Unofficial English Translation of the Judgment of the Court

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| Merck Canada inc. c. Procureur général du Canada | | | | | 2022 QCCA 240 |
| COURT OF APPEAL | | | | | |
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| CANADA | | | | | |
| PROVINCE OF QUEBEC | | | | | |
| REGISTRY OF | | | MONTREAL | | |
| No.: | 500-09-029316-213 | | | | |
| (500-17-109270-192) | | | | | |
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| DATE: | February 18, 2022 | | | | |
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| CORAM: | | THE HONOURABLE | | ROBERT M. MAINVILLE, J.A.  BENOÎT MOORE, J.A.  GUY COURNOYER, J.A. | |
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| MERCK CANADA INC. | | | | | |
| JANSSEN CANADA INC. | | | | | |
| SERVIER CANADA INC. | | | | | |
| BOEHRINGER INGELHEIM (CANADA) LTD. /LTÉE | | | | | |
| BAYER INC. | | | | | |
| THERATECHNOLOGIES INC. | | | | | |
| AVIR PHARMA INC. | | | | | |
| APPELLANTS / INCIDENTAL RESPONDENTS – Plaintiffs | | | | | |
| v. | | | | | |
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| ATTORNEY GENERAL OF CANADA | | | | | |
| RESPONDENT / INCIDENTAL APPELLANT – Defendant | | | | | |
| and | | | | | |
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| ATTORNEY GENERAL OF QUEBEC | | | | | |
| IMPLEADED PARTY – Impleaded Party | | | | | |
| and | | | | | |
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| CANADIAN CYSTIC FIBROSIS TREATMENT SOCIETY | | | | | |
| CYSTIC FIBROSIS CANADA | | | | | |
| CANADIAN ORGANIZATION FOR RARE DISORDERS | | | | | |
| BIOTECANADA | | | | | |
| IMPLEADED PARTIES – Intervenors | | | | | |
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| JUDGMENT | | | | | |
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1. The pharmaceutical companies appeal from the judgment dated December 18, 2020 (the Honourable Sophie Picard, J.S.C., District of Montreal), the conclusions of which read as follows:

[translation]

[430] **GRANTS** in part the application for judicial review;

[431] **DECLARES** valid ss. 79 to 103 of the *Patent Act*, R.S.C. 1985, c. P-4;

[432] **DECLARES** valid: (i) the entire *Patented Medicines Regulations*, SOR/94-688 and (ii) the amendments to the *Regulations* published in the *Canada Gazette*, Part II, on August 21, 2019 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*: SOR/2019-298), except the new ss. 4(4)(a) and 4(4)(b);

[433] **DECLARES** *ultra vires*, invalid, null, and without effect the new ss. 4(4)(a) and 4(4)(b) of the amendments to the *Patented Medicines Regulations*, SOR/94-688, published on August 21, 2019 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements*), SOR/2019-298);

[434] **ORDERS** the provisional execution of this judgment notwithstanding appeal, with respect to the new ss. 4(4)(a) and 4(4)(b) of the amendments to the *Patented Medicines Regulations*, SOR/94-688, published on August 21, 2019 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements*), SOR/2019-298), the application of which will be suspended for the duration of any appeal proceedings, and the former ss. 4(4)(a) and 4(4)(b) of the *Patented Medicines Regulations*, SOR/94-688 will continue to apply during any appeal proceedings;

[435] **THE WHOLE**, with each party paying its own legal costs.

1. The Attorney General of Canada filed an incidental appeal against the part of the judgment declaring *ultra vires*, invalid, null, and without effect the new paragraphs 4(4)(a) and 4(4)(b) introduced into the *Patented Medicines Regulations*, SOR/94-688 by the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements*), SOR/2019-298, published on August 21, 2019.
2. For the reasons of Mainville J.A., with which Moore and Cournoyer JJ.A. agree, **THE COURT**:
3. **ALLOWS** the appeal in part;
4. **DISMISSES** the incidental appeal;
5. **REVERSES** the trial judgment in part to replace paragraphs [432] and [433] with the following:

[translation]

[432] **DECLARES** valid: (i) the entire *Patented Medicines Regulations*, SOR/94-688 and (ii) the amendments to the *Regulations* published in the *Canada Gazette*, Part II, on August 21, 2019 (*Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298), except subsection 3(4) introducing the new paragraphs 4(4)(a) and 4(4)(b) and section 4 introducing the new sections 4.1 to 4.4 into the *Patented Medicines Regulations*, SOR/94-688;

[433] **DECLARES** *ultra vires*, invalid, null, and without effect subsection 3(4) and section 4 of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements),* SOR/2019 introducing the new paragraphs 4(4)(a) and 4(4)(b) and the new sections 4.1 to 4.4 into the *Patented Medicines Regulations*, SOR/94-688.

1. **THE WHOLE**, with legal costs in favour of the appellants, both at trial and on appeal.

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|  | | ROBERT M. MAINVILLE, J.A. |
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|  | | BENOÎT MOORE, J.A. |
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|  | | GUY COURNOYER, J.A. |
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| Counsel for BIOTECanada | | |
|  | | |
| Dates of hearing: | December 13, 14, and 15, 2021 | |

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| REASONS OF MAINVILLE, J.A. |
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1. This case concerns the scope of the federal government’s jurisdiction over the regulation of the price of patented medicines sold in Canada. Only the federal jurisdiction over “Patents of Invention and Discovery/*brevets d’invention et de découverte*) set out in subsection 91(22) of the *Constitution Act, 1867* is at issue. It should be noted that the central issue of the appeal is not whether .medicine prices should be regulated, but rather which level of government can act in this matter.

\* \* \*

1. The appellant pharmaceutical companies appeal from the judgment dated December 18, 2020 (the Honourable Sophie Picard, J.S.C., District of Montreal),[[1]](#footnote-1) which declared constitutionally valid:

(a) sections 79 to 103 of the *Patent Act*[[2]](#footnote-2) concerning the special regime to control excessive prices for patented medicines;

(b) the entire *Patented Medicines Regulations*[[3]](#footnote-3)as it read before the 2019 amendments; and

(c) the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*[[4]](#footnote-4)(the “*2019 Regulatory Amendments*”), except subsection 3(4), which introduced the new paragraphs 4(4)(a) and (b) into the *Patented Medicines* *Regulations*, requiring patentees to disclose to the Patented Medicine Prices Review Board (the “Board”) the price obtained for patented medicines, taking into account the confidential rebates granted to the public prescription drug insurance plans.

1. Most aspects of the pharmaceutical companies’ appeal are supported by the impleaded parties-intervenors, who represent patients suffering from rare diseases. The appeal is also supported by the Attorney General of Quebec, but only in regard to the constitutional invalidity of the main provisions of the *2019 Regulatory Amendments*.
2. The Attorney General of Canada filed an incidental appeal against the declaration of constitutional invalidity concerning the new paragraphs 4(4)(a) and (b) introduced into the *Patented Medicines Regulations* by the *2019 Regulatory Amendments*.
3. The coming into force of the *2019 Regulatory Amendments*, scheduled for July 1, 2020, has been delayed a few times.[[5]](#footnote-5) The coming into force of these amendments is now scheduled for July 1, 2022.[[6]](#footnote-6)

**I - STATUTORY PROVISIONS**

1. To understand the context underlying this dispute, it is appropriate to first summarily describe the legislative history of the aspects of the *Patent Act* relevant to this appeal. What follows is a brief description of the impugned provisions of the *Patent Act* and the current version of the *Patented Medicines Regulations*, as well as a summary of the *2019 Regulatory Amendments*. We conclude this part with a brief overview of the provincial measures concerning the price of medicines.
2. ***Legislative history***

*The 1869 Act*

1. Parliament’s first statute concerning patents was the 1869 *Act respecting Patents of Invention*.[[7]](#footnote-7) It contained no specific provision on medicines. However, it provided that a patent, regardless of its subject, expired after three years if it was not acted upon in such a way as to permit its use at a “reasonable price”.[[8]](#footnote-8)

*The 1923 Act*

1. It was only in 1923 that the *Act to Amend and Consolidate the Acts Relating to Patents of Invention*[[9]](#footnote-9) expressly addressed methods for making medicines, while prohibiting the patenting of medicinal substances.[[10]](#footnote-10)
2. With certain exceptions, the Commissioner of Patents therefore had to grant a licence to use the patented method of making a medicine to any person who applied for it. The conditions of such a licence and the amount of the fees to be paid to the patentee were fixed by the Commissioner, who had to consider “the desirability of making the … medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention”.[[11]](#footnote-11) A licence did not allow the medicine to be imported; rather, it allowed it to be made in Canada.[[12]](#footnote-12)
3. It was in fact the Canadian version of the British statute in force at the time, as explained by Commissioner Harry C. Eastman in his 1985 report of inquiry (the “Eastman Report”), to which I will return:[[13]](#footnote-13)

The nature of the policies specific to the pharmaceutical industry has varied by country and over time. In response to concern about the lack of British-owned pharmaceutical firms, which was attributed to excessively broad product patent protection for foreign firms in the United Kingdom before World War I, the British Patent Act was amended in 1919 and restricted the patent protection given to food and drugs to process or product by process, not to the product itself. The amendment also introduced compulsory licensing of patents to permit the entry of new firms. This legislation was widely imitated in other parts of the British Empire. It was introduced in Canada in 1923 in a form that required manufacture of the patented active ingredient in Canada.

1. The purpose of the compulsory licensing scheme for drug-manufacturing processes was to mitigate the effect on prices of the monopoly granted by the patent through commercial competition permitted under licence, while rewarding the research that led to the invention with royalties. Abbott J. in *Hoffman-LaRoche v. Bell-Craig Pharmaceutical Division of L.D. Craig Ltd.* explained the purpose of the scheme as follows:[[14]](#footnote-14)

In my view the purpose of s. 41 (3) is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may be "available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention".

1. The *1923 Act* also provided for the granting of licences when a patentee did not satisfy the reasonable requirements of the public with reference to the patent within three years, regardless of its subject.[[15]](#footnote-15) This licensing system applied to all patents and is found today, in a modified form, in the provisions of the *Patent Act* concerning the abuse of patent rights,[[16]](#footnote-16) although the term “abuse” was not expressly used in the *1923 Act*.
2. According to the 1923 regime on what we now call abuse of patent, if the patentee did not satisfy the reasonable requirements of the public within three years of its issue, the Commissioner of Patents could order the patentee to supply the patented article “at such price as may be fixed by him and in accordance with the custom of the trade to which the invention relates as to the payment and delivery”.[[17]](#footnote-17) The Commissioner could also grant licences for the use of the patented invention on conditions “as may be fixed by him”.[[18]](#footnote-18)
3. That being said, we must not confuse these licences related to patent abuse with those granted in connection with patented medicines, which could be obtained without regard for the concept of abuse, as the House of Lords concluded in *Parke-Davis and Co.,* rendered in 1954, with respect to the British legislation from which the Canadian Parliament drew inspiration.[[19]](#footnote-19) In this regard, Lord of Bishopstone stated the following:[[20]](#footnote-20)

Applications for orders under section 41 are not, as I read that section, based on the abuse of patent rights by the patentee. In this respect section 41, in my judgment, contrasts with section 37, application for orders under which are based on such “abuses.” The provisions of section 41 are based on the special position of food, medicines and surgical appliances as articles in urgent demand.

*The 1969 Act*

1. Various federal commissions recommended legislative amendments to the patent regime for medicines and their manufacturing processes. In 1960, the Ilsley Commission recommended authorizing patents for medicinal substances themselves, subject to the implementation of a compulsory licensing mechanism.[[21]](#footnote-21) On the contrary, in 1963, the Restrictive Trade Practices Commission instead recommended the outright abolition of patents for the pharmaceutical industry.[[22]](#footnote-22)
2. In 1964, the Royal Commission on Health Services recommended maintaining patents for the pharmaceutical industry in accordance with a more rational process that included standard royalties and compulsory licensing, not only to make patented medicines, but also to import them:[[23]](#footnote-23)

In view of the circumstances, two courses of action appear to be indicated : one is to follow the proposal made by the Restrictive Trade Practices Commission and to recommend that patents on drugs be abolished in Canada ; the other is to modify the existing patent system as it affects drugs by permitting compulsory licensing of imports and to streamline generally procedures as they relate to compulsory licensing together with an amendment of the Patent Act which would extend to provincial governments and their agencies the right to use patented inventions, a right presently extended only to the Crown in the name of the Government of Canada.

We are inclined to follow the second course which aims at making every attempt to use a modified patent system to achieve the desired objectives of bringing down drug prices in Canada while still encouraging manufacturing of drugs in this country where such undertakings are economically justifiable.

1. Following the recommendations of that Commission and of a 1966 parliamentary committee report that studied drug prices,[[24]](#footnote-24) Parliament amended the *Patent Act* in 1969 to extend compulsory licences, still irrespective of the parallel regime of abuse of patent, to the importation of patented medicines, including the implementation of an interim licensing process for that purpose.[[25]](#footnote-25) The Commissioner of Patents then set a royalty of 4% of the price at which the medicine was sold for such licences.[[26]](#footnote-26)
2. The principle aspects of this legislation was thus to allow the importation of medicines into Canada by way of compulsory licences, as well as their manufacture in Canada through such licences. The purpose of these amendments was to encourage competition to “mak[e] the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention and for such other factors as may be prescribed”.[[27]](#footnote-27)
3. The constitutional validity of this compulsory licensing regime was confirmed by the courts on numerous occasions.[[28]](#footnote-28) I will return to this.
4. The licence had to be issued regardless of the reasonableness of the price at which the medicine was sold. Commissioner of Patents Laidlaw, citing Jackett J., stated the following in this regard in *Frank W. Horner v. Hoffman-La Roche Ltd.*:[[29]](#footnote-29)

[18] One other point of principle. It is also well settled that the Commissioner's decision to grant a licence under the subsection must not depend on whether or not the patentee's prices for its product are reasonable. Jackett, P., in *Hoffmann-La Roche v. Bell-Craig,* [46 C.P.R. 32, [1965] 2 Ex.C.R. 266] stated at p. 50:

"there is no duty imposed upon the Commissioner by s. 41(3) of the Patent Act, when he is considering whether there is 'good reason' to reject an application for compulsory licence, to conduct an investigation as to whether the prices at which the patentee has been selling the patented product are in fact 'reasonable'."

[19] In short, compulsory licences applied for under s. 41 of the Patent Act leave little discretion to the Commissioner of Patents. These licences, in fact, amount almost to licences of right. What the Commissioner of Patents is required to do is mandatory unless he sees good reason not to grant the licence applied for.

1. The purpose of this legislation was therefore to encourage increased competition through licences in order to mitigate the effect on prices of the monopoly granted by the patent.[[30]](#footnote-30) This statutory regime in fact led to the development of a significant pharmaceutical industry for so called [translation] “generic” medicines in direct competition with the traditional pharmaceutical industry based on research and development, the so called [translation] “innovative” medicine industry.[[31]](#footnote-31)

*The 1987 Act*

1. The 1985 Eastman Report proposed significant amendments to the patent and compulsory licensing regime for medicines and their manufacturing processes, in particular to encourage pharmaceutical research and development activities and expenditures in Canada. While not all of those recommendations were accepted, Parliament carried out a major legislative reform in response to the Eastman Report by enacting the 1987 *Act to amend the Patent Act and to provide for certain matters in relation thereto*.[[32]](#footnote-32)
2. The relevant elements of this new legislative regime were:
3. The earlier prohibition against obtaining a patent on medicines was eliminated;[[33]](#footnote-33)
4. The compulsory licensing regime was amended to provide patentees with an exclusivity period of 7 to 10 years from the date of the notice of compliance for the medicine in question in accordance with the regulations established under the *Food and Drugs Act*;[[34]](#footnote-34) and
5. The Patented Medicine Prices Review Board was established; its primary function was to manage the compulsory licensing system to ensure that patented medicines were not sold at excessive prices;[[35]](#footnote-35) a new excessive price control regime was established under the Board’s direction, in addition to the compulsory licensing regime.[[36]](#footnote-36)
6. Thus, while these legislative amendments substantially increased the rights of patentees, they also introduced a new regulatory price control regime. To ensure its implementation, patentees were now required to provide the Board with information concerning the price at which the medicine was sold both in Canada and elsewhere, on revenues from sales of the medicine in Canada, and on the cost of making and marketing the medicine in Canada.[[37]](#footnote-37)
7. If the Board was of the view that a medicine related to a patented invention was sold at an excessive price, it could then allow compulsory licences for the medicine to be issued or order the patentee to reduce its price “so that the maximum price at which the medicine is sold … is not, in the opinion of the Board, excessive”.[[38]](#footnote-38)
8. The relevant factors allowing the Board to determine whether a medicine sold in any market in Canada is being or has been sold at an excessive price are the following:[[39]](#footnote-39)
9. the prices at which the patentee sold the medicine during the previous five years;
10. the prices of other medicines in the same therapeutic class sold during the previous five years;
11. the prices at which the medicine and other medicines in the same therapeutic class were sold in countries other than Canada during the previous five years; and
12. the Consumer Price Index for Canada.

Where, after taking these factors into consideration, the Board was unable to determine whether the price was excessive, it could take into consideration the costs of making and marketing the medicine and other factors that it deemed relevant or that were prescribed by regulation.[[40]](#footnote-40)

1. These are essentially the same factors as those set out in the *Patent Act* in its current form.[[41]](#footnote-41)
2. The constitutional validity of the 1987 legislative reform was also the subject of contestation, which the Manitoba courts dismissed in *Manitoba Society of Seniors*.[[42]](#footnote-42) I will return to this as well.

*The 1993 Act*

1. Another legislative reform was introduced by the *Patent Act Amendment Act, 1992*,[[43]](#footnote-43) assented to on February 4, 1993. The enactment of the 1993 *Act* coincided with Canada’s participation in several international commercial negotiations, including those surrounding the *Agreement on Trade-Related Aspects of Intellectual Property Rights*[[44]](#footnote-44) (“TRIPS”), adopted under the auspices of the World Trade Organization and the North American Free Trade Agreement[[45]](#footnote-45) (“NAFTA”). The commercial obligations that Canada committed to in the context of these negotiations were then incompatible with the compulsory licensing regime for patented medicines. Accordingly, amendments to the *Patent Act* were required to terminate it.[[46]](#footnote-46)
2. Further to the abolition of the compulsory licensing regime, the regime managed by the Board was now limited to controlling excessive prices for patented medicines. To that end, the regime was enhanced to allow the Board to intervene not only in the case of existing excessive prices,[[47]](#footnote-47) but also to require compensation from patentees when the price of the medicine exceeded established thresholds,[[48]](#footnote-48) and to allow the introductory prices of new medicines to be monitored.[[49]](#footnote-49)
3. Because the 1993 legislative amendments are the foundation of the current regime, I will address them in detail in subsection “B” below. Last, I note at the outset that these amendments were held to be constitutionally valid by the Federal Court of Appeal in *Sandoz/Ratiopharm* in 2015,[[50]](#footnote-50) a judgment to which I will also return.

