Federal Court of Appeal  Cour d'appel fédérale

Date: 20180802

Docket: A-137-17

Citation: 2018 FCA 147

CORAM: **WEBB J.A.**
NEAR J.A.
LASKIN J.A.

BETWEEN:

APOTEX INC.

Appellant

and

MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA

Respondents

Heard at Toronto, Ontario, on June 26 and 27, 2018.

Judgment delivered at Ottawa, Ontario, on August 2, 2018.

REASONS FOR JUDGMENT BY: LASKIN J.A.

CONCURRED IN BY: WEBB J.A.
NEAR J.A.

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REASONS FOR JUDGMENT

LASKIN J.A.

I. Overview

[1] On judicial review in the Federal Court, Apotex Inc. obtained judgments quashing two decisions of Health Canada relating to facilities in India owned by Apotex affiliates: the decision in September 2014 to impose an import ban on drug products from these facilities, and the

decision in August 2015 to vary the terms and conditions of the licences for the facilities, with the effect of continuing the import ban for certain drugs and relaxing it for others, depending on when they were made.

[2] The first decision was quashed by Justice Manson (*Apotex Inc. v. Canada (Health)*, 2015 FC 1161) on the basis that, in imposing the import ban, the Minister of Health acted for an improper purpose and failed to comply with the duty of procedural fairness. He found that the import ban was motivated not by a legitimate concern for protecting health and safety, but by the Minister's desire to relieve political pressure from the media and from the opposition in the House of Commons, a purpose outside the Minister's delegated authority. Justice Manson quashed the second decision (*Apotex Inc. v. Canada (Health)*, 2016 FC 673) on the basis that it was interconnected with the first decision and tainted by the same improper purpose.

[3] Apotex also sought judicial review of a third decision by Health Canada: the decision in the fall of 2015, after the release of Justice Manson's first decision, to refuse to end a requirement put in place through a decision made in November 2014. The November 2014 decision was that regulatory approval would not be granted for products manufactured in or containing active pharmaceutical ingredients sourced from the facilities in India unless Health Canada was provided with information confirming the integrity of test data from the facilities. Apotex argued that this decision too was tainted by the Minister's improper purpose when it was made in November 2014, and that this improper purpose continued to motivate Health Canada when it refused in the fall of 2015 to end the requirement imposed by the November 2014 decision. Apotex also submitted that the refusal was unreasonable.

[4] In the decision under appeal (2017 FC 315), Justice Russell of the Federal Court dismissed Apotex's third application. In lengthy and thorough reasons, he found that Apotex had failed to establish that the decision to maintain the requirement imposed by the 2014 decision was bound up with and based upon the import ban. Instead, he concluded, Health Canada put the requirement in place in November 2014 based on legitimate concerns about the integrity of test data from the Indian facilities, and continued to be motivated by those legitimate concerns when it determined not to end the requirement in the fall of 2015. He also found the decision not to end the requirement to be reasonable in light of the concerns about data integrity and the extent to which Apotex itself had recognized the need to address them.

[5] Apotex now appeals to this Court. It focuses its submissions primarily on Health Canada's decision in November 2014, and on its motivation at that time, which it says continued to be Health Canada's motivation when it refused in the fall of 2015 to end the requirement that the November 2014 decision put in place. It submits that the application judge erred in law by bifurcating his analysis of the evidence bearing on how and why Health Canada made the November 2014 decision. It argues that he also erred in failing to draw an adverse inference against Health Canada because it produced no documents to establish the basis for the November 2014 decision, put forward a witness with no memory of key events and led no evidence from other individuals with first-hand knowledge bearing on its motivations. It further argues more generally that, in making his finding as to motivation, the application judge committed palpable and overriding error.

[6] I would dismiss the appeal. In my view Apotex fails to demonstrate any error of law on the part of the application judge, and does not meet the burden of establishing palpable and overriding factual error.

[7] In explaining why I reach these conclusions, I will first briefly describe the regulatory context. I will then outline the factual context, including the measures taken by Health Canada and Apotex's response to them, before turning to the decision under appeal and the issues the appeal raises. Though the decision taken by Health Canada in November 2014 was not itself the target of the application heard by Justice Russell – the notice of application for judicial review challenged the decision in the fall of 2015 to maintain the requirement put in place in November 2014 after Justice Manson rendered his first decision – I will, consistent with the approach taken in argument by Apotex, focus largely on the application judge's conclusions regarding the November 2014 decision. As Apotex acknowledges, a finding that the November 2014 decision was motivated by an improper purpose is an essential building block for its argument that the fall 2015 decision was improper.

[8] In view of the course of the argument, it is not necessary in my view to consider whether the application judge erred in determining that, assuming that it was not improperly motivated, the decision in the fall of 2015 was reasonable. Apotex did not squarely raise this issue in its memorandum of fact and law, and made no oral submissions directed to it. Rather, as already indicated, its submissions were directed to the question of motivation.

II. Regulatory context

[9] The *Food and Drugs Act*, R.S.C. 1985, c. F-27, and the *Food and Drug Regulations*, C.R.C., c. 870, govern the manufacture, import and sale of drug products in Canada. They are administered by Health Canada on behalf of the Minister of Health. Two elements of the regulatory scheme are of particular relevance in this appeal.

