Federal Court  Cour fédérale

Date: 20160928

Docket: T-365-14

Citation: 2016 FC 1091

Ottawa, Ontario, September 28, 2016

PRESENT: Madam Prothonotary Mireille Tabib

BETWEEN:

NOVARTIS PHARMACEUTICALS CANADA INC.

Applicant

and

MYLAN PHARMACEUTICALS ULC AND THE MINISTER OF HEALTH

Respondents

and

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG

Interveners

ORDER AND REASONS

[1] A protective order was issued on consent of the parties in the context of this application for a prohibition order, brought pursuant to the *Patented Medicines (Notice of Compliance)*

Regulations SOR/93-133 (the "*PM(NOC) Regulations*"). This order covers Mylan's information concerning its proposed rivastigmine transdermal patch, including any samples that may be provided voluntarily or by compulsion of a Court order, and any testing or analysis performed on or with such samples. It provides that Mylan's information "shall be used solely for this proceeding as well as any appeal or other proceeding related thereto".

[2] This application was resolved on consent of the parties in August 2015. Novartis now moves for an order amending the protective order so that it may use the samples it obtained from Mylan and the expert affidavits setting out the results and analysis of tests performed on those samples for the purposes of litigation taking place in Portugal between it and a company related to Mylan, involving the same rivastigmine transdermal patches. Mylan opposes the motion.

[3] One of the key factual issues in this application was whether Mylan's patch contains an antioxidant. Mylan alleged that it does not. Novartis sought production of samples so that it could test them for the presence of antioxidants. Mylan initially refused. It is well known that under the *PM (NOC) Regulations*, production of samples can only be compelled if the generic has submitted samples of its product to the Minister of Health as part of its application for an NOC. Novartis did not attempt to compel production of samples under the *PM (NOC) Regulations*. Rather, it deduced from publicly available information that Mylan's patches were manufactured in the United States, and it applied to the courts of that jurisdiction for a show cause order as to why a subpoena for production of samples should not be issued in aid of the Canadian proceedings. In the materials filed in support of that request, Novartis states that: "Novartis Canada intends to use the information obtained in response to the subpoenas solely to

assist the Canadian Federal Court in resolving the Canadian Litigation". The show cause hearing did not take place. Mylan consented to producing the samples in the PM(NOC) proceedings, subject to the existing protective order.

[4] It is worth noting that the Portuguese proceedings, for the purposes of which Novartis seeks to use the samples, were already pending at that time.

[5] I understand from the evidence filed by the parties on this motion that the Portuguese proceeding is a statutorily mandated arbitration between Novartis and a corporation related to Mylan, and that its purpose is similar to that of Canadian PM(NOC) proceedings: it is a proceeding designed to determine whether the patch which the Mylan entity seeks to market in Europe would infringe Novartis' European patent. One of the key factual issues in dispute in the Portuguese proceeding is whether the patch at issue contains an antioxidant.

[6] The evidence before me shows that that is it is very likely that the patch at issue in the Portuguese proceeding is manufactured by the same facility and with the same process and formula as the patch that was at issue in this application. The evidence led by Novartis on this issue is not conclusive because most of the evidence from the Portuguese proceeding is covered by a strict confidentiality order. However, Mylan has access to all of the evidence and is free to use it as it wishes, but it chose not to adduce any evidence to contradict the circumstantial evidence led by Novartis as to the identity of the patches. I draw from this an adverse inference and conclude that the patches at issue in both proceedings are the same.

[7] The evidence before me shows that samples of Mylan's patch were produced in the Portuguese arbitration, but that under the applicable procedural rules, testing is conducted by an independent laboratory, according to a protocol designed by a jointly selected expert. Novartis is dissatisfied with the protocol that was adopted and has tried several times to have the joint expert authorize tests similar to those Novartis conducted in the Canadian PM(NOC) proceedings. Its request has been refused every time and that is why Novartis wants to introduce the testing evidence constituted in this matter directly in the Portuguese proceeding. There is no guarantee that the Portuguese arbitration panel will permit that evidence to be adduced. In the end, the question of the relevance and admissibility of the Canadian testing evidence for the purposes of the Portuguese proceeding would be a matter to be determined by the Portuguese arbitrators. The question, however, does not arise so long as Novartis is precluded by the terms of the protective order from using the Canadian testing evidence for the purposes of the Portuguese proceeding, hence the present motion.