*The 2017 Act*

1. The *Act* was again amended in 2017 by the *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*[[51]](#footnote-51) to incorporate a supplementary protection regime for medicinal ingredients to take into account Canada’s obligations in the context of the economic and trade agreement reached with the European Union. Let us consider this.
2. For pharmaceutical patents, the period during which the privileges attached to a patent may be exercised is often in fact shortened because any new medicine must be evaluated by the regulatory authorities to determine its effectiveness and its safety. In Canada, this evaluation process is regulated in accordance with the provisions of the *Food and Drugs Act* and of the *Food and Drug Regulations*.[[52]](#footnote-52) It is not unusual for that process to span several years. The patentee of a new medicinal ingredient must often wait a long time before being able to make, use, and sell its invention.
3. Like other countries, and in accordance with its international obligations, in 2017, Canada implemented measures to compensate for the delay in granting authorizations to market medicines containing new medicinal ingredients. Certificates of supplementary protection were thus introduced into the *Patent Act* to allow patentees to obtain a supplementary protection period that could extend up to two years.
4. The special regime to control excessive prices for patented medicines was also amended at that time to expand the Board’s jurisdiction to medicines concerned by these certificates of supplementary protection. In addition, a new compulsory licensing regime was introduced into the *Patent Act*, applicable in cases of abuse of patent rights referred to in a certificate of supplementary protection.[[53]](#footnote-53)
5. ***The current legislative and regulatory regime***
6. Medicines may be patented if they are the result of an invention. The patent may concern the medicine’s active ingredient, or its formulations, manufacturing methods, and uses.
7. The purpose of the patent regime is to stimulate innovation through the disclosure of patented inventions in exchange for a monopoly in favour of patentees for a specific term, which has been fixed at 20 years since October 1, 1989.[[54]](#footnote-54) To this end, section 42 of the *Patent Act* grants the patentee rights, that is, the exclusive privilege, for the term of the patent, to make, construct, use, and sell the invention to others.
8. This monopoly, established by law, confers an undeniable commercial privilege to the patentee.[[55]](#footnote-55) That is the intended effect of the patent regime.
9. However, that monopoly is subject to abuse by the patentee, in particular when the patentee does not meet the demand for the product or the patented process.[[56]](#footnote-56) The *Patent Act* in fact defines abuse of patent in section 65[[57]](#footnote-57) and allows the Commissioner of Patents to remedy such abuse through various mechanisms, in particular by granting a licence to a third person on the terms the Commissioner deems expedient,[[58]](#footnote-58) or by ordering the patent to be revoked,[[59]](#footnote-59) as set out in section 66 of the *Act*.
10. Nothing seems to prevent the application of these provisions of the *Patent Act* to patented medicines. In fact, as mentioned above, since 2017, section 127 of the *Patent Act* explicitly provides for it with respect to medicines subject to a certificate of supplementary protection.
11. That being said, in addition to this regime related to the abuse of patent, a special regime for patented medicines is set out in sections 79 to 103 of the *Patent Act*. As noted in the overview of the history of the *Act*, this special regime developed in parallel to the other regime concerning abuse of patent. The reason for this is quite simple. The monopolies granted on medicines by patents raise questions of public interest specific to the pharmaceutical sector, given that the health of Canadians is at issue.[[60]](#footnote-60) A special regime to control abuses resulting from the monopoly granted by a pharmaceutical patent is therefore considered necessary to protect the Canadian public.
12. This special legislative regime replaced the former compulsory licensing regime that had become inoperative as a result of Canada’s international obligations. Its purpose is to prevent patented medicines from being sold at excessive prices.[[61]](#footnote-61) The *Patent Act* does not define an excessive price, but it can be understood from the factors set out in the *Act* that it is a price that, without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada.
13. The principal elements of the regime include an obligation to disclose prices as well as control mechanisms.
14. With respect to the disclosure obligations, subsection 80(1) of the *Patent Act* and the *Patented Medicines Regulations* state that the patentee[[62]](#footnote-62) must provide the Board with the information necessary to allow it to implement the regime. In particular, such information concerns the identity of the medicine,[[63]](#footnote-63) the price at which it is sold on the Canadian markets, and the price at which it is sold on the foreign markets identified by the *Regulation*, that is, (for the time being) France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.[[64]](#footnote-64) The information on the price at which the medicine is sold in Canada and elsewhere must concern sales made by the patentee itself or, in other words, at the ex-factory price.[[65]](#footnote-65)
15. As for the control mechanisms, subsection 85(1) of the *Patent Act* sets out the factors that the Board must take into account to determine whether a medicine is being or has been sold at an excessive price in any market in Canada. These are essentially the same factors established since the Board’s creation in 1987:[[66]](#footnote-66)
16. the prices at which the medicine has been sold in the relevant market;
17. the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
18. the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
19. changes in the Consumer Price Index; and
20. the other factors specified by regulation, it being noted that no additional regulatory factor was established before the *2019 Regulatory Amendments*.
21. Where, after taking these factors into consideration, the Board is unable to determine whether the medicine is being or has been sold at an excessive price, the Board may take into consideration the costs of making and marketing the medicine.[[67]](#footnote-67) Note that the Board cannot take into consideration research costs other than the Canadian portion of the world costs of the research that led to the invention, development, or commercialization of the medicine, calculated in proportion to the ratio of sales by the rights holder in Canada to total world sales.[[68]](#footnote-68)
22. Applying these factors, where the Board finds that a patentee is selling the medicine in any market in Canada at an excessive price, the Board may direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to a specified level that the Board considers not to be excessive.[[69]](#footnote-69)
23. Moreover, when the excessive price is related to past sales, the Board may also direct the patentee to adopt compensatory measures, including: (a) reducing the price at which the patentee sells the medicine in question in any market in Canada, to the extent and for the period that are specified in the order; (b) reducing the price at which the patentee sells, in any market in Canada, any other medicine to which a patented invention of the patentee pertains, to the extent and for the period that are specified in the order; and (c) paying the Government of Canada a compensatory amount that is specified in the order.[[70]](#footnote-70)
24. In addition, if the Board is of the opinion that the patentee has engaged in a policy of selling the medicine at an excessive price, it may direct the patentee to do one or more things to offset up to twice the amount of excess revenues derived from the sale at an excessive price.[[71]](#footnote-71)
25. The terms of application of the regime are set out in the Board’s guidelines adopted in accordance with subsections 96(4) and (5) of the *Patent Act*. Although these guidelines are not formally binding, they are in fact the core of the excessive price control regime implemented by the Board. The importance of these guidelines for the purpose of the special regime established by the *Patent Act* is reflected in the Board’s statutory duty, before it issues any guidelines, to consult with the federal minister responsible, all provincial ministers responsible for health, and such representatives of consumer groups and representatives of the pharmaceutical industry as the federal minister may designate for that purpose.[[72]](#footnote-72) These are the same extensive consultation mechanisms as those that must be undertaken prior to the enactment of regulations by the Governor in Council in accordance with paragraphs 101(1)(d), (f), (h), and (j) of the *Patent Act*.[[73]](#footnote-73)
26. Since its creation, the regime administered by the Board is based largely on the application of the guidelines. This is achieved mainly through notices to patentees regarding the suggested introductory price of a patented medicine established on the basis of the guidelines and the voluntary compliance undertakings subscribed to by the pharmaceutical companies when the guidelines indicate that the price of a medicine is excessive. The Board’s intervention by means of an order following a hearing is thus rather rare. The regime is essentially based on the principle that the pharmaceutical companies will voluntarily comply with the prices established in accordance with the formulas set out in the Board’s guidelines.[[74]](#footnote-74)
27. In the guidelines in force before the *2019 Regulatory Amendments*[[75]](#footnote-75)(the “current guidelines”), the Board states that it “determines the Maximum Average Potential Price and the Non-Excessive Average Prices at which these medicines can be sold in Canada”.[[76]](#footnote-76) The methodology established in the current guidelines to determine these prices is rather complex. It consists of precise calculations that are largely based on convoluted formulas and tests, applied mechanically.
28. For our purposes, it is sufficient to note that the Board conducts a review to determine the therapeutic improvement of a new medicine compared to existing drug products. The level of therapeutic improvement of a patented drug product is used to determine the maximum average potential price. The levels of therapeutic improvement are classified as either breakthrough, substantial improvement, moderate improvement, or slight or no improvement. Various tests are applied according to the level of therapeutic improvement to determine the maximum average potential price at which a new patented medicine may be sold and to determine whether or not the existing price may be considered excessive.
29. In any event, the maximum average price of a new medicine must not exceed the price obtained using the international price comparison test established by the Board by comparing prices with the countries listed in the *Regulation*, that is, France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States.[[77]](#footnote-77)
30. The price of an existing medicine will be presumed to be excessive if the national average transaction price exceeds the change in the Consumer Price Index after the application of an adjustment methodology, or, as the case may be, if it exceeds the threshold of the international price comparison test.
31. The Regulatory Impact Analysis Statement appended to the *2019 Regulatory Amendments* briefly describes the current process followed by the Board:[[78]](#footnote-78)

Under the [Board’s] current practices, new patented medicines are assessed for the degree of therapeutic benefit they provide relative to existing medicines on the market. Depending on the outcome of that process, patentees are expected to set their prices with regard to a price ceiling for new patented medicines that is based either on the price of that same medicine in the PMPRB7 countries [France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States], the price of medicines in Canada in the same therapeutic class, or some combination of the two. Once a patentee sets a medicine’s introductory price in relation to that ceiling and it enters the market, the patentee may increase its price but subject to limitations based on changes in the Consumer Price Index.

1. To provide a concrete illustration of the application of the regime applicable prior to the *2019 Regulatory Amendments*, it is useful to refer to the simplified example of the process described in the affidavit dated March 13, 2020, provided by a senior officer of the Board, Guillaume Couillard, Director, Regulatory Affairs & Outreach:[[79]](#footnote-79)

[translation]

62. In this [simplified] example, the staff is assessing the fictional medicine MED. The patentee PatCo filed the prescribed information regarding MED shortly after making its first sale of MED in Canada. It did so because it holds a patent for an invention pertaining to a medicine.

63. First, the medicine is subject to scientific review by the advisory panel (HDAP) so that it may be assigned a level of therapeutic improvement and to identify other medicines that may be considered therapeutically comparable. The HDAP reviews the scientific information pertaining to the medicine and may consult other experts on the medicine. It may also obtain data from PatCo and from the staff.

64. For this example, we will assume that, on the basis of all the relevant available information, the HDAP found that MED is a moderate improvement and MEDCompA and MEDCompB are the only therapeutically comparable medicines (the therapeutic comparators). I note that these findings are often the subject of significant debate and that they affect the way the staff then reviews the price of the medicine under the current guidelines. I will set out the difference between the possible results below.

65. In this example, we will also assume the following in regard to MED:

a. MED is sold in five (5) of the seven (7) countries on which PatCo must report (i.e., the “PMPRB7”) at the following gross prices (public list) (in CAN$): United States, $20; Switzerland, $15; Germany, $10; United Kingdom, $8; France, $5.

b. MED’s therapeutic comparators, MEDCompA and MEDCompB, are sold in Canada for an equivalent therapeutic treatment at a gross price of $7.00 and $8.00, respectively.

66. Once the scientific review has been completed, the staff will review MED’s introductory price (that is, the price of its first sales). Because the level of improvement of MED’s price is moderate, the staff will compare the price of MED in Canada to the price of MED elsewhere in the world (that is, the international prices available for MED in the PMPRB7) and the price in Canada of medicines therapeutically comparable to MED.

67. This comparison is conducted using MED’s net Canadian price, that is, its price after deducting any rebates, discounts, or other reductions listed in subsection 4(4) of the current *Regulations*. However, gross prices are used for MED internationally and for its Canadian therapeutic comparators. PatCo’s lowest net price will therefore be compared to higher gross prices.

68. According to the current guidelines, in view of MED’s moderate therapeutic improvement, the staff will find that MED’s price may be considered excessive if its average net price exceeds the highest of the following two amounts:

a. The highest therapeutic comparator, which would be MEDCompB at $8.00; and

b. The midpoint between the price identified at point (a) and MED’s median international gross price. The median price is the price in Germany of $10.00. The midpoint is therefore $9.00 (that is, the midpoint between $8.00 and $10.00).

69. The staff will therefore find that MED’s net introductory price in Canada may be considered excessive if it is greater than $9. The review of the introductory price ensures that subsequent reviews do not use a potentially excessive price as a starting point.

70. As noted above, the level of therapeutic improvement assigned to MED will have an impact on the price that the staff will consider excessive; in other words, the higher the level of therapeutic improvement, the higher the applicable price ceiling. In this example, in light of the tests established in the current guidelines for the other levels of therapeutic improvement, the staff would find that MED’s introductory price may be considered excessive if it is greater than: $10 for a breakthrough; $10 for a substantial improvement; and $8 for slight or no improvement.

71. After conducting this preliminary assessment, the staff will re-examine MED’s price every year. This annual review is the same for all medicines, regardless of the level of therapeutic improvement attributed. The staff will compare the variations in the medicine’s average net price in Canada with the Consumer Price Index (CPI). For example, and greatly simplifying the assessment based on the CPI, if it is 3% each year, the staff would find that MED’s average net price could not be considered excessive if it does not increase more than 3% every year. In other words, MED’s average price could increase to $9.27 after the first year, to $9.55 after the second year, to $9.84 after the third year, etc. However, these possible increases are limited by MED’s highest international price, which is $20 (i.e., MED’s price in the United States).

72. Except for the scientific review, a large part of this assessment is conducted automatically by computers on the basis of data submitted electronically by PatCo. The staff’s involvement in reviewing the price of medicines will increase if and when factors triggering an investigation are present. The same tests described above will be applied in the investigation, but the review will be more thorough.

***C - The new regulatory framework established by the 2019 Regulatory Amendments***

1. The *2019 Regulatory Amendments* introduced significant changes to the regime.
2. The new *Regulations* add additional factors to those established under subsection 85(1) of the *Patent Act* to determine whether the price of a medicine sold in any Canadian market is excessive, that is:[[80]](#footnote-80)
3. the medicine’s pharmacoeconomic value in Canada;
4. the size of the market for the medicine in Canada; and
5. the gross domestic product in Canada and the gross domestic product per capita in Canada.
6. These new factors will result in a significant reduction in the price of patented medicines in Canada, which the Government of Canada estimates at $3.8 billion over 10 years.[[81]](#footnote-81) As we will see, these significant price reductions will result from the application of arbitrary price reductions ranging from 20% to 50% for certain medicines in accordance with their pharmacoeconomic value and from 0% to 35% for others, depending on the size of their market in Canada.
7. The list of foreign countries used to compare the price of the medicine was also amended to exclude the United States and Switzerland – countries that have a large innovative pharmaceutical industry and pricing policies that are favourable to it – and to add Australia, Belgium, Spain, Japan, Norway, and the Netherlands,[[82]](#footnote-82) countries with pricing policies that are often perceived – rightly or wrongly – as not being favorable to this industry. The practical impact of this new list will also be to reduce the price of patented medicines, this time by $2.8 billion according to the Government of Canada.[[83]](#footnote-83)
8. New information requirements are also provided. These are intended not only to inform the Board so that it can take these new factors into account, but also to considerably modify the Board’s application of factors already provided in the legislation.
9. Thus, with respect to the price at which the medicine is sold in Canada, subsection 4(4) of the *Patented Medicines Regulations* was amended to include the obligation for patentees to disclose to the Board the prices and amount of revenues obtained for a medicine “taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine”.[[84]](#footnote-84) This is so that the Board can determine the prices and the revenues obtained by patentees taking into account confidential rebates negotiated with public insurers (the provinces) and more rarely with large private insurers, in view of the considerable quantity of medicines for which they provide total or partial reimbursement to their insureds. According to the Government of Canada, requiring patentees to report on prices and revenues that take into account these negotiated rebates should lower drug expenditures by $2 billion over 10 years.[[85]](#footnote-85)
10. As for the information related to the new factor based on the medicine’s pharmacoeconomic value in Canada, the new *Regulations* require patentees to provide the Board with every cost-utility analysis prepared by a publicly funded Canadian organization, if published and communicated to the patentee, for which the outcomes are expressed as the cost per quality-adjusted life year, commonly referred to as “QALY”,[[86]](#footnote-86) for each indication that is the subject of analysis, including any redacted portions of the analysis.[[87]](#footnote-87) These consist mainly of the analyses of the Canadian Agency for Drugs and Technologies in Health, and in Quebec, the Institut national d’excellence en santé et services sociaux (“INESSS”).
11. These analyses are intended to help the provinces assess the therapeutic effectiveness of a new medicine in relation to its price and to other medicines and treatments available for the same disease. These analyses may then be taken into consideration by the provinces when deciding whether to add a new medicine to the list of those that may be reimbursed and to establish the reimbursement levels of the medicines in question.
12. These analyses will now be provided to the Board if the cost for the medicine as identified in the analysis is, when calculated based on the medicine’s 12-month cost of use, is greater than or equal to 50% of the gross domestic product per capita in Canada at the time of publication of the analysis.[[88]](#footnote-88) These analyses will be used to establish price reduction caps of 20% to 50% for the medicines in question depending on the pharmacoeconomic value they are attributed.
13. Patentees will also have to provide the Board with information related to the new factor based on the size of the market in Canada by means of the estimated maximum use of the medicine.[[89]](#footnote-89) This information will also be used to determine the percentage of the price reduction, from 0% to 35% depending on the size of the market.
14. The manner in which the Board will apply these new price factors and use this new information is set out in the Board’s new guidelines. Once again, using highly complex formulas and tests, the application of which is essentially mechanical, the Board will use the new factor of pharmaceutical value to impose downward price adjustments ranging from 20% to 50% for medicines whose individual 12-month cost of use is greater than or equal to 50% of the gross domestic product per capita in Canada.[[90]](#footnote-90) The Board will also impose significant downward price adjustments of up to 25% and even 35% for medicines whose market size exceeds $50 million or $100 million annually.[[91]](#footnote-91) These downward adjustments are in addition to those arising from the new list of comparator countries and the consideration of confidential rebates negotiated with the provinces.
15. There is no doubt that this new regulatory regime will lead to impressive reductions in the prices of medicines in Canada. It will also have a considerable financial and commercial impact on the innovative pharmaceutical industry. In the Regulatory Impact Analysis Statement, it is estimated that the industry will lose $8.8 billion in revenues over 10 years.[[92]](#footnote-92) Industry representatives estimate that lost revenues will be much higher and even claim that this new regulatory regime could lead to refusals to introduce or sell certain new medicines in Canada. According to studies, lost revenues in the industry could exceed $26 billion over 10 years.[[93]](#footnote-93)
16. The issues are such that there is concern that some innovative medicines may become unavailable in Canada, with serious consequences for the health and quality of life of certain patients. There is also concern that pharmaceutical research and development in Canada will decrease considerably. I will return to these impacts in the analysis of the trial judge’s findings of fact.
17. The issues are therefore significant, which all the parties to the appeal acknowledge.

***D - Medicine price control by the provinces***

1. The provinces have implemented mechanisms to control the price of medicines reimbursed by the public drug insurance plans or required by the public hospital care system. In particular, these consist of listing agreements permitting patented and non-patented medicines to be added to the list of medicines reimbursed by a province’s insurance plan or acquired by a province’s hospitals.
2. These negotiations are usually held with the pan-Canadian Pharmaceutical Alliance, which represents the provinces. Each province can pursue its own negotiations. Before reaching an agreement, the health care technology assessment agencies make recommendations regarding the price of a medicine on the basis of studies permitting an assessment of its therapeutic value, the reasonableness of its price in relation to its cost-effectiveness, and the budgetary impact on the province. As noted above, in Quebec, the INESSS is mandated to make such recommendations.
3. To use the example of Quebec, the INESSS first assesses the therapeutic value of the medicine. If it considers that its value has been demonstrated, it then assesses the reasonableness of the price, the cost-effectiveness ratio of the medication, the impact that entering the medication of the list of insured medications will have on the other components of the health system, and the advisability of entering the medication on the list.[[94]](#footnote-94) The provincial health minister decides whether to enter the medication on the list, taking into account the recommendation of the INESSS.
4. For its medication to be accredited, the manufacturer must also comply with the requirements of the *Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications*.[[95]](#footnote-95) The *Regulation* provides that the manufacturer must undertake to respect the guaranteed selling price, which must not be higher than any selling price granted by the manufacturer for the same drug under other provincial drug insurance programs.
5. The Quebec Minister of Health may also, before entering a medication on the list, make a listing agreement with its manufacturer. The purpose of such an agreement may be to provide for the payment of a rebate according to the volume of sales. That being said, the price of the medication indicated on the list does not take into account the rebates paid pursuant to the agreement, which is confidential.[[96]](#footnote-96)
6. Further to her analysis of the evidence, the trial judge found that these mechanisms are effective means of ensuring that that the prices of medicines covered by the public plans are reasonable.[[97]](#footnote-97)

**II - JUDICIAL PROCEEDINGS**

1. In response to the *2019 Regulatory Amendments,* on August 22, 2019, the appellant pharmaceutical companies brought legal proceedings before the Quebec Superior Court seeking to have not only those amendments declared unconstitutional, but also sections 73 to 103 of the *Patent Act* concerning the special regime for patented medicines and the entire *Patented Medicine Regulations*.[[98]](#footnote-98)
2. They submit that the federal jurisdiction over patents does not permit the federal government to fix a maximum price at which a good is sold when one of its components is patented and it is sold in the context of a private transaction. They argue that the federal jurisdiction is limited to the conditions for obtaining a patent, to defining the resulting rights, within the limits arising from Canada’s international obligations, to the sanctions in the case of abuse, to the fees for maintaining the patent, and to the remedies for patent infringement. Moreover, in the event of abuse, the intervention of the federal government is limited to measures directly related to patents, such as the revocation of a patent or the granting of a compulsory licence, not the product itself.
3. They add that since the Board’s creation in 1987, it has been controlling the price of medicines under the pretext of preventing the sale of patented medicines at an excessive price. However, they claim that it has no constitutional jurisdiction to do so. Only abuse of patent falls within federal jurisdiction. Otherwise, it is the provinces that can regulate the price of medicines, patented or not, under their general jurisdiction over property and civil rights, hospitals, and health. In fact, the provinces already tightly control the price of patented medicines through various mechanisms, in particular though their purchasing policies.
4. The appellant pharmaceutical companies submit that the Board is simply regulating the price of patented medicines, irrespective of any notion of abuse of patent or even excessive prices. They state the following in their originating application:[[99]](#footnote-99)

[translation]

1. In the decisions rendered by the Board, when a medicine is sold in Canada at a price that is higher than other medicines of the same class or when its price is higher than the median of the group of reference countries, the Board finds that the price is “excessive” and fixes a maximum [translation] “non-excessive” price that the patentee may not exceed;
2. In all decisions rendered by the Board, the only consideration analyzed is the price of the medicine in relation to thresholds set out in the guidelines and nothing else. The Board conducts no analysis to verify whether the patentee abused its patent or if, in the presence of other conditions, the price is truly “excessive” to the point that it is akin equivalent to an abuse of patent;
3. Once the patentee increases its price in excess of the annual increase in the Consumer Price Index in one year, the Board finds that the price is “excessive”, without verifying whether there is any economic justification for such increase;
4. The Board does not even analyze the factors relevant to determining the price of a product from an economic perspective, such as the costs of development or the exchange rate that could explain an increase in price beyond the median for a specific year. Nor does it consider the reasons that might explain why a price is lower in other markets or in the group of reference countries.
5. The appellant pharmaceutical companies add that the *2019 Regulatory Amendments* reinforce the unconstitutionality of the Board’s mandate because they simply seek to impose a substantial reduction in the price of the patented medicines sold in Canada, a function that has no rational connection with the federal jurisdiction over patents.
6. Several groups, including patient associations, intervened before the Superior Court to support the pharmaceutical companies’ applications, that is, the Canadian Cystic Fibrosis Treatment Society, The Intellectual Property Owners Association, Cystic Fibrosis Canada, Canadian Organization for Rare Disorders, and BIOTECanada. The Attorney General of Quebec was also an intervenor in the proceeding.
7. Abundant documentary evidence was adduced at trial, including numerous expert reports. Hearings limited to the representations and arguments of counsel were held before the Superior Court from September 28 to October 2, 2020, and from November 17 to 20, 2020. The trial judgment was rendered on December 18, 2020.

**III - THE TRIAL JUDGMENT**

1. The judge first analyzed the abundant evidence submitted before her. It is not necessary to repeat that analysis on appeal because it is sufficient to refer to the summary of the evidence set out in the trial judgment, which is consistent with the factual record submitted by the parties. In fact, none of the parties contests the judge’s summary of the evidence.
2. To identify the pith and substance of the impugned provisions, the judge followed a two-step process. First, she characterized sections 79 to 103 of the *Patent Act*  and the *Patented Medicines Regulations* as it read before the *2019 Regulatory Amendments* – which she called Regime 1 – and then characterized the new regime arising from these amendments – which she called Regime 2.
3. Addressing the wording of the existing regime (Regime 1), the judge found, referring extensively to the Board’s current guidelines, she found that its purpose was to regulate the price of patented medicines so as to ensure that they are not excessive. She stated the following:[[100]](#footnote-100)

[translation]

[239] Parliament did not define the expression “excessive price” but instead left it up to the Board to determine whether such “excess” existed, in particular through a comparative study of the prices of the medicines in question and those of the same therapeutic class, in Canada and in seven other countries.