[10] First, the Regulations prohibit the sale or advertising of a new drug unless the Minister has issued a notice of compliance, or NOC. To obtain an NOC for a new generic drug, a generic drug manufacturer like Apotex must file an abbreviated new drug submission, or ANDS. The ANDS must contain "sufficient information and material to enable the Minister to assess the safety and effectiveness of" the drug. The Minister is given a discretion to require the manufacturer to provide, where "the Minister considers it necessary to assess the safety and effectiveness of the new drug," "any additional information or material" respecting its safety and effectiveness. Health Canada's Therapeutic Products Branch, or TPD, is responsible for this element of the regulatory scheme. Its Director General has been delegated authority to issue NOCs. In carrying out its function, TPD does not carry out its own testing, but relies on the data submitted by the manufacturer.

[11] The second relevant element of the scheme is its prohibition on a manufacturer's importing any drug into Canada except in accordance with an establishment licence. To add a foreign facility to an establishment licence, the manufacturer must show that the facility complies with good manufacturing practices and meets other regulatory requirements. The Minister may include in an establishment licence terms and conditions respecting any matters

"necessary to prevent injury to the health of consumers." The part of Health Canada known at the relevant time as the Health Products and Food Branch Inspectorate, or the Inspectorate, is responsible for compliance and enforcement relating to establishment licences, including their issuance and amendment.

III. Factual context

[12] The application judge provided a helpful summary of the factual context at paragraphs 6 to 18 of his reasons. I will not repeat all of it but will borrow from it, with some supplementation, in outlining the facts necessary to situate the issues in the appeal.

A. *Data integrity concerns*

[13] In January 2014, the United States Food and Drug Administration carried out an inspection at one of the Indian facilities. The inspection found issues concerning data integrity. It revealed among other things an apparent practice of re-testing samples when tests produced failing or other undesirable results, continuing to re-test until acceptable results were obtained, failing to report the undesirable results, and failing to record supporting raw data.

[14] In April 2014, based on the results of the inspection, the FDA imposed an import alert refusing admission to the United States of drugs manufactured at the facility. Apotex advised the Inspectorate of the FDA's findings. It acknowledged the "critical nature of the improvements required" at the facility, and stated that it would conduct a review and assessment of practices there.

[15] The Inspectorate asked that Apotex voluntarily cease sales of drugs containing an active pharmaceutical ingredient, or API, from the facility. Apotex did not agree to take this step. Ultimately, the Inspectorate and Apotex agreed that Apotex would conduct confirmatory testing on these products before distributing them in Canada. In June 2014, the FDA found similar data integrity issues in an inspection of the other Indian facility.

[16] The Inspectorate carried out an inspection of the first facility jointly with the Australian drug regulator in August 2014. While the inspection found certain deficient data integrity practices, the Inspectorate prepared a draft post-inspection notice rating the facility as compliant with the terms and conditions of the establishment licence. This draft was never finalized. In the meantime, TPD continued to issue NOCs for products that incorporated APIs made at the facility.

[17] On September 23, 2014, the FDA imposed an import alert on products from the second Indian facility. On that or the following day, the Inspectorate advised Barbara Sabourin, the Director General of TPD, of the concerns with respect to data integrity at the two facilities. The Inspectorate sent a follow-up email to Ms. Sabourin passing on the FDA's findings.

B. *The import ban*

[18] Meanwhile, on September 11, 2014, a Toronto newspaper had published an article and an editorial highly critical of Health Canada on the basis that, unlike the FDA, it had failed to take adequate steps to deal with problems in Indian drug manufacturing facilities, including those of Apotex. This failure, it was asserted, had led to the sale in Canada of defective drugs, and was

putting patients' health at risk. This theme was picked up by the opposition in the House of Commons, where the Minister came under attack. The critical newspaper coverage continued.

[19] The Minister demanded that Health Canada take action quickly. A senior political advisor made it clear to Health Canada that the Minister wanted "stronger measures" taken against Apotex. One of the participants from Health Canada in briefings and discussions with the Minister and her advisors was Dr. Supriya Sharma, then Acting Associate Deputy Minister and Senior Medical Advisor, and before that Ms. Sabourin's predecessor as Director General of TPD. Based on information she had received, Dr. Sharma "doubted that Health Canada could trust Apotex."

[20] On September 30, 2014, the Inspectorate modified Apotex's establishment licence to include the import ban – a restriction on the importation of finished commercial drug products from the two Indian facilities. Ms. Sabourin did not participate in making this decision.

[21] Apotex sought judicial review. In a decision released in October 2015, Justice Manson quashed the import ban, concluding (at para. 107) that it was not implemented based on a legitimate concern for protecting Canadians' health and safety, but "was motivated by the Minister's desire to ease pressure triggered from the media and in the House of Commons – a purpose falling outside her delegated authority from the enabling legislation, which must be exercised in accordance with the rule of law." In his decision, Justice Manson recognized that Health Canada had concerns about the integrity of data from the two plants, but did not accept

the evidence given by the deponents of affidavits filed by the Minister, including Dr. Sharma, as to the reasons why the import ban was imposed.

C. *The August 2015 decision*

[22] In August 2015, in light of corrective and preventative measures taken by Apotex to address data integrity at the two facilities, the Inspectorate amended the terms and conditions of Apotex's establishment licences to eliminate the requirement that Apotex provide additional information to support test data from the two facilities for tests conducted after June 2015. However, the requirement remained in effect for tests conducted earlier.

