex having failed to meet this threshold requirement in respect of any redaction other than those to pages 100 to 102 of Janssen's motion record (being section 3.2.S.2 .2 of the ANDS and of the open portion of the DMF), I find that the redactions are not justified and that Apotex must produce un-redacted copies of these sections.

[20] If I am wrong as to the test applicable to redactions, I also find, for the reasons more fully set out below, that the information provided by Apotex is not sufficient for the proper determination of the issues in this proceeding and that it must disclose the additional information that is most likely contained in the redacted portions of the sections.

II. Redactions to the process steps (pages 100-102)

[21] With respect to the sections relating to the description of manufacturing process, Apotex has led evidence to the effect that the redacted portions only concern the starting compounds and intermediates used to prepare the final intermediate compound that will be further reacted to first create darunavir (in any form). Since none of these starting compounds and intermediates is darunavir, it follows that no darunavir can be made during those steps. Apotex therefore argues that they are irrelevant.

[22] Janssen agrees with this general proposition as regards the early compounds and intermediates, but submits that information as to the solvents used in those early stages of the process, and which would be identified in the redacted portions, are relevant because solvents would remain as impurities in the final API and drug product, and have an effect both on the crystallization process of any intermediate darunavir product, and on the conversion over time of the final API or drug product.

[23] Apotex, in turn, does not contest this general statement, but counters with the following three arguments:

(1) Long-term conversion

[24] With respect to long-term conversion, Apotex says that it has provided stability studies that conclusively show that neither the darunavir contained in the API nor in the drug product converts to a claimed form of darunavir over time, so that the residual presence of solvents is irrelevant.

[25] I do not agree that the information provided by Apotex conclusively establishes that there is no conversion of the darunavir contained in the API or drug product over time. The evidence of Dr. Myerson, for Janssen, which has not been effectively contradicted by Apotex's expert, is to the effect that the characterization test results produced by Apotex are only conclusive of the form of darunavir present in the sample within the limit of detection of the method used. In other words, the tests would not detect very small quantities of the claimed forms (typically less than 5%) that might be present in the sample. Given Apotex's concession, at the outset of the hearing, that relevance for the purpose of this motion would be established by reference to the presence of even a single molecule of the claimed forms of darunavir, I am satisfied that information as to solvents used in the early part of the process is relevant, as residual impurities from the solvents could, depending on the solvent used, cause the conversion of darunavir into a claimed form over time.

(2) Intermediate crystallization

[26] Apotex points to the opinion of its expert, Dr. Rohani, to the effect that none of the steps in the manufacturing process involve the type of crystallization process from which the claimed forms of darunavir could be produced. As a result, Apotex says that that the introduction of other solvents in the early stages of the process, and their residual presence in subsequent steps, are irrelevant.

[27] It is common ground between the parties that such information as is available in the ANDS and the open portion of the DMF as to the steps between the creation of the final intermediate compound and the final product has been produced, but is of the barest kind. The

details are in the closed portion of the DMF, which is not currently in Apotex's possession. The only information available at this point is the identity of the solvents and compounds used in each step, and the resulting compounds for each step. There is no information whatsoever about the quantities of materials, the type of reaction(s) used, the conditions or speed of the reaction(s), any residual materials, or even whether the compounds are in solution or solid state at any stage of the process.

[28] Despite the lack of information, each of the party's expert has speculated as to what the intermediate steps might involve. Given the starting solvents and compounds, Dr. Myerson posits that certain crystallization steps occur, which may produce a claimed form of darunavir as an intermediate. Given the form of the final darunavir API produced and the solvents involved, Dr. Rohani posits that the only possible kind of reactions involved would be incapable of producing the claimed forms of darunavir.

[29] I do not accept Dr. Rohani's opinion to the effect that the information provided points so clearly to the type of reactions he surmises that it would effectively exclude the possibility of the formation of claimed forms of darunavir, or even make it less likely than his own proposed scenario. I find that Dr. Rohani's conclusion as to the nature of the intermediate reactions is more the product of assumptions drawn from preconceptions than the product of an objective analysis of the information provided to him. Knowing the predominant form of the resulting API, he has assumed that it would be produced without recourse to an infringing intermediate, and projected that result onto the blank canvas of the bare process description. Dr. Myerson's opinion is equally tainted by unsupported assumptions. Likely drawing from his knowledge of how the

claimed forms of darunavir are made, he has posited from the incomplete process information a route that uses an infringing intermediate to arrive at the known final product. Both experts' hypotheses as to whether or not the intermediate steps involve the creation of claimed forms of darunavir are credible, but the information given is clearly insufficient to determine which is most likely correct.

