Section de première instance de la Cour fédérale du Canada

Federal Court of Canada Trial Division

T-375-94

BETWEEN:

CIBA-GEIGY CANADA LTD.

Applicant

- AND -

PATENTED MEDICINE PRICES REVIEW BOARD

Respondent

REASONS FOR ORDER

McKEOWN, J.

CIBA-Geigy Canada Limited (CIBA) is seeking judicial review of the Order of the Patented Medicine Prices Review Board (the Board) dated February 1, 1994, dismissing CIBA's request for disclosure and production of all documents relating to the matters in issue in an upcoming hearing to be held by the Board. The upcoming hearing is to determine whether the drug Habitrol, marketed in Canada by CIBA, is being sold at an excessive price. The applicant is seeking an Order:

1. setting aside the decision of the Board dated February 1, 1994 and identified as PMPRB-94-1/HABITROL.PHC in file No. PMPRB-94-D1/HABITROL; and

2. requiring the Board and Board staff to disclose and produce all documents in their power, possession or control which relate to matters at issue in the proceeding commenced by the Board against CIBA by Notice of Hearing dated November 24, 1993.

Both parties agree that the doctrines of fairness and natural justice apply here. The question is whether, in the circumstances of this case, CIBA is only entitled to the documents which the Board intends to rely on at the hearing, or whether CIBA is entitled to all "the fruits of the investigation" of

Board staff, as provided in *Regina v. Stinchcombe*, [1993] 3 S.C.R. 326 (*Stinchcombe*). If CIBA is not entitled to the "fruits of the investigation", the issue then becomes whether CIBA is entitled to all of the documents in the possession of the Chairperson or members of the Board. Pursuant to the Notice of Hearing issued on November 24, 1993, and the Board's pre-hearing decision at issue here, the respondent has undertaken to provide the applicant with comprehensive prior disclosure of the factual allegations and opinion evidence it will have to meet. In addition, the respondent has undertaken to provide CIBA with all documents which will be used to cross-examine witnesses for the applicant.

The Board refused CIBA's request for exhaustive disclosure *inter alia* on the following grounds:

> In the Board's view, in a hearing before it, the party to whom the hearing relates must be provided with a level of disclosure and production which ensures that the party is fully informed of the case to be made against it. Further, the procedure followed must provide the party to whom the hearing relates a reasonable opportunity to meet that case by bringing forward its own position and by correcting or contradicting any statement or evidence related to the case which is prejudicial to its position.
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> It is the Board's view that, in matters of the disclosure and production of information and documents in the context of a public hearing, the Board must balance its duty to give every opportunity to a Respondent to be heard against its responsibility to ensure that its orders do not have the effect of limiting its ability to discharge its responsibilities in the public interest on an ongoing basis. In order to discharge such responsibilities, the Board must be confident that it is getting candid, complete and objective advice from its staff. This is particularly the case in respect of the preliminary views it receives as to whether there is sufficient evidence to justify calling a hearing into a matter. This balancing need not in any way affect the Board's duty in law to make its decisions on the basis of the evidence placed and tested before it during a hearing.

The Patented Medicine Prices Review Board

The Board was created in 1987 pursuant to S.C. 1987 c.41, which amended the *Patent Act*, R.S.C. 1985 c. P-4 (the "*Act*"). Under the *Act* the Board is responsible, *inter alia*, for obtaining information with respect to the price being charged in Canada for patented medicines and ensuring that such

prices are not, in the opinion of the Board, excessive. In order to carry out its statutory mandate the Board has access to Board staff whose role is to monitor the price of patented medicines. This monitoring function by Board staff begins when a patented medicine is first sold. It is based in part upon information filed with the Board by the patentee. The information filed includes background information and the identity of the medicine as well as the price and dosage of the medicine when it is first sold and at six month intervals thereafter. Board staff report directly to the Chairperson of the Board who is the Board's Chief Executive Officer pursuant to subsection 93(2) of the *Act*. He has the ultimate responsibility for supervising and directing the work of Board staff. Accordingly, under the *Act*, the Chairperson is responsible for the investigation as well as the adjudication of the question of whether a patented medicine is being sold at an excessive price.