[23] Apotex also sought judicial review of this decision. In June 2016, Justice Manson granted the application and quashed the decision. He noted (at para. 70) that in neither of his decisions was he intending to suggest that Health Canada did not have data integrity concerns, but concluded (at para. 75) that it was "the interconnectedness of the decisions, coupled with the dearth of evidence justifying an Import Ban in August of 2015, that makes it both legally and logically unsound to now find that the August 2015 Decision was not also tainted by the improper purpose that led to the quashing of the 2014 Terms and Conditions in the First Judicial Review."

D. *The November 2014 decision*

[24] As noted above, Ms. Sabourin, the Director General of TPD, was made aware of the data integrity issues at the two facilities by late September 2014. At first, TPD continued to review

ANDSs from Apotex, including those relying on data from the two facilities, in the ordinary course.

[25] In mid-November 2014, Ms. Sabourin received for her approval a draft NOC for Apotex's drug Apo-Rasagiline. Apotex's ANDS for the drug indicated that the two Indian facilities would be responsible for manufacturing and testing it. A day earlier Ms. Sabourin had convened a meeting of TPD staff to discuss TPD's response to the data integrity concerns. Ms. Sabourin expressed reluctance to sign the NOC in light of these concerns.

[26] Ms. Sabourin ultimately declined to sign the NOC. She called the President and CEO of Apotex, Dr. Jeremy Desai, to discuss the concerns about the integrity of data from the two facilities and to advise that TPD would not be issuing the NOC for Apo-Rasagiline at that time. During the call she told Dr. Desai that, until further notice, TPD would not issue NOCs based on ANDSs containing data from the Indian facilities. However, she also advised that TPD would continue to work through its review of Apotex's ANDSs, and make specific requests for further information as required.

[27] The circumstances surrounding Ms. Sabourin's disposition of the draft NOC for Apo-Rasagiline, and the nature and extent of the evidence of those circumstances, are central to this appeal. I will return to these subjects later in these reasons.

E. *The fall 2015 refusal to end the requirement imposed by the November 2014 decision*

[28] Following Ms. Sabourin's communication to Dr. Desai of TPD's position, TPD continued to work through its review of ANDSs containing data from the two facilities. It sought further information from Apotex as it considered necessary. Though Apotex objected to providing additional information relating to data integrity, it generally complied with these requests, and TPD issued a number of NOCs for drugs for which the ANDSs included data from the two Indian facilities.

[29] In January 2015, TPD developed a general policy setting out in writing its approach to managing submissions containing data from facilities (including but not limited to Apotex's Indian facilities) in respect of which there were data integrity concerns. The policy, like the requirement put in place in November 2014, required drug manufacturers to provide additional information to establish the reliability of data from these facilities. All drug manufacturers were formally notified of the policy in May 2015.

[30] Justice Manson's decision quashing the import ban was released on October 14, 2015. Later that day, Apotex wrote to Ms. Sabourin. It asked, in effect, that in light of the decision Health Canada end the requirement imposed in November 2014. Ms. Sabourin responded that she and others at Health Canada were reviewing the implications of the decision.

[31] At some point in the fall of 2015, Ms. Sabourin communicated to Apotex TPD's position that lifting the requirement imposed in November 2014 was not warranted, since the Court's decision did not address the reliability of data generated at the Indian facilities before Apotex

implemented corrective and preventative measures. It is this decision that was the target of the application for judicial review decided by Justice Russell.

F. *The July 2016 decision*

[32] In July 2016, a fresh review conducted by Ms. Sabourin's successor at TPD concluded that it was still necessary, on a case-by-case basis, for additional confirmatory information to be submitted to support requests for NOCs involving data from the two Indian facilities. By agreement of the parties, the propriety and reasonableness of this decision were not argued before Justice Russell.

IV. The application for judicial review

[33] In its application for judicial review, Apotex sought an order quashing the Minister's refusal to end the requirement imposed in November 2014 and orders in the nature of *mandamus* in effect requiring the Minister to approve all products manufactured at or having API sourced from the two Indian facilities without regard to the requirement. The notice of application listed 30 drugs as having been adversely affected by the requirement imposed in November 2014.

[34] By the time the application was heard in November 2016, Apotex had submitted the additional information requested by TPD in accordance with the requirement for 28 of the 30 drugs. TPD had approved 26 of the 28, and two others were not approvable for reasons unrelated to data integrity. Apotex had not submitted the further information requested for two drugs, and their status remained unresolved. These were drugs in respect of which Apotex had submitted

data from stability studies conducted in 2013. This data was stored on the company's Empower 2 computer system. While Apotex had reviewed the more recent data stored on its newer Empower 3 computer system as part of its response to the data integrity concerns, it had not yet reviewed the Empower 2 data.

V. The additional evidence

[35] Much of the argument of this appeal was devoted to the significance and treatment of the additional evidence provided on behalf of the Minister after the initial hearing of the application.

[36] In response to the application, the Minister filed an affidavit of Ms. Sabourin. Both in her affidavit and in cross-examination on the affidavit, Ms. Sabourin gave evidence regarding the circumstances surrounding the decision not to issue an NOC for Apo-Rasagiline, and the adoption and communication to Apotex of the November 2014 decision.

[37] In her affidavit, Ms. Sabourin deposed that on November 13, 2014, she had convened a meeting of TPD scientists to discuss how to handle the concerns, not limited to Apotex's two Indian facilities, about the integrity and reliability of data in new drug submissions. No solutions other than re-testing had emerged.

