Federal Court of Canada
Trial Division

Section de première instance de
la Cour fédérale du Canada

T-1652-97

Between:

ABBOTT LABORATORIES, LIMITED
and ABBOTT LABORATORIES

Applicants

- and -

APOTEX INC.,
and THE MINISTER OF HEALTH CANADA

Respondents

T-1653-97

Between:

ABBOTT LABORATORIES, LIMITED
and ABBOTT LABORATORIES

Applicants

- and -

NU-PHARM INC.
and THE MINISTER OF HEALTH CANADA

Respondents

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REASONS FOR ORDER

[Delivered from the Bench at Toronto, Ontario on Tuesday, September 16, 1997, as edited]

ROTHSTEIN J.:

At the commencement of this hearing on the merits of these prohibition applications under the ***Patented Medicines (Notice of Compliance) Regulations,*** SOR/93-133 which were heard together, the respondents make a preliminary motion to dismiss the applications on the grounds that the issue in these applications is *res judicata*, having been decided by Lutfy J. in court file T-1721-95. In that matter, on June 9,

1997, Lutfy J. issued an order prohibiting the Minister of National Health and Welfare from issuing a Notice of Compliance to Nu-Pharm for terazosin hydrochloride dihydrate[1] (THD) until after expiration of Abbott's patent 1081229 (the 229 patent)[2]. All other things being equal, after expiration of the 229 patent on July 8, 1997, the Minister would be free to issue to Nu-Pharm and others a Notice of Compliance for THD.

However, on June 3rd, 1997, Abbott was granted three new patents pertaining to terazosin hydrochloride. On June 9, 1997 these patents were submitted by Abbott to the Minister pursuant to subsection 4(5) of the Regulations as amendments to its existing patent list. On July 4 and July 7, 1997 respectively, Apotex and Nu-Pharm each issued a Notice of Allegation pursuant to subparagraph 5(1)(*b*)(iv) of the Regulations alleging that no claim for the medicine itself and no claim for the use of the medicine would be infringed by their making, constructing, using or selling THD. On July 31, 1997, Abbott responded to the Notices of Allegation by filing Originating Notices of Motion in these court files for orders prohibiting the Minister from issuing Notices of Compliance to Apotex and Nu-Pharm based on the three new patents.

On this preliminary motion, Apotex and Nu-Pharm say that upon a proper reading of Lutfy J.'s order of June 9, 1997, the Minister is no longer prohibited from issuing Notices of Compliance to them in respect of THD. In addition, they say that Abbott cannot in a claim under a new patent, seek to protect an old product, namely THD, which is now off patent.

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1 Abbott sells terazosin hydrochloride dihydrate under the trade-mark "hytrin". Hytrin is a drug used in the treatment of hypertension and in certain doses benign prostatic hypertrophy.

2 A patent for terazosin hydrochloride had also been raised as a ground for prohibition but it had expired prior to the hearing before Lutfy J.

Abbott concedes that if the medicine which was the subject of Lutfy J.'s order was THD there is no basis for a further prohibition order as its three new patents pertain to TH and not THD. However, Abbott argues that the medicine is not THD but rather is TH, THD only being the dihydrate form of TH. Abbott says that if, in making THD, Apotex or Nu-Pharm, in the steps leading to THD, make an anhydrous crystal form of TH covered by one of Abbott's three new patents, patent infringement will occur and Apotex and Nu-Pharm will not be able to justify their allegations of non-infringement under subparagraph 5(1)(*b*)(iv) of the Regulations. I emphasize that Abbott's argument is reliant on the medicine being TH and not THD as Abbott's new patents only relate to TH. If Lutfy J. treated THD as the medicine in that case, the Minister would be entitled to issue Notices of Compliance to Apotex and Nu-Pharm after expiry of the 229 patent on July 8, 1997.

Indeed Lutfy J. did consider the medicine before him to be THD. At page 2 of his decision he states:

> The Abbott Patent is for terazosin hydrochloride dihydrate. The drug is described in Nu-Pharm's Notice of Allegation, in Abbott's patent list and in the originating notice of motion as terazosin hydrochloride. The patent list includes a reference to the appropriate number of the Abbott Patent. The parties knew precisely which drug was in issue. In my view, both parties referred to terazosin hydrochloride when in fact they intended terazosin hydrochloride dihydrate. Nu-Pharm's submission that Abbott's application must fail for the sole reason that the name of the drug on the patent list is incomplete is rejected. Form should not prevail over substance, particularly in the absence of uncertainty or ambiguity.

In recognizing that the parties intended THD although they referred in some documents to TH, it is clear that Lutfy J. was of the view that what was at issue before him was THD. In rejecting Nu-Pharm's argument that Abbott's prohibition application should fail on account of incomplete reference to the "drug" in that case, the necessary implication is that he considered the medicine to be THD. Clearly, he was

dealing with Abbott's 229 patent which could, for purposes of the Regulations, only protect claims for the medicine itself or claims for the use of the medicine. (See ***Deprenyl Research Ltd. v. Apotex Inc.*** (1994), 55 C.P.R. (3d) 171 at 175 and 176 aff'd (1995), 60 C.P.R. (3d) 501 (F.C.A.).)