[8] Novartis submits that the test to be applied to this motion is the test applicable to motions to be relieved from the implied undertaking rule, as set out in *Juman v Doucette*, 2008 SCC 8. According to Mylan, the applicable test is the test that was developed in *Smith, Kline and French Laboratories Ltd v Canada (Attorney General)* (1989) 24 CPR (3d) 484, aff'd 74 CPR (3d) 165, and subsequently applied in *Faulding (Canada) Inc. v Pharmacia Italia & Upjohn S.P.A.* 2004 FC 1273 and *Astrazeneca Canada Inc. v Canada (Minister of Health)*, 2004 FCA 226. Under this test, Novartis has to establish a change in circumstances or a compelling reason not directly considered when the order was given.

[9] I am satisfied that the appropriate test to apply here is the strict test of *Smith, Kline and French*. That is because the production of the samples in this case was entirely voluntary. Absent evidence that Mylan had submitted samples to the Minister of Health (and none has been submitted), Novartis could not have compelled Mylan to produce samples. The implied undertaking rule is designed to protect from use for other purposes information disclosed during discoveries. The implied undertaking rule is meant, in part, to encourage parties to provide full and frank disclosure of all relevant evidence. Parties are, however, obliged by the rules of the court to produce on discovery all relevant evidence and information. The implied undertaking rule therefore is not intended as an incentive for parties to produce information that they could otherwise choose to withhold: it is there to facilitate and foster compliance by the parties with their disclosure obligations. It is accordingly appropriate that the test for lifting the implied undertaking rule be more liberal than the test for modifying protective orders negotiated by parties and issued by the Court in circumstances where parties might have been entitled to withhold production of information. My determination might have been quite different if the information at issue had been contained in documents that could have been compelled, such as Mylan's ANDS; I do not, however, need to make that determination here.

[10] The protective order negotiated by the parties in this case stipulated that Mylan's information could not be used otherwise than for the purposes of this application, any appeals therefrom or proceedings related thereto. It is clear that the Portuguese litigation is not a proceeding related to this application. If that was the case, Novartis would not need to apply for a variation of the protective order. The words "proceedings related thereto", as used in the protective order, clearly mean litigation or proceedings that are related to the prohibition

application and not litigation or proceedings that relate to the same product, to a related or corresponding patent or to similar factual issues. The Portuguese arbitration may concern the same product, related parties and a related patent but it is not a litigation that is related to the prohibition proceeding: It is completely independent from the prohibition application; it proceeds independently; the determination of this application does not affect the Portuguese litigation and the determination of the Portuguese litigation does not affect this application; the two proceedings have no consequences on each other nor do they give rise to rights that may be recognized, enforced or contested through the other proceeding.

[11] At the time the protective order was negotiated between the parties in this proceeding, Novartis was aware of the existence of the Portuguese proceedings; the potential relevance of the samples obtained for the purpose of the Canadian proceeding to the issues raised in the Portuguese proceedings might not have been as clear as it is now, but it was conceivable. Accordingly, there is no change in circumstances that could justify a variation of the protective order.

[12] Novartis argues that it could not have known at the time that the samples it obtained from Mylan were in fact relevant to the Portuguese proceedings because it had not been able to confirm that the patches were the same until recently. I am not persuaded that this is the case. Novartis applied for a show cause order in the United States on the basis of the same public information that Novartis now tenders before this Court to show that the patches at issue are likely to be the same because they are manufactured in the same facility. Novartis could equally have used that information at the time to reach the same conclusion in respect of the European

product. Obtaining additional information to corroborate or even confirm a deduction that could have been made at the time does not constitute a change in circumstances. I am satisfied that Novartis has not met the strict test in *Smith, Kline and French*.