[38] The following day, she deposed, she had received the submission for Apo-Rasagiline for review and approval. She stated that she had noted that Apotex's two Indian facilities were to be responsible for manufacturing and testing the drug and that, given the concerns over the reliability of data generated from the two facilities, she was concerned about signing the NOC.

[39] She had therefore sent an e-mail to one of her senior colleagues, Dr. Craig Simon, expressing her concern about signing the NOC "[g]iven the issues under discussion," and seeking his advice. She deposed that "after discussing the issue with Dr. Simon, [she had] concluded that [she] could not issue the Notice of Compliance for Rasagiline until the concerns about the integrity of the data from the manufacturing sites had been looked into further." She stated that "[w]ithout confidence in the integrity of the data in the Rasagiline submission, [she] could not assure [herself] that there was a reliable basis on which to assess the quality, safety and effectiveness of Rasagiline." She had then, the next business day, called Dr. Desai to inform him of TPD's new requirement.

[40] In cross-examination on her affidavit as to the basis for the November 2014 decision, Ms. Sabourin stated, "I wasn't concerned about the import ban. I was concerned about the data integrity issues." She described the import ban as "like a side piece." She was asked whether she had consulted with anyone other than Dr. Simon before she concluded that she could not issue the NOC for Apo-Rasagiline. She responded at first that she did not believe so, and after some further questions and responses stated, "I don't recall speaking to anyone else about whether I could sign or couldn't sign, wouldn't sign the NOC." She also stated that she may have spoken with her colleague Dr. Patrick Stewart before the call with Dr. Desai.

[41] Ten days after oral argument of the application concluded and judgment was reserved, counsel for the Minister wrote to counsel for Apotex "to provide a correction to the evidence given by Barbara Sabourin on her cross-examination." Counsel advised that Ms. Sabourin now recalled, following review and discussion in connection with an action for damages arising from

the import ban that Apotex had brought against the Minister and others, that she had spoken with Dr. Sharma about issuing the NOC for Apo-Rasagiline. According to the letter, the call occurred shortly after Ms. Sabourin spoke with Dr. Simon on November 14, 2014. While Ms. Sabourin could not recall the details of the conversation, she believed that "similar to her conversation with Dr. Simon, she would have told Dr. Sharma about her concerns about issuing the NOC, and that Dr. Sharma would have advised her that she could not sign the NOC in the circumstances." The letter also disclosed a telephone call on November 10 in which Ms. Sabourin participated with Dr. Sharma and others, the subject of which, Ms. Sabourin believed, was the approach that TPD was developing to deal with sites with data integrity concerns.

[42] Counsel for the Minister also produced further documents, which they advised had not been located earlier because of the search terms used in document review. The additional documents included an e-mail from Dr. Simon to colleagues about the status of the NOC for Apo-Rasagiline, which stated, "Barb [Sabourin] spoke to Supriya [Sharma] and was told she couldn't sign it." They also included an "issues management report" prepared within TPD relating to the possibility of rejecting submissions from the facilities subject to data integrity concerns. It listed among the potential risks that "Reputational/Media related risks could result from the approval of new products from the implicated sites."

[43] Following the letter and the further production, Ms. Sabourin's cross-examination was reconvened. In her continued cross-examination, she confirmed that the letter from counsel set out her belief as to what had occurred. She testified that she had no independent recollection of the content of the two calls involving Dr. Sharma, and several times described her recollection of

events as “hazy.” However, she stated, “I think I would remember if [Dr. Sharma] told me explicitly not to sign something when it’s my delegated authority and not hers.” She also explained that “it was unusual but not out of the ordinary on a difficult file for [her] to consult Dr. Sharma,” who had previously filled the same role at TPD, and might be in a position to provide advice or relevant knowledge. She reiterated that “[her] concerns all along [were] with the reliability of data in submissions that [she] was responsible for when [she] was responsible for determining whether [she] would sign [an NOC] and allow those products to be sold in Canada.”

[44] Following the further cross-examination, a further hearing took place before the application judge, at which the parties made submissions concerning the additional evidence and its impact on the issues in the application.

VI. Reasons of the application judge

A. *Standard of review*

[45] The application judge saw the question whether the decision in the fall of 2015 not to end the requirement imposed by the November 2014 decision was unlawful based on its proximity to the import ban, which had been quashed on the basis of improper motivation and unfairness, as a legal question subject to review for correctness. He determined that, if the decision was not tainted by the quashed import ban, it should be reviewed on the reasonableness standard.

B. *Motivation for the decision not to end the November 2014 policy*

[46] The application judge began his discussion of this question by observing that though the decision under review was the decision made in the fall of 2015 not to end the requirement imposed in November 2014, Apotex's focus in the application was very much on the November 2014 decision. He noted that even if Apotex could demonstrate that the November 2014 decision was tainted by its association with the import ban, to succeed in the application Apotex would have to show that TPD continued to be motivated by an improper purpose in refusing to end the policy and in continuing to require additional information to confirm the integrity of data from the two Indian facilities.

[47] The application judge found that TPD was not seeking to perpetuate the motives that lay behind the import ban either in making the November 2014 decision to require additional information to confirm data integrity, or in refusing to end the requirement in the fall of 2015. In coming to this overall conclusion he reviewed at length the evidence relating to, among other things,

- the communications between Ms. Sabourin and Dr. Desai in November 2014;
- the extent of any nexus between the Minister's response to political pressure and TPD's implementation of the November 2014 decision;
- the alignment between the November 2014 decision and the import ban;
- the absence of documentation of TPD's deliberations before deciding to implement the November 2014 decision;
- other links between the November 2014 decision and the import ban;
- TPD's response to Justice Manson's first decision;

- events in 2016 that were said to reinforce TPD's dependence on the Inspectorate's approach to products from the Indian facilities;

- TPD's response to Justice Manson's second decision;

- TPD's delay in taking regulatory measures when it learned of the FDA's concerns about data integrity; and

- Ms. Sabourin's memory problems in cross-examination.