[240] In addition, as the process of reporting information by patentees and the review of prices by the Board is relatively complex, the Board established non-binding Guidelines under s. 96(4) of the Act to aid in understanding the application of certain relevant provisions of the Act and the Regulations.

[241] The Guidelines currently in force related to Regime 1 show that in several circumstances, the median price for a medicine (or medicines of the same class) in the seven comparator countries provided in the schedule to the Regulations is used to calculate the maximum price above which a price will be considered excessive. Therefore, the price in Canada must necessarily be lower than in three (of the seven) countries in which the prices are the highest.

[242] Consequently, in light of the wording of ss. 79 to 101 of the *Act* and the wording of the *Regulations*, the purpose of Regime 1 is to regulate the price of patented medicines so as to ensure that they are not excessive, or in other words, that they are acceptable and reasonable. The Guidelines confirm this interpretation

[Citations omitted.]

1. In her analysis of the evidence, the judge found that the impact of the regime might be inconsistent with the legislative and regulatory wording. The evidence shows that the Board establishes the thresholds of prices deemed “excessive” almost mechanically, irrespective of the commercial realities of the markets in question, which – according to the judge – leads it to find that prices are “excessive” in arguable cases, such as in situations where the price in Canada exceeds the international median by as little as 0.0008% or when the price increase is wholly attributable to fluctuations in the exchange rate of the Canadian dollar.[[101]](#footnote-101)
2. However, because the pharmaceutical companies generally chose not to contest the Board’s arguable or problematic decisions regarding excessive prices, but instead chose to abide by their voluntary compliance undertakings in such situations, the judge was of the view that they could not complain about it now.
3. The judge therefore found that the pith and substance of the current regime was that set out in the wording of the *Act* and the *Regulations* and is thus to control prices of patented medicines to ensure that they were below a threshold that the Board deems excessive. The objective is to prevent overly high prices due to the abolition of the patented medicines compulsory licensing regime.[[102]](#footnote-102)
4. As for the pith and substance of the *2019 Regulatory Amendments*, the judge had no hesitation in finding that [translation] “Parliament’s objective is to significantly reduce the price of patented medicines”,[[103]](#footnote-103) because in light of the evidence, [translation] “the objective of lowering the price of patented medicines could not be clearer”.[[104]](#footnote-104) The federal government is of the view that the cost of patented medicines, especially medicines sold at high prices, has continuously increased and that it is necessary to take steps to significantly reduce those prices.[[105]](#footnote-105)
5. While the proposed amendments will significantly reduce the price of patented medicines in Canada, the judge also found that the evidence showed that several foreseeable, adverse effects would result from these regulatory amendments, in particular the abandonment or decrease of policies granting confidential rebates to the provincial drug insurance plans, a significant decrease in clinical studies conducted in Canada, and the delay, sometimes indefinite, in introducing certain new medicines in Canada, with deplorable consequences on several categories of patients suffering from rare diseases, a decrease in the activities and even the possible closure of several small innovative pharmaceutical companies. It is worth reproducing the trial judge’s conclusions in this regard:[[106]](#footnote-106)

[translation]

[279] In addition, the requirement set out in the Amendments to disclose to the Board the net prices after deducting the confidential rebates granted to the provincial drug insurance plans means that the applicants will no longer be in a position to offer such rebates (because of the impact of the disclosure on prices in the Canadian private insurance market and markets outside Canada). These rebates often represent an average reduction of 25% to 30% of the prices indicated on the provincial forms (Lists). They are not considered in the price reimbursed by public insurance plans, but are instead claimed by them from the manufacturers further to sales made.

…

[282] Moreover, according to expert Palmer, the Amendments have already caused a significant reduction of clinical trials being conducted in Canada. The drop in the annual number of such trials conducted from 2013 to 2018 and the corresponding number from February 2019 to February 2020 is significant and a direct result of the anticipated concerns of the innovative pharmaceutical industry regarding the impact of the Amendments. The same is true with respect to the availability of new medicines in Canada; a marked reduction in 2019 is noted.

[283] According to the applicants’ sworn statements, which are based on the 2019 draft Guidelines, the Amendments will result in very significant price reductions. In certain cases, the expected reductions will be so drastic that the introduction of some medicines in Canada will be delayed, sometimes indefinitely. The decision to obtain Canadian patents could even be questioned in some instances.

[284] The sworn statements of the representatives of EMD Serono, Avir, and Theratechnologies speak volumes as to the even greater effect of the Amendments (if applied on the basis of the 2019 draft Guidelines) on smaller firms or those that develop medicines to treat rare diseases. They are disappointed to have to abandon their plans to introduce certain new medicines in Canada due to the planned reduction of “excessive” prices. Avir’s representative even fears for the firm’s survival.

[285] Finally, the evidence filed by the intervenor Canadian Cystic Fibrosis Treatment Society also describes the patients’ perspective of the deplorable consequences that the Amendments have on access in Canada to medicines to treat rare diseases.

[286] Thus, it seems that the expected price reductions have already had a negative effect in Canada on the quantity of clinical research being conducted and on the availability of particularly costly medicines to treat rare diseases.

[Emphasis added; citations omitted.]

1. However, the judge said that the wisdom and efficacy of the new regulatory regime were not relevant to the constitutional analysis and thus found that the pith and substance of the proposed regulatory amendments is essentially the same as that of the current regime, that is, to control the excessive prices of patented medicines. She stated:[[107]](#footnote-107)

[translation]

[287] In light of all the evidence, the pith and substance of the Amendments is increased control of the price of patented medicines through additional tools to ensure the reasonableness of prices, especially the prices of a certain category of medicines sold at very high prices. These additional tools hinge on an amended list of comparator countries, additional factors to consider (pharmacoeconomic value of the medicine, size of the market for the medicine in Canada, gross domestic product in Canada, and gross domestic product per capita in Canada), and new data to provide to the Board regarding sales, taking into account the confidential rebates granted to the provincial prescription drug insurance plans. These factors are still intended to determine the threshold above which the price of a medicine will be excessive (there is no distinction between Regime 2 and Regime 1 in regard to this requirement set out in ss. 83(1) and 85(1) and (2) of the *Act*).

[Emphasis added.]

1. Having established the pith and substance of the impugned provisions, the judge proceeded to classify them constitutionally. After an extensive review of the relevant case law, she stated that the real issue related to that classification was whether the Board was engaging in an exercise of fixing the prices of patented medicines – which is not a matter of federal jurisdiction – or rather an exercise of controlling excessive prices of these medicines that is akin to abuse of patent.[[108]](#footnote-108)
2. The judge found that the sale of patented medicines at excessive prices is a form of abuse of patent.[[109]](#footnote-109) Controlling abuse of patent has always been a part of the federal jurisdiction over patents, as the courts have confirmed on several occasions. The judge found that, at the very least, the current regime (which she called Regime 1) falls within the federal jurisdiction. She found this to be the case despite the fact that the Board’s application of this regime may raise serious questions.[[110]](#footnote-110)
3. However, the judge noted that the same could not clearly be said with respect to the *2019 Regulatory Amendments*.[[111]](#footnote-111) That being so, she found that the amendments still concern excessive prices:[[112]](#footnote-112)

[translation]

[391] Indeed, the Regulatory Impact Analysis, under the heading “Canada’s changing market and rising medicine costs”, informs us that the prices of an increasing number of medicines in Canada have reached significant peaks in that more and more higher-cost medicines are being developed (biologics, genetic therapies targeted to smaller patient populations, medicines prescribed for rare diseases), and the risk of excessive pricing is often greater for these products since they have few, if any, substitutes, and thus little competition. Remarkably, between 2007 and 2017, the number of medicines in Canada with annual per-patient treatment costs of at least $10,000 swelled from 20 to 135. In addition, the prices of medicines in Canada are comparatively high as, among the OECD countries, only the United States, Switzerland, and Japan spend more per capita for medicines than Canada.

[392] The concerns of the Canadian government with respect to the risk of excessive prices of certain patented medicines are real and sincere, and the Amendments seek to respond to that situation, which does not appear speculative and has a direct connection with patents.

[393] It is hard not to see a real and rational connection between such significant prices and the existence of patents (conferring a statutory monopoly), even if patents are of course only one component (added to, *inter alia*, production and marketing costs, the size of the market, and part of the sums invested in R&D) in the establishment of prices by manufacturers.

[394] Further to the government’s observation that the price of certain patented medicines is excessive (in the sense of unacceptable and unreasonable) and where it appears logical to conclude that the existence of patents is the cause, there is reason to infer that the Amendments are genuinely connected to patents and fall within that federal jurisdiction.

[395] Indeed, in the Court’s view, the addition of pharmacoeconomic value factors (which is public information), market size, gross domestic product, and gross domestic product per capita seems relevant in that these factors may further inform and more firmly anchor the analysis the Board must perform to determine whether the prices of medicines are excessive (in particular for the higher-cost medicines to which the Regulatory Impact Analysis refers). The same is true with respect to the change in the list of comparator countries, which is not static and may certainly evolve to more accurately reflect the Canadian situation.

1. To draw this conclusion, the judge decided not to consider the Board’s new guidelines. She instead proceeded to harshly criticize the guidelines and the Board by warning it not to use the new factors for the purpose of fixing [translation] “an ideal price or the lowest possible price, because the analysis would then be clearly constitutionally invalid, having no significant connection to patents”.[[113]](#footnote-113)
2. In this respect, the judge directly criticized the Board’s new guidelines and even invited the Federal Court to quash the Board’s decisions made pursuant to their application:[[114]](#footnote-114)

[translation]

[400] The same concern arises from the drastic price reductions expected by the applicants and their experts in light of the explanations set out in the 2019 and 2020 draft Guidelines. Because of their significance, these reductions are likely to cause problems with access to certain medicines and for the survival of certain firms, as well as call into question the need for patents in certain cases. These consequences raise concerns that in implementing the Amendments, the Board is moving away from the control of excessive prices to embrace the outright control of prices (a power it does not have). It is true that these drafts were replaced by the 2021 Guidelines that are to come into force on January 1, 2021, which contain several relaxations favourable to patentees compared with the two initial drafts. However, the core concerns with respect to the 2019 and 2020 draft Guidelines, summarized on page 9 of Report P-230 prepared by expert Palmer, are essentially unchanged in the 2021 Guidelines, as counsel for the AGC confirmed in reply to a question from the Court: essentially, (1) the ceiling price of patented medicines whose market size in Canada is greater than $50,000,000 per year will be reduced by 20% to 50% depending on the therapeutic level, and (2) the ceiling price of medicines whose annual cost per person is more than $90,000 will be reduced by the same percentages, and the concept of QALY will apply to that analysis.

[401] The Amendments do not dictate the manner in which the factors lead to the conclusion that a price is or is not excessive; the weight attributed to each factor falls within the expertise and discretion of the Board, guided by its statutory mandate to ensure that patentees do not use their patents to sell their medicines at excessive prices. Thus, the Board cannot use the Guidelines, which allow it to analyze the new factors and the prices in the 11 comparator countries, for any purpose other than to determine the amount at which the price of a patented medicine becomes excessive in Canada (ceiling price). If the implementation of this analysis becomes a disguised way of engaging in the outright control of prices or fixing the lowest prices possible, regardless of whether excessive prices existed, it would be unacceptable, because there would be no significant connection with the jurisdiction over patents. In such case, the Board’s decision could be quashed in judicial review proceedings before the Federal Court.

[402] The concerns of the applicants and the intervenors appears to arise from the risk, in view of the draft Guidelines and the final 2021 version, that despite the use of the expression “excessive price” in the Act, the new regulatory factors prescribed by the Amendments perniciously distort this expression in practice and replace it with price fixing. Counsel for the applicants refer to the Trojan horse in describing this phenomenon.

[Emphasis added; citation omitted.]

1. Nevertheless, the judge refused to consider the Board’s new guidelines in her constitutional analysis because she considered them distinct and detached from the *Patent Act*, the *Patented Medicines Regulations*,and the *2019 Regulatory Amendments*. In the judge’s view, it will be up to the Federal Court to set aside these guidelines, if need be:[[115]](#footnote-115)

[translation]

[403] It is not up to the Court, at this stage, to rule on the constitutionality of the 2021 Guidelines or the 2019 and 2020 draft Guidelines. Indeed, the analysis of the constitutional validity of the Amendments can be distinguished from their implementation through the non-binding Guidelines, which the Board is not required to make or apply, and which, strictly speaking, are not rules of law. To the extent that the Amendments may be applied in a constitutional manner, that is, to prevent prices that are excessive in the sense of unacceptable and unreasonable (by determining price ceilings), rather than for the purpose of fixing prices (so that they are as low and as affordable as possible), their constitutional validity must be recognized independently of what the 2021 Guidelines (which are foreign to Parliament and up the Board to implement) may provide.

…

[406] During an application for judicial review of a Board decision, the Federal Court (or possibly the Superior Court) could consider the administrative implementation of the Amendments and rule on the appropriateness of applying the 2021 Guidelines in a specific situation to determine whether recourse to the Guidelines exceeds the control of excessive prices and is therefore unconstitutional.

[Emphasis added.]

1. However, she decided to declare unconstitutional the new paragraphs 4(4)(a) and (b) introduced into the *Patented Medicines Regulations* by the *2019 Regulatory Amendments* and concerning the Board’s consideration of the confidential rebates granted to the public drug insurance plans. According to the judge, the Board’s role would be [translation] “superfluous” in the case of medicines reimbursed by the provincial public plans.[[116]](#footnote-116)
2. Contrary to her previous conclusion in this regard, the judge acknowledged that in the case of requests for information concerning the confidential rebates, the purpose of the new regulatory regime is to fix prices so as to significantly reduce prices, rather than to control excessive prices:

[translation]

[420] It is unreasonable for the Board, whose role is limited to preventing excessive prices (which remains useful with respect to medicines reimbursed by private insurance companies or paid for by Canadians (1.8%) who pay for the cost of their medicines themselves), to have access to information concerning the confidential rebates negotiated between manufacturers and public prescription drug insurance plans, knowing that it will have a negative impact on the provinces’ ability to fix [emphasis in original] the lowest possible prices through significant rebates. The Board is encroaching on the price-fixing process established by the provinces. While the federal government has jurisdiction to ensure medicines are not sold at excessive prices it cannot, in so doing, hinder the provinces’ power to fix (for the purpose of public prescription drug insurance plans) [translation] “particularly advantageous” prices due to the confidentiality of the rebates negotiated. Indeed, in practice, the disclosure to the Board of the confidential rebates and the resulting substantial reductions in prices on the private market would have the perverse effect of limiting the scope of the rebates that the provincial prescription drug insurance plans could obtain. This market reality adduced into evidence by the applicants was not contradicted.

[421] The Court is of the view that such disclosure would cause the Board’s role to shift from the control of excessive prices to the fixing of prices. These two concepts, which differ significantly in terms of the amount to gauge, are also distinguishable with respect to the constitutional division of powers (the first being directly related to patents while the second is foreign thereto, because it completely disregards the statutory monopoly).

[Emphasis added, except where indicated otherwise.]

1. The judge therefore declared the entire impugned regime constitutional, including the *2019 Regulatory Amendments*, except the new paragraphs 4(4)(a) and (b) of the *Patented Medicines Regulations*, which she declared *ultra vires*. She also ordered the provisional execution of the declaration of invalidity.

**IV - THE ARGUMENTS OF THE PARTIES**

**A- *The appellant pharmaceutical companies***

1. The appellant pharmaceutical companies submit that the special regime concerning patented or protected medicines set out in sections 79 to 103 of the *Patent Act* and the *Patented Medicines Regulations*, in its present form, in intended to control of the price of patented medicines. They add that the *2019 Regulatory Amendments* simply reinforce that control by imposing significant reductions on the price of patented medicines.
2. According to the appellants, controlling the price of medicines falls within provincial jurisdiction over property and civil rights, matters of a merely local or private nature, and the establishment, maintenance, and management of hospitals. They acknowledge that the federal government does indeed have jurisdiction to control the abuse of patent, but submit that its jurisdiction to remedy such abuse is limited to revoking the patent or granting a licence to a third person, not to directly regulate the product. They submit that the current regime and the *2019 Regulatory Amendments* are therefore unconstitutional as a whole. During the appeal hearing, their counsel drew an analogy with the federal jurisdiction over copyright, which permits the regulation of such rights and even the establishment of tariffs in connection with the exercise of such rights, but which does not, however, permit the federal government to regulate or fix the market prices of books (for example, dictionaries), paintings, or concert halls, which falls within provincial jurisdiction.

**B - *The Attorney General of Canada***

1. The Attorney General of Canada submits, on the contrary, that federal jurisdiction over patents extends to the control of [translation] “all the negative consequences that may arise from the grant of a patent”.[[117]](#footnote-117) Thus, whether the existing regime or its amendments are characterized as concerning the control of abuse of patent, the control of excessive prices, or simply the control of the price of patented medicines, it falls within the federal jurisdiction over patents of invention and discovery to the extent that it seeks to control the negative consequences that may arise from the grant of a patent. The control of excessive prices thus includes the determination of a reasonable price, which are two sides of the same coin that make up the federal jurisdiction over patents.
2. Regardless of its ultimate characterization, the regime thus falls within the federal jurisdiction over patents in view of the fact that the appellants may avoid it by renouncing their existing Canadian patents or by not patenting in Canada a medicine that they wish to sell here. In addition, if the federal government can revoke a patent, it necessarily has the lesser, included jurisdiction to control the price of patented medicines. There is therefore a direct connection between the patent granted and the federal regime regulating the price of patented medicines, as [translation] “price control is the consideration required for the benefit of patent protection”.[[118]](#footnote-118)
3. It is further alleged that the trial judge erred by invalidating the new paragraphs 4(4)(a) and (b) of the *Patented Medicines Regulations*, which requires patenteesto provide the Board with pricing information that takes into account the confidential rebates granted to public insurers. Indeed, according to the Attorney General of Canada, these paragraphs have the same objective as the regime as a whole and are therefore constitutional. Moreover, by relying on the anticipated negative incidental effects of these new paragraphs on the contracts between the pharmaceutical companies and the public and private insurers, the trial judge took into account considerations that are not relevant to the constitutional analysis.

**C - *The Attorney General of Quebec***

1. The Attorney General of Quebec does not challenge the constitutional validity of the provisions of the *Patent Act* and the *Patented Medicines Regulations* in its current form. Rather, it challenges the *2019 Regulatory Amendments*.
2. According to the Attorney General of Quebec, these amendments will transform the federal regime controlling the excessive prices of patented medicines into a regime of outright control of the prices of patented medicines, [translation] “resulting in a massive reduction in the price of patented medicines whether or not they are currently excessive”.[[119]](#footnote-119) Thus, it is alleged that the pith and substance of these regulatory amendments is the inclusion of [translation] “new criteria in the Board’s analysis to control the price of patented medicines, resulting in a significant price reduction”.[[120]](#footnote-120)
3. It is alleged that these regulatory amendments exceed the federal jurisdiction over patents of invention and discovery because, according to the case law, that jurisdiction extends [translation] “only to cases where the price of a medicine is excessive to the point of being an abuse of patent”.[[121]](#footnote-121)
4. In so doing, it is alleged that these regulatory amendments directly impinge on the provincial jurisdiction over property and civil rights and over health, thereby constituting a direct encroachment into these areas of jurisdiction.
5. The Attorney General of Quebec therefore asks the Court to declare unconstitutional the new regulatory factors that the Board must consider under the *2019 Regulatory Amendments* (the pharmacoeconomic value of the medicine in Canada, the size of the market for the medicine in Canada, the gross domestic product in Canada, and the gross domestic product per capita in Canada), as well as the new schedule containing the new list of foreign countries for the purpose of international price comparisons.

**D - *The intervenors***

*Canadian Cystic Fibrosis Treatment Society*

1. The intervenor Canadian Cystic Fibrosis Treatment Society is an association that advocates on behalf of patients suffering from cystic fibrosis, a rare, serious disease for which medical treatment can involve high annual costs. It notes in its brief that the cost of such treatment raises major ethical and budgetary issues that fall under provincial jurisdiction over health, hospitals, property and civil rights, and matters of a merely local or private nature in the province. It is concerned that the new regime introduced by the *2019 Regulatory Amendments* will delay, even prevent, access by patients suffering from rare, serious diseases to new medicines that may be able to treat their conditions.
2. Like the Attorney General of Quebec, it mainly challenges the *2019 Regulatory Amendments*, which it claims seek to regulate the price of patented medicines outright to control pharmaceutical costs and expenditures in Canada, subjects that fall under the exclusive jurisdiction of the provinces.It therefore supports the arguments of the appellants and of the Attorney General of Quebec with respect to the constitutional invalidity of the new regime. However, to avoid repeating the arguments already submitted, its brief is focussed on explaining why the trial judge should have taken the Board’s guidelines into account for the purpose of the constitutional analysis.

*Cystic Fibrosis Canada*

1. The intervenor Cystic Fibrosis Canada is a charitable organization whose primary mission is to find a cure for cystic fibrosis and to improve its treatment. Its intervention is focussed mainly on the *2019 Regulatory Amendments*, which it claims seek to regulate the price of patented medicines outright to control pharmaceutical costs and expenditures in Canada, subjects that do not fall within the federal jurisdiction over patents of invention and discovery.
2. In its brief, it mainly addresses (a) the deleterious impact of the new regulations on the availability of innovative medicines in the Canadian market, particularly those used to treat cystic fibrosis and other rare diseases; and (b) the adverse effects of the new regulations on research and clinical trials in Canada, especially for medicines used to treat rare diseases.
3. During his arguments, counsel for the intervenor noted that the argument presented does not concern the wisdom of the new regulations, but rather their impact on the provincial jurisdiction over health. Because the new regulatory regime will considerably limit the choices available to the provinces, since its likely effect will be to substantially reduce the supply of innovative medicines for Canadians, provincial jurisdiction over treatment options and opportunity costs for the provincial health and hospital systems will necessarily be reduced.