That he considered the medicine in question to be THD is confirmed by his determination on the merits at page 12:

> For these reasons, on the basis of the evidence in these summary proceedings, the application will be granted. Abbott has established, on a balance of probabilities, that Nu-Pharm's allegations of non-infringement of the claims of the Abbott Patent are not justified. Accordingly, an order will issue prohibiting the Minister from issuing a Notice of Compliance to Nu-Pharm in connection with the drug in issue until after the expiration of the Abbott Patent.
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> [emphasis added]

The only unexpired patent before Lutfy J. was the 229 patent and the only claim for "medicine itself" in that patent was for THD (claim 6). All other claims in the 229 patent are process claims which Abbott concedes are irrelevant for purposes of the Regulations and there is no claim for the medicine TH.

Counsel for Abbott strongly argues that the "real" medicine is TH only and relies upon the terminology of various documents that only make reference to TH. He says that THD is only a form of TH but that it is not itself a medicine. However, the documents to which counsel refers are not determinative. The document that is determinative is patent 229 which refers only to THD. In his decision, Lutfy J. could only be dealing with the medicine in claim 6 of the 229 patent, namely THD.

In ***Hoffmann-LaRoche Ltd. v. Canada (Minister of National Health and Welfare)*** (1995), 62 C.P.R. (3d) 58, aff'd (1995), 67 C.P.R. (3d) 25

(F.C.A.), Noël J. extensively analyzed whether the term "claim for the medicine itself" in section 2 of the Regulations only referred to active ingredients or could include a composition containing both active and inactive ingredients. At pages 72 and 74 he states:

> The construction advocated by Nu-Pharm requires that the word "medicine" be given a meaning which departs from both its defined and its commonly understood meanings [footnote omitted]. Pharmaceutical compositions with therapeutic value are a medicine in common parlance. Indeed, most active ingredients must be combined with stabilizing agents or absorption vehicles in one form or another to allow a patient to effectively ingest a medicine and achieve the intended therapeutic effect. As such, a medicine, like a drug, is generally understood to be a preparation or composition including active and non-active ingredients. This commonly understood meaning is unaltered by the definition of the word "medicine" under the *Regulations*. While this definition refers to a "substance" in the singular, it obviously can encompass more than one substance when regard is had to s. 33(2) of the *Interpretation Act*, R.S.C. 1985, c. I-21. A substance does not cease to be a medicine when joined or mixed with another substance just the same as a medicine does not cease to be a medicine because it can cure more than one disease. (The word "disease" in the definition of medicine is also in the singular form.)
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> . . .
>
> Against this background, it seems clear that the words "drug" and "medicine" as they appear in s. 4(1) of the *Regulations* are not used in contradistinction and are not intended to draw a line between an active ingredient and a preparation or composition which includes an active ingredient. Both types of substances when capable or intended to be used for the treatment or prevention of a disease are a "medicine" within the meaning of the *Regulations* and a claim for the medicine itself, whether in the form of a singular active ingredient or in the form of a composition comes within the ambit of the *Regulations*.

Noël J.'s analysis is applicable here. What we have in Abbott's 229 patent is a claim for the dihydrate form of terazosin hydrochloride. Just as "medicine" may include both active and non-active ingredients it may also include active ingredients or combinations in different forms. To paraphrase Noël J., a substance does not cease to be a "medicine" because it takes a particular form. Accordingly, THD is a medicine for purposes of the Regulations. When Lutfy J. prohibited the Minister from issuing a Notice of Compliance to Nu-Pharm in court file T-1721-95, it was with respect to the medicine THD and when the 229 patent expired on July 8, 1997, the Minister was no longer prohibited from issuing a Notice of Compliance to Nu-Pharm, Apotex or others for THD. The three

new Abbott patents, not pertaining to the medicine THD, cannot be used as a basis for a further prohibition in respect of THD.

The preliminary application of Apotex and Nu-Pharm is granted and the Abbott prohibition applications are dismissed. Costs are reserved for further submissions by the parties.

Marshall Rothstein

JUDGE

OTTAWA, ONTARIO

SEPTEMBER 19, 1997

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TRIAL DIVISION

NAMES OF COUNSEL AND SOLICITORS ON THE RECORD

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DATE OF HEARING:	September 16, 1997

REASONS FOR ORDER OF THE HONOURABLE MR. JUSTICE ROTHSTEIN

DATED: September 19, 1997

APPEARANCES:

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Mr. Alfred Schorr Mr. Joseph Etigson Mr. Ivan Hughes	FOR THE RESPONDENT; Nu-Pharm Inc.

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