[13] Novartis submits that Mylan's production of the samples was not truly voluntary. It argues that "the writing was on the wall" as to whether Mylan would be compelled to produce samples of its patches, because it had been successful in obtaining a show cause order in the United States and that there was little Mylan could do to avoid the issuance of a subpoena. That argument does not assist Novartis. Had the samples been compelled through completion of the US subpoena process, rather than voluntarily and subject to the protective order already issued in the Canadian proceedings, the statement of intention contained in Novartis' submissions to the US court would have been equally restrictive: Novartis had represented to the US court that it intended to use the samples solely to assist the Canadian court in determining the prohibition proceeding pending before it.

[14] If I am wrong and the strict test of *Smith, Kline and French* is not applicable or has been displaced in favour of the test in *Juman v Doucette*, I still conclude that this is not a case where the protective order ought to be varied to permit the use of the Canadian evidence in the Portuguese litigation.

[15] *Juman v Doucette* does not set out a list of criteria to be considered. Rather, it requires careful weighting of the public interest asserted by the person seeking relief against the public interest in maintaining the confidentiality of the information. "What is important is the

identification of the competing values, and the weighting of one in light of the others, rather than setting up an absolute barrier to occasioning “any injustice to the person giving discovery”” (at para 33).

[16] There is a public interest in ensuring that when, as here, parties arrive at an agreement on disclosure to avoid litigation, such that disclosure is volunteered on terms that include a protective order, the terms of the protective order not be modified unless there is a compelling reason to do so. The parties negotiated the terms of this protective order to include appeals from the application and litigation related to it. Extending those exceptions to any litigation between the same or related parties on the same or related facts, merely on the basis that there can be no prejudice to the producing party, would cause parties to lose confidence in their ability to rely on the negotiated terms of protective orders. It would either lead to protracted and sterile debates as to more restrictive wordings for protective orders, or discourage parties from volunteering information in one litigation unless they have completed a full analysis of the risk to which disclosure might expose them in other unrelated litigation.

[17] I am not satisfied that there is, on the other hand, a genuine public interest in allowing Novartis to use the evidence for the purposes of the Portuguese proceedings. This is not a case where the maintenance of confidentiality would allow Mylan to be less than truthful in another litigation or to present different facts or different versions of the same facts to different courts. Novartis does not simply want to use the evidence for the purpose investigating the facts or to get at the truth by verification or cross-examination. It wants to use the Canadian evidence as part of its evidence in the Portuguese proceedings.

[18] Novartis argues that the interest of justice would be served by allowing it to use the evidence for the purpose of the Portuguese litigation because without it, the Portuguese arbitrators would be deprived of complete and relevant evidence. The evidence shows, however, that the Portuguese tribunal had access to samples and could have, under its own rules, authorized the tests suggested by Novartis. While it is not for this Court to comment on whether the Portuguese arbitrators should permit the use of the Canadian evidence before them, it is not obvious how the public interest would be served by assisting Novartis' attempts to shoehorn the expert evidence constituted in this application into another proceeding where the processes for adducing expert evidence did not contemplate it.

[19] Finally, the interest of justice is not served by encouraging the collateral use of evidence constituted under the rules and for the specific purposes of one proceeding in a different proceeding governed by different rules where it would have been possible for a party to proceed by direct means. Novartis obtained the samples it tested for this proceeding by leveraging a specific US court process. At that time, Novartis clearly declared to the US court its intended use for the samples. There is no indication on the record before me that Novartis could not have used the same process to obtain from the US court an order for production of samples for the direct and declared purpose of the Portuguese proceedings, and that it could not then have tested the samples and constituted the evidentiary record it needs in compliance with any applicable rules of the Portuguese arbitration. Novartis has not explained why it did not use that route. In the circumstances, I am not satisfied that what Novartis proposes to do is a particularly fair use of this Court's process and I find that the public interest is better served by dismissing Novartis' motion to vary the terms of the protective order.

ORDER

THIS COURT ORDERS that:

1. The motion is dismissed, with costs in the amount of $2,000 plus disbursements, payable by Novartis to Mylan.

"Mireille Tabib"
Prothonotary

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-365-14
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