*Canadian Association for Rare Disorders*

1. The intervenor Canadian Association for Rare Disorders represents patients suffering from rare disorders. It submits that the current regulatory framework, in place since 1993, regulates the prices of patented medicines to ensure that they are sold at affordable prices.[[122]](#footnote-122) The *2019 Regulatory Amendments* simply reinforce that legislative objective.
2. However, that objective has no connection with the federal jurisdiction over patents of invention and discovery. Rather, the purpose of that federal jurisdiction is to ensure fair and sufficient consideration for investments in pharmaceutical research and development and to control excessive prices of medicines that are akin to abuse of patent. Thus the current regime as a whole, like the *2019 Regulatory Amendments,* is *ultra vires* the federal jurisdiction.

*The other intervenors*

1. The Intellectual Property Owners Association did not appear on appeal, while the intervenor BIOTECanada did not file an appeal brief.

**V - ISSUES**

1. The appeal and the incidental appeal concern the constitutionality of the special regime for protected or patented medicines set out in the *Patent Act*, the *Patented Medicines Regulations*, and the *2019 Regulatory Amendments*.
2. Note that the Attorney General of Canada raises no other head of power in support of the constitutionality of its *Act* and *Regulations* concerning the price of patented medicines. Neither the jurisdiction over criminal law underlying the *Food and Drugs Act* and the *Competition* Act, nor any other federal jurisdiction, was the subject of debate before the Superior Court or this Court.
3. Nor does the appeal concern whether the *Patented Medicines Regulations* or the *2019 Regulatory Amendments* are invalid because they exceed the mandate granted by Parliament in the *Patent Act.* That issue, at least with respect to the *2019 Regulatory Amendments*, was addressed in a recent judgment of the Federal Court in *Innovative Medicines Canada*, which has been appealed before the Federal Court of Appeal.[[123]](#footnote-123) Therefore, the Court need not intervene in that debate concerning the compatibility of the federal regulations with the wording of the *Patent Act*, an issue that the parties in fact avoided raising before both the Superior Court and this Court.
4. Last, the appellants do not raise the issue of the incompatibility of the federal regime with respect to Canada’s international obligations, in particular those agreed to under NAFTA[[124]](#footnote-124) or in accordance with TRIPS.[[125]](#footnote-125)

**VI - ANALYSIS**

**A - *The general analytical framework***

1. When the Court is asked to decide an appeal concerning the constitutional validity of a legislative or regulatory regime, the applicable standard of review is that of correctness, except in regard to findings of fact underlying the analysis, including legislative facts, which are subject to the standard of palpable and overriding error.[[126]](#footnote-126)
2. The constitutional validity of a statute or regulation pursuant to the division of powers must be resolved further to a two-step analysis. It starts with the characterization of the statute or regulation in question. What is its subject matter? What does it concern? What is its purpose, its pith and substance? Once this exercise has been completed, the second step involves referring to the heads of power listed in sections 91 and 92 of the *Constitution Act, 1867*, and verifying whether Parliament or the provincial legislatures have jurisdiction to legislate in regard to a subject matter covered by the statute or regulation. The second exercise is one of classification.[[127]](#footnote-127)
3. The difficulty posed by this analysis arises from the fact that, in some cases, the statute or regulation may present several aspects that fall within federal jurisdiction, and others that fall within provincial jurisdiction. It then becomes necessary to determine the dominant aspect. To do so, the Court must examine the wording of the statute or regulation, as well as the context of its enactment, and its practical and legal effects.[[128]](#footnote-128)
4. The effects of a statute or regulation are objective in nature with respect to its true purpose, whereas the explicitly stated aim or object may not correspond to reality. In that case, the statute or regulation may look as though it deals with a particular subject matter, but in essence concerns another subject matter outside the jurisdiction of the enacting government.[[129]](#footnote-129)
5. Last, and because the modern vision of Canadian federalism increasingly permits overlap between the federal and provincial governments, one level of government may trench in an ancillary manner on the jurisdiction of the other, even significantly, to establish a comprehensive regulatory scheme and legislate effectively.[[130]](#footnote-130) That being so, the pith and substance of the impugned statute or regulation must of course fall within the jurisdiction of the enacting legislature and not impair the basic, minimum, and unassailable content of the power of the other level of government.[[131]](#footnote-131)

**B - *The pith and substance of the impugned provisions***

1. Because sections 91 and 92 of the *Constitution Act, 1867*, provide that Parliament and the provincial legislatures may make laws in relation to the “matters” enumerated therein, the pith and substance analysis seeks to identify the “matter” of the impugned statute or regulation.[[132]](#footnote-132) The Supreme Court has described the pith and substance or matter of a statute or regulation as its “leading feature or true character”, its “dominant purpose”, or its “dominant or most important characteristic”.[[133]](#footnote-133) To determine the pith and substance of a statute or regulation, it is necessary to examine its purpose, that is, what the legislature wanted to accomplish,[[134]](#footnote-134) and its legal and practical effects.[[135]](#footnote-135)
2. As LeBel J. stated in *Kitkatla Band*, the pith and substance analysis looks at both the purpose of the impugned statute or regulation and its legal and practical effects:[[136]](#footnote-136)

[53] A pith and substance analysis looks at both (1) the purpose of the legislation as well as (2) its effect. First, to determine the purpose of the legislation, the Court may look at both intrinsic evidence, such as purpose clauses, or extrinsic evidence, such as Hansard or the minutes of parliamentary committees.

[54] Second, in looking at the effect of the legislation, the Court may consider both its legal effect and its practical effect. In other words, the Court looks to see, first, what effect flows directly from the provisions of the statute itself; then, second, what “side” effects flow from the application of the statute which are not direct effects of the provisions of the statute itself: see*R. v. Morgentaler*, 1993 CanLII 74 (SCC), [1993] 3 S.C.R. 463, at pp. 482-83.

1. Binnie and LeBel JJ. adopted this approach in *Canadian Western Bank*. Again, they indicated that extrinsic evidence may be useful for this purpose. The true purpose of the legislation must be established, as opposed to its stated purpose, taking its effects into account:[[137]](#footnote-137)

[27]  To determine the pith and substance, two aspects of the law must be examined: the purpose of the enacting body and the legal effect of the law (*Reference re Firearms Act*, at para. 16). To assess the purpose, the courts may consider both intrinsic evidence, such as the legislation’s preamble or purpose clauses, and extrinsic evidence, such as Hansard or minutes of parliamentary debates. In so doing, they must nevertheless seek to ascertain the*true*purpose of the legislation, as opposed to its mere stated or apparent purpose (*Attorney-General for Ontario v. Reciprocal Insurers*, 1924 CanLII 460 (UK JCPC), [1924] A.C. 328 (P.C.), at p. 337). Equally, the courts may take into account the effects of the legislation. For example, in *Attorney-General for Alberta v. Attorney-General for Canada*, 1938 CanLII 251 (UK JCPC), [1939] A.C. 117 (“*Alberta Banks*”), the Privy Council held a provincial statute levying a tax on banks to be invalid on the basis that its effects on banks were so great that its true purpose could not be (as the province argued) the raising of money by levying a tax (in which case it would have been *intra vires*), but was rather the regulation of banking (which rendered it *ultra vires*, and thus invalid).

1. The overarching principles of the characterization analysis were recently stated by Wagner C.J. in *References re Greenhouse Gas Pollution Pricing Act*:[[138]](#footnote-138)

[51]  At the first stage of the division of powers analysis, a court must consider the purpose and effects of the challenged statute or provision in order to identify its “pith and substance”, or true subject matter: *2018 Securities Reference*, at para. 86; *Reference re Genetic Non-Discrimination Act*, 2020 SCC 17, at paras. 28 and 166. The court does so with a view to identifying the statute’s or provision’s main thrust, or dominant or most important characteristic: *Desgagnés Transport Inc. v. Wärtsilä Canada Inc.*, 2019 SCC 58, at para. 31. To determine the purpose of the challenged statute or provision, the court can consider both intrinsic evidence, such as the legislation’s preamble or purpose clauses, and extrinsic evidence, such as Hansard or minutes of parliamentary committees: *Kitkatla Band v. British Columbia (Minister of Small Business, Tourism and Culture)*, 2002 SCC 31, [2002] 2 S.C.R. 146, at para. 53; *Canadian Western Bank*, at para. 27. In considering the effects of the challenged legislation, the court can consider both the legal effects, those that flow directly from the provisions of the statute itself, and the practical effects, the “side” effects that flow from the application of the statute: *Kitkatla*, at para. 54; *R. v. Morgentaler*, 1993 CanLII 74 (SCC), [1993] 3 S.C.R. 463, at p. 480. The characterization process is not technical or formalistic. A court can look at the background and circumstances of a statute’s enactment as well as at the words used in it: *Ward v. Canada (Attorney General)*, 2002 SCC 17, [2002] 1 S.C.R. 569, at para. 18.

1. To this end, Wagner C.J. emphasized three points concerning the characterization of the pith and substance, (1) the pith and substance of the impugned statute or regulation must be described as precisely as possible; (2) it is permissible in some circumstances to include the legislative choice of means in the definition of a statute’s or regulation’s pith and substance, as long as we do not lose sight of the fact that the goal of the analysis is to identify the true subject matter of the impugned legislation or provision; and (3) the characterization and classification stages of the division of powers analysis are and must be kept distinct. In this regard, it is worth reproducing the comments of the Chief Justice on these three points:[[139]](#footnote-139)

[52] Three further points with respect to the identification of the pith and substance are important here. First, the pith and substance of a challenged statute or provision must be described as precisely as possible. A vague or general description is unhelpful, as it can result in the law being superficially assigned to both federal and provincial heads of powers or may exaggerate the extent to which the law extends into the other level of government’s sphere of jurisdiction: *Desgagnés Transport*, at para. 35; *Reference re Assisted Human Reproduction Act*, 2010 SCC 61, [2010] 3 S.C.R. 457 (“*Assisted Human Reproduction Act*”), at para. 190. However, precision should not be confused with narrowness. Instead, the pith and substance of a challenged statute or provision should capture the law’s essential character in terms that are as precise as the law will allow: *Genetic Non-Discrimination*, at para. 32. It is only in this manner that a court can determine what the law is in fact “all about”: *Desgagnés Transport*, at para. 35, quoting A. S. Abel, “The Neglected Logic of 91 and 92” (1969), 19 *U.T.L.J.* 487, at p. 490.

[53] Second, it is permissible in some circumstances for a court to include the legislative choice of means in the definition of a statute’s pith and substance, as long as it does not lose sight of the fact that the goal of the analysis is to identify the true subject matter of the challenged statute or provision. In the courts below, a central issue was the permissibility of including the means of the statute in the definition of the subject matter of the *GGPPA*. In *Ward*and other cases, this Court cautioned against “confus[ing] the purpose of the legislation with the means used to carry out that purpose”: *Ward*, at para. 25; see also *Quebec (Attorney General) v. Canada (Attorney General)*, 2015 SCC 14, [2015] 1 S.C.R. 693, at para. 29; *Goodwin v. British Columbia (Superintendent of Motor Vehicles)*, 2015 SCC 46, [2015] 3 S.C.R. 250, at para. 24. However, those cases did not establish a blanket prohibition on considering the means in characterizing the pith and substance of a law. Rather, they stand for the basic proposition that Parliament’s or a provincial legislature’s choice of means is not determinative of the legislation’s true subject matter, although it may sometimes be permissible to consider the choice of means in defining a statute’s purpose. This Court has in fact frequently included references to legislative means when defining the pith and substance of laws: *Ward*, at para. 28; *Reference re Firearms Act (Can.)*, 2000 SCC 31, [2000] 1 S.C.R. 783 (“*Firearms*”), at paras. 4 and 19; *Reference re Employment Insurance Act (Can.), ss. 22 and 23*, 2005 SCC 56, [2002] 2 S.C.R. 669, at para. 34; *2011 Securities Reference*, at para. 106. And there may be cases in which an impugned statute’s dominant characteristic or main thrust is so closely tied to its means that treating the means as irrelevant to the identification of the pith and substance would make it difficult to define the matter of a statute or a provision precisely. In such a case, a broad pith and substance that does not include the means would be the very type of vague and general characterization, like “health” or “the environment”, that this Court described as unhelpful in *Desgagnés Transport*, at paras. 35 and 167 (citing *Assisted Human Reproduction Act*, at para. 190).

[54] Even this Court’s jurisprudence on the national concern doctrine illustrates that there is nothing impermissible about defining a matter with reference to the legislative means. In *Munro v. National Capital Commission*, 1966 CanLII 74 (SCC), [1966] S.C.R. 663, the Court defined the matter in terms of both the overarching objective — ensuring that “the nature and character of the seat of the Government of Canada may be in accordance with its national significance” — and the legislative means for achieving this objective — “development, conservation and improvement of the National Capital Region”: pp. 669 and 671. Similarly, in *Crown Zellerbach*, the Court did not define the matter of the statute broadly in terms of marine pollution. The definition of the matter was in fact a combination of the overarching purpose — controlling marine pollution — and the particular means that had been chosen — controlling the dumping of substances into the sea: pp. 436-37. La Forest J., dissenting, pointed out that regulating the dumping of substances into the sea was only one of multiple means to control marine pollution, given that pollution could also enter the sea through fresh water and through the air: p. 457.

[55] I therefore agree with Hoy A.C.J.O.’s statement in the case at bar that in some cases the choice of means may be so central to the legislative objective that the main thrust of a statute or provision, properly understood, is to achieve a result in a particular way, which would justify including the means in identifying the pith and substance: para. 179.

[56] Third, the characterization and classification stages of the division of powers analysis are and must be kept distinct. In other words, the pith and substance of a statute or a provision must be identified without regard to the heads of legislative competence. As Binnie J. noted in *Chatterjee v. Ontario (Attorney General)*, 2009 SCC 19, [2009] 1 S.C.R. 624, at para. 16, a failure to keep these two stages of the analysis distinct would create “a danger that the whole exercise will become blurred and overly oriented towards results”. The characterization exercise must ultimately be rooted in the purpose and the effects of the impugned statute or provision.

1. What is the case here?

*The regime prior to the 2019 Regulatory Amendments*

1. As for the existing regime, the wording of sections 83 and 85 of the *Patent Act* allows the Board to make certain binding orders and sets out the factors to consider to that end. Their wording is clear; they prevent the monopoly granted by patent from being used to charge “excessive” prices for patented medicines. Thus, subsection 83(1) allows the Board to intervene only if it “finds that a rights holder for an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board’s opinion, is excessive” [emphasis added], while subsection 85(1) provides that the factors set out therein are to be taken into consideration in “determining … whether a medicine is being or has been sold at an excessive price in any market in Canada” [emphasis added]. It is the control of excessive prices that is contemplated. What constitutes an excessive price emerges from the factors set out in this regard in the *Act*.
2. The factors set out in subsection 85(1) of the *Patent Act* ensure that the price at which the patented medicine is sold in Canada is objectively compared to (a) the price at which medicines in the same therapeutic class are sold in Canada; and (b) the price at which the same medicine and medicines in the same therapeutic class are sold in countries other than Canada. The purpose is to ensure that the price charged for the patented medicine in Canada compares favourably to the price charged for the same medicine and medicines in the same therapeutic class in Canada and in other countries. The non-excessive price thus determined may then evolve in accordance with the Consumer Price Index (“CPI”), which is the other factor to consider.
3. As the current wording of the *Patented Medicines Regulations* provides no additional factors other than those set out in section 85 of the *Act*, which factors are clearly connected to the control of excessive prices according to the terms of the *Act*, they clearly have the same purpose, that is, to prevent excessive prices for patented medicines.
4. As for the Board’s guidelines in force before the *2019 Regulatory Amendments* (the “current guidelines”), they are entirely consistent with the *Act’*s purpose, that is, to prevent excessive prices using the prices charged in Canada and other countries for the same medicine and for medicines in the same therapeutic class as objective price comparators. This objective price comparison exercise allows the Board to determine an introductory price in Canada that is not excessive, and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board.
5. The pith and substance of the current regime also emerges from the parliamentary debates surrounding the enactment of the legislative amendments that created the Board and granted it its statutory mandate.
6. It appears that in 1987, Parliament wanted to offset the substantially increased protection granted to patents on medicines with an effective mechanism to protect Canadian consumers from the excessive prices that could result from the strengthened monopoly granted by the enhanced patent.
7. Then, in 1993, Parliament, confronted with the evolution of international trade agreements providing for the abolition of the compulsory licensing regime for patented medicines, wanted to ensure that a strengthened control mechanism was implemented to mitigate the abandonment of compulsory licences. The substitution mechanism chosen was an objective comparison between the price charged for the same medicine or medicines in the same therapeutic class in Canada and in countries comparable to Canada. The purpose was to remedy the effect on prices of the monopoly granted by the patent in the absence of a compulsory licensing regime.
8. In *Manitoba Society of Seniors*, the Manitoba Court of Queen’s Bench, in a judgment confirmed by the Manitoba Court of Appeal, found that the provisions of the regime introduced in 1987 was intended to control the excessive prices of patented medicines that could result from the monopoly granted by the patent:[[140]](#footnote-140)

As the legislation reestablishes exclusivity for patented medicines to an extent not enjoyed since 1931, Parliament also provided for a mechanism to deal with price abuse that may incidentally occur as a result of these monopolies it created. The Board is only empowered to deal with the excessive prices of medicines patented under the new regime. It is not a scheme of general supervision of all patented pharmaceutical inventions. It clearly deals with the potential abuse flowing incidentally from the newly created patent exclusivity.

[Emphasis added.]

1. In fact, this characterization has also been repeated with respect to the 1993 legislative amendments by every court that has since addressed them.[[141]](#footnote-141) By way of example, I reproduce the following excerpt from the judgment of Cullen J. in *ICN Pharmaceuticals*, cited with approval by Abella J. on behalf of a unanimous Supreme Court in *Celgene*:[[142]](#footnote-142)

[24]   Sections 79 to 103 of the *Patent Act*, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime.Parliament’s intent was certainly to address the “mischief” that the patentee’s monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels.Accordingly, the words of these sections of the *Patent Act* should be read purposively.

[Emphasis added.]

*The 2019 Regulatory Amendments*

1. The *2019 Regulatory Amendments* have a dual purpose.
2. First, these amendments seek to strengthen the regime already established in the *Patent Act* and the *Patented Medicines Regulations.* As a result, the Board will continue to objectively compare the price at which patented medicines are sold in Canada with the price at which medicines in the same pharmaceutical class are sold in Canada, as well as with the price at which that medicine and medicines in the same therapeutic class are sold in countries other than Canada. However, the list of foreign countries used as price comparators will be amended and the Canadian price of the patented medicine will henceforth have to take into account the confidential rebates granted to public insurers. In any event, the purpose of the regime remains the same, that is, to determine a price in Canada that is not excessive for the medicine in question so as to mitigate the effect on prices of the monopoly granted by the patent.
3. Second, however, through the application of new factors added by the *2019 Regulatory Amendments*, the Board will now also have to impose a substantial and arbitrary reduction in the price of a patented medicine after its price has previously been found not to be excessive further to the application of the factors set out in the *Act.* This second component does not involve establishing a price that is not objectively excessive, but rather effecting a substantial and arbitrary price reduction irrespective of the price at which medicines in the same therapeutic class are sold in Canada or in countries other than Canada and irrespective of the price at which the same medicine is sold in foreign countries reasonably comparable to Canada. It is thus simply an arbitrary price reduction established by dictate of the Board, applying the new government policy of substantial price reductions.
4. The Regulatory Impact Analysis Statement published in the Canada Gazette – which may serve to establish the pith and substance[[143]](#footnote-143) – in fact clearly states that the context of the new regulations is in keeping with the federal government’s undertaking to “improve the accessibility, affordability, and appropriate use of medicines to better meet health care system needs”, adding:[[144]](#footnote-144)

The Government of Canada is committed to this work and is taking action to lower the cost of medicines, provide faster access to new medicines that are safe and effective, and support the development of tools for more appropriate prescribing. … These Amendments contribute to the Government’s commitment by lowering the prices of patented medicines in Canada.

As can readily be seen, we are a long way from controlling the effects on price of the monopoly granted by a patent.

1. The Regulatory Impact Analysis Statement adds that the purpose is to reorient the Board’s role towards controlling the affordability of prices of patented medicines rather than controlling excessive prices:[[145]](#footnote-145)

The desired result of these changes is for the gross and net ceiling prices of patented medicines in Canada to be more closely aligned with prices in like-minded countries, more reflective of their value to Canadian consumers and more informed by the affordability constraints of the Canadian economy.

1. This new objective appears throughout the Regulatory Impact Analysis Statement. For example, to explain the rationale for the new factor based on the pharmacoeconomic value of medicines, it states that “the private market for pharmaceuticals in Canada is an offshoot of the public system and cannot function without it, the policy intent is for the PMPRB to adopt the perspective of the public health care system and favour a supply-side cost-effectiveness threshold in estimating opportunity cost”.[[146]](#footnote-146)
2. Moreover, taken together “the addition of the three new section 85 factors enable the PMPRB to assess the economic impact of a patented medicine’s price on both insurers and individual consumers and enable it to develop screening criteria and market size tests for medicines that are likely to pose affordability challenges for the Canadian health care system”.[[147]](#footnote-147)
3. The desired effect of these new factors could not be clearer, that is, the “[l]ower overall spending on patented medicines in Canada [that] is anticipated to result from lower prices”.[[148]](#footnote-148) Indeed, it seeks a significant and arbitrary reduction in the price of patented medicines.
4. That is in fact the objective stated in the title of the Government of Canada’s news release dated August 9, 2019, announcing the regulatory amendments: “[The] Government of Canada Announces Changes to Lower Drug Prices …”.[[149]](#footnote-149) The Minister responsible, Ginette Petitpas Taylor, explained that this is the rationale behind the new regulations:[[150]](#footnote-150)

Today, we take the biggest step to lower drug prices in a generation. Building on the progress we've already made towards lower drug prices, these bold reforms will both make prescription drugs more affordable and accessible for all Canadians—saving them an estimated $13 billion dollars in the next decade—and lay the foundation for National Pharmacare.

