IN THE MATTER OF the *Patent Act, R.S. 1985,* c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.) and as further amended by S.C. 1983, c. 2;

AND IN THE MATTER OF Canadian Patent Nos. 997,756, 1,028,264, 1,261,265, 1,297,057 and 1,297,058

AND IN THE MATTER OF ICN Canada Limited and ICN Pharmaceuticals, Inc. (Respondents)

Introduction

In 1996, the Board conducted a hearing into the pricing of the medicine Virazole. Virazole was being sold in Canada by ICN Canada Ltd., a wholly-owned subsidiary of its U.S. parent ICN Pharmaceuticals, Inc. (hereinafter collectively called "ICN"). Virazole is the brand name for the generic medicine ribavirin, which is a drug used in the treatment of hospitalized infants and children who suffer from lower respiratory tract infection due to respiratory syncytial virus.

After its hearing the Board concluded that Virazole was being sold at excessive prices and, furthermore, that ICN had engaged in a policy of excessive pricing. On July 26, 1996, the Board ordered ICN to make an immediate cash payment, followed by sales of Virazole at reduced prices, in amounts that would offset twice the excessive revenues that ICN had earned by selling Virazole at excessive prices. In the event that the cumulative excess revenues could not be offset by December 31, 1999, ICN was to make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues outstanding (the "1996 Order"). The period during which ICN was required to complete the offset of excessive revenues expired on December 31, 1999. When that date arrived, Board Staff asserted that under the 1996 Board Order, a cash payment of $1,711,957.00 remained to be paid; ICN, on the other hand, maintained that no amount remained to be paid.

By its motion dated February 8, 2000, the Staff of the Board brought a motion seeking an order for directions as to the amount that remained to be paid by ICN in order to satisfy the 1996 Order. Board Staff and ICN each filed written materials to support their positions on the motion. Discussions then ensued between ICN and Board Staff, and the parties arrived at terms of a variation of the 1996 Order(the “Variation Order”) that both could support. For the reasons described below, the Board agrees that the Variation Order is in the public interest and the Board has issued the Variation Order on the terms to which the parties have consented.

The Variation Order

Board Staff and ICN have proposed, in effect, that the term of the 1996 Order be extended, albeit on somewhat different terms. The Variation Order will continue the combination of cash payments and reduced prices for Virazole for a further four years. ICN will make an initial cash payment of $350,000 and reduce the price of Virazole by at least $200 per vial below the MNE until ICN’s full obligation of $1,711,957.00 has been satisfied (the applicable MNE is $410.84). If in any calendar year, starting with the year 2000, there are not sufficient sales of Virazole to result in a reduction of the obligation by at least $350,000, ICN is required to make a cash payment to ensure that the obligation is reduced by at least $350,000 for that year. In the event that sales of Virazole generate net revenues of less than $27,500.00, or if Virazole is removed from the market, the balance of ICN’s obligation, then owing, becomes payable.

The Board considers this variation of the 1996 Order to be in the public interest, and to be superior in that regard by a considerable degree to an immediate one-time payment to the Crown of the full $1,711,957.00. When the Board made the 1996 Order, it anticipated that sales of Virazole would have been sufficiently strong during the term of the 1996 Order that the $1,711,957.00 would have been offset by reduced prices of Virazole, not paid to the Crown. There is demand by Canadian hospitals for Virazole, and prices during 2000 to date have been approximately at the MNE for Virazole. The Variation Order will restore and extend the period during which Virazole is available at considerably reduced prices. In this fashion the offsetting of previous excessive revenues accrues most directly to the benefit of those who paid the excessive prices for Virazole. The Variation Order will provide ICN with an incentive to keep Virazole on the market and to encourage sales at prices that are reduced by at least $200 per vial from the MNE for Virazole. Depending on the revenues from sales, ICN could have an incentive to reduce the price of Virazole even further. ICN has also agreed that the MNE for Virazole – the benchmark from which the price reductions will be made – will not decrease regardless of any deflation during the term of the Variation Order.

Board Staff also noted that the Variation Order will avoid the costs of litigating the interpretation of the 1996 Order, and while avoiding such costs is doubtless in the public interest, the Board saw absolutely no merit in ICN’s interpretation of the 1996 Order and considered there to be no probability that ICN’s position would prevail in litigation. The Board would not have approved the Variation Order if it were not preferable in result, as matters have turned out, to the effect of the 1996 Order.