[48] He concluded, among other things, that

- the communications between Ms. Sabourin and Dr. Desai in November 2014 were on their face independent of the import ban – though Ms. Sabourin referred to the import ban, her concern was with the significant underlying data integrity issues;

- the evidence, including the additional evidence, did not establish that the decision to implement the November decision was made by Dr. Sharma or that Ms. Sabourin made the decision based on "marching orders" to take stronger measures rather than on genuine data integrity concerns;

- the fact that the Inspectorate's actions in imposing the import ban turned out to be improper did not relieve TPD of its own regulatory responsibilities, or by itself render its pursuit of its own mandate an improper response to pressure from the Minister;

- there was no evidence to support Apotex's suggestion that the absence of documentation of TPD's deliberations was "a deliberate choice to shield from scrutiny TPD's deliberations over the Minister's desired 'stronger measures'";

- references to the import ban by TPD in correspondence to Apotex requesting further evidence to establish data reliability did not mean that TPD was seeking to further the import ban, rather than address data integrity concerns;

- TPD's taking time to consider its position in light of Justice Manson's first decision was evidence that TPD saw itself as operating independently of the import ban and for a different purpose;

- TPD's review in 2016 of the need to maintain the requirement of further information to address data integrity concerns amounted only to TPD's noting what was happening at the Inspectorate and reviewing the Apotex situation in light of its own requirements;

- the situation before Justice Manson when he made his second decision, finding that the Inspectorate had simply continued the import ban by other means, was very different from that relating to the actions taken by TPD;

- TPD's delay in taking regulatory measures when it learned of the FDA's concerns about data integrity did not indicate that its approach was improperly influenced by or intertwined with the import ban – data integrity was a new issue for TPD, and it took some time to develop a response; and

- Ms. Sabourin's memory problems (which Apotex accepted were real and reflected no dishonesty on her part) did not establish that she was simply following the Minister's directive, or detract from the genuineness of her concerns about data integrity.

[49] The application judge also noted at several places in his reasons that Apotex had itself recognized the genuineness and seriousness of the data integrity concerns both in the evidence of Dr. Desai and in the vigorous measures that it had taken to address the FDA's inspection findings.

[50] He expressed his conclusion as to the motivation for the November 2014 decision, based on his review of the evidence, as follows (at paragraph 161 of his reasons):

> All in all, the evidence suggests to me that the Import Ban was a catalyst for TPD. It prompted and galvanized TPD to put its own house in order with regard to data integrity concerns emanating from [the two facilities], as well as other sites and other drug manufacturers. But those data integrity concerns are, and continue to be, genuine and, what is more, have to be addressed as part of TPD's statutory mandate. TPD went about this task in a rational and cooperative way, and worked with Apotex and others to ensure that their NOC submissions were dealt with and processed while, at the same time, ensuring that the health and safety of Canadians were not compromised. TPD did not, and does not, require data integrity packages in order to perpetuate the motives that lay behind the Import Ban and the Inspectorate's decision.

[51] He had earlier in his reasons (at paragraph 106) responded with the following observations to Apotex's argument that the refusal in the fall of 2015 to end the requirement imposed in November 2014 was motivated by the same considerations that motivated the import ban:

> But the central issue before the Court is why did TPD decide in the Fall of 2015 that it would continue to require data integrity packages for products from [the two facilities] manufactured or tested prior to June 10, 2015, a date that was later pushed back to January 2015. The Court is being asked to accept that behind this decision are not genuine data integrity concerns for the health and safety of Canadians, but rather actions taken by the Minister back in 2014 in response to adverse media and political criticism. For reasons already given, I regard this as too much of a stretch. TPD has worked with Apotex and others to ensure that data integrity concerns associated with NOC submissions are resolved and overcome and, in the case of Apotex, there are only two drugs in dispute, and both of them have 2013 data integrity concerns that Apotex has itself been attempting to resolve […].

C. *Reasonableness of the fall 2015 decision*

[52] The application judge began his consideration of this issue by recognizing that his conclusion that the fall 2015 decision was not improperly motivated did not necessarily mean that it was reasonable. He centred his approach to the question of reasonableness on TPD's actions in relation to the two remaining drugs of the list of 30 for which TPD was continuing to require additional information to meet data integrity concerns.

[53] He noted again that, on the evidence, including the evidence of Apotex's own actions, there were genuine concerns with the integrity of data from the two Indian facilities. The data from stability studies for the two drugs, conducted at one of the facilities in 2013, was stored on Apotex's Empower 2 computer system, and therefore had not yet been reviewed. Nothing in any

decisions of or actions by the Inspectorate had answered concerns about the integrity of this data. In the absence of relevant information, TPD was not in a position to make a decision on the two drugs. It was therefore not unreasonable, he concluded, for TPD to maintain in the fall of 2015 its requirement of additional information to establish the reliability of the data.

VII. The issues on appeal

[54] Based on the written and oral submissions of the parties, I see the following issues as requiring this Court's consideration.