[30] In the absence of further information from the closed portion of the DMF, I am satisfied that it is as likely as not that claimed forms of darunavir are made during the manufacturing process, and that information as to the solvents used in the early stages of the process is relevant and required to determining whether Apotex's allegation that claimed forms of darunavir are not made in the course of manufacture of the API is justified.

(3) Information available from the elemental analysis

[31] Apotex argues that information as to the residual presence of the solvents used in the early stages of its manufacturing process, even if relevant, can be found in the elemental analysis, results for the final API that it has produced, and that the redacted portions of the synthetic process steps are therefore unnecessary.

[32] Apotex has cross-examined Dr. Myerson on that very issue. Dr. Myerson's testimony was to the effect that it may be possible to detect residual solvents from elemental analysis, but that it depends on how the sample was prepared. He explained that elemental analysis is typically performed to demonstrate that the correct compound was made, and not to detect the presence of

impurities or residual solvents. I am satisfied that the provision of elemental analysis results by Apotex is not sufficient to allow for the determination of the issues in this matter.

III. Additional productions in respect of stability studies and process steps to make Apo-darunavir

[33] Apotex has produced only certain pages of the section of its submissions regarding stability studies, which appear to contain physical stability data or test results. There is no direct evidence to the effect that Apotex ever undertook to produce or has produced all of the physical stability data or test results available to it. The only assurances are in the form of Dr. Rohani's affidavit statement to the effect that he has been advised by Apotex's counsel that any submissions available to it that relate to the physical stability of the darunavir API or tablets have been produced. It has however been established on cross-examination that Dr. Rohani has not been given access to the ANDS and has not attempted to verify that advice.

[34] Without implying any criticism of Apotex's counsel, and for the simple sake of clarity and avoiding errors in communication, it seems prudent to order Apotex to produce all physical stability testing and data for the API and finished drug product, if it has not already done so.

[35] Janssen also requests chemical stability data, even though it would not speak directly to the structural form of the darunavir present in the API or drug product.

[36] Janssen's argument, supported both by Dr. Myerson's testimony and the cross-examination evidence of Dr. Rohani, is that given the limits of detection of the methods of analysis used, neither the characterization data provided for the final API or drug product nor the

physical stability data produced are conclusive of the absence of claimed forms of darunavir in the API and drug product, as produced or over time from conversion. Chemical stability studies would provide additional information as to the characteristics and properties of the API and drug product at various stages and residual solvent levels found therein. This additional information, coupled with knowledge of the process used to make finished tablets from the API, may be the only way to detect the presence of claimed forms of darunavir, both in the product as manufactured or as it may convert over time.

[37] I do not accept Apotex's argument that the evidence of conversion over time is purely speculative, as was the case in *Bristol-Myers Squibb Canada Co v Mylan Pharmaceuticals ULC* 2011 FC 919. The evidence on the record before me, including notably the evidence of Dr. Rohani in cross-examination, is to the effect that some claimed forms of darunavir are more stable than the form predominantly present in the API and final drug product. That evidence also establishes that it is reasonable to suppose that the conditions exist for the conversion of the form predominantly made to a claimed form of darunavir during the processes for making final tablets and over time in normal conditions.

[38] I am satisfied that the chemical stability data and process information as to the making of the drug product are relevant and necessary to the determination of the issues in this application.

IV. Additional productions in respect of characterization of darunavir intermediates, API and drug product

[39] The conclusions reached above as to the lack of conclusivity of the XRPD and IR data provided as to the possible presence of claimed forms of darunavir in the final API support the relevance and necessity of the complete characterization data and information for any darunavir intermediate used or formed in the manufacturing process, and for the final API and final drug product, if same is not already contained in the unredacted documents to be produced.

V. Closed portions of the DMF

[40] As I have concluded above, I am satisfied that further information as to the process used to make the API, from the creation of the final non-darunavir intermediate to the creation of the final API, including all characterization data for any intermediate darunavir compound produced, is necessary and relevant to the determination of the issues, as would be all additional characterization and stability data related to the final API that might be found therein.

[41] I am satisfied that Apotex does not currently have access to the relevant parts of the closed DMF. While Apotex did dispute the necessity of disclosing the closed portion of the DMF, it does not dispute that if this Court holds, as it has, that it is relevant and necessary, then Apotex was required to make best efforts to secure access to it. The only issue left for determination on this motion is whether Apotex has discharged this obligation.