While the Board appreciates ICN's consent to the Variation Order and prefers its effect, the Board considers it highly regrettable that ICN resisted compliance with the 1996 Order. ICN could have approached the Board in late 1999 and proposed to extend the term of the regime of reduced prices for Virazole and, for the reasons described above, the Board would likely have been receptive to such a proposal. Instead, ICN chose to assert a wholly unreasonable interpretation of the 1996 Order and to accompany that assertion with very doubtful allegations of reliance on the interpretation. It stated that it would resist amendment of the order by court proceedings even though, in the view of this Board, that entailed an untenable legal position. These actions were taken despite the fact that ICN's earlier conduct, the subject of the original proceedings, were found by the Board to warrant the exercise of its remedial power to the full extent permitted by the *Patent Act* and were the subject of comment in the Federal Court of Appeal. The Board relies on and appreciates the cooperation and good faith it receives from the pharmaceutical industry, and is hopeful that ICN's agreement with the Variation Order, and not its original resistance to fulfilling its obligations, is demonstrative of the approach that will inform ICN's relationship with the Board in the future.

Conclusion

For the reasons set out above, the Board orders as follows:

1. The amount owing by the Respondents under the Board's Order of July 26, 1996, is $1,711,957.00 as of January 31, 2000. The obligation to make payment in this amount shall be that of ICN Canada Ltd. and ICN Pharmaceuticals, Inc. jointly and severally.

2. The Respondents' obligation of $1,711,957.00 aforesaid shall be satisfied by way of price reductions and payments in the following manner:

   (a) By April 29, 2000, the Respondents shall make a payment to Her Majesty in right of Canada in the amount of $350,000.00, by which amount the Respondents' obligation hereunder shall be reduced;

   (b) From and after March 31, 2000, the Respondents shall reduce the price at which Virazole is sold in Canada such that the average price (on an annual calendar year basis) at which Virazole is sold in Canada shall be an amount that is at least $200.00 per 6 gram vial less than the MNE for Virazole in each year. For the purpose of calculating the future MNE for Virazole, sales of Virazole at prices reduced in accordance with this Order shall be deemed to have been made at the applicable MNE for Virazole, such MNE to be no less than the 1999 MNE of $410.84;

(c) The price reduction described in paragraph 2(b) above, shall remain in effect until the Respondents have satisfied their total obligation of $1,711,957.00;

(d) The Respondents shall comply with their obligation to provide information concerning Virazole to the Board in accordance with the Regulations;

(e) In addition, by January 31st in each year, the Respondents shall provide the Board with copies of all invoices relating to sales of Virazole in Canada during the preceding year;

(f) Effective January 31st in each year, beginning with January 31, 2001 and continuing until the Respondents have satisfied their total obligation of $1,711,957.00, the sum of the price reductions for the preceding year shall be determined in accordance with the following formula: number of vials sold x MNE - total net revenues from sales of Virazole (referred to hereinafter as the “Offset”);

(g) By February 28th in each year, beginning with February 28, 2001 and continuing until the Respondents have satisfied their total obligation of $1,711.957.00, the Respondents shall make a payment to Her Majesty in right of Canada equal to the amount, if any, by which $350,000.00 exceeds the Offset for the preceding year;

(h) Effective February 28th in each year the Respondents’ obligation shall be reduced each year by the total of the Offset calculated for the preceding year under paragraph 2(f) plus the amount, if any, paid pursuant to 2(g).

3. If the Respondents’ total net revenues (net of credits and rebates) from sales of Virazole in Canada fall below $27,500.00 in any year, the Respondents shall pay Her Majesty in right of Canada the sum of $1,711,957.00, less Offsets and payments made prior to that time, by January 31 of the following year.

4. If the Respondents cease offering Virazole for sale in Canada at any time prior to satisfaction of their total obligation of $1,711,957.00, they shall pay Her Majesty in right of Canada the sum of $1,711,957.00, less Offsets and payments made prior to that time, within 30 days of the date on which they cease offering Virazole for sale in Canada.

5. Any sale or supply of Virazole which is not made to an arms’ length purchaser pursuant to a bona fide purchase order or request for use in Canada, shall not be included in the determination of Offsets for the purposes of this Order.

6. In the event that any payment or price reduction required by this Order is not made within 30 days of the receipt by the Respondents of notice in writing from the Board of the default, the Respondents shall pay Her Majesty in right of Canada the sum of $1,711,957.00, less Offsets and payments made prior to that time within 30 days of receipt of the said notice.

7. In the event that the manner of implementing or complying with this Order requires further direction from the Board, either Board Staff or the Respondents may apply in writing for such direction.

8. The proceeding in this matter will be terminated once the Respondents have satisfied their total obligation of $1,711,957.00 in accordance with this Order.

Board Members: Robert G. Elgie, Chairperson
Réal Sureau, Vice Chairperson

Board Counsel: Gordon K. Cameron

Sylvie Dupont
Secretary of the Board

March 31, 2000