Federal Court  Cour fédérale

Date: 20200514

Docket: T-1353-19

Citation: 2020 FC 618

Ottawa, Ontario, May 14, 2020

PRESENT: Mr. Justice Pentney

BETWEEN:

NATCO PHARMA (CANADA) INC.

Applicant

and

MINISTER OF HEALTH and ATTORNEY GENERAL OF CANADA and GILEAD SCIENCES CANADA INC.

Respondents

ORDER AND REASONS

I. Introduction

[1] This application for judicial review was scheduled to be heard on May 12, 2020. The materials were all filed. Counsel were preparing to argue the matter on the appointed day. The Court was also preparing to hear the matter in the usual way. Then a pandemic happened.

[2] Like everyone else in the country, including public and private institutions, the Court had to adjust to the rules public health authorities put in place to protect public safety and prevent the rapid rise in infection by the new COVID-19 virus. This included adjourning previously scheduled hearings, because the public health measures made it impossible to continue to conduct court hearings in person. The measures adopted by the Court are set out in three Practice Directions and Orders, dated March 17, April 4, and April 29, 2020.

[3] In the most recent Practice Direction and Order, the Court continued the general adjournment of all previously scheduled matters (described as a Suspension Period), subject to several exceptions. The third exception provides:

> ***Exception 3: By request of a party:*** The Court will endeavour to accommodate any requests for a hearing by telephone or video conference during the Suspension Period. These requests will be assessed on a case-by-case basis and subject to the requirements set forth in the attached Order.

[4] Pursuant to this exception, the Applicant, Natco Pharma (Canada) Inc., requested that its application for judicial review proceed by way of a video conference hearing during the week of June 8, 2020. The Respondent Attorney General of Canada (Respondent Minister) does not oppose this request, but has a number of questions about how such a hearing would proceed. The Respondent Gilead Sciences Canada Inc. (Respondent Gilead) opposes the request, and argues that its important rights should not be adjudicated other than at an in-person hearing, and that the matter is not so urgent that a delay of a few months will prejudice any party.

[5] I heard submissions of the parties on this request on May 8, 2020, by teleconference. During the proceeding, it became clear that part of the reluctance to proceed by way of video conference hearing related to the lack of clarity about how such hearings would proceed in the

Court. I provided further details to the parties, and gave them an opportunity to consult their clients and make further submissions based on this further information. In the end, no party made further submissions.

[6] These are my reasons for granting the Applicant's request to proceed by video conference hearing, at a date in June to be fixed by the Judicial Administrator following the usual consultation with the parties.

II. Background Context

[7] This case concerns an attempt by a generic drug company (the Applicant) to bring its drug to market based on a comparison with another drug, developed and marketed by a "brand" or "innovator" drug company (the Respondent Gilead). The Respondent Minister refused to accept the Applicant's submissions seeking approval of its product, because the Minister interpreted the relevant regulations as forbidding such an application at this time.

[8] The parties agree that the case turns on whether the Minister's interpretation of the provision can be sustained in accordance with the appropriate legal test for judicial review, a question which is not to be decided today. The only issue before me is whether this matter should proceed by video conference or whether the hearing should be delayed until it can be heard in person.

[9] A brief summary of the underlying application will assist in understanding the context for the request to proceed by way of video conference.

[10] On August 21, 2019, the Applicant filed an application for judicial review in respect of the decision of the Office of Submissions and Intellectual Property at Health Canada refusing to accept its Abbreviated New Drug Submission (ANDS) for a Notice of Compliance (NOC) for a generic drug it wanted to bring to market. The ANDS sought to compare the Applicant's generic product with a drug marketed by the Respondent Gilead, under the brand name DESCOVY.

[11] The Respondent Minister refused to accept the Applicant's ANDS on the basis of paragraph C.08.004.1(3)(a) of the *Food and Drugs Regulations*, CRC c 870 [the *Regulations*], which provides a six year "no file" data protection term where a manufacturer seeks an NOC for a new drug on the basis of a comparison to an innovative drug that has previously been approved.

[12] The Applicant's ANDS made a comparison between its product and the Respondent's product. It alleges that the Respondent Minister concluded that this drug is not an "innovative drug" and is not eligible for its own separate term of data protection. The Minister also found, however, that DESCOVY was entitled to benefit from the same period of data protection as GENVOYA, another drug marketed by the Respondent Gilead. It appears that the Respondent's drug products share at least one similar ingredient, and the Minister found that it was consistent with the intent of the *Regulations* to provide the same period of data protection for both products.

[13] In the application for judicial review, the Applicant argues that it made no comparison to an "innovative drug" because the DESCOVY product marketed by the Respondent Gilead was not the product that had received data protection under the regulatory regime. It states that it did not seek to compare its product with the GENVOYA product that had received data protection. The applicant argues that the Respondent Minister erred in its interpretation of the *Regulations*.