Subsection 85(1) of the *Act* provides that in determining whether a medicine is being or has been sold at an excessive price, the Board must consider :

> (a) the prices at which the medicine has been sold in the relevant market;
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada, and
> (d) the changes in the consumer price index.

The Board has also adopted certain guidelines in order to encourage and facilitate compliance by patentees. These guidelines, *inter alia*, establish three categories of medicines. Each new patented medicine is slotted into one of these categories, according to the recommendation of a group of independent scientific experts called the Human Drug Advisory Panel (HDAP). The category the medicine is assigned to determines which other medicines are used in the price comparison tests performed by Board staff. The extent of the Board's work can be gauged by the fact that as of December 31, 1992, the

Board monitored the prices of 738 different patented drugs on the market in Canada, with total sales of $2.1 billion.

In carrying out its investigations, Board staff relies in large measure upon the recommendation of HDAP and the information provided by the patentee. In addition, however, Board staff will communicate with other experts in the field to obtain their opinions on the patented drug in issue and to obtain other relevant information which may be of assistance in the investigation. Typically, this information is provided on a confidential basis and may eventually be discarded by Board staff. The confidential relationships which Board staff entertain with third parties are very important to their ability to discharge their statutory responsibilities. The Board staff will communicate to the patentee the substance of the evidence upon which any excessive pricing determination is made. If the investigation suggests that the price exceeds the guidelines, the patentee is provided with the basis for the Board staff's conclusion and is requested to enter into a Voluntary Compliance Undertaking (VCU) to adjust its price. Regardless of the patentee's response to Board staff's request, upon completing its investigation, Board staff prepares a confidential report which is forwarded to the Chairperson of the Board. It is upon review of this report that the Chairperson decides whether or not there is sufficient evidence to issue a Notice of Hearing. The Notice of Hearing sets out the grounds upon which the Chairperson believes a remedial order may be issued; i.e. that a *prima facie* case exists, and the material facts which led the Chairman to this conclusion.

Subsection 83(6) of the *Act* requires the Board to provide the patentee with a reasonable opportunity to respond to the Notice of Hearing. If, after

this, the Board concludes that the medicine has been sold at an excessive price, the Board may make an order under subsection 83(2):

> a) directing the patentee to reduce the price at which it sells the medicine or some other patented medicine in Canada to a level which would off-set the excess revenues estimated to have been derived by the patentee from the sale of the medicine at an excessive price;
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> b) directing the patentee to pay to Her Majesty an amount in the order; or
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> c) in circumstances where the Board finds that the patentee has engaged in a policy of selling the medicine at an excessive price, directing the patentee to do one or more of the things referred to in paragraphs a) and b) above, so as to off-set, by not more than twice the amount, the excess revenues estimated by the Board to have been derived by the patentee from the sale of the medicine at an excessive price.

The Facts

CIBA sells numerous medicinal products in Canada, approximately 19 of which fell within the jurisdiction of the Board as of December 31, 1992. CIBA has been continually filing with the Board the requisite information concerning these products. Board staff continues to have regular, frequent contact with CIBA personnel concerning the statutory requirements relating to the CIBA patented medicines. On July 8, 1992, CIBA advised Board staff that it intended to market Habitrol, a nicotine patch used in smoking cessation therapy, and filed information with the Board in order to justify the price being charged for the new product. There have been numerous and extensive discussions and documentary exchanges between Board staff and CIBA throughout the Habitrol investigation. Board staff has also had discussions with and received advice from HDAP and obtained and considered important information from third party sources. CIBA takes the position that notwithstanding its filing of information pursuant to the *Act*, the Board does not have jurisdiction over the pricing of Habitrol as CIBA, with respect to Habitrol, is not a patentee within the meaning of the *Act*.

The issue of how Habitrol would be categorized by the Board was first raised by CIBA in a letter dated November 13, 1992. CIBA made additional submissions which were provided to HDAP, and were given a summary of the discussion held by HDAP regarding the categorization of Habitrol. Finally, the recommendation of HDAP, that Habitrol be considered a Category III new medicine, and the reasons therefor, were the focus of a meeting held on January 11, 1993 between Board staff and CIBA. This meeting lasted over two hours.