(a) What is the proper standard of appellate review of the application judge's finding as to the motivation for Health Canada's decision in the fall of 2015 not to end the requirement imposed in the November 2014 decision?

(b) Did the application judge commit reviewable error in bifurcating his analysis of the evidence bearing on how and why Health Canada made the November 2014 decision?

(c) Did the application judge commit reviewable error in failing to draw an adverse inference against Health Canada based on the nature and extent of the evidence that it put forward?

(d) Did the application judge otherwise commit reviewable error in making his finding as to the motivation for Health Canada's decision in the fall of 2015 not to end the requirement imposed in the November 2014 decision?

VIII. Analysis of the issues

A. *What is the proper standard of appellate review of the application judge's finding as to the motivation for Health Canada's decision in the fall of 2015 not to end the requirement imposed in the November 2014 decision?*

[55] The Supreme Court of Canada has held that in an appeal from the judgment of a first instance court in an application for judicial review, the appellate court is to determine whether

the application judge selected the correct standard of review and applied it correctly. In practice, when this standard of review is applied the appellate court must step into the shoes of the application judge, and focus directly on the administrative decision rather than on the decision under appeal: *Agraira v. Canada (Public Safety and Emergency Preparedness)*, 2013 SCC 36, [2013] 2 S.C.R. 559 at paras. 45-47.

[56] The Minister submits that *Agraira* is applicable to the question of Health Canada's motivation, and that given the breadth of the Minister's discretion, the correct standard of review should be reasonableness. Apotex argues that in view of the nature of the findings concerning Health Canada's motivation, the standard applicable to that question is instead that laid down in *Housen v. Nikolaisen*, 2002 SCC 33, [2002] 2 S.C.R. 235, for appellate review of findings of fact or mixed fact and law: palpable and overriding error, except where a finding of mixed fact and law presents an extricable question of law, in which case the decision on that question is reviewable for correctness.

[57] I agree with Apotex. The *Agraira* standard of appellate review does not necessarily apply with respect to all of the issues decided in an application for judicial review. Both this Court and other appellate courts have recognized that where the application judge made findings of fact or mixed fact and law based on the consideration of evidence at first instance, rather than on a review of the administrative decision, these findings are reviewable on the *Housen* standard: see, for example, *Austria v. Canada (Citizenship and Immigration)*, 2014 FCA 191, [2015] 3 F.C.R. 346 at paras. 54-56; *Canada (Attorney General) v. Rapiscan Systems, Inc*., 2015 FCA 96 at para. 21; *Prudential Steel Ltd. v. Bell Supply Company*, 2016 FCA 282, [2017] 3 F.C.R. 165 at para.

11; *Sturgeon Lake Cree Nation v. Hamelin*, 2018 FCA 131 at paras. 36-39; *Northern Regional Health Authority v. Manitoba Human Rights Commission et al.*, 2017 MBCA 98 at paras. 37-39; *Buterman v. St. Albert Roman Catholic Separate School District No. 734*, 2017 ABCA 196 at paras. 23-24.

[58] Here, the finding of the application judge as to what motivated Health Canada was an original finding of fact, not a finding made at first instance by the regulator. In making this finding the application judge was performing functions the same in substance as those performed by trial judges. He was thus better placed to make this finding than an appellate court, and the rationales for application of the *Housen* standard apply: see John M. Evans, "The Role of Appellate Courts in Administrative Law" (2007), 20 Can. J. Admin. L. & Prac. 1 at pp. 30-31. In my view, therefore, this finding, including the application judge's inferences of fact relating to his conclusion, are reviewable on appeal on the *Housen* standard.

[59] Courts have expressed in a variety of ways what constitutes palpable and overriding error. In *Housen*, above at para. 6, the Supreme Court emphasized that to be palpable, an error must be plainly seen. More recently, in *Benhaim v. St-Germain*, 2016 SCC 48, [2016] 2 S.C.R. 352 at para. 38, the Supreme Court adopted the description by Stratas J.A. in *South Yukon Forest Corp. v. R.*, 2012 FCA 165, 4 B.L.R. (5th) 31 at para. 46:

> Palpable and overriding error is a highly deferential standard of review . . . . "Palpable" means an error that is obvious. "Overriding" means an error that goes to the very core of the outcome of the case. When arguing palpable and overriding error, it is not enough to pull at leaves and branches and leave the tree standing. The entire tree must fall.

[60] It has also been said that "[a] court will fall into palpable and overriding error when it comes to a conclusion for which there is no factual basis, or when its reasoning is illogical or unrelated to the evidence": *Ciba Specialty Chemicals Water Treatments Limited v. SNF Inc.*, 2017 FCA 225 at para. 27. Apotex asks us to apply the formulation espoused by the British Columbia Court of Appeal in *Statton v. Johnson*, 1999 BCCA 170, 172 D.L.R. (4th) 535 at para. 35, and find palpable and overriding error on the basis that a finding is "out of harmony with the preponderance of the probabilities which a practical and informed person would readily recognize as reasonable."

[61] Regardless of how the standard is expressed, it is axiomatic that the palpable and overriding error standard does not give an appellate court title to reweigh the evidence or retry the case: *Housen*, above at paras. 3, 21-23.

B. *Did the application judge commit reviewable error in bifurcating his analysis of the evidence bearing on how and why Health Canada made the November decision?*

[62] Apotex submits that the application judge made an extricable error of law in bifurcating his analysis as a result of the timing of delivery of the additional evidence. It argues that the application judge first accepted and made findings based on Ms. Sabourin's original evidence, and then considered whether the evidence disclosed after the initial hearing displaced those findings. As a result, it argues, he failed to consider the evidence in its totality, and failed to consider whether Ms. Sabourin's evidence as to the motivation for the November 2014 policy was credible in light of the evidence as a whole.