1. Overall, the new guidelines also clearly reveal that the pursued objective going forward will be to control not only the excessive prices of patented medicines, but also their affordability, in particular through significant, arbitrary price reductions. That is in fact the very purpose of the new factors introduced by the new regulations, that is, the pharmacoeconomic value of the medicine in Canada, the size of the market for the medicine in Canada, and the gross domestic product per capita in Canada.[[151]](#footnote-151)
2. In this regard, the Board’s new guidelines teach us that these new factors will be used to impose arbitrary reduction caps ranging from 20% to 50% (depending on the pharmacoeconomic level at which they are classified) on the maximum list price of new medicines considered to be “Category I”, including those whose 12-month treatment cost is greater than 150% of GDP per capita.[[152]](#footnote-152) In addition, these additional arbitrary downward adjustments, which may be as much as 25% and even 35%, may be imposed on medicines whose market size exceeds $50 million or $100 million annually, as the case may be.[[153]](#footnote-153) Again, recall that these substantial reductions will apply on prices already deemed non-excessive on the basis of the criteria set out in the *Patent Act* itself.
3. In short, the pith and substance of the current regime is to control excessive prices charged for patented medicines to mitigate the effect on prices of the monopoly granted by the patent, whereas the pith and substance of the *2019 Regulatory Amendments* has twoaspects: (a) first, with the objective of reducing prices, to reinforce the existing excessive price control regime by amending the list of foreign countries used to compare prices and by taking into account the confidential rebates granted to large public insurers; and (b) second, to impose significant arbitrary price reductions so that patented medicines are more affordable.
4. The characterization of the pith and substance of the existing regime and the first component of the *2019 Regulatory Amendments* is essentially the same as that accepted by the trial judge. However, the characterization of the pith and substance of the second component of the *2019 Regulatory Amendments* differs from that accepted by the judge.
5. The reason for this divergence is largely based on the trial judge’s refusal to take into account in her constitutional analysis the part of the Regulatory Impact Analysis Statement concerning the purpose of the new factors as well as the Board’s new guidelines, which provide a detailed explanation of how these new factors will apply. That being said, a review of the trial judge’s reasons, taken as a whole, makes it clear that she would have characterized the second component of the *2019 Regulatory Amendments* in the manner I propose had she indeed taken them into account in her analysis. Although the Regulatory Impact Analysis Statement, taking all its components into consideration, is itself sufficient to characterize the pith and substance of the second component of the *2019 Regulatory Amendments*, the new guidelines confirm and reinforce that characterization. The trial judge should have taken the new guidelines into account in her analysis, as she in fact did with the current guidelines.[[154]](#footnote-154) Here is why.
6. First, the Federal Court of Appeal reminded us in 2021, in *Alexion Pharmaceuticals*, that although the guidelines are not formally binding, the Board cannot set them aside without justification.[[155]](#footnote-155) The new guidelines are therefore very important and particularly useful in identifying the pith and substance of the *2019 Regulatory Amendments* because they reflect their practical effects, which are in fact repeated in many passages of the Regulatory Impact Analysis Statement that were not addressed by the judge.
7. In addition, these are not simply internal administrative rules or vague general principles. On the contrary, although they are non-binding, the Board’s guidelines are prescribed by the *Patent Act* and are at the heart of the excessive price control regime administered by the Board. As noted above, the guidelines are of such importance that the Board cannot adopt them without consulting the federal minister responsible, all of the provincial health ministers, and representatives of consumer groups and the pharmaceutical industry in accordance with a process similar to the one set out in the *Patent Act* for the adoption by the Governor in Council of important regulations governing the regime.
8. In this regard, *Little Sisters*,[[156]](#footnote-156)on which the trial judge relied to exclude the guidelines from her analysis, does not have the scope she gave it. That judgment concerns the violation of fundamental rights guaranteed by the *Canadian Charter of Rights and Freedoms* (the “*Canadian Charter*”), not the pith and substance of a statute or regulation whose constitutional validity is challenged on the basis of the division of powers. In that case, the Court had to decide whether the provisions of the *Customs Act* granting discretion to customs officials to prohibit the entry into Canada of pornographic material was unconstitutional due to the fact that those officials discriminated against the gay and lesbian community, in violation of the *Canadian Charter*. The *Act* provided no policy or guideline in this regard and none had been adopted to guide the officials’ discretion. Binnie J. found that that there was no cause to invalidate the statutory provisions at issue on the ground that they violated the *Canadian Charter* given that it was the customs officials’ exercise of the discretion that was problematic, not the legislation itself.
9. Thus, *Little Sisters* has no relevance to determining the pith and substance of a statute or regulation for the purposes of sections 91 and 92 of the *Constitution Act, 1867*, or to the guidelines prescribed by legislation and adopted by a federal administrative body further to extensive consultations required by the legislation. With respect, *Little Sisters* appears to me to be of no relevance to this case.
10. As mentioned above, the pith and substance analysis allows us to verify whether the true purpose of the impugned statutory or regulatory provisions falls outside the area of jurisdiction of the enacting government. In my view, the guidelines developed by the administrative body responsible for implementing the impugned statutory and regulatory provisions are particularly relevant for this purpose. This observation is supported by the fact that in this case, the guidelines are at the heart of the regime administered by the Board. In addition, the new guidelines adopted pursuant to the new regulatory context operationalize the new regulatory factors in a manner that is entirely consistent with what is set out in the Regulatory Impact Analysis Statement.
11. I do not see how, in the pith and substance analysis, one may consider regulatory impact analysis statements, parliamentary speeches, and other statements made by the ministers responsible regarding the impugned provisions relevant as extrinsic evidence on the one hand, and on the other exclude the guidelines, whose adoption is provided for in the *Act* and whose implementation is closely related to the purpose of the impugned provisions, on the ground that they are not formal rules of law. In this respect, the ministerial statements and regulatory impact analysis statements are also not rules of law, and yet it is legitimate and sometimes even necessary to consider them in the pith and substance analysis.
12. Although the guidelines may evolve over time further to the extensive consultation prescribed by the *Act*, the fact remains that they faithfully reflect the Regulatory Impact Analysis Statement with respect to the purpose of the new factors introduced by the new regulations and confirm that purpose. As the judge herself remarked in her analysis of the pith and substance of Regime 1, [translation] “[t]he Guidelines confirm this interpretation”.[[157]](#footnote-157)
13. In fact, the usefulness of the Board’s guidelines in determining the pith and substance of the *2019 Regulatory Amendments* appears indisputable in this case, considering that the new regulations are specifically intended to allow the Board to establish new guidelines to implement the new government policy on the reduction of patented medicine prices. This is in fact expressly set out in the Regulatory Impact Analysis Statement: “Under a modernized regulatory framework, the [Board] will have a stronger basis from which to modernize its Guidelines”.[[158]](#footnote-158)
14. In my view, it would be unacceptable for a regulatory regime to escape constitutional review on the ground that a court could not consider guidelines, whose adoption is prescribed by the *Act*, and which are indeed determinative in the application of the regime as a while. In fact, Laskin C.J. noted this in 1979 in *Central Canada Potash*:[[159]](#footnote-159)

It is nothing new for this Court, or indeed, for any Court in this country seized of a constitutional issue, to go behind the words used by a Legislature and to see what it is that it is doing. It is especially important for Courts, called upon to interpret and apply a constitution which limits legislative power, to do so in a case where not only the authorizing legislation but regulations enacted pursuant thereto are themselves couched in generalities, and the bite of a scheme envisaged by the parent legislation and the delegated regulations is found in administrative directions.

[Emphasis added.]

1. The courts must be able to assess the anticipated effects of regulations as established by the evidence. Otherwise, the credibility of the judicial review of their constitutionality could be called into question. This observation is particularly acute in this case because the very purpose of the second component of the *2019 Regulatory Amendments* is to achieve a result, a reduction in the price of patented medicines, by a specific means, arbitrary price reductions of 20% to 50% in some cases and of 25% to 35% in others. Both the Regulatory Impact Analysis Statement and the new guidelines confirm this unequivocally.
2. As Wagner C.J. recently observed in *References re Greenhouse Gas Pollution Pricing Act*,[[160]](#footnote-160)inan excerpt reproduced above, “the choice of means may be so central to the legislative objective that the main thrust of a statute or provision, properly understood, is to achieve a result in a particular way, which would justify including the means in identifying the pith and substance”.

**C - *Constitutional classification***

1. At the second step of the analysis, the pith and substance of the impugned provision must be connected to one of the heads of power enumerated in sections 91 and 92 of the *Constitution Act, 1867*, to determine whether it falls within the jurisdiction of the federal government or that of the provinces.[[161]](#footnote-161) There must be a rational and direct connection between the pith and substance of the provisions at issue and an enumerated head of power within which the legislation falls.
2. That being said, it is necessary to bear in mind that the Constitution “must be interpreted flexibly … to meet new social, political and historic realities”, while remaining consistent with the principle of federalism to ensure that “[c]lasses of subjects … not be construed so broadly as to expand jurisdiction indefinitely”.[[162]](#footnote-162)

*The regime prior to the 2019 Regulatory Amendments*

1. The trial judge did not err in concluding that the impugned provisions of the *Patent Act* as well as the *Patented Medicines Regulations*, as they read prior to the *2019 Regulatory Amendments*, fall within the federal jurisdiction over patents of invention and discovery. The pith and substance of these provisions, that is, the control of excessive prices charged for medicines to mitigate the effect on prices of the monopoly granted by the patent, is a subject matter that the case law has always recognized as falling within the federal jurisdiction over patents. There is no reason to depart from these authorities as the appellant pharmaceutical companies suggest.
2. In 1970 in *American Home Products*, the Ontario Superior Court of Justice and the Court of Appeal for Ontario found the compulsory licensing regime for patented medicines, the precursor to the current regime, constitutionally valid,[[163]](#footnote-163) although the reasons given in both judgments are sparse.
3. In 1986 in *Smith, Kline & French*, the Federal Court and the Federal Court of Appeal both reached the same conclusion as the Manitoba courts, for reasons which they set out in detail.[[164]](#footnote-164) The plaintiffs in that case submitted that the pith and substance of the compulsory licensing regime for patented medicines fell within the provincial jurisdiction over property and civil rights because its purpose and its effects concerned the regulation of medicine prices. Strayer J. of the Federal Court rejected that argument and found that the federal jurisdiction over patents of invention and discovery included the right to control the effects of the monopoly granted by the patent on the price of patented medicines:[[165]](#footnote-165)

It appears to me that under its authority with respect to patents of invention and discovery, Parliament is entitled to regulate patents in a variety of ways. Essentially, this power enables it to create a monopoly for one party and to exclude other parties from the use, manufacture, sale, or importation of products which are the subject of a patent. … I can find no constitutional imperative that Parliament must exercise its authority over patents of invention and discovery in one way only, namely to grant the typical or conventional type of patent exclusivity to the patentee of any product whatsoever. …

…

I therefore conclude that this subsection, by making the grant of a patent for medicine subject to compulsory licensing is simply limiting the scope of the property right, the monopoly, which Parliament is authorized but not obliged to grant.

Nor do I think it can otherwise be characterized in any way in pith and substance a law in relation to property and civil rights. It is true that the grant of a compulsory licence affects incidentally, though in important ways, contractual and property rights of the patentee as well as those of the licensee. But subsection 41(4) is not a law in relation to "prices" as contended by the plaintiffs. It does not purport to fix prices. One of its principal objects is, obviously, to bring about a reduction in prices through competition, but the prices are to be fixed by the vendors of drugs. Merely because the exercise of a federal power affects prices does not make it invalid.

[Emphasis added.]

1. In *Manitoba Society of Seniors* in 1992,[[166]](#footnote-166)the Manitoba Court of Queen’s Bench and the Manitoba Court of Appeal confirmed the constitutional validity of the regime introduced in 1987 creating the Board and for the first time allowing a federal body to impose restrictive measures on prices to ensure that patented medicines are not sold at excessive prices. In that case, the applicant challenged the constitutional validity of the 1987 legislative amendments on the ground that they introduced a new price control regime for patented medicines, a matter that the applicants argued fell within the exclusive jurisdiction of the provinces. Dureault J. rejected that argument, noting that the purpose of the legislative amendments was, one, to extend the rights of patent holders to medicines, and two, to establish mechanisms to control the adverse effects on the price of medicines resulting from the strengthened monopoly granted by the enhanced patent. He stated the following:[[167]](#footnote-167)

[21] The policy of the impugned amendments appears to me to be primarily directed at increasing patent protection or exclusivity for new inventions of medicines. It is intended to provide greater financial rewards for pharmaceutical firms developing new medicines. Ordinarily, it should foster greater research and development. That does not strike me as an improper use of the patent power. And while Parliament was not oblivious to the risk that patent exclusivity might result in excessive prices, it sought to deal with that incidental mischief by instituting the regulatory Board with its monitoring and reviewing powers.

[22] The price review regime is but one component of the broader regime of patent exclusivity brought about by the impugned provisions and is essentially a device for dealing with excessive prices resulting from patent abuse. As indicated, the remedial actions are loss of patent exclusivity or reintroduction of competition through compulsory licensing. How could such actions, directing a return to the earlier regime of immediate compulsory licensing, be considered anything but the valid exercise of patent power. The fact that, as a last resort, the Board may seek enforcement of its rollback orders through a superior court process does not change the fundamental nature of the legislation from the field of patent to that of property and civil rights, *i.e*., price control.

[23] I conclude that in pith and substance the impugned amendments pertain to the field of patents of invention. As the legislation reestablishes exclusivity for patented medicines to an extent not enjoyed since 1931, Parliament also provided for a mechanism to deal with price abuse that may incidentally occur as a result of these monopolies it created. The Board is only empowered to deal with the excessive prices of medicines patented under the new regime. It is not a scheme of general supervision of all patented pharmaceutical inventions. It clearly deals with the potential abuse flowing incidentally from the newly created patent exclusivity. Any firm not wishing to submit to the Board's authority can do so by renouncing its right to obtain a patent. Thus, the legislation is targeted to patent and patent abuse.

[24] I conclude that the impugned legislation was validly enacted by the Parliament of Canada pursuant to its constitutional power in the field of patents of invention. Accordingly, the application for the declaratory relief must be denied.

[Emphasis added.]

1. As for the regime in its current form, which was introduced into the *Patent Act* by the 1993 legislative amendments, the Federal Courts confirmed its constitutional validity, in particular in *Sandoz/Ratiopharm* in 2015 and in *Alexion Pharmaceuticals* in 2017.[[168]](#footnote-168)
2. The issue in the 2017 *Sandoz/Ratiopharm* case concerned the Board’s jurisdiction over generic pharmaceutical companies that were subsidiaries of innovative pharmaceutical companies that held patents on “generic” medicines marketed by their subsidiaries. In the context of this dispute, pharmaceutical company Sandoz Canada Inc. submitted that the 1993 legislative amendments had the effect of introducing a price control regime for medicines, which fell within provincial jurisdiction. O’Reilly J. of the Federal Court rejected this argument and found that the 1993 legislative amendments did not have the effect of fundamentally changing the federal regime in relation to the one introduced in 1987, the constitutional validity of which was recognized in *Manitoba Society of Seniors*:[[169]](#footnote-169)

[35] Even though the relevant provisions of the Act have already been found to be constitutional (*Manitoba Society of Seniors Inc*), Sandoz argues that subsequent amendments to the Act relating to the Board’s powers now place those provisions beyond federal jurisdiction over patents, encroaching on provincial jurisdiction over Property and Civil Rights.

[36] Their purpose was to enable the Board “to influence the pricing of patented medicines to much the same extent that the competition fostered by compulsory licensing used to influence it”. Those amendments “strengthened the Board’s remedial and punitive powers” to offset the effect of abolishing the prior scheme of compulsory licensing (*ICN Pharmaceuticals, Inc* at para 12).

[37] As I see it, the amendments giving the Board the power to address the pricing of patented medicines more directly through monetary remedies and penalties did not alter the basic purpose of the legislation or expand the Board’s mandate. Therefore, I see no basis for departing from the conclusion reached in *Manitoba Society of Seniors Inc* that the provisions of the *Patent Act* dealing with patented medicines, properly interpreted, fall within federal jurisdiction over patents of invention; they are constitutional.

1. The conclusion regarding the constitutional validity of the 1993 regime was confirmed by the Federal Court of Appeal. Noël C.J. noted that the reasoning in *Manitoba Society of Seniors* on the constitutional validity of the 1987 regime remained applicable to the 1993 regime:[[170]](#footnote-170)

[116] In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867*when applied to a patent holder or owner. The respondents recognize as much when they state that the Federal Court judge’s interpretation of “patentee” maintained the connection to the federal head of power, such that the reasoning in *Manitoba Society* remained intact (respondents’ respective replies to the response by the Attorney General of Canada to the Notice of Constitutional Question (respondents’ replies) at para. 46).

[Emphasis added.]

1. In the 2017 judgment in *Alexion Pharmaceuticals*, the pharmaceutical company in question wanted to once again contest the constitutional validity of the regime administered by the Board on the ground that it constituted price control, which falls within the exclusive jurisdiction of the provinces. The pharmaceutical company in fact presented abundant evidence on the issue to distinguish its case from the one addressed in *Sandoz/Ratiopharm*. The Attorney General of Canada opposed the application on the ground that the Federal Court of Appeal had definitively decided the issue in *Sandoz/Ratiopharm*. Prothonotary Alto granted the Attorney General of Canada’s application:[[171]](#footnote-171)

[39] In my view, the Federal Court of Appeal has determined explicitly that the Impugned Provisions are constitutional. This decision is binding on this Court. It may very well be, that as Alexion argues, none of these cases have conducted a proper pith and substance analysis nor has there been before those courts a full record which would include its legislative history and the impact of the Impugned Provisions. Alexion endeavoured to distinguish both *Manitoba Seniors* and *Sandoz* with other inventive arguments. Notwithstanding these efforts to distinguish those cases, in my view, having carefully reviewed all of them, as far as this application is concerned, the Federal Court of Appeal’s conclusion on constitutionality prevails. Thus, this application is bereft of any chance of success and the motion of the AG should be granted.

1. Simpson J. of the Federal Court dismissed the appeal of that decision,[[172]](#footnote-172) and the Federal Court of Appeal agreed. Laskin J.A. reiterated that the Federal Court of Appeal had “[decided] in *Sandoz* that the price control scheme as a whole is constitutional”.[[173]](#footnote-173)
2. The appellant pharmaceutical companies nevertheless submit that all of this abundant case law could be set aside in view of the evidence they presented before the Superior Court supporting the conclusion that the pith and substance of sections 79 to 103 of the *Patent Act* is not the one previously accepted by the courts. They failed to convince the trial judge of this, however, nor have they convinced me. Accordingly, although the Court is not formally bound by this abundant case law,[[174]](#footnote-174) there is no reason to set it aside.
3. In any event, even if I did not take that case law into account, I would nevertheless conclude that sections 73 to 103 of the *Patent Act* and the entire *Patented Medicines Regulations*,in their current form, fall within the federal government’s jurisdiction over patents of invention and discovery. Indeed, I agree with the trial judge’s conclusion[[175]](#footnote-175) that controlling the excessive prices charged for patented medicines resulting from the monopoly granted by a patent has a rational, real, and direct connection with the federal jurisdiction over patents and does not unconstitutionally encroach on the jurisdiction of the provinces. I will return to this in greater detail when I address the limits of the federal jurisdiction.

*The 2019 Regulatory Amendments*

1. As noted above, the pith and substance of the *2019 Regulatory Amendments* has two aspects: (a) first, with the objective of reducing prices, to reinforce the existing excessive price control regime by amending the list of foreign countries used to compare prices and by taking into account the confidential rebates negotiated with large public insurers; and (b) second, to impose additional significant arbitrary price reductions so that patented medicines are more affordable.
2. The constitutional classification of these regulatory amendments must be conducted in light of the principle parameters defining the federal jurisdiction over the regulation of patented medicine prices, that is, (i) a patented medicine; (ii) the ex-factory price; and (iii) the control of the effect on prices of the monopoly granted by the patent. That is what needs to be addressed now.
3. Federal jurisdiction covers only patented medicines
4. It seems clear to me that the federal jurisdiction over patents of invention and discovery cannot permit the federal government to control the price of medicines in general, but only those medicines that are subject to a monopoly granted by the *Patent Act* by means of a patent. Thus, the federal jurisdiction over patents of invention and discovery cannot permit the federal government to regulate the price of non-patented medicines, either because the patent has expired or was never obtained.
5. As federal Deputy Minister Jocelyne Bourgon in fact stated in a memorandum on this issue addressed to the minister responsible, [translation] “constitutional grounds prevent expanding the Board’s mandate to include non-patented medicines”.[[176]](#footnote-176) None of the parties to the appeal challenge this basic constitutional principle.
6. In this context, the appellants suggest that subsection 79(2) of the *Patent Act* is unconstitutional because it allows the Board to regulate non-patented medicines.[[177]](#footnote-177) This statutory provision permits the Board to act in regard to the price of a medicine if it pertains to a patented invention, that is, if the patented invention “is intended or capable of being used for medicine or for the preparation … of medicine”.[[178]](#footnote-178) Contrary to the assertions of the appellant pharmaceutical companies, however, this statutory provision is not unconstitutional.
7. Indeed, the federal jurisdiction also extends to patented inventions that permit the making and marketing of medicines so that the patentee can logically benefit from the commercial advantage conferred by the monopoly granted by the patent, whether or not the medicine itself is patented. It is the *monopoly* granted by a patent that permits the federal government to act, whether the monopoly is the result of a patent directly concerning the medicine itself or is rather the result of a patented invention that logically grants the same type of monopoly. That is in fact what emerges clearly from the Federal Court of Appeal’s judgment in *ICN Pharmaceuticals v. Canada*:[[179]](#footnote-179)

That there must be a rational connection or nexus between the invention outlined in a patent and the medicine which is being sold in Canada cannot be doubted. Without such a statutory requirement the constitutional authority of Parliament to enact price control legislation would be in issue. The competence of Parliament to enact legislation which seeks to regulate the prices of goods, which legislation would otherwise intrude upon the legislative competence of the provinces to enact legislation affecting property and civil rights, arises from Parliament's jurisdiction to legislate with respect to patents …

1. According to the current version of the *Patent Act*, it is up to the Board to decide whether such rational connection exists in a given case. The Board’s decisions in this respect are subject to judicial review by the Federal Courts, which fulfill that mandate.[[180]](#footnote-180) Thus, the appellant pharmaceutical companies have not convinced me that the provisions of the current regime or of the *2019 Regulatory Amendments* are in part unconstitutional on the ground that they concern non-patented medicines.
2. Federal jurisdiction over the price of patented medicines does not extend beyond the ex-factory price
3. Federal jurisdiction cannot extend beyond the ex-factory price, that is, the selling price of a medicine fixed by the patentee for a client to whom the patentee sells directly, which excludes the subsequent resale price of the medicine, such as the sale by a pharmacist to a patient. Otherwise, the federal government would no longer be regulating within its jurisdiction over patents, but would instead be regulating secondary sales, thereby encroaching on the provincial jurisdiction over property and civil rights, which includes jurisdiction over commercial contracts, marketing, and the sale of patented or non-patented medicines.[[181]](#footnote-181)
4. In fact, this constitutional limit emerges from the very wording of the *Patent Act* because subsection 83(1) limits the Board’s jurisdiction to circumstances where “a rights holder for an invention pertaining to a medicine is selling the medicine in any market in Canada”. This limit on the ex-factory price also appears in subparagraph 4(1)(f)(i) of the current version of the *Patented Medicines Regulations*, which requires information on the quantity of the medicine sold and the price at which “the medicine was sold by the rights holder or former rights holder”.
5. These statutory limits reflect the constitutional constraints of the federal jurisdiction, as McTavish J., then of the Federal Court, in fact concluded in *Pfizer Canada*, rendered in 2019:[[182]](#footnote-182)

[61] Similarly, during the legislative process leading up to the 1993 amendments to the *Patent Act*, Barbara Sparrow, the Parliamentary Secretary to the Minister of Health and National Welfare, noted that federal jurisdiction was confined to the regulation of the “factory-gate” prices of patented medicines. It was the provinces that had jurisdiction over retail prices and dispensing fees for patented medicines.