[14] The Respondent Minister defends its interpretation, and indicates that it intends to be an active participant in this matter because it is the Minister's decision that is under review. The Respondent Gilead seeks to defend its interests, including its interest in the period of market exclusivity provided by the six year "no file" rule set out in the *Regulations*.

[15] For the purposes of this decision, it is neither necessary nor appropriate to say more about the nature or merits of the issues in dispute.

[16] On February 18, 2020, the Court set this matter down for hearing on May 12, 2020, in Toronto, for a duration of three hours. When the pandemic broke out, the hearing was adjourned by virtue of the Suspension Period imposed by the Practice Directions and Orders of the Court. On May 1, 2020, the Applicant wrote to the Court pursuant to the April 29, 2020 Practice Direction and Order, requesting a hearing by video conference. The Respondents provided their positions on this issue, and their dispute was heard by teleconference on May 8, 2020. As noted above, the parties were provided a brief period after the hearing to make further submissions, but none were received.

[17] The only question before the Court is whether to grant the Applicant's request to proceed with the hearing by video conference.

III. Analysis

A. *Position of the Parties*

[18] The Applicant submits that its application should be set down for hearing during the week of June 8, 2020, because "this is an ideal case to be conducted by video conference." The

record is complete and available in electronic form. The only evidence in the record is a single affidavit, and there was no cross-examination on it. The material facts are not in dispute. The application is of limited scope in that it relates solely to whether the data protection granted to an innovative drug can be extended to a different branded drug, which is a question of statutory interpretation.

[19] The Applicant argues that there is some urgency in having the matter heard and decided as early as possible. The data protection for the Respondent Gilead's GENVOYA product ends on May 27, 2024, and a generic drug company may file a submission seeking approval of its comparator product as of November 27, 2021. The Applicant argues that if it is successful in its application and the Respondent Minister is ordered to accept its ANDS for filing, it will have a first filer advantage in entering the market.

[20] The Applicant notes that the matter had been set for hearing on May 12, 2020, the records had been completed, and all parties had been aware of that hearing date for several months. They had ample opportunity to prepare. As to the timing of the video conference hearing, the Applicant stated that when the matter was first adjourned counsel discussed their mutual availabilities, and at that time the week of June 8, 2020 was available for all counsel. It is therefore proposing that the Court set the matter down for hearing during that week.

[21] The Respondent Minister did not object to proceeding by way of video conference, and took no position on the urgency of the matter. Its position was that while an in-person hearing was preferable, it was prepared to participate in a video conference as long as all parties had a full and fair opportunity to present their cases. The Respondent Minister noted the importance of the case, since the question of statutory interpretation at the heart of this matter will have an

impact beyond the specific dispute between the parties. As well, it noted that arrangements would be needed to allow for consultation during the hearing with co-counsel, client representatives and possibly with counsel for the other Respondent in the matter. Subject to these technical questions, the Respondent Minister had no objection to proceeding by video conference.

[22] The Respondent Gilead opposes the request to proceed by way of video conference on several grounds: it has significant rights in issue in this proceeding and it should have an opportunity for a full and fair hearing; there is no urgency to hear the matter in June, as waiting a few months to schedule an in-person hearing will still allow for a determination of the Applicant's case well in advance of the November 27, 2021 deadline for filing its ANDS; there is no prejudice to the Applicant by virtue of this short delay; and, there are multiple parties involved, which will make a video conference hearing more complicated.

[23] Regarding its significant rights, the Respondent Gilead argues that the period of market exclusivity granted to its drug product DESCOVY pursuant to the data protection provisions of the *Regulations* is of significant commercial value, and it should be provided a full and fair opportunity in open court to defend its interests.

[24] Insofar as timing is concerned, it argues that there is no urgency that requires this matter to be heard by video conference in June 2020. The Respondent Gilead points out that any manufacturer seeking to sell a generic version of DESCOVY is prohibited from filing an ANDS until at least November 27, 2021. Therefore, waiting a few months to schedule an in-person hearing will allow for a hearing and determination of the Applicant's case well in advance of that deadline.

[25] Regarding prejudice, the Respondent Gilead submits that there is no evidence that the Applicant would be adversely impacted by a short delay. It adds that the there is no evidence that the Applicant is the only generic that is ready to file an ANDS in relation to this drug product, and so it is unclear whether it will actually have any first filer advantage. It also points out that DESCOVY's data protection term has been in place and published in the Register of Innovative Drugs since April 29, 2016, but the Applicant did not file its ANDS or challenge the data protection for this product until March of 2019, so it has already delayed by three years. A few months more will not cause it prejudice.