[63] I would not give effect to these submissions. There is no prescriptive methodology for a judge at first instance to follow in arriving at his or her findings, provided that all of the evidence is considered. Nor is there anything untoward in the judge testing tentative conclusions against further evidence on point. Moreover, an appellate court, unless persuaded otherwise, must presume that the first instance court has considered all of the evidence: *Hennessey v. Canada*, 2016 FCA 180, 484 N.R. 77 at paras. 7-11.

[64] Here there is no need in my view to resort to this presumption. The application judge reviewed the evidence in detail, including the evidence put forward following the initial hearing, and plainly appreciated its potential significance: see paragraphs 93 to 101 and 104 to 111 of his reasons. As he stated at paragraph 161 of his reasons, he came to his conclusion as to the motivation of Health Canada after considering the evidence "[a]ll in all." In my view his reasons fully bear out this statement.

C. *Did the application judge commit reviewable error in failing to draw an adverse inference against Health Canada based on the nature and extent of the evidence that it put forward?*

[65] Whether this asserted error is still in issue is not entirely clear from my perspective. From its oral submissions in chief, Apotex first appeared to be arguing that the application judge erred in law in failing to draw an adverse inference against the Minister for three reasons – that she produced no contemporaneous documents to establish the basis for the November 2014 decision, put forward affidavit evidence only from Ms. Sabourin, who had no memory of certain relevant events, and led no evidence from Dr. Sharma or Dr. Simon, who had first-hand knowledge bearing on how and why the November 2014 decision was made. However, in response to

questions from the bench, Apotex indicated that it is not seeking to have the Court go so far as to determine that an adverse inference should have been drawn, but merely to consider that to the extent that there is an evidentiary vacuum as to the Minister's motivation, it was open to the Minister to ensure that no vacuum existed. The Minister nonetheless addressed the adverse inference issue in responding submissions. In reply, Apotex submitted, while acknowledging that it bore the onus of showing an improper purpose, that if there was a failure by the Minister to lead available evidence to respond to the case that Apotex put forward, then the negative inference doctrines apply.

[66] Given the submissions on this issue, I will address it. I do not see a reviewable error on the part of the application judge in failing to draw an adverse inference against the Minister.

[67] The law with respect to the drawing of adverse inferences appears to have evolved in recent years. At one point it was generally accepted, based in part on the decision of the Supreme Court of Canada in *Lévesque v. Comeau*, 1970 CanLII 4, [1970] S.C.R. 1010, that an adverse inference had to be drawn where a party failed to call material evidence that was available to it. The inference was that the evidence would have been unhelpful to the party or would not have supported its case: see S.N. Lederman, A.W. Bryant and M.K. Fuerst, The Law of Evidence in Canada, 5th ed. (Markham, Ontario: LexisNexis Canada Inc., 2018 at pp. 406-407; CED 4th (online) *Evidence*, "Calling and Questioning Witnesses: Calling and Failing to Call Witnesses: Parties in Civil Cases," at § 201.

[68] However, more recent decisions have treated the drawing of an adverse inference as a matter of discretion, to be exercised only where warranted in all of the circumstances: CED 4th *Evidence*, above at § 202; Lederman, Bryant and Fuerst, The Law of Evidence in Canada, above at p. 407, n. 706. There appear to be two reasons for this evolution. First, court rules now go a long way towards rendering witnesses and documents available to both sides, through discovery and other procedural mechanisms. Second, courts have recognized that "[w]hether or not an adverse inference is warranted on particular facts is bound up inextricably with the adjudication of the facts": *Toronto Real Estate Board v. Commissioner of Competition*, 2017 FCA 236 at para. 107, quoting from *Ellis-Don Ltd. v. Ontario (Labour Relations Board)*, 2001 SCC 4, [2001] 1 S.C.R. 221 at para. 73. Leaving the drawing of adverse inferences to the discretion of the trial judge (or judge performing an equivalent act-finding task) furthers the policies on which the *Housen* standard is based.

[69] Here, Apotex acknowledges that only the first basis for its submission that an adverse inference should have been drawn – the failure to produce contemporaneous documents – was raised before the application judge, and he was not asked to draw an adverse inference from the failure of the Minister to put forward affidavit evidence from Dr. Sharma or Dr. Simon. The application judge cannot be faulted for declining to draw an adverse inference from the Minister's failure to tender their evidence when he was not asked to do so. In any event, it was open to Apotex to seek leave under paragraph 41(4)(c) of the *Federal Courts Rules*, SOR/98-106, to obtain subpoenas for additional witnesses. It did not take this step.

[70] As for the alleged failure to produce contemporaneous documents to establish the basis for the November 2014 decision, the Minister explained that she did not produce a rule 317 record (comprising relevant material "in the possession of a tribunal whose order is the subject of the application") in response to Apotex's request because she regarded the November 2014 decision as a policy rather than an order. Ultimately, the Court was advised, the parties agreed to further production by the Minister under paragraph 91(2)(c) of the Rules, and this production included some documents that informed Ms. Sabourin in the development of TPD's policy on data integrity. It was also possible for Apotex to seek further documents in cross-examination of Ms. Sabourin. Further, as noted above, the application judge found that there was no evidence to support Apotex's suggestion that the Minister's approach to production of documents was a deliberate choice to shield its deliberations from scrutiny.