[62]  The term “factory-gate” appears to be one that is generally understood in the industry to refer to the transaction between the patentee and the first purchaser of the patented medicine in question. As was noted earlier, this first purchaser is most commonly a wholesaler.

[63] The Board itself understands that its jurisdiction is limited to the regulation of the factory-gate prices for patented medicines, and that it has no jurisdiction over prices subsequently charged by wholesalers and retailers. The Board also recognizes that it has no jurisdiction over matters such as whether the costs of patented medicines are covered by public drug plans: see the affidavit of Barbara Ouellet, the Board’s Executive Director, at paras. 4 and 5.

…

[83]  I would also observe that my interpretation of the *Patent Act* and the *Patented Medicines Regulations* is consistent with the constitutional limitation on the Board’s ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain.

[Emphasis added.]

1. The remarks of Noël C.J. in *Sandoz/Ratiopharm* are consistent with this. That case involved the sales of a supposedly “generic” pharmaceutical company related to an innovative pharmaceutical company that held the patents on the products,[[183]](#footnote-183) which could have had the effect of circumventing the excessive price control regime set out in the *Patent Act.* The judgment focusses largely on the definition of “patentee” or “patent holder” and does not call into question the notion of ex-factory price.[[184]](#footnote-184)
2. Contrary to what the Attorney General of Canada submits, *Celgene*[[185]](#footnote-185)does not support the conclusion that the federal government’s constitutional jurisdiction over the control of excessive prices charged for patented medicines could extend beyond the ex-factory price. The judgment concerns the issue of whether an ex-factory sale concluded in the United States with Canadian clients could be considered an ex-factory sale in Canada for the purposes of the *Patented Medicines Regulations*. It does not extend the Board’s jurisdiction to selling prices subsequent to the ex-factory price.
3. In fact, even in its new guidelines, the Board acknowledges that it “has no authority over prices charged by parties other than patentees, such as prices charged by wholesalers or retailers, or over pharmacists’ professional fees”.[[186]](#footnote-186)
4. However, the new paragraphs 4(4)(a) and (b) of the *Patented Medicines Regulations*, introduced by the *2019 Regulatory Amendments*, extend the Board’s jurisdiction beyond the ex-factory price. The Attorney General of Canada indeed acknowledges that [translation] “the new provisions take into account price adjustments that occur beyond the first point of sale, in particular between the patentee and third-party insurers”.[[187]](#footnote-187) Moreover, it should be noted that as a general rule, public and private insurers do not purchase patented medicines, but rather reimburse their cost. These insurers are therefore not party to the ex-factory sales.[[188]](#footnote-188)
5. In so doing, the new paragraphs 4(4)(a) and (b) of the *Patented Medicines Regulations*, introduced by the *2019 Regulatory Amendments*, exceed the federal government’s constitutional jurisdiction in that they encroach on areas of provincial jurisdiction, that is, commercial contracts, marketing, and sales of consumer products.
6. I am therefore of the view that the trial judge was correct to conclude that the new paragraphs 4(4)(a) and (b) of the *Patented Medicines Regulations* are *ultra vires* the federal jurisdiction over patents of invention and discovery, but for different reasons.
7. Moreover, I note that the judgment of Manson J. of the Federal Court in *Innovative Medicines Canada* is consistent with this conclusion. Although that judgment concerns the incompatibility of the new paragraphs (4)(a) and (b) of the *Regulations* with the Board’s statutory mandate, the reasoning is relevant to this case:[[189]](#footnote-189)

[196] I cannot accept the Respondent’s submission that Celgene and Sandoz generally instruct this Court to adopt a broad interpretation of the price at which a medicine is sold. Contrary to the Respondent’s suggestion that the Federal Court of Appeal in Sandoz focused on the price obtained by the patentee, the analysis in fact focused on the definition of “patentee” and the “price charged by the patentee” (Sandoz at para 76, emphasis added). In both Celgene and Sandoz, the Courts recognized that the Board’s jurisdiction is over sales made by patentees to customers.

[197] Because the New Price Calculation directly links to paragraph 80(1)(b) of the Patent Act, the Governor in Council’s regulation-making authority is limited to specifying information respecting the price at which the patentee sells the medicine. I adopt the words of Justice Mactavish that to interpret the term “sale” (or “sold”) in such a way as to encompass the relationship between patentees and third parties who do not purchase or take title of medicines from patentees would “do violence to the ordinary meaning of the term” (Pfizer at para 78).

[198] Furthermore, the New Price Calculation is inconsistent with subparagraph 4(1)(f)(i) of the Regulations, which requires patentees to indicate the price at which a medicine was “sold by the patentee … to each class of customer”. Requiring patentees to take into account financial transactions with third parties who are not customers—and are[[190]](#footnote-190) strangers to the original sale transaction—exceeds the scope of the Governor in Council’s statutory mandate by untethering the price calculation from the sale of the patented medicine.

[199] It bears repeating that the Board’s mandate under the Patent Act is not to set prices for patented medicines, and the Board does not regulate profits made by patentees.The Board’s mandate to control prices is only engaged where it finds a patentee has abused its monopoly by charging excessive prices. The Board’s role is “to monitor the prices charged by patentees for patented medicines, so as to ensure that these prices are not excessive” (Pfizer at para 70, emphasis added). This interpretation of the Board’s role accords with the extrinsic evidence of legislative intent quoted above at paragraphs 85-87.

[Emphasis added.]

1. The federal jurisdiction concerns the effects on prices of the monopoly granted by patents on medicines
2. Recall that the federal jurisdiction over patents is based on the very concept of patent. It is thus well established that the patent represents a market agreed upon between the inventor and the public, which, in exchange for the patent monopoly, requires the patentee to make public the inventive solutions to practical problems through the disclosure of information that reveals how the invention functions.[[191]](#footnote-191)
3. In certain cases, however, the monopoly granted by the patent can have the effect of increasing the price of the patented product.[[192]](#footnote-192) Although this possible effect on prices resulting from the monopoly may be socially acceptable for most patented products and processes, that is not always the case for patented medicines, since human health is at stake.
4. Pharmaceutical patents thus raise issues of public interest that distinguish them from patents on other types of products or processes. While the monopoly granted by the patent allows innovative pharmaceutical companies to generate significant revenue to promote pharmaceutical research and development – a highly important social objective – it can also have the effect of increasing the price of a patented medicine in relation to what the pharmaceutical company could otherwise charge for the medicine in a competitive market free of any monopoly.
5. It is this public interest aspect specific to patented medicines that permits the federal government to regulate them to mitigate the effects on prices of the monopoly granted by the patent in this particular sector. The monopoly remains, thereby ensuring that the patentee has an exclusive source of revenue from the patented medicine, but the price increase that could result is controlled to prevent the patentee from unduly profiting at the expense of the public’s access to the medicine.
6. The distinctiveness of patented medicines is reflected in the provisions of TRIPS. While that agreement requires member countries to extend their patent system to the pharmaceutical industry with respect to both manufacturing processes and the medicines themselves, paragraph 1 of article 8 nevertheless allows member countries to adopt measures necessary to protect public health, provided that such measures are consistent with the provisions of the agreement. This distinctiveness is also reflected in paragraph 3 of article 27 of TRIPS, which applies notwithstanding the general rules of the agreement and permits a State to exclude diagnostic, therapeutic, and surgical methods for the treatment of humansfrom patentability.[[193]](#footnote-193) The Doha *Declaration on the TRIPS agreement and public health*[[194]](#footnote-194)in fact notes that it is important that TRIPS be interpreted and implemented in a manner supportive of member countries’ right to protect public health and, in particular, to promote access to medicines for all.
7. This distinctiveness is also reflected in sections 21.01 to 21.1 of the *Patent Act* concerning the use of patents on pharmaceutical products for humanitarian purposes[[195]](#footnote-195) and in the new section 19.4 of the *Patent* Act, which allows the use, through compulsory licences, of patents necessary to respond to a public health emergency, such as the COVID-19 pandemic.[[196]](#footnote-196)
8. The distinctiveness of patented medicines appears from the historical evolution of the *Patent Act*. Thus, as noted above, the medicines themselves were removed from patentability in Canada from 1923 to 1987. Drug manufacturing processes were subject to a strict compulsory licensing regime established in the public interest, whose purpose was to ensure that prices remained competitive.[[197]](#footnote-197) Since 1987, and especially since 1993, still with the same public interest objective, the Board can control the price of patented medicines to ensure that they are not excessive so as to mitigate the effects on prices of the monopoly granted by the patent. This special regime is based, for the same purpose, on objective price comparisons with both prices in countries other than Canada and prices for medicines in the same therapeutic class. We therefore note that for almost 100 years, the *Patent Act* has provided a regulatory regime for medicines that is separate from the one applicable in cases of abuse of patent for other types of patented products.[[198]](#footnote-198)
9. As Strayer J. confirmed in *Smith, Kline* *& French*,[[199]](#footnote-199) if the federal government can grant a monopoly on a medicine through a patent, it certainly has jurisdiction to counter the effects of that monopoly through measures that favour competitive prices for those medicines. Although Strayer J. drew that conclusion in respect of a legislative regime concerning compulsory licences that was not intended to directly regulate excessive prices,[[200]](#footnote-200) his remarks regarding the scope of the federal jurisdiction also apply to the control of excessive prices arising from the monopoly granted by the patent.
10. This approach is also entirely consistent with that established by Abella J. in *Celgene*. Although that case did not concern the federal government’s constitutional jurisdiction, it nevertheless states that the purpose of the *Act* is to control the monopoly resulting from the patent, which suggests that this legislative purpose falls within the federal jurisdiction over parents of invention and discovery:[[201]](#footnote-201)

[28] The Board’s consumer protection purpose was affirmed in *ICN Pharmaceuticals Inc. v. Patented Medicine Prices Review Board* (1996), 108 F.T.R. 190, aff’d [1997] 1 F.C. 32 (C.A.), where Cullen J. said:

Sections 79 to 103 of the *Patent Act*, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime.Parliament’s intent was certainly to address the “mischief” that the patentee’s monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels.Accordingly, the words of these sections of the *Patent Act* should be read purposively . . . . [Emphasis added; para. 24.]

[29] This is the approach to its mandate that the Board applied, one that took into paramount account its responsibility for ensuring that the monopoly [Emphasis added by the Court] that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers [Emphasis added by the Court]:

The mandate of the Board includes balancing the monopoly power held by the patentee of a medicine, with the interests of purchasers of those medicines.  The patentee of a medicine sold in Canada is subject to the jurisdiction of the Board, and this jurisdiction requires the patentee to report information to the Board concerning the price at which it has been selling the patented medicine in any market in Canada.  The Board compares this price to the price of comparable medicines, and to the price at which the medicine is sold in other countries, to determine whether or not its price in Canada is excessive. In consultation with industry, government and consumer stakeholders, the Board has developed detailed guidelines that patentees and Board Staff use to ensure that the prices of patented medicines in Canada are not excessive . . . . [Emphasis added; para. 5.]

[Emphasis in original, except where otherwise indicated.]

1. Thus, the federal jurisdiction over the price of patented medicines concerns the effects of the monopoly granted by the patent, not the effects on the market as a whole. It therefore concerns the control of excessive prices resulting from the monopoly.[[202]](#footnote-202) This jurisdiction may be distinguished from that concerning patent abuse set out in sections 65 to 71 and 127 to 128 of the *Patent Act*, but it is based on a similar concept that is reinforced by the particular public interest nature that patented medicines present. That is in fact what Deputy Minister Bourgon stated in a memorandum dated November 30, 1990, to the federal minister responsible:[[203]](#footnote-203)

[translation]

In general, fixing prices is considered an issue of property and civil rights. This head of power belongs to the provinces under subsection 92(13) of the *Constitution Act, 1867*.

Nevertheless, the courts have held that it is possible and consistent with the Constitution for the federal government to impose conditions on the issuance of a patent to ensure that there is no abuse of the monopoly granted by the patent.

It was from this perspective that the Patented Medicine Prices Review Board was created, pursuant to the *Patent Act*, to review the prices charged by patent holders on medicines for patented medicines, and that it was vested with the power to order the reduction of the price of a medicine or to cancel the exclusivity period of the medicine in question and/or that of another medicine for which the patent holder was issued a patent.

1. Is the new excessive price control regime introduced by the *2019 Regulatory Amendments* consistent with this constitutional limit? To answer this question, the new schedule of foreign countries used to compare prices and the new regulatory factors should be discussed separately.
2. *The new schedule of foreign countries*
3. In addition to an objective comparison with the price of medicines in the same therapeutic class, the regime established by the *Patent Act* is intended to ensure that the price of patented medicines sold in Canada does not exceed those charged for the same medicines in foreign countries that are reasonably comparable to Canada. This method of controlling the monopoly granted by the patent serves as an alternative solution to the compulsory licensing method. This alternative solution seeks to ensure that the price of patented medicines remain objectively competitive, at least in relation to the price at which the same medicine or similar medicines are sold in countries that are reasonably comparable to Canada.
4. When this regime was first introduced, the Government of Canada also hoped to encourage research and development in the pharmaceutical sector in Canada, as the Eastman Report in fact recommended. The list of seven foreign countries used to compare prices was therefore established, although it was very likely to generate prices for medicines sold to Canadians that exceeded those charged in most other countries reasonably comparable to Canada. The objective was to encourage the pharmaceutical industry to invest in research and development in Canada.
5. Accordingly, the median prices of patented medicines in Canada are in fact lower than the median prices of patented medicines in the seven foreign comparator countries listed in the schedule to the *Patented Medicines Regulations*,[[204]](#footnote-204) but higher than the median prices for all Organisation for Economic Co-operation and Development (“OECD”) countries.[[205]](#footnote-205) This is not surprising because it is one of the intended effects of the regime, which, in addition to protecting Canadians from excessive prices for patented medicines, also seeks to encourage pharmaceutical research and development in Canada.
6. Almost 30 years later, we note that the expected result in terms of pharmaceutical research and development has not materialized. This observation led the Government of Canada to amend the list of comparator countries, as explained in the *2019 Regulatory Amendments* impact analysis statement:[[206]](#footnote-206)

The Regulations include a schedule of countries the PMPRB must look to when comparing prices in Canada with prices in other countries as required under subsection 85(1). At the time the original schedule was composed, it was believed that patent protection and price were key determinants of the locus of pharmaceutical R&D investment globally. The choice was made to offer a comparable level of patent protection and pricing for patented medicines in Canada as existed in countries with a strong pharmaceutical industry presence on the assumption that Canada would come to enjoy comparable levels of R&D. However, that policy presumption has proven flawed and is no longer considered to be the most appropriate basis for the composition of the countries listed in the schedule.

1. In this regard, it is up to the Government of Canada to establish the list of countries used for the objective analysis of competitiveness with international prices. There is nothing from a constitutional standpoint that prevents it from excluding a reasonably comparable country, such as the United States, and replacing it with another, such as Belgium, for example. The fact that such substitution of reasonably comparable countries could have the effect of reducing the price of medicines in Canada is not relevant to the analysis of the measure’s constitutional validity, because the objective sought remains that of ensuring that prices in Canada are competitive in relation to those in other countries. As we have seen, this legislative objective is directly connected to the federal jurisdiction over patents, because it seeks to control the effects on prices of the monopoly granted by the patent.
2. In its choice of comparator countries, the federal government may consider the impact on research and development, both in Canada and abroad, and adjust this choice on the basis of its policies in this regard, which may change over time. In so doing, the federal government is still acting within its jurisdiction over patents of invention and discovery because that jurisdiction indubitably includes a research and development component. It is in fact one of the foundations of this federal jurisdiction.
3. The Government of Canada’s decision to amend the list of comparator countries, due to a reversal of its previous policy encouraging pharmaceutical research and development in Canada, is therefore constitutionally valid because it is based on considerations that are clearly part of the federal jurisdiction over patents, that is, taking into account research and development in Canada, while controlling the adverse effects of the monopoly granted by patents on the price of patented medicines.
4. That is why I cannot accept the submissions of the appellants and the Attorney General of Quebec to the effect that the new schedule of foreign countries introduced into the *Patented Medicines Regulations* by the *2019 Regulatory Amendments* are unconstitutional for the sole reason that they could cause a reduction in the price of patented medicines.
5. *The new regulatory factors*
6. As we have seen, the new factors introduced by the *2019 Regulatory Amendments* (i.e., the pharmacoeconomic value of the medicine in Canada, the size of the market for the medicine in Canada, and the gross domestic product per capita in Canada) impose arbitrary significant reductions in the price of patented medicines in Canada, irrespective of the international market or any market factor. In fact, only the affordability of the price is considered in this regard. These new factors are therefore used to fix a state price. However, the imposition of a state price does not concern the regulation of the monopoly granted by the patent. Rather, it concerns the regulation of the market *per se*.
7. It is worth repeating that these new factors will result in significant reductions to prices that have already been deemed not excessive on the basis of the factors listed in the *Patent Act* itself. Therefore, the objective sought by introducing these new regulatory factors is not to control the effect on prices of the monopoly granted by the patent, but rather to reduce the price of patented medicines so that they are more affordable, nothing more. Both the Regulatory Impact Analysis Statement and the Board’s new guidelines are clear in this respect.
8. As the trial judge concluded, and rightly so, if it were necessary to take into account the Board’s new guidelines, the new factors prescribed in the *Regulations* would be unconstitutional because they [translation] “raise concerns that in implementing the Amendments, the Board is moving away from the control of excessive prices to embrace the outright control of prices (a power it does not have)”.[[207]](#footnote-207)
9. Although the trial judge recognized the unconstitutionality of the arbitrary price reductions of 20% to 50% in some cases, and 25% to 35% in others, as a result of the direct application of the new regulatory factors, she stated that she was nonetheless of the view that these new factors were not, in themselves, the source of the unconstitutionality. In her view, the unconstitutionality is instead a result of the implementation of the new factors proposed by the Board in its new guidelines, which, however, were irrelevant to the constitutional analysis. For the reasons expressed above, it is not possible to simply exclude the new guidelines from the constitutional analysis, as they are unquestionably connected.
10. Indeed, the trial judge’s approach does not take into account the fact that the very reason the new factors were introduced into the *Regulations* was precisely to impose arbitrary price reductions. The Impact Analysis Statement concerning the new *Regulations* is clear in this respect:[[208]](#footnote-208)

The new price regulatory factors are expected to lower patented medicine spending by $3.8 billion …

In calculating these benefits, only new high-priority medicines were assessed against the new price regulatory factors. The application of the new factors meant that the price of new high-priority medicines was reduced by 40% on average relative to the baseline forecasts. This would lead to a 5.4% reduction in projected patented medicine revenues by year 10.

The 40% average reduction in price for high-priority medicines assumes that the PMPRB would apply a $50,000 cost-per-QALY threshold for medicines for standard diseases (including cancer), a $150,000 threshold for medicines for rare diseases, and a $35,000 threshold for medicines with a high-prevalence population. The 40% impact was calculated following the application of anticipatory Guidelines’ tests on a basket of 70 medicines that were launched in Canada between 2010–2015 and were used as a proxy for high-priority medicines. The 40% reduction represents an average across all 70 medicines, which was then projected forward as the necessary reduction for all new high-priority medicines that are expected to be sold in Canada for the first 10 years after the Amendments come-into-force.

[Emphasis added.]

1. It is clear from a reading of the Regulatory Impact Analysis Statement that the very purpose of the new factors – their pith and substance – is to impose significant arbitrary reductions in the price of patented medicines. The Board’s guidelines are therefore not distinct from the new regulatory factors; they rather faithfully reflect their pith and substance.
2. Moreover, the Attorney General of Canada, who is well aware of the constitutional precariousness of the new regulatory factors, proposes that we adopt a new interpretation of the federal jurisdiction over patents of invention and discovery that would extend this federal jurisdiction to controlling the price of all patented products, including medicines, in all circumstances where the federal government deems it appropriate to intervene.
3. The Attorney General of Canada thus submits that the federal government may regulate all aspects of the price of patented medicines because patentees can always avoid it by abandoning their existing Canadian patents or by not patenting their products and processes in Canada.[[209]](#footnote-209) The Attorney General of Canada argues that the connection between the federal jurisdiction over patents and the federal regulation of prices is thus established by the mere fact that patentees continue to maintain their patents, despite the effects of the regulatory regime attached to them.
4. If it were to be accepted, however, such a novel interpretation of the federal jurisdiction over patents would subvert the constitutional balance, because the federal government could then invoke its jurisdiction over patents to regulate all aspects of the price of all patented products, at its discretion. In fact, the Attorney General of Canada’s representatives confirmed at the appeal hearing that the position argued with respect to the extent of the federal jurisdiction over price control was not limited to medicines, but extended to all patented products, irrespective of their nature.
5. It should be recalled that, with a few exceptions, the provinces have jurisdiction to regulate prices in an industry. As Beetz J. noted in *Re: Anti-Inflation Act*,[[210]](#footnote-210) the control and regulation of local trade and commodity pricing lies, with few exceptions, within provincial jurisdiction:[[211]](#footnote-211)

The control and regulation of local trade and of commodity pricing and of profit margins in the provincial sectors have consistently been held to lie, short of a national emergency, within exclusive provincial jurisdiction.