[26] Finally, the Respondent points out that there are multiple parties involved in this matter, and proceeding by video conference will be challenging because there are two co-respondents with separate counsel and clients. At a minimum, if a video conference hearing proceeds, arrangements will be needed to permit appropriate consultations among and between counsel and clients, and extra time will be required for the hearing of the matter.

[27] The Respondent Gilead underscores that in the absence of any immediate urgency that requires this matter to be heard by video conference in June 2020, its request to have its important substantive rights litigated in-person should be prioritized with a hearing rescheduled in the coming months in accordance with the most recent Practice Direction and Order of the Court.

B. *Discussion*

[28] Having considered the submissions of the parties, I am persuaded that this matter should proceed by video conference hearing to be scheduled in June 2020. These are my reasons why.

[29] We must begin from first principles. First, the Court must seek to ensure that all parties to this proceeding are treated fairly and have a full and fair opportunity to know the case they have to meet, and to present their arguments to the Court. Second, the Court must respect the open court principle. These principles, captured by the oft-cited phrase "justice must be done and it must be seen to be done" (*R v Sussex Justices*, [1924] 1 KB 256, [1923] All ER Rep 233), must guide the Court in determining whether a hearing should be in person or by video conference.

[30] I have determined that a hearing by video conference will respect these foundational principles as much as a hearing in person would, in light of the particular circumstances of this case.

[31] In this regard, I consider it to be important that this matter involves a question of statutory interpretation, and the facts are not seriously in dispute. No oral testimony will be heard. The factual record is comprised of a single affidavit as well as the documents that formed the basis for the decision-making process within Health Canada. The parties have each perfected their records including books of authorities, and the record is available in electronic form. To the extent that any documents in the record are not available electronically, the Applicant has provided an undertaking to ensure that the paper records are scanned, served, and filed in electronic form well in advance of the hearing.

[32] I accept that the Respondent Gilead has important rights and interests that may be affected by the decision in this matter. It has a legitimate business interest in seeking to protect its period of market exclusivity. Similarly, the Applicant has important interests it seeks to vindicate, based on its position that there is no statutory bar preventing it from seeking approval to enter the market with its generic product. If indeed there is no statutory protection for the

Respondent Gilead's product, there may be no basis to delay Canadian consumers from taking the benefit of gaining access to the Applicant's product. In addition, the Respondent Minister has important interests in play, to the extent that its interpretation reflects its understanding of the intention and public purpose of the regulatory regime.

[33] The fact that all parties have important and legitimate interests may explain why this case is before the Court and proceeding to a hearing. In the circumstances of this case, however, the importance of the parties' respective interests are a neutral factor in assessing whether a hearing by video conference is appropriate, given the nature of the proceeding, the legal and factual issues, and the uncertainty as to when a hearing in-person will be possible. Important matters can be dealt with in an appropriate, dignified, and effective manner through a video conference or an in-person hearing, and in this case this is not a persuasive consideration.

[34] While it is true that a hearing involving multiple parties will be more complex than a hearing involving only two, this is by no means an insurmountable obstacle. The Court has recently heard a complex matter by video conference involving a lengthy urgent motion with over thirty counsel, co-counsel, and client representatives, and the hearing was orderly, dignified, and efficient (see *Iris Technologies Inc v Canada (National Revenue)*, 2020 FC 532).

[35] The Court has taken steps to be able to hear matters by means of the Zoom video conferencing platform. Appropriate security measures are in place to ensure appropriate control over the hearing and to prevent any security breaches. In any event, this case was set to be heard in open court and no issues of a confidential nature have been raised. Court staff have been trained on the use of the technology, and detailed guidance will be available shortly from the

Court about how to prepare for and participate in a hearing using this technology. Other similar guidance is already available from other sources.

[36] A growing number of matters have already been heard in this way in this Court, and similar hearings are proceeding elsewhere in Canada and in other countries (see, for example: *Canada (Citizenship and Immigration) v Kljajic*, 2020 FC 570 at paras 59-62, a pre-pandemic case involving oral testimony by video conference). Since the pandemic occurred, a number of courts have moved forward with virtual hearings. See for example: *Capic v Ford Motor Company of Australia Limited (Adjournment)*, [2020] FCA 486; *Arconti v Smith*, 2020 ONSC 2782; *Ontario v Ontario Association of Midwives*, 2020 CanLII 25862, and remotecourts.org for information on these developments.

[37] I must also take into account the current reality. While the parties may prefer a hearing in person because that is what they are used to, the reality is that it is simply not possible to hear this case in that way at the present time. This situation may not change for an unknown period into the future.

[38] The Court suspended its regular hearing schedule because of the public health risks and the measures imposed across Canada in order to address those risks. Under the latest Practice Direction and Order dated April 29, 2020, regular hearings are suspended until May 29, 2020, and the Court will not hold regular hearings until June 29, 2020, at the earliest.