The issue of which medicines, if any, and in which dosages, should be used as comparators for the purpose of determining an appropriate price range for Habitrol, was also the subject of extensive discussions between Board staff and CIBA. Meetings were held to deal with this issue on November 30, 1992 and January 11, 1993. Following both these meetings, CIBA sent to Board staff, letters, dated December 18, 1992 and January 12, 1993, containing information the company deemed relevant to the concerns raised by Board staff at the meetings. In response, by letter dated June 17, 1993, Board staff provided CIBA with the reasons why CIBA's contentions were not accepted and the basis for the calculations which led Board staff to believe that Habitrol was excessively priced. Board staff advised that if CIBA did not elect to provide a VCU for consideration by the Chairperson of the Board, Board staff would report the matter to the Chairperson, who might issue a Notice of Hearing. On June 24, 1993, CIBA advised Board staff that it would not provide a VCU of the kind requested by Board staff and set forth once again its submissions as to why the pricing of Habitrol was not excessive.

The issue of whether Habitrol was a patent pertaining to medicine and thus within the jurisdiction of the Board was first raised by Board staff on July 8, 1992 (before Habitrol was even on the market), and was also discussed in

face to face meetings between Board staff and CIBA on November 30, 1992, January 22, 1993, May 20, 1993 and September 20, 1993. In addition, clarification of the status of the patent was requested by Board staff in a letter to CIBA dated January 26, 1993, to which CIBA responded on February 3, 1993.

The Board staff analysis with respect to the price of Habitrol was forwarded to the Chairperson in a confidential report. The Chairperson, after considering the confidential report, decided to issue the Notice of Hearing on November 23, 1993, wherein the material facts relied on by the Chairperson in support of the issuance of the Notice of Hearing were clearly set out. The Notice of Hearing states that the price of Habitrol exceeded the Board's guidelines and proposed orders, *inter alia*, reducing the price at which CIBA sells Habitrol and directing CIBA to pay Her Majesty in Right of Canada a specified amount of money. CIBA's counsel requested further particulars concerning the allegations contained in the Notice of Hearing. On December 2, 1993, Board staff provided CIBA with detailed particulars of its understanding of the allegations. This was done in order to enable CIBA to respond to the Notice by December 13, 1993, as was required under the Board's rules of practice. CIBA also advised the Board and Board staff that it intends to challenge the constitutionality of the *Act* as it relates to the Board's power to regulate prices.

In a memorandum dated January 10, 1994, Board staff set out its position on all the substantive issues that will be raised in the forthcoming hearing. Pursuant to the proposed rules respecting practice before the Board, Board staff will have to file the affidavits of all of the expert witnesses on whose evidence it will rely by May 13, 1994. Moreover, at the suggestion of Board staff, on the same date, the parties will also pre-file an outline of the

evidence of each non-expert witness they intend to call. Board staff will also pre-file copies of all documents that they will rely upon at the hearing.

In its January 10, 1994 memorandum, Board staff also suggested that, after delivery of the expert evidence and the outlines of the non-expert witnesses' evidence, a process of written interrogatories should be initiated. The object of this process would be to clarify each party's evidence through requests for further information, prior to the commencement of the hearing. Counsel for CIBA objected to this suggestion.

At the pre-hearing conference held on January 18, 1994, CIBA requested that the Board issue an Order requiring both the Board and Board staff to produce copies of all documents relating to any matter at issue in the proceedings that were or had been in the power, possession or control of the Board or Board staff. This request was for all relevant documents, whether favourable or prejudicial to CIBA's position and whether or not Board staff planned to rely on the relevant document as part of its case. There is no evidence to indicate whether Board staff has any documents which are not in the possession of the Board. The Chairperson of the Board indicated that the Board did not have any documentation which was not in the possession of Board staff.