1. Moreover, it has long been recognized that the federal government cannot regulate an entire industry solely because a federal licence, authorization, or permit is required to allow that industry to function. Thus, on several occasions, the Privy Council dismissed the federal government’s attempts to expand its jurisdiction over trade and commerce through the granting of licences, at the expense of property and civil rights.[[212]](#footnote-212) Similarly, the Supreme Court refused to expand the federal jurisdiction over the regulation of fisheries to the licensing of fish canneries or to the regulation of trade processes once the resource had been extracted and converted into a commodity, as that stage fell within provincial jurisdiction.[[213]](#footnote-213)
2. Overall, the Attorney General of Canada’s argument that the federal government can regulate all aspects of the price of patented medicines seems completely contrary to the body of Canadian case law on the matter and constitutes a novel approach to the division of powers.
3. This novel approach seeks to considerably expand the federal jurisdiction over patents of invention and discovery to provide constitutional justification for the arbitrary price reductions for patented medicines prescribed by the *2019 Regulatory Amendments*.
4. In short, under the guise of its jurisdiction over patents, the Government of Canada simply seeks to regulate the price of patented medicines to impose significant price reductions by introducing new factors that have little or nothing to do with the monopoly granted by patents.
5. The fact that the Board may in certain rare cases exclude the application of its new guidelines also cannot validate the constitutionality of the new price control regime resulting from the new regulatory factors. Indeed, it is clear that the federal government is trying to give the Board a new role so as to substitute it for the provincial bodies, such as the INESSS, and for the provincial health ministers. Thus, the Board could then play a greater, determinative role when choosing between pharmaceutical treatments that are innovative but costly and traditional treatments that may be just as (or even more) costly for the provincial health systems.
6. The Regulatory Impact Analysis Statement is in fact quite explicit in this respect:[[214]](#footnote-214)

The Amendments add three new price regulatory factors that, in addition to those already specified in subsection 85(1) of the *Patent Act*, are to be considered by the PMPRB. The new factors include: pharmacoeconomic value; market size; and gross domestic product (GDP) and GDP per capita in Canada. The need for these new factors arises from the limitations of evaluating whether a price is excessive on the basis of unit price information alone. Unit price divorced from overall cost to consumers does not capture key inputs in determining whether a medicine represents **reasonable value for money** or **the ability of constrained health budgets to absorb new costs without rationing access or displacing other needed treatments**. These are critical considerations in an era marked by an aging population and a burgeoning number of medicines with annual average treatment costs in the tens of thousands and hundreds of thousands of dollars.

…

In a public health care system, a new medicine will only improve health outcomes overall if its additional health benefits exceed the opportunity costs associated with the additional resources required to pay for it. Opportunity cost is measured by reference to the estimated health foregone by other patients within the health care system when fixed and fully allocated resources are used to adopt a new medicine. Such an assessment of health opportunity cost reflects the maximum a health care system can pay for the health benefits that a new medicine offers without reducing total population health. This is referred to as a supply-side threshold and requires knowledge of the marginal cost of a QALY within that health system (i.e. the point at which spending on a new medicine for one set of patients in the public system will result in the loss of one QALY for another set of patients in the system).

…

… Requiring the [Board] to consider the pharmacoeconomic value of these medicines **will ensure that the concept of opportunity cost is taken into account** in determining whether their price is excessive. Given that the private market for pharmaceuticals in Canada is an offshoot of the public system and cannot function without it, the policy intent is for the [Board] to **adopt the perspective of the public health care system** and **favour a supply-side cost-effectiveness threshold in estimating opportunity cost**.

[Emphasis added.]

1. It could not be stated more clearly.
2. In summary, federal control of the price of patented medicines is constitutionally valid to the extent that its pith and substance is to prevent the adverse effects on prices of the monopoly granted by the patent. Conversely, such control is unconstitutional when it is no longer intended to control the effect on prices of the monopoly granted by patent.
3. While it is necessary to give the heads of power a flexible and progressive interpretation to take into account the changes in Canadian society, it must nevertheless be rooted in the natural limits fixed by sections 91 and 92 of the *Constitution Act, 1867*, and must seek to preserve the balance between the federal and provincial jurisdictions.[[215]](#footnote-215) However, by imposing arbitrary price reductions of up to 20% to 50% in certain cases, and of 25% to 35% in others, on prices already deemed not to be excessive, the federal government is no longer acting within its jurisdiction over patents of invention and discovery because it does not want to regulate the effects on prices of the monopoly granted by the patent, but rather the market itself. In addition, by giving the Board a new, determinative role in the optimization of provincial resources and provincial health budgets, the federal government is directly intruding into provincial heads of power.

**VII - CONCLUSION**

1. I therefore propose that the Court allow the appeal in part and dismiss the incidental appeal, with legal costs on appeal and at trial in favour of the appellants.
2. I therefore propose to reverse the trial judgment in part to replace paragraphs [432] and [433] with the following:

[translation]

[432] **DECLARES** valid: (i) the entire Patented Medicines Regulations, SOR/94-688 and (ii) the amendments to the Regulations published in the Canada Gazette, Part II, on August 21, 2019 (Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019-298), except subsection 3(4) introducing the new paragraphs 4(4)(a) and 4(4)(b) and section 4 introducing the new sections 4.1 to 4.4 into the Patented Medicines Regulations, SOR/94-688;

[433] **DECLARES** ultra vires, invalid, null, and without effect subsection 3(4) and section 4 of the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), SOR/2019 introducing the new paragraphs 4(4)(a) and 4(4)(b) and the new sections 4.1 to 4.4 into the Patented Medicines Regulations, SOR/94-688;

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| ROBERT M. MAINVILLE, J.A. |

