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 No. 1,283,053 and No. 1,312800

**CEPMB** 

AND IN THE MATTER OF CIBA-Geigy Canada Ltd. (Respondent)

EXHIBIT .

AFFIDAVIT OF

SWORN DEFORE ME ON

VOLUNTARY COMPLIANCE UNDERTAKING OF CIBA-GEIGY CANADA LTD.

A COMMISSIONER

- Habitrol [(S(-)-Nicotine) Transdermal Therapeutic System] delivers nicotine, the active 1. component of tobacco smoke, transdermally via a patch into the systemic circulation continuously over 24 hours. It is indicated as a temporary aid used to facilitate smoking cessation.
- Health and Welfare Canada issued a Notice of Compliance for Habitrol on May 12, 1992 2. and it was first sold in Canada by CIBA-Geigy Canada Ltd. ("CIBA-Geigy") in September 1992 at a price of \$3.71 per patch.
- CIBA-Geigy undertakes to reduce the prices of Habitrol, effective January 1, 1995, to 3. be, and remain, within the Board's Excessive Price Guidelines ("Guidelines"), as amended from time to time. Specifically, CIBA-Geigy will reduce the prices of Habitrol, effective January 1, 1995, so that the prices at which it is sold in Canada do not exceed:

\$3.16/patch; 7 mg Habitrol \$3.28/patch; Habitrol 14 mg \$3.31/patch. 21 mg Habitrol

- CIBA-Geigy has received revenues from the sales of Habitrol at prices in excess of the 4. Guidelines of at least \$3.6 million as set out in the Appendix. To offset those revenues, CIBA-Geigy undertakes:
  - to pay to Her Majesty the Queen in right of Canada the amount of \$2,950,000, (a) such payment to be made within one month of the date of an Order of the Board approving and incorporating the terms of this Voluntary Compliance Undertaking;

- (b) beginning on January 1, 1995 and until December 31, 1996, to reduce the prices of Habitrol sold in Canada below the prices stipulated above in paragraph 3, so as to offset \$651,595 plus the amount of revenues received from prices above the Guidelines for the period July 1 to December 31, 1994; and,
- in the event that the price reductions necessary to offset the excess revenues in accordance with paragraph (b) are not fully implemented by December 31, 1996, to pay the remainder to Her Majesty the Queen in right of Canada no later than January 31, 1997.
- 5. This Voluntary Compliance Undertaking constitutes no admission by CIBA-Geigy that the prices of Habitrol are or were excessive.
- 6. This Voluntary Compliance Undertaking will be in force until the later of January 19, 2010 or such other date as any Canadian patent pertaining to Habitrol expires.
- 7. During the period for which this Voluntary Compliance Undertaking will be in force, CIBA-Geigy Canada Ltd. will continue to abide by the provisions of the <u>Patent Act</u>, as amended, and the <u>Patented Medicines Regulations</u> (the "Regulations"), applicable to a patentee in respect of Habitrol. In particular, CIBA-Geigy Canada Ltd. will continue to file price and sales information in the manner prescribed by the Regulations in effect at the relevant time.

Signature:

Original signature redacted

Company Officer:

DWALT R RIDLEY

Position:

Senier 47: Servetary

Date:

18/10/94

CALCULATION OF PRICES AND REVENUES IN EXCESS OF THE GUIDELINES

HABITROL 7, 14 AND 21 MG

Pricing	Strength	Revenues	No. of	(e)	Unit Price (f)	(8)	Excess Revenues
renog (a)	(Q)	<b>^</b> 3	Patches Sold (d)	Actual Price \$	MNE Price® \$	% Above MNE Price	<b>&amp;</b> €
	7	4,698,385.70	1,270,752	3.70	3.15	17.46	698,913.60
1993**	14	9,834,202.48	2,656,780	3.70	3.27	13.15	1,142,415.40
	21	13,131,022.16	3,546,760	3.70	3.30	12.12	1,418,704.00
	7	725,050.69	211,582	3.43	3.20	7.19	48,663.86
1994***	14	1,719,295.75	481,950	3.57	3.32	7.53	120,487.50
	21	2,483,575.09	689,640	3.60	3.35	7.46	172,410.00
TOTALS		32,591,531.87					3,601,594.36

<sup>\*</sup> Maximum Non-Excessive Price calculated in accordance with the Excessive Price Guidelines.

se January 19 to December 31, 1993.

<sup>\*\*\*</sup> January 1 to June 30, 1994.