Analysis

The central issue in this case is whether, in light of the statutory mandate of the Board, fairness entitles the applicant to more disclosure than that which it has and will have been afforded prior to the commencement of the hearing scheduled for May 24, 1994. If I decide that CIBA is not entitled to the fruits of the investigation, i.e. documents that are favourable to it as

well as unfavourable to it, the issue is whether the applicant is entitled to any documents which have been provided to the Chairperson or any members of the Board who will be sitting at the hearing. In this case all five members of the Board, including the Chairman, will be sitting at the hearing.

The first issue arises out of the *Stinchcombe, supra* decision. In that case, the accused was charged with breach of trust, theft and fraud. During the investigation by the RCMP, a witness was interviewed by a police officer and a written statement was taken. Defence counsel was informed of the existence, but not of the content, of the statement. His request for disclosure was refused. The Crown decided not to call the witness. Defence counsel sought an order that the witness be called or that the Crown disclose the contents of the statement. The trial judge dismissed the application. The trial proceeded and the accused was convicted of a breach of trust and fraud. The Court of Appeal affirmed the convictions without giving reasons, but the Supreme Court of Canada allowed the appeal and ordered a new trial. The Supreme Court found that the Crown had a legal duty to disclose all relevant information to the defence. Sopinka J. delivered the unanimous judgment of the Court. He states at p. 332 of the decision:

> Production and discovery were foreign to the adversary process of adjudication in its earlier history when the element of surprise was one of the accepted weapons in the arsenal of the adversaries. This applied to both criminal and civil proceedings. Significantly, in civil proceedings this aspect of the adversary process has long since disappeared, and full discovery of documents and oral examination of parties and even witnesses are familiar features of the practice. This change resulted from acceptance of the principle that justice was better served when the element of surprise was eliminated from the trial and the parties were prepared to address issues on the basis of complete information of the case to be met.

He then reviews the arguments for and against disclosure of the fruits of an investigation at p. 333, stating:

> It is difficult to justify the position which clings to the notion that the Crown has no legal duty to disclose all relevant information. The arguments against the existence of such a duty are groundless while those in favour, are, in my view, overwhelming. The suggestion that the duty should be reciprocal may

> deserve consideration by this Court in the future but is not a valid reason for absolving the Crown of its duty. The contrary contention fails to take account of the fundamental difference in the respective roles of the prosecution and the defence. In *Boucher v. The Queen*, [1955] S.C.R. 16, Rand J. states, at pp. 23-24:
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> > It cannot be over-emphasized that the purpose of a criminal prosecution is not to obtain a conviction, it is to lay before a jury what the Crown considers to be credible evidence relevant to what is alleged to be a crime. Counsel have a duty to see that all available legal proof of the facts is presented: it should be done firmly and pressed to its legitimate strength but it must also be done fairly. The role of prosecutor excludes any notion of winning or losing; his function is a matter of public duty than which in civil life there can be none charged with greater personal responsibility. It is to be efficiently performed with an ingrained sense of the dignity, the seriousness and the justness of judicial proceedings.
>
> I would add that the fruits of the investigation which are in the possession of counsel for the Crown are not the property of the Crown for use in securing a conviction but the property of the public to be used to ensure that justice is done. In contrast, the defence has no obligation to assist the prosecution and is entitled to assume a purely adversarial role toward the prosecution. The absence of a duty to disclose can, therefore, be justified as being consistent with this role.

In my view, in the case at bar, I must examine the statutory scheme pursuant to which the Patented Medicine Prices Review Board was created, and construe it as a whole to determine the degree to which Parliament intended the principle of fairness to apply. Before reviewing the relevant provisions of the *Act* further, I will continue with Justice Sopinka's comments in *Stinchcombe* which are relevant to the issues before me. Justice Sopinka deals with the suggestion that the disclosure may put at risk persons who provide the prosecution with information. At p. 335, he states:

> No doubt measures must occasionally be taken to protect the identity of witnesses and informers. Protection of the identity of informers is covered by the rules relating to informer privilege and exceptions thereto ...