1. *Merck Canada inc. c. Procureur general du Canada*, 2020 QCCS 4541 (the “trial judgment”). [↑](#footnote-ref-1)
2. *Patent Act*, R.S.C. 1985, c. P-4. [↑](#footnote-ref-2)
3. *Patented Medicines Regulations*, SOR/94-688, published in the *Canada Gazette*, Part II (1947–1997), Vol. 128, No. 24, Supplement, November 30, 1994, at 3851. There are several earlier versions of these *Regulations*: SOR 94-688, in force from March 22, 2006, to March 5, 2008; SOR 94-688, in force from March 6, 2008, to June 30, 2008; SOR 94-688, in force from July 1, 2008, to December 31, 2013; SOR 94-688, in force from January 1, 2014, to July 29, 2021. [↑](#footnote-ref-3)
4. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298, published in the *Canada Gazette*, Part II, Vol. 153, No. 17, at 5940. [↑](#footnote-ref-4)
5. *Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements),* SOR 2020-126, s. 2(3), published in the *Canada Gazette*, Part II, Vol. 154, No. 12, at 1189; *Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*,SOR 2020-298, s. 1(3), published in the *Canada Gazette*, Part II, Vol. 155, No. 2, at 75; *Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR 2021-162, s. 1(3), published in the *Canada Gazette*, Part II, Vol. 155, No. 14, at 2325. [↑](#footnote-ref-5)
6. *Regulations Amending the Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR 2021-273, December 21, 2021, published on January 5, 2022, in the *Canada Gazette*, Part II, Vol. 156, No. 1, at 293. [↑](#footnote-ref-6)
7. *Act respecting Patents of Invention*, S.C. 1869, c. 11. [↑](#footnote-ref-7)
8. *Ibid.*, s. 28. [↑](#footnote-ref-8)
9. *An Act to Amend and Consolidate the Acts Relating to Patents of Invention*, S.C. 1923, c. 23. [↑](#footnote-ref-9)
10. *Ibid.* at s. 17(1). [↑](#footnote-ref-10)
11. *Ibid.* at s. 17(2). [↑](#footnote-ref-11)
12. *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274, 1985 CanLII 3151 at para. 8 of the CanLII ed. [↑](#footnote-ref-12)
13. Harry C. Eastman, Commissioner, *Report of The Commission of Inquiry on the Pharmaceutical Industry* (1985) at xxxiv (“Eastman Report”). [↑](#footnote-ref-13)
14. *Hoffman-LaRoche v. Bell-Craig Pharmaceutical Division of L.D. Craig Ltd.*, [1966] S.C.R. 313 at 319. See also *Eli Lilly and Co. v. U. Chemicals Ltd.*, [1977] 1 S.C.R. 536 at 545. [↑](#footnote-ref-14)
15. *An Act to Amend and Consolidate the Acts Relating to Patents of Invention*, S.C. 1923, c. 23, s. 40. [↑](#footnote-ref-15)
16. *Patent Act*, R.S.C. 1985, c. P-4, ss. 65–71. [↑](#footnote-ref-16)
17. *An Act to Amend and Consolidate the Acts Relating to Patents of Invention*, S.C. 1923, c. 23, s. 40(1)*(*c). [↑](#footnote-ref-17)
18. *Ibid.* [↑](#footnote-ref-18)
19. *Parke-Davis and Co. v. The Comptroller General et al*. (1954) 71 R.P.C. 169 (H.L.). [↑](#footnote-ref-19)
20. *Ibid.* at 327. [↑](#footnote-ref-20)
21. Canada, Royal Commission on Patents, Copyright, Trade Marks and Industrial Designs, *Report on patents of invention* (Ottawa: Queen’s Printer, 1960) at 93–98. [↑](#footnote-ref-21)
22. Canada, Department of Justice, Restrictive Trade Practices Commission, *Report Concerning the Manufacture, Distribution and Sale of Drugs* (Ottawa: Queen’s Printer, 1963) at 516–524. [↑](#footnote-ref-22)
23. Canada, Royal Commission on Health Services, *Report of the Royal Commission on Health Services* (Ottawa: Queen’s Printer, 1964), Vol. 1 at 701–709 and recommendations 67–69 at 43. [↑](#footnote-ref-23)
24. Canada, House of Commons, *Special Committee on Drug Costs and Prices* (Ottawa: Queen’s Printer, 1966). [↑](#footnote-ref-24)
25. *Patent Act*, R.S. 1969, c. 203, s. 41. [↑](#footnote-ref-25)
26. Eastman Report at 19–20. [↑](#footnote-ref-26)
27. *Patent Act*, R.S. 1969, c. 203, s. 41(4). [↑](#footnote-ref-27)
28. *American Home Products Corp. v. Commissioner of Patents* (1970), 62 C.P.R. 155, [1970] O.J. No. 191 (QL) (Ont. C.A.) at 160–161; *Lilly v. S & U Chemicals Ltd.*, (1973), 9 C.P.R. (2d) 17 at 18; *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274 (F.C.), 1985 CanLII 3151; *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 2 F.C. 359, 1986 CanLII 3976 (F.C.A.). [↑](#footnote-ref-28)
29. *Frank W. Horner v. Hoffman-La Roche Ltd.* (1970), 61 C.P.R. 243, 1970 LNCPAT 11 (QL) at paras. 18–19 [cited to QL]. [↑](#footnote-ref-29)
30. *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274 (F.C.), 1985 CanLII 3151 at paras. 16 and 43 [cited to CanLII]. [↑](#footnote-ref-30)
31. Eastman Report at xvii, xviii, and 348–349; *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 35 C.P.R. (3d) 1224 (Man. Q.B.) at para. 6; *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274 (F.C.), 1985 CanLII 3151 at para. 10 [cited to CanLII]. [↑](#footnote-ref-31)
32. *Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41. [↑](#footnote-ref-32)
33. *Ibid.*, s. 14, repealing and replacing s. 41(1) of the *Patent Act* as it then read. [↑](#footnote-ref-33)
34. *Ibid.*, s. 15 introducing s. 41.11 into the *Patent Act* as it then read. [↑](#footnote-ref-34)
35. *Ibid.*, s. 15 introducing ss. 41.18 to 41.24 into the *Patent Act* as it then read. [↑](#footnote-ref-35)
36. *Ibid.*, s. 15 introducing s. 41.15 into the *Patent Act* as it then read. [↑](#footnote-ref-36)
37. *Ibid.*, s. 15 introducing ss. 41.15(1)(1.1) and 41.25(1) into the *Patent Act* as it then read. [↑](#footnote-ref-37)
38. *Ibid.*, s. 15 introducing s. 41.15(2) into the *Patent Act* as it then read. [↑](#footnote-ref-38)
39. *Ibid.*, s. 15 introducing s. 41.15(5) into the *Patent Act* as it then read. [↑](#footnote-ref-39)
40. *Ibid.*, s. 15 introducing s. 41.15(6) into the *Patent Act* as it then read. [↑](#footnote-ref-40)
41. *Patent Act,* R.S.C. 1985, c. P-4, ss. 85(1) and (2). [↑](#footnote-ref-41)
42. *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, 1991 CanLII 8289 (Man. Q.B.); aff’d *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1992) 45 C.P.R. (3d) 194, 1992 CanLII 8541 (Man. C.A.). [↑](#footnote-ref-42)
43. *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2. [↑](#footnote-ref-43)
44. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, April 15, 1994, 1869 U.N.T.S. 332 (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), art. 27. [↑](#footnote-ref-44)
45. *North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America*, Can T.S. 1994, No. 2, art. 1709(10). [↑](#footnote-ref-45)
46. As Robertson J. noted in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, 1996 CanLII 4089 (FCA), [1997] 1 F.C. 32 (FCA) at para. 8 [cited to CanLII]: “The most recent legislation affecting patented medicines were enacted in 1993: *Patent Act Amendment Act, 1992*, S.C. 1993, c. 2 and the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the NOC Regulations). A primary motivation for these amendments was Canada's involvement in GATT and NAFTA negotiations: see Horton, at pages 150-153; and Marusyk, at page 162. As Canada was the only major industrialized nation to have a system of compulsory licensing, it was felt that its patent laws should be brought into line with those of other industrialized countries: see Horton, at page 153; and Government of Canada News Release, NR-10770/92-21, at page 3.”  [↑](#footnote-ref-46)
47. *Patent Act Amendment Act*, S.C. 1993, c. 2, s. 7 introducing s. 83(1) into the *Patent Act* as it then read. [↑](#footnote-ref-47)
48. *Ibid.*, introducing ss. 83(2) to (5) into the *Patent Act* as it then read. [↑](#footnote-ref-48)
49. *Ibid.*, introducing s. 82 into the *Patent Act* as it then read. [↑](#footnote-ref-49)
50. *Canada (Attorney General) v. Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited*), 2015 FCA 249 at paras. 109–122; aff’g on this point *Sandoz Canada Inc. v. Canada (Attorney General)*, 2014 FC 501 at paras. 35–37. See also *Alexion Pharmaceuticals Inc. v. Canada (Attorney General])*, 2017 FCA 241 at para. 63. [↑](#footnote-ref-50)
51. *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*, S.C. 2017, c. 6. [↑](#footnote-ref-51)
52. *Food and Drugs Act*, R.S.C. 1985, c. F-27 and *Food and Drug Regulations*, C.R.C., c. 870, Part C, Division 8. [↑](#footnote-ref-52)
53. *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act*, S.C. 2017, c. 6, s. 59, introducing ss. 127 and 128 into the *Patent Act*. [↑](#footnote-ref-53)
54. *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66 at para. 42; *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 at para. 185; *Apotex Inc. v. Welcome Foundation Ltd.*, 2002 SCC 77 at para. 37. [↑](#footnote-ref-54)
55. *Monsanto Canada Inc. v. Scheimeser*, 2004 SCC 34 at para. 36. [↑](#footnote-ref-55)
56. *Celotex Corp. v. Donnacona Paper Co.*, [1939] Ex. C.R. 128, 2 C.P.R. 26; *Gordon Johnson Co. v. Callwood*, [1960] Ex. C.R. 466; *Thorpharm Inc. v. Canada (Commissioner of Patents)*, 2004 F.C. 673. [↑](#footnote-ref-56)
57. *Patent Act*, s. 65(2). [↑](#footnote-ref-57)
58. *Ibid.*,ss. 66(1)(a) and (b) and s. 66(4). [↑](#footnote-ref-58)
59. *Ibid.*, s. 66(1)(d). [↑](#footnote-ref-59)
60. *Canada (Commissioner of Patents) v. Farbwerke Hoechst Aktien-Gesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 at 56; *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd*., 1959 CanLII 52 (SCC), [1959] S.C.R. 219 at 222. [↑](#footnote-ref-60)
61. *Patent Act*, R.S.C. 1985, c. P-4, ss. 83 and 85(1). [↑](#footnote-ref-61)
62. Subsection 80(1) refers to “rights holder”, which is defined in s. 79(2) as “in respect of an invention pertaining to a medicine, a patentee and the person for the time being entitled to the benefit of a certificate of supplementary protection for that invention, and includes, if any other person is entitled to exercise rights in relation to the certificate, that other person in respect of those rights.” For the purposes of these reasons, I use the term “patentee” to refer to all rights holders as defined in the *Act*. [↑](#footnote-ref-62)
63. *Patent Act*,ss. 80(1)(a) and (2)(a); *Patented Medicines Regulations*, s. 3. [↑](#footnote-ref-63)
64. *Patent Act*, ss. 80(1)(b) and (2)(b), *Patented Medicines Regulations*, s. 4 and Schedule. [↑](#footnote-ref-64)
65. *Patent Act*, s. 83(1); *Patented Medicines Regulations*, ss. 4(1)(f), 4(4)(a) and (b), and 4(9). [↑](#footnote-ref-65)
66. *Patent Act*, s. 85(1). [↑](#footnote-ref-66)
67. *Patent Act*, s. 85(2). [↑](#footnote-ref-67)
68. *Ibid.*, s. 85(3). [↑](#footnote-ref-68)
69. *Ibid.*, s. 83(1). [↑](#footnote-ref-69)
70. *Ibid.*, s. 83(2). See also s. 83(3) in connection with former rights holders. [↑](#footnote-ref-70)
71. *Ibid.*, s. 83(4). [↑](#footnote-ref-71)
72. *Ibid.*, s. 96(5). [↑](#footnote-ref-72)
73. *Ibid.*, s. 101(2). [↑](#footnote-ref-73)
74. Exhibit P-39: Affidavit of Susan Kokakis dated December 4, 2019, at para. 50; Exhibit P-40: Affidavit of Beena Kuriakose dated December 4, 2019, at para. 69; Exhibit P-43: Affidavit of Carole Bradley-Kennedy dated December 5, 2019, at para. 63; Exhibit P-45: Affidavit of Kirk Duguid dated December 5, 2019, at para. 79; Exhibit P-46: Affidavit of Dake Toki dated December 5, 2019, at para. 54. [↑](#footnote-ref-74)
75. Because the new regulatory regime will come into force only on July 1, 2022, I will refer to the guidelines applicable as of the date of this judgment as the [translation] “current” guidelines as opposed to the [translation] “new” guidelines that will apply when the new regime comes into force. [↑](#footnote-ref-75)
76. Canada, Patented Medicine Prices Review Board, *Compendium of Policies, Guidelines and Procedures*, updated February 2017, at 9–10. [↑](#footnote-ref-76)
77. *Patented Medicines Regulations*, s. 4(1)(f)(iii) and Schedule. [↑](#footnote-ref-77)
78. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*,SOR/2019-298, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5950–5951. [↑](#footnote-ref-78)
79. Exhibit D-2: Affidavit of Guillaume Couillard, March 13, 2020, at paras. 62–79. [↑](#footnote-ref-79)
80. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*,SOR/2019-298, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5940 *et seq*., s. 4, introducing s. 4.4 into the *Patented Medicines Regulations.* [↑](#footnote-ref-80)
81. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298, Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5967 (“Regulatory Impact Analysis Statement”). [↑](#footnote-ref-81)
82. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*,SOR/2019-298, *Canada Gazette*, Part II, Vol.153, No. 17, August 21, 2019, at 5940 *et seq*., s. 6, replacing the schedule to the *Patented Medicines Regulations*. [↑](#footnote-ref-82)
83. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5968. [↑](#footnote-ref-83)
84. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5940 *et seq*., s. 3(4) replacing ss. 4(4)(a) and (b) of the *Patented Medicines Regulations*. [↑](#footnote-ref-84)
85. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5969. [↑](#footnote-ref-85)
86. Quality-adjusted life year (“QALY”). [↑](#footnote-ref-86)
87. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5940 *et seq*., s. 4 introducing s. 4.1 into the *Patented Medicines Regulations.* [↑](#footnote-ref-87)
88. *Ibid.*, s. 4 introducing s. 4.1(5) into the *Patented Medicines Regulations.* [↑](#footnote-ref-88)
89. *Ibid.*, s. 4 introducing s. 4.2 into the *Patented Medicines Regulations*. [↑](#footnote-ref-89)
90. New *Guidelines of the Patented Medicine Prices Review Board*, at paras. 55–66, Appendices A and C. [↑](#footnote-ref-90)
91. *Ibid.*, Appendix D. [↑](#footnote-ref-91)
92. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5971. [↑](#footnote-ref-92)
93. Trial judgment at paras. 85–86. [↑](#footnote-ref-93)
94. *Act respecting the Institut national d'excellence en santé et en services sociaux*, CQLR c. I-13.03, s. 7. [↑](#footnote-ref-94)
95. *Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications*, CQLR, c. A-29.01, r. 2. See also the *Act respecting health services and social services*, CQLR, c. S-4.2, s. 116, and the *Act respecting prescription drug insurance*, CQLR, c. A-29.01, s. 80. [↑](#footnote-ref-95)
96. *Act respecting prescription drug insurance*, CQLR, c. A-29.01, s. 60.0.1. [↑](#footnote-ref-96)
97. Trial judgment at para. 409. [↑](#footnote-ref-97)
98. The pharmaceutical companies also sought a declaration of invalidity with respect to all the Board’s policies, guidelines, and procedures. The trial judge did not address that application, and it is not contemplated by this appeal. [↑](#footnote-ref-98)
99. Amended application dated February 19, 2020, at para. 133. [↑](#footnote-ref-99)
100. Trial judgment at paras. 239–242. [↑](#footnote-ref-100)
101. *Ibid.* at paras. 256–260. [↑](#footnote-ref-101)
102. *Ibid.* at para. 261: [translation] “In light of all these elements, the Court finds that the pith and substance of Regime 1 is to control the prices of patented medicines to ensure that they are below a threshold that the Board deems excessive. The objective was to prevent overly high prices due to the complete abolition of the patented medicines compulsory licensing regime.” [↑](#footnote-ref-102)
103. *Ibid.* at para. 263. [↑](#footnote-ref-103)
104. *Ibid.* at para. 271. [↑](#footnote-ref-104)
105. *Ibid.* at paras. 273–274 [↑](#footnote-ref-105)
106. *Ibid.* at paras. 279 and 282–286. [↑](#footnote-ref-106)
107. *Ibid.* at para. 287. [↑](#footnote-ref-107)
108. *Ibid.* at para. 364. [↑](#footnote-ref-108)
109. *Ibid.* at paras. 372–376. [↑](#footnote-ref-109)
110. *Ibid.* at paras. 384–386. [↑](#footnote-ref-110)
111. *Ibid.* at para. 388. [↑](#footnote-ref-111)
112. *Ibid.* at paras. 391–395. [↑](#footnote-ref-112)
113. *Ibid.* at para. 397. [↑](#footnote-ref-113)
114. *Ibid.* at paras. 400–402. [↑](#footnote-ref-114)
115. *Ibid.* at paras. 403 and 406. [↑](#footnote-ref-115)
116. *Ibid.* at para. 411. [↑](#footnote-ref-116)
117. Arguments in the Attorney General of Canada’s brief at para. 5. [↑](#footnote-ref-117)
118. *Ibid.* at para. 6. [↑](#footnote-ref-118)
119. Arguments in the Attorney General of Quebec’s brief at para. 91. [↑](#footnote-ref-119)
120. *Ibid.* at para. 92. [↑](#footnote-ref-120)
121. *Ibid.* at para. 101. [↑](#footnote-ref-121)
122. Arguments in the Canadian Association for Rare Disorders’ brief at para. 67. [↑](#footnote-ref-122)
123. *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725, notice of appeal filed with the Federal Court of Appeal. [↑](#footnote-ref-123)
124. *North American Free Trade Agreement Between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America*, Can T.S. 1994 No. 2. [↑](#footnote-ref-124)
125. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, April 15, 1994, 1869 U.N.T.S. 332 (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization). [↑](#footnote-ref-125)
126. *Consolidated Fastfrate Inc. v. Western Canada Council of Teamsters*, 2009 SCC 53, [2009] 3 S.C.R. 407 at para. 26; *Canada (Attorney General) v. Bedford*, 2013 SCC 72,[2013] 3 S.C.R. 1101 at paras. 53–56; *Danson v. Ontario (Attorney General)*,[1990] 2 S.C.R. 1086 at 1099; *Procureur general du Québec c. Association canadienne des télécommunications sans fil*, 2021 QCCA 730 at para. 62; *Procureur général du Québec c. Murray-Hall,*2021 QCCA 1325 at para. 25, leave to appeal to S.C.C. requested, 39774. [↑](#footnote-ref-126)
127. *Reference re Genetic Non‑Discrimination Act*, 2020 SCC 17 at paras. 26–29;  *Reference re Pan‑Canadian Securities Regulation*, 2018 SCC 48 at para. 86; *Canadian Western Bank v. Alberta*, 2007 SCC 22 at para. 25. [↑](#footnote-ref-127)
128. *Canadian Western Bank v. Alberta*, 2007 SCC 22, [2007] 2 S.C.R. 3 at paras. 27 to 30. [↑](#footnote-ref-128)
129. *R. v. Morgentaler*, [1993] 3 S.C.R. 463 at 482–483. [↑](#footnote-ref-129)
130. *Quebec (Attorney General) v. Lacombe*, 2010 SCC 38, [2010] 2 S.C.R. 453 at para. 36; *Canadian Western Bank v. Alberta*, 2007 SCC 22, [2007] 2 S.C.R. 3 at paras. 28 and 29. [↑](#footnote-ref-130)
131. *Transport Desgagnés Inc. v. Wärtsilä Canada Inc*., 2019 SCC 58 at para. 90 *et seq*.; *Canada (Attorney General) v. PHS Community Services Society*, 2011 SCC 44, [2011] 3 S.C.R. 134 at para. 58; *Canadian Western Bank v. Alberta*, 2007 SCC 22, [2007] 2 S.C.R. 3 at para. 33 *et seq*. [↑](#footnote-ref-131)
132. *Reference re Genetic Non‑Discrimination Act*, 2020 SCC 17 at para. 28; *Quebec (Attorney General) v. Canada (Attorney General)*, 2015 SCC 14, [2015] 1 S.C.R. 693 atpara. 29. [↑](#footnote-ref-132)
133. *Reference re Assisted Human Reproduction Act*, 2010 SCC 61 at para. 184; *Friends of the Oldman River Society v. Canada (Minister of Transport)*, [1992] 1 S.C.R. 3 at 62. [↑](#footnote-ref-133)
134. *Ward v. Canada (Attorney General)*, 2002 SCC 17 at para. 17. [↑](#footnote-ref-134)
135. *Reference re Genetic Non‑Discrimination Act*, 2020 SCC 17 at para. 30; *Quebec (Attorney General) v. Lacombe*, 2010 SCC 38, [2010] 2 S.C.R. 453 atpara. 20. [↑](#footnote-ref-135)
136. *Kitkatla Band v. British Columbia (Minister of Small Business, Tourism and Culture)*, 2002 SCC 31, [2002] 2 S.C.R. 146 at paras. 53–54. [↑](#footnote-ref-136)
137. *Canadian Western Bank v. Alberta*, 2007 SCC 22, [2007] 2 S.C.R. 3 at para. 27. [↑](#footnote-ref-137)
138. *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11 at paras. 51–56. [↑](#footnote-ref-138)
139. *Ibid.* at paras. 52–55. [↑](#footnote-ref-139)
140. *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, 1991 CanLII 8289 (Man. Q.B.) at para. 23 [cited to CanLII], aff’d (1992) 45 C.P.R. (3d) 194, 1992 CanLII 8541 (Man. C.A.). [↑](#footnote-ref-140)
141. See in particular *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, (1996) 108 F.T.R. 190, [1996] F.C.J. No. 206 (QL) at para. 24 [cited to QL], aff’d [1997] 1 F.C. 32 (C.A.); *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 at paras. 28–29; *Canada (Attorney General) v. Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited*), 2015 FCA 249 at para. 116; *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 at paras. 76–89; *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 at paras. 49–50. [↑](#footnote-ref-141)
142. *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, (1996) 108 F.T.R. 190, [1996] F.C.J. No. 206 (QL) at para. 24 [cited to QL], aff’d [1997] 1 F.C. 32 (C.A.), cited with approval in *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 at para. 28. [↑](#footnote-ref-142)
143. *RJR-MacDonald Inc. v. Canada (Attorney General)*, [1994] 1 S.C.R. 311 at 352–353; *Friesen v. Canada*, [1995] 3 S.C.R. 103 at para. 63; *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 S.C.R. 533 atparas. 156–157; *Merck & Co. v. Canada (Attorney General)*, [1999] 176 F.T.R. 21, [1999] F.C.J. No. 1825 (QL), at para. 51 [cited to QL], aff’d [2000] F.C.A. No. 380 (QL), leave to appeal to SCC refused, 27861; *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, 2004 FC 736, [2004] F.C.J. No. 883 (QL) at para. 23 [cited to QL]; *Bayer Inc. v. Canada (Attorney General)* (1999), 87 C.P.R. (3d) 293 (F.C.A.), [1999] F.C.J. No. 826 (QL) at para. 10 [cited to QL]. [↑](#footnote-ref-143)
144. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5950–5949. [↑](#footnote-ref-144)
145. *Ibid.* at 5954. [↑](#footnote-ref-145)
146. *Ibid.* at 5955. [↑](#footnote-ref-146)
147. *Ibid.* at 5957. [↑](#footnote-ref-147)
148. *Ibid.* at 5963. [↑](#footnote-ref-148)
149. Exhibit P-164: Health Canada, News release, *Government of Canada Announces Changes to Lower Drug Prices*, August 9, 2019. [↑](#footnote-ref-149)
150. *Ibid.* [↑](#footnote-ref-150)
151. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*,SOR/2019-298, s. 4 introducing new s. 4.4 into the *Patented Medicines Regulations*, SOR/94-688. [↑](#footnote-ref-151)
152. New guidelines at paras. 55–66 and Appendix C. [↑](#footnote-ref-152)
153. *Ibid.*, Appendix D. [↑](#footnote-ref-153)
154. Trial judgment at paras. 240–242. [↑](#footnote-ref-154)
155. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 atparas. 57–63, relying in part on *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65 at para. 131. [↑](#footnote-ref-155)
156. *Little Sisters Book and Art Emporium v. Canada (Minister of Justice)*, 2000 SCC 69, [2000] 2 S.C.R. 1120. [↑](#footnote-ref-156)
157. Trial judgment at para. 242. [↑](#footnote-ref-157)
158. *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298, published in the *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5950–5962. [↑](#footnote-ref-158)
159. *Central Canada Potash Co. Ltd. et al. v. Government of Saskatchewan*, [1979] 1 S.C.R. 42 at 76. [↑](#footnote-ref-159)
160. In this respect, see *References re Greenhouse Gas Pollution Pricing Act*, 2021 SCC 11 at para. 55. [↑](#footnote-ref-160)
161. *Reference re Firearms Act (Can.)*, 2000 SCC 31, [2000] 1 S.C.R. 783 at para. 15; *Quebec (Attorney General) v. Lacombe*, 2010 SCC 38, [2010] 2 S.C.R. 38 at para. 24; *Reference re Pan‑Canadian Securities Regulation*, 2018 SCC 48, [2018] 3 S.C.R. 189 at para. 86. [↑](#footnote-ref-161)
162. *Ward v. Canada (Attorney General)*, 2002 SCC 17, [2002] 1 S.C.R. 559 at para. 30. See also *Transport Desgagnés Inc. v. Wärtsilä Canada Inc.*, 2019 SCC 58 at para. 48. [↑](#footnote-ref-162)
163. *American Home Products Corp. v. Commissioner of Patents*, [1969] O.J. No. 805 (QL) (Ont. Sup. Ct. J.), aff’d 62 C.P.R. 155, [1970] O.J. No. 191 (QL) (Ont. C.A.). [↑](#footnote-ref-163)
164. *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274 (F.C.), 1985 CanLII 3151, aff’d *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 2 F.C. 359, 1986 CanLII 3976 (F.C.A.). [↑](#footnote-ref-164)
165. *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274, 1985 CanLII 3151 (FC) at 294–295 and 296 [cited to F.C.]. [↑](#footnote-ref-165)
166. *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, 1991 CanLII 8289 (Man. Q.B.), aff’d *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1992) 45 C.P.R. (3d) 194, 1992 CanLII 8541 (Man. C.A.). [↑](#footnote-ref-166)
167. *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485, 1991 CanLII 8289 (Man. Q.B.) at paras. 21–24 [cited to CanLII]. [↑](#footnote-ref-167)
168. *Canada (Attorney General) v. Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited*), 2015 FCA 249, rev’g *Sandoz Canada Inc. v. Canada (Attorney General)*, 2014 FC 501 and *Ratiopharm Inc. v. Canada (Attorney General)*, 2014 FC 502; *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2017 FCA 241, aff’g *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2017 FC 22 and *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2016 FC 716. [↑](#footnote-ref-168)
169. *Sandoz Canada Inc. v. Canada (Attorney General)*, 2014 FC 501 at paras. 35–37. [↑](#footnote-ref-169)
170. *Canada (Attorney General) v. Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited*), 2015 FCA 249 at para. 116. [↑](#footnote-ref-170)
171. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2016 FC 716 at para. 39. [↑](#footnote-ref-171)
172. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2017 FC 22 atpara. 23. [↑](#footnote-ref-172)
173. *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2017 FCA 241 at para. 63. [↑](#footnote-ref-173)
174. *R. c. Lapointe*, 2021 QCCA 360 at para. 32 [↑](#footnote-ref-174)
175. Trial judgment at para. 385. [↑](#footnote-ref-175)
176. Exhibit P-221: Memorandum dated November 30, 1990, from Deputy Minister Jocelyne Bourgon to the Minister of Consumer and Corporate Affairs Canada at 3. [↑](#footnote-ref-176)
177. Arguments in the appellant’s brief at paras. 23 and 81–83. [↑](#footnote-ref-177)
178. *Patent Act*, s. 79(2). [↑](#footnote-ref-178)
179. *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, 1996 CanLII 4089 (FCA), [1997] 1 F.C. 32 (F.C.A.) at para. 55 [cited to CanLII]. [↑](#footnote-ref-179)
180. *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board*), 1996 CanLII 4089 (F.C.A.), [1997] 1 F.C. 32 (F.C.A.); *Canada (Attorney General) v. Galderma Canada Inc.*, 2019 FCA 196. [↑](#footnote-ref-180)
181. *Re Board of Commerce Act*, *1919*, [1922] 1 A.C. 191; *Re: Anti-Inflation Act*, [1976] 2 S.C.R. 373 at 441–442, 452–453. See also *Home Oil Distributors Ltd. et al. v. A.G. British Columbia et al*., [1940] S.C.R. 444; *Carnation Co. Ltd. v. The Quebec Agricultural Marketing Board et al.*, [1968] S.C.R. 238; *A.G. Can. v. A.G. Alta (Insurance Reference)*, [1916] 1 A.C. 588; *Re Insurance Act of Can*., [1932] A.C. 41; *Re Board of Commerce Act*, [1922] 1 A.C. 191; *A.G. Canada v. A.G. Ontario (Unemployment Insurance Reference)*, [1937] A.C. 355; *Re: Anti-Inflation Act*, [1976] 2 S.C.R. 373; *Labatt Breweries of Canada Ltd. v. Attorney General of Canada*, [1980] 1 S.C.R. 914 at 942–944; *Reference re Securities Act*, 2011 SCC 66. [↑](#footnote-ref-181)
182. *Pfizer Canada Inc. v. Canada (Attorney General)*, 2009 FC 719 at paras. 61–63 and 83. See also *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 at paras. 176–177. [↑](#footnote-ref-182)
183. *Canada (Attorney General) v. Sandoz Canada Inc. and Ratiopharm Inc. (now Teva Canada Limited*), 2015 FCA 249 at paras. 72–79. [↑](#footnote-ref-183)
184. *Ibid.* at paras. 2 and 74–79. [↑](#footnote-ref-184)
185. *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3. [↑](#footnote-ref-185)
186. New Board guidelines at para. 15 concerning the applicable legal framework. [↑](#footnote-ref-186)
187. Arguments in the Attorney General of Canada’s brief at para. 235. [↑](#footnote-ref-187)
188. *Pfizer Canada Inc. v. Canada (Attorney General)*, 2009 FC 719 at para. 73; *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 atparas. 166–170; Exhibit P-152, NP-B: Expert report of Neil Palmer at para. 29: “In this context, it is important to distinguish rebates from discounts. A discount is an “on-invoice” reduction off the list price paid by a purchaser and visible to the purchaser at the time of purchase. Public drug plans do not purchase drugs from manufacturers rather, they reimburse the citizens who are purchasing the drugs”. [↑](#footnote-ref-188)
189. *Innovative Medicines Canada v. Canada (Attorney General)*, 2020 FC 725 atparas. 196–198. [↑](#footnote-ref-189)
190. The French translation of this part of the sentence that appears in the Federal Court Reporter reads as follows: “*et qui ne sont pas étrangers à la transaction de vente initiale*” [Emphasis added]. This translation is incorrect, however, and should read “*et qui [sont] étrangers à la transaction de vente initiale*”. The sentence was therefore corrected in the original French version of this judgment to faithfully reflect the original English version of the judgment cited. [↑](#footnote-ref-190)
191. *Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 37. See also *Whirlpool Corp. v. Camco Inc*., 2000 SCC 67, [2000] 2 S.C.R. 1067 at para. 37; *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66, [2000] 2 S.C.R. 1024 at para. 13. [↑](#footnote-ref-191)
192. *Apotex Inc. v. Wellcome Foundation Ltd*., 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 37. [↑](#footnote-ref-192)
193. *Agreement on Trade-Related Aspects of Intellectual Property Rights*, April 15, 1994, 1869 U.N.T.S. 332 (Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization), para. 3 of art. 27. [↑](#footnote-ref-193)
194. WTO, Doha *Declaration on the TRIPS agreement and public health*, November 14, 2001. [↑](#footnote-ref-194)
195. See also the *Use of Patented Products for International Humanitarian Purposes Regulations*, SOR/2005-143. [↑](#footnote-ref-195)
196. *COVID-19 Emergency Response Act*, S.C. 2020, c. 5, s. 51 introducing s. 19.4 into the *Patent Act.* [↑](#footnote-ref-196)
197. See *Hoffman-LaRoche v. Bell-Craig Pharmaceutical Division of L.D. Craig Ltd.*, [1966] S.C.R. 313 at 319; *Eli Lilly and Co. v. U. Chemicals Ltd.*, [1977] 1 S.C.R. 536 at 545; *Frank W. Horner v. Hoffman-La Roche Ltd.* (1970), 61 C.P.R. 243, 1970 LNCPAT 11 (QL) at paras. 18–19 [cited to QL]; *Parke, Davis & Co. v. Fine Chemicals of Canada Ltd.*, [1959] S.C.R. 219 at 222; *Canada (Commissioner of Patents) v. Farbwerke Hoechst Aktien-Gesellschaft Vormals Meister Lucius & Bruning*, [1964] S.C.R. 49 at 56. [↑](#footnote-ref-197)
198. This separate regime is now set out in ss. 79–103 of the *Patent Act* and is distinct from the regime concerning abuse of patent set out in ss. 65–71 and 127–128 of the *Act*. [↑](#footnote-ref-198)
199. *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 1 F.C. 274, 1985 CanLII 3151 (F.C.) at paras. 42–43 [cited to CanLII], aff’d *Smith, Kline & French Laboratories v. Canada (Attorney General)*, [1986] 2 F.C. 359, 1986 CanLII 3976 (F.C.A.). [↑](#footnote-ref-199)
200. *Ibid.* at para. 51. [↑](#footnote-ref-200)
201. *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1, [2011] 1 S.C.R. 3 at paras. 28–29. [↑](#footnote-ref-201)
202. In fact, Stratas J.A. of the Federal Court of Appeal agreed with this conclusion in an *obiter* remark in the recent judgment in *Alexion Pharmaceuticals Inc. v. Canada (Attorney General)*, 2021 FCA 157 at para. 49: “Were the excessive pricing provisions of the federal *Patent Act* aimed at reasonable pricing, price-regulation or consumer protection at large, they would be constitutionally suspect”. [↑](#footnote-ref-202)
203. Exhibit P-221: Memorandum dated November 30, 1990, from Deputy Minister Jocelyne Bourgon to the Minister of Consumer and Corporate Affairs Canada at 1 and 2. [↑](#footnote-ref-203)
204. PMPRB Annual Report 2017, figure 22; Exhibit P-152, NP-B: Expert Report of Neil Palmer at para. 109 and figure 9. [↑](#footnote-ref-204)
205. PMPRB Annual Report 2017, figure 23; Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5952: “In 2017, median OECD prices for patented medicines were on average 19% below those in Canada”. The expert Palmer harshly criticized the methodology used to obtain this percentage of 19%, while suggesting that the median prices for the entire group of OECD countries are lower than in Canada, but to a lesser degree: Expert Report of Neil Palmer at para. 130 and figure 12.1, paras. 150–157. [↑](#footnote-ref-205)
206. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5953. [↑](#footnote-ref-206)
207. Trial judgment at para. 400. [↑](#footnote-ref-207)
208. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5967–5968. [↑](#footnote-ref-208)
209. Arguments in the Attorney General of Canada’s brief at para. 6. [↑](#footnote-ref-209)
210. *Re: Anti-Inflation Act,* [1976] 2 S.C.R. 373 at 441. See also Peter. W. Hogg, *Constitutional Law of Canada*, Vol. 1, 5th ed. (Scarborough, Ont.: Thomson/Carswell, 2007) (loose-leaf updated 2021) at para. § 21.8. [↑](#footnote-ref-210)
211. *Ibid.* at 441. Although Beetz J. was dissenting in that case, the principle cited that he set out is not the subject of controversy. [↑](#footnote-ref-211)
212. *A.G. Can. v. A.G. Alberta* (Insurance Reference), [1916] 1 A.C. 588; *Re Insurance Act of Can.*, [1932] A.C. 41; *A.G. Canada v. A.G. Ontario* (*Unemployment Insurance Reference*), [1937] A.C. 355. [↑](#footnote-ref-212)
213. *Reference re Fisheries Act, 1914 (Canada)*, [1928] S.C.R. 457, aff’d on this point by the Privy Council, *Reference as to Constitutional Validity of Certain Sections of Fisheries Act, 1914*,  [1930] A.C. 111. [↑](#footnote-ref-213)
214. Regulatory Impact Analysis Statement, *Canada Gazette*, Part II, Vol. 153, No. 17, August 21, 2019, at 5954–5955. [↑](#footnote-ref-214)
215. *Marcotte v. Fédération des caisses Desjardins du Québec*, 2014 SCC 57, [2014] 2 S.C.R. 805 at para. 20; *Canada (Attorney General) v. Hislop*, 2007 SCC 10, [2007] 1 S.C.R. 429 at para. 94; see also, in the context of interpreting the *Canadian Charter*: *Quebec (Attorney General) v. 9147-0732 Québec inc.*, 2020 SCC 32 at paras. 8–13. [↑](#footnote-ref-215)