[42] The evidence before me is to the effect that, as of March 6, 2018, the manufacturer has declared itself satisfied with the confidentiality measures in place in this litigation and has

expressed a willingness to provide the portions of the closed part of the DMF relating to the description of the manufacturing process and controls, including process description, control of materials and control of critical steps and intermediates. However, the manufacturer has added, as a condition to the provision of these portions of the DMF, that Apotex agree to a particular commercial arrangement with the manufacturer. That arrangement, on its face, appears to have significant commercial and financial consequences, and does not appear to be a rational or necessary consequence or outcome of the disclosure. It appears it to be an opportunistic request for a quid pro quo. I am satisfied that making a concession of such commercial and financial significance goes beyond the "best efforts" a second person is required to make to secure access to a manufacturer's DMF.

[43] Janssen has argued that Apotex was required to disclose the current state of the commercial agreements between itself and the manufacturer in order to satisfy the Court that the conditions requested by the manufacturer represent a departure or modification from their existing relationship. In the circumstances and on the record before me, Janssen's argument amounts to a suggestion that the correspondence between the manufacturer and Apotex relating to that condition, which Apotex has produced, are a sham. There is no evidence before me to support such an accusation and I am satisfied that Apotex was not required to provide confirmatory evidence of the truth and veracity of what clearly appears from the correspondence as disclosed.

[44] That said, the evidence before me indicates, and counsel for Apotex confirmed, that further discussions and communications were held between Apotex and its supplier between

March 6 and the date of the hearing on March 22, 2018. All we know of these discussions is that they did not result in an agreement. Where a second person was required to deploy its best efforts but fails to obtain the desired result, it must account for the efforts it has made. It cannot be left to be the sole judge of the sufficiency of its efforts.

[45] In my view, what is missing from Apotex's account of its efforts is evidence that it has requested from the supplier that it abandon its demand for the commercial concession, and evidence of the supplier's response, including whether it has counter-offered with a request for concessions or conditions of a different kind, so that the Court may be satisfied that any such counteroffer equally goes beyond the scope of what best efforts should entail. Again, without implying any criticism of the good faith of counsel for Apotex's laconic report of failure, Janssen and the Court are entitled to a more complete account of Apotex's efforts after March 6, 2018, so as to be able to assess whether Apotex has indeed completed its efforts and whether the remaining obstacles are also beyond the scope of the best efforts requirement. Only then can it be established that Apotex has discharged its obligation.

VI. Verification Order

[46] Janssen's motion also requests a verification order. Counsel for the Minister did not appear on the motion, and is taken not to object to the issuance of such an order in principle. However, the record is unclear as to whether the Minister of Health has been consulted as to the specific terms and deadlines for the order, as is the practice in such matters. Further, the issue of whether Apotex has complied with its obligation to use best efforts to secure access to the closed

portion of the DMF remains to be fully resolved, so that the scope of production may yet change. In the circumstances, the issuance of a verification order appears premature at this juncture.

VII. Costs

[47] Janssen being substantially successful on this motion, it shall be entitled to its costs. The parties as between themselves have agreed that the sum of $5000 plus reasonable disbursements constitutes a reasonable award in the circumstances.

ORDER

THIS COURT ORDERS that:

1. Apotex shall, within 10 days from the date of this Order, produce to Janssen the following portions of its ANDS and/or open portions of its DMF for the product at issue in this proceeding:

    a) Unredacted copies of the sections that it has already produced to Janssen in redacted form. With respect to the pages found at p. 100-102 of Janssen's motion record, redactions may remain in respect of the compounds, but solvents must be disclosed.

    b) To the extent they are not included in the production to be made pursuant to paragraph 1 (a) of this order, any portion which discloses the data and all analyses and characterizations of the API, of Apo-darunavir or of darunavir intermediates made or used during the synthetic process.

    c) Complete details of the composition of Apo-darunavir.

    d) Manufacturing process for Apo-darunavir.

    e) All stability testing and data for the API and finished Apo-darunavir product, including physical and chemical stability.

2. Apotex shall also provide to Janssen and to the Court within the same delay, an account of the best efforts it has made, between March 6, 2018 and the date of the account, to obtain the portions of the closed DMF that contain information as to the process used to make the API, from the creation of the final non-darunavir intermediate to the creation of the final API, including all characterization data for

any intermediate darunavir compound produced or used, and characterization and stability data related to the final API. Apotex may file its account to the Court under seal. Janssen's right to contest the sufficiency of Apotex's efforts and for further relief is hereby reserved.

3. Janssen's right to apply to the Court informally, by submitting a verification order approved as to form and content by Apotex and the Minister of Health, is hereby reserved.

4. Costs, in the amount of $5000 plus reasonable disbursements, shall be payable by Apotex to Janssen.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1658-17
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