In the case before me I must deal with the common law in respect of the provision of confidential information. Justice Sopinka goes on to say at pp. 335-336:

> It will, therefore, be a matter of the timing of the disclosure rather than whether disclosure should be made at all. The prosecutor must retain a degree of discretion in respect of these matters. The discretion, which will be subject to review, should extend to such matters as excluding what is clearly irrelevant, withholding the identity of persons to protect them from harassment or injury, or to enforce the privilege relating to informers. The discretion would also extend to the timing of disclosure in order to complete an investigation. I shall return to this subject later in these reasons.

He then states at p. 339:

> As indicated earlier, however, this obligation to disclose is not absolute. It is subject to the discretion of counsel for the Crown. This discretion extends both to the withholding of information and to the timing of disclosure. For example, counsel for the Crown has a duty to respect the rules of privilege. In the case of informers the Crown has a duty to protect their identity. In some cases serious prejudice or even harm may result to a person who has supplied evidence or information to the investigation. While it is a harsh reality of justice that ultimately any person with relevant evidence must appear to testify, the discretion extends to the timing and manner of disclosure in such circumstances. A discretion must also be exercised with respect to the relevance of information. While the Crown must err on the side of inclusion, it need not produce what is clearly irrelevant.

He then summarizes the general principles with respect to disclosure when he states at p. 343:

> ... the general principle to which I have referred is that all relevant information must be disclosed subject to the reviewable discretion of the Crown. The material must include not only that which the Crown intends to introduce into evidence but also that which it does not. No distinction should be made between inculpatory and exculpatory evidence.

He then applies that principle to the case before him and states at p. 345:

> I am of the opinion that, subject to the discretion to which I have referred above, all statements obtained from persons who have provided relevant information to the authorities should be produced notwithstanding that they are not proposed as Crown witnesses. Where statements are not in existence, other information such as notes should be produced, and, if there are no notes, then in addition to the name, address and occupation of the witness, all information in the possession of the prosecution relating to any relevant evidence that the person could give should be supplied. I do not find the comments of the Commission in its 1984 Report persuasive. If the information is of no use then presumably it is irrelevant and will be excluded in the exercise of the discretion of the Crown. If the information is of some use then it is relevant and the determination as to whether it is sufficiently useful to put into evidence should be made by the defence and not the prosecutor.

However, Justice Sopinka notes that this same general principle of disclosure may not apply in all criminal cases. He states at p. 342:

> The general principles referred to herein arise in the context of indictable offenses. While it may be argued that the duty of disclosure extends to all offenses, many of the factors which I have canvassed may not apply at all or may apply with less impact in summary conviction offenses. Moreover, the content of the right to make full answer and defence entrenched in s. 7 of the *Charter* may be of a more limited nature. A decision as to the extent to which the general principles of disclosure extend to summary conviction offenses should be left to a case in which the issue arises in such proceedings.

There is no discussion of disclosure principles and matters before administrative tribunals in the *Stinchcombe* case. However, in *Ontario Human Rights Commission v. Jeffry House et al.*, Ont. Court General Division (Ct. file 520/93), November 8, 1993 (unreported), leave to appeal denied January 31, 1994 (Ont.C.A.) (*House*), the Divisional Court did apply *Stinchcombe*. In the *House* case, the Board of Inquiry under the *Ontario Human Rights Act* had ordered production of witness statements and other documents related to the investigation of certain complaints made pursuant to the provisions of the *Ontario Human Rights Code*. This is unlike the case at bar where the Board has refused the wide ranging production of documents demanded by CIBA. I must also keep in mind that curial deference is a key principle in judicial reviews.

Furthermore, in the *House* case, the Board states at p. 13 of its reasons, that one of its considerations, when determining the degree of disclosure required in that instance, was that:

> it appears to me that the allegations are very serious indeed with the potential, if made out, to ruin reputations and cast a pall over the future career prospects of anyone found to have so discriminated.