[71] In these circumstances, there was in my view no reviewable error on the part of the application judge in the exercise of his discretion whether to draw an adverse inference.

D. *Did the application judge otherwise commit reviewable error in making his finding as to the motivation for Health Canada's decision in the fall of 2015 not to end the requirement imposed in the November 2014 decision?*

[72] Apotex accepts that Health Canada had legitimate concerns about the integrity of the data from the two Indian facilities. It points out that Justice Manson also recognized the legitimacy of these concerns, but nonetheless found the motivations for the decisions that he reviewed to be improper. It submits that the application judge here committed palpable and overriding error in failing to come to the same conclusion. In oral argument, it took the Court through the evidence

that it submits should lead this Court to determine that the burden of showing palpable and overriding error is met.

[73] I have carefully considered the evidence to which Apotex refers. I do not agree that this burden is met. In my view, the submissions of Apotex on this issue amount in substance to an invitation for this Court to reweigh the evidence and substitute our findings for those of the application judge.

[74] For example, Apotex reviewed at length the evidence bearing on Ms. Sabourin's second call with Dr. Sharma. As set out above, Ms. Sabourin's initial evidence was that she had consulted only with Dr. Simon on whether to issue the NOC for Apo-Rasagiline. But she subsequently recalled that, shortly after her call with Dr. Simon, she had also spoken with Dr. Sharma.

[75] Apotex asks us to find this version of events to be, in counsel's words, "highly problematic." It queries why Ms. Sabourin would have called Dr. Sharma if she had obtained advice from Dr. Simon either that she should or that she shouldn't sign the NOC. It argues that "the most likely sequence of events" was that Ms. Sabourin did not speak to Dr. Simon at all – that it was "more likely" that she spoke only to Dr. Sharma, and that it was Dr. Sharma's view of the matter that was dispositive.

[76] I accept that it might have been open to the application judge to make this finding, although it seems somewhat speculative. But there was evidence to support his interpretation of

the events, including Ms. Sabourin's e-mail to Dr. Simon seeking his advice, and her evidence that it was not out of the ordinary for her to consult Dr. Sharma on a difficult file. Given the deference owed to first instance fact-finders, in my view there is simply no error here, let alone an error that rises to the level of palpable.

[77] Apotex also submits that the application judge committed palpable and overriding error in accepting, based on what he described (at paragraph 110 of his reasons) as certain "objective facts," Ms. Sabourin's evidence that there were concerns about data integrity separate and apart from the import ban. Apotex takes issue in particular with the "objective facts" that "TPD had data integrity concerns before the Import Ban and was looking for a way to deal with them," and that "[t]he Import Ban – whatever its motivation – was an obvious wake-up call to TPD that it needed to address data integrity concerns for Apotex's NOC submissions that relied upon products manufactured […] or having APIs sourced from [the two Indian facilities]."

[78] Apotex submits that there is no evidence to support these "objective facts," and that they are inconsistent with other findings of the application judge, including the finding that after the import ban, TPD at first continued to review in the ordinary course Apotex's NOC submissions incorporating data from the two Indian facilities.

[79] But as already noted, Apotex accepts that Ms. Sabourin had genuine concerns about data integrity. There was, in addition, evidence from Ms. Sabourin that she acted quickly to start addressing these concerns after she became aware of them in late September 2014, before the import ban was imposed. And among the other "objective facts" on which the application judge

relied was the fact that "TPD implemented a process of internal review that eventually resulted in a policy to deal with data integrity concerns that was applicable to all NOC submissions and not just to those belonging to Apotex."

[80] Looking at the reasons and the record as a whole, I do not find it possible to conclude that the application judge transgressed the highly deferential standard of palpable and overriding error. The application judge cannot be said to have come to a conclusion "for which there is no factual basis," or that was based on reasoning that is "illogical or unrelated to the evidence." Nor, even adopting the standard set out by the British Columbia Court of Appeal that Apotex urges on us, can it be said that his finding is "out of harmony with the preponderance of the probabilities which a practical and informed person would readily recognize as reasonable."

[81] Once it is determined that the application judge made no reviewable error in finding that the November 2014 decision was not improperly motivated, then the case that the refusal in the fall of 2015 not to lift the requirement that it imposed was improperly motivated falls away. There is in my view nothing in the record to support the proposition that the fall 2015 decision was tainted independently of the November 2014 decision. Given his finding, it is also unnecessary in my view to address the question, on which we heard competing submissions, whether Health Canada's decisions would be fatally tainted if motivated by an improper purpose only in part.

IX. Proposed disposition

[82] For these, reasons, I would dismiss the appeal. The parties are agreed that costs should follow the event.

"J.B. Laskin"
J.A.

"I agree.
Wyman W. Webb J.A."

"I agree.
"D. G. Near J.A."

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKET:	A-137-17
(APPEAL FROM A JUDGMENT OF THE HONOURABLE JUSTICE RUSSELL OF THE FEDERAL COURT, DATED MARCH 27, 2017, DOCKET T-1915-15)	
STYLE OF CAUSE:	APOTEX INC. v. MINISTER OF HEALTH AND ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	JUNE 26 AND 27, 2018
REASONS FOR JUDGMENT BY:	LASKIN J.A.
CONCURRED IN BY:	WEBB J.A. NEAR J.A.
DATED:	AUGUST 2, 2018

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