[39] In some places, certain of the public health restrictions and emergency orders put in place to deal with the pandemic have begun to be lifted, but all authorities agree that the nature, scope, and timing of these steps remain unknown and to a certain extent unknowable at the current time.

As of today, there is simply no rational basis to predict that the hearing of this matter could be re-scheduled for an in-person hearing in a few months.

[40] I recognize and accept that it would be unfair to proceed in a situation where one or more parties cannot get access to their paper records or to an electronic version of the record in order to prepare for a hearing. The same may be true where a party does not have access to reliable high-speed internet. Likewise, it would not be appropriate to proceed where one or more parties would not have the required access to clients or witnesses. However, none of these considerations applies in the present proceeding.

[41] In fact, this case is ideally suited to a video conference hearing. The record is prepared and available in electronic form, and anything that is not already available will be scanned and provided by the Applicant. The parties are all represented by experienced counsel, and they were prepared to argue the case in May. Going ahead in June will not prejudice anyone. The facts are not seriously in dispute, and the case will turn on a question of statutory interpretation.

[42] The Court has made arrangements to hear matters by video conference using the Zoom platform, which will permit all parties to have a full and fair hearing of their arguments, and will respect the open court principle. In addition, arrangements will be made to ensure that counsel can engage in appropriate and necessary consultations during the hearing with co-counsel, their clients and counsel for the co-respondent. The hearing will be scheduled for a suitable duration, so that the parties are given an adequate opportunity to present their case. If counsel have any questions about any of these matters, they may wish to contact the Registry to seek a pre-hearing case management conference. In addition, the presiding judge may decide to convene such a

discussion, or to issue a detailed Direction to the parties setting out the specifics as to how the hearing will proceed.

[43] At this stage, it is not necessary or appropriate for me to set out these details. Further, although the Applicant had asked for the hearing to be fixed for the week of June 8, 2020, based on the prior discussion between counsel, the Respondent Gilead indicated during the hearing that a date in mid-June would be preferred. The Judicial Administrator will consult with counsel in the usual manner, to fix the specific date and time of the hearing.

[44] For these reasons, I am granting the Applicant's request that this matter be heard by video conference in June 2020. The specific details regarding the modalities of the hearing, as well as the specific date and time, will be fixed in due course.

[45] In conclusion, it is worth noting that the pandemic has caused many public institutions to re-consider how they do business. It has accelerated a move from the traditional physical presence to a way of functioning in a virtual setting for many workplaces and institutions, including Parliament, provincial legislative assemblies, and courts. For many people this is an uncomfortable change, and some may see it as a "second best" temporary solution. In this regard, I would simply repeat the words of Justice Roger Lafrenière in *Rovi Guides, Inc v Videotron Ltd.*, 2020 FC 596:

> [26] The Court remains open to revisiting this Order should the relevant public health authorities accept that the risk of contracting and spreading COVID-19 has passed or been minimized to an acceptable degree.
>
> [27] Until then, I can do no better than repeat the words of Mr. Justice Nye Perram of the Federal Court of Australia in *Capic v Ford Motor Company of Australia Limited* (Adjournment) [2020] FCA 486 at paragraph 25:

> […] we have entered a period in which much that is around us is and is going to continue to be unsatisfactory. I think we must try our best to make this trial work. If it becomes unworkable then it can be adjourned, but we must at least try.

[46] The simple reality is that until the risks associated with the pandemic diminish and public health restrictions are lifted, it is necessary to adapt to the new reality. Access to justice is simply too important to wait. It is also a "public good," which must be considered in light of the interests of the litigants to the matter, other litigants waiting for their cases to be heard, and the wider public who also seek access to the courts.

[47] Viewed in this light, delaying a case which is ripe for hearing by video conference will impose a cost not just to the immediate parties, but also to the other parties whose cases will thereby be delayed as the impact of the adjourned cases cascade through the schedule. It is incumbent on everyone involved in the legal system to try to mitigate this impact to the extent possible. The parties immediately affected, other parties waiting their turn for a hearing in this Court, and all Canadians, deserve no less.

[48] In this case, I have found that this case can and should proceed by video conference in June 2020. The presiding judge who will be assigned to hear the matter can address any specific questions about how the hearing will proceed. The Judicial Administrator will consult the parties in the usual way to fix the specific time and place of the hearing.

ORDER in T-1353-19

THIS COURT ORDERS that:

1. The Applicant's request to have this matter heard by video conference is granted.

2. The matter is to be set down for hearing in June 2020, at a time and date to be fixed by the Judicial Administrator following consultations with the parties.

3. The judge who will be assigned to hear the matter can address any questions about the specifics as to how the hearing will proceed so as to ensue a full, fair, and appropriate hearing of the matter.

"William F. Pentney"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

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ORDER AND REASONS:	PENTNEY J.
DATED:	MAY 14, 2020

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