CIBA alleges that if the Board finds it has charged an excessive price for Habitrol, it could cost CIBA approximately $20 million. It is also alleged that the possibility of finding that CIBA engaged in a policy of excessive pricing would impact on the public and commercial reputation of CIBA and the personal reputations and careers of its officers, directors and employees. However, this is always a potential result of economic regulation. In my view, the finding that CIBA engaged in a policy of excessive pricing would not impact any more negatively on the public and commercial reputation of CIBA or the personal reputations and careers of its officers, directors and employees, than a finding of excessive pricing.

As stated earlier I must look at how the statutory scheme operates as a whole. In the *House* case, the Court states at p. 6 that:

> In rejecting the claim of privilege, the Board of Inquiry separated the investigation stage from the subsequent conciliation stage and the third "prosecution" stage.

The Court in *House* applied the reasoning in *Stinchcombe* to the proceedings under the *Ontario Human Rights Code*, but drew a distinction between privilege at the investigation stage and privilege at the litigation stage. The relevant part of the *Patent Act*, i.e. the part dealing with patented medicines, section 79 to section 102, concerns economic regulation. The Board monitors the prices of all medicine produced under patent. The Chairperson of the Board has administrative and adjudicative functions as a regulator. The applicant concedes that the legislation provides for institutional bias and this cannot be attacked under the case law.

There is a further difference between the legislation in issue here and the Human Rights legislation, in that there are not two parties involved. The Board staff is not a party in the same sense as the investigative staff under the Human Rights legislation. The investigators under the Human Rights legislation are clearly separated from the adjudicators. Also, there are search and seizure provisions under section 33 of the *Ontario Human Rights Code*, which make the powers of the investigators more akin to those exercised during a police investigation. Finally, the nature of the rights the *Ontario Human Rights Code* is designed to protect are very personal individual characteristics. Tribunals charged with regulating economic activity have not had placed on them the same high standards as tribunals dealing with personal individual rights.

After quoting Sopinka J. in respect of justice being better served when the element of surprise was eliminated from the trial, the Divisional Court concluded that:

> In the appropriate case, justice will be better served in proceedings under the Human Rights Code when there is complete information available to the Respondents.

It is interesting to note that the Divisional Court recognized that only in the appropriate case the complete information should be made available. Disclosure must always be decided upon in the context of the matter involved.

The Divisional Court also was of the opinion that the role of Commission counsel is analogous to that of the Crown in criminal proceedings. The role of the Board in the statutory scheme is to monitor prices and where necessary regulate to avoid excess prices.

At p. 12 of the *House* decision, the Divisional Court reiterated the well-known principle that:

> in any particular case the requirements of 'natural justice' will depend upon the particular circumstances of the case.

My view that the Board's primary mandate is economic regulation is supported by a review of the historical development of the patent legislation. Dureault J. undertook such a review in *Manitoba Society of Seniors Inc. v. The Attorney-General of Canada*, Man. Q.B. (CI 89-01-36107), January 17, 1991, (unreported), a constitutional challenge to price control in the pharmaceutical industry. He states at pp. 3 *et seq.*:

> . . . The Patent Act, S.C. 1923, c. 23, s. 17 allowed for compulsory licenses to be granted for the manufacture, use and sale of patented processes. Up until 1969, when the 1923 Act was amended (S.C. 1968-69, c. 49) to permit compulsory licenses to import patented pharmaceutical products, few applications for compulsory licenses were made. Subsequent to the 1969 amendment, however, 559 licenses to import and sell have been applied for; or these, 306 have been granted, 15 have been refused or terminated, 96 have been abandoned or withdrawn, and 142 were still pending as of January 31, 1985.
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> The 1969 amendment resulted in the licensing of brand name patented products by generic firms which then produced and marketed their own brand or copy of the patented medicine. Compulsory licensing to import medicines resulted in increased competition by generic firms against patent-holding

firms. This competition was further encouraged by the provincial policy of generic substitution under their respective pharmacare plans. The result has been the growth of large and profitable Canadian-owned generic pharmaceutical firms, which in turn led to lower prices. Needless to say, this aspect of compulsory licensing permitting a competitor (generic firm) to import and produce a copy of the patent holder's product (brand name) has been the object of intense political lobbying by the patent-holding firms. There was no such thing as patent exclusivity for an invention of medicine. Indeed an applicant could apply for a compulsory license immediately upon the grant of the patent.

Restoration of patent exclusivity and revocation of compulsory licensing for patented medicine had for some time been the elusive goal of the patent-holding firms. Reacting to the pharmaceutical lobby, the government appointed Dr. H.C. Eastman as Commissioner to inquire into and report upon the then current situation in the pharmaceutical industry in Canada. The Commissioner's report was submitted on February 28, 1985.

The government's response to the Eastman report was the introduction in Parliament of Bill C-22, entitled "An Act to amend the Patent Act and to provide for certain matters in relation thereto", 33rd Parl., 2nd Sess. (1986). It was given first reading on November 7, 1986. The Bill, following its usual legislative route including several references to both the House of Commons Legislative Committee and the Special Committee of the Senate, was eventually passed by Parliament and received Royal Assent on November 19, 1987 (See S.C. 1987, c. 41, also R.S.C. 1985, c. 33 (3rd Suppl.)).

It is widely acknowledged that s. 14 of Bill C-22 created a new regime of patent exclusivity applicable to medicines. The amending provisions were designed to give back some measure of patent exclusivity to the brand name firms. While compulsory licensing was retained, it carried with it a prohibition from exercising any rights obtained under the compulsory license for periods varying generally from seven to ten years.

Patents in respect of medicine, as for any other patent, are issued for 17 or 20-year terms. What is exceptional about these patents, however, is the provision for their immediate compulsory licensing. The new regime does not change this unique provision. It merely prohibits a licensee from exercising the rights given under the license for a particular period of time. In other words, a monopoly is created for the patent holder for the period during which the licensee is prohibited from working the patent.

Under this limited monopoly, it was recognized that the price of new medicines would be introduced and maintained at higher levels than otherwise would be the case with competition under compulsory licensing. The increased financial return to the brand name firm was expected to encourage pharmaceutical research and development in Canada. From the government's standpoint, growth of this industry with enhanced employment opportunities was considered to be a desirable objective. On the other hand, legitimate concerns arose that, from the consumer's standpoint, prices might escalate to unacceptable levels during the exclusivity period. To counteract this mischief, the impugned amending provisions were also linked to a regulatory scheme to be administered by the Board referred to earlier.

The scheme in this part of the *Patent Act* is similar to other statutory schemes to regulate monopolies such as the Canadian Radio-Television and Telecommunications Commission and the National Energy Board. The Board and its staff are receiving a constant supply of information on prices of

medicines. In my view, information supplied pursuant to statutory authority for purposes of economic regulation is, *prima facie*, confidential.

In this case there has been very extensive disclosure to CIBA as outlined briefly earlier in the Facts. In sworn material submitted to this Court the Manager of Compliance and Enforcement testified that:

> If the investigation suggests that the price exceeds the Guidelines, the patentee is notified, provided with the basis of Board staff's conclusion, and the patentee is provided an opportunity to submit a VCU to adjust its price. Whether the patentee submits a VCU, or refuses to do so, the matter is referred to the Chairperson of the Board, who may either accept the VCU or may issue a Notice of Hearing. In this regard, Board staff prepare a confidential report which is forwarded to the Chairperson.

The Manager was not cross-examined on the need for confidentiality.

Section 96 of the *Act* empowers the Board, with the approval of the Governor in Council, to make general rules for regulating its practice and procedure. The Board uses proposed rules at the present time. Subsection 97(1) provides that:

> 97. (1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

The Board has made a decision refusing disclosure of the documents requested and I should give such a decision curial deference unless fairness or natural justice requires otherwise. Disclosure cannot be decided in the abstract. The Board is supposed to proceed efficiently and to protect the interest of the public. This requires, *inter alia*, that a hearing shall not be unduly prolonged. Certainly, the subject of an excess price hearing is entitled to know the case against it, but it should not be permitted to obtain all the evidence which has come into the possession of the Board in carrying out its regulatory functions in the public interest on the sole ground that it may be relevant to the matter at hand. The Board's function is not to obtain information solely for investigative purposes; its primary role is to monitor

prices. In its decision, the Board recognized the need to balance its duty to the applicant against limiting its ability to discharge its responsibilities in the public interest on an ongoing basis. The Board has exercised its duty properly in the case at bar.

In deciding whether the Board's decision to refuse disclosure in this matter is correct I must also examine the question in light of the disclosure by the Board to date. I have already outlined the extensive amount of disclosure provided by the Board in numerous meetings and otherwise. I also note the future disclosures that the Board has agreed to provide.

In summary, when the statutory scheme of this Board is looked at, the Board is a regulatory board or tribunal. There is no point in the legislature creating a regulatory tribunal if the tribunal is treated as a criminal court. The obligations concerning disclosure imposed by the doctrine of fairness and natural justice are met if the subject of the inquiry is advised of the case it has to meet and is provided with all the documents that will be relied on. CIBA has been provided with much more than the minimum disclosure required to enable it to meet the case. Law and policy require that some leeway be given an administrative tribunal with economic regulatory functions, if, in pursuing its mandate, the tribunal is required by necessity to receive confidential information. It is not intended that proceedings before these tribunals be as adversarial as proceedings before a court. To require the Board to disclose all possibly relevant information gathered while fulfilling its regulatory obligations would unduly impede its work from an administrative viewpoint. Fairness is always a matter of balancing diverse interests. I find that fairness does not require the disclosure of the fruits of the investigation in this matter.

Since I have determined that the applicant is not entitled to the fruits of the investigation, I must determine whether the applicant is entitled to all documents placed before the Chairperson or other members of the Board. Again I must examine this problem in light of the statutory scheme of this Board.

In my view, the reasoning in *Canadian Cable T.V. Association v. The American College Sports Collective of Canada*, [1991] 3 F.C. 626 (C.A.) is still valid even though it was decided prior to *Stinchcombe*. In that case, the Copyright Board had both an investigative and an adjudicative function, such as the Board here has. The applicant made the same argument in that case as was made before me. The applicant submitted that he was:

> prejudiced in all the circumstances, not by any reason of any adverse effect, but rather by being denied the opportunity to exploit in its favour the evidence received.

In his reasons, the dissenting member of the Board referred to information not placed before the Board at the hearing. The majority did not refer to this information. The Court rejected the applicant's argument, saying at p. 650, that there was

> not a shred of evidence that any of the information received [by the dissenting member] had any influence whatsoever, on the Board's decision, that is to say, on the decision of the Board majority.

The test is whether the Board acted on evidence which was prejudicial or had an adverse effect on the applicant. MacGuigan J.A. elaborated on this at p. 650:

> In my opinion, this review of the case law indicates the fallacy of the applicant's argument. Contrary to its contention that a court will not inquire into the question of prejudice, all of the authorities which focus on the matter show that the question of the possibility of prejudice is the fundamental issue: *Kane, Consolidated-Bathurst, Cardinal Insurance, Civil Employees' Union*, and *Hecla Mining*.
>
> . . . The authorities, moreover, have taken "prejudicial" in the sense of "adverse effect".

Many of the questions resolved above are also relevant with respect to the second issue; that is: whether the applicant is entitled to all of the documents placed before the Chairperson or other members of the Board. I will not review them a second time. This is not a case where individual rights are an issue, it is a case of economic regulation, which is not in form or substance criminal, nor does it involve the procedural safeguards constitutionalized in section 7 of the *Charter*.

CIBA sought in particular to have the Board's report disclosed. This report was prepared for the Chairperson and was only used to decide if a Notice of Hearing should issue. It is no different than any other document put before the Board. The documents only become relevant if the Board is going to rely on them.

> The Chairperson has stated that the Board's duty in law is:
>
> to make its decision on the basis of the evidence placed and tested before it during the hearing.

Accordingly there is no prejudice and no adverse effect to the applicant when it does not receive all the documents in the Board's possession. If the Board should rely on evidence not before it, then it would be open to the applicant to bring a further application at that time.

The application is dismissed.

William P. McKeown
Judge

OTTAWA, ONTARIO
May 3, 1994