IN THE MATTER OF AN OPPOSITION by
Apotex Inc.
to application No. 815,153
for the trade-mark Red-brown Tablet Design
filed by Astra Aktiebolag and now owned by AstraZeneca AB

On June 12, 1996, Astra Aktiebolag filed an application to register the trade-mark Red-brown Tablet Design. The application is based upon use of the trade-mark in Canada in association with pharmaceutical tablets containing omeprazole magnesium for use in the treatment of duodenal ulcer, gastric ulcer, reflux esophagitis, Zollinger-Ellison syndrome and other conditions where a reduction of gastric acid secretion is required since at least as early as February, 1996. The application was advertised for opposition purposes in the Trade-marks Journal of March 4, 1998. The English language portion of the advertisement is reproduced below:

The opponent, Apotex Inc., filed a statement of opposition on May 4, 1998. The applicant filed and served a counterstatement in which it denied each of the grounds of opposition and pleaded that all of the grounds, save one, fail to comply with paragraph 38(3)(a) of the *Trade-marks Act*.

By letter dated August 26, 1999, the opponent requested leave to amend its statement of opposition but on February 10, 2000 the Opposition Board refused to grant such leave. By letter dated August 9, 2000, the opponent requested leave to make a different amendment to its statement of opposition. The Opposition Board granted this request on November 2, 2000.

The opponent filed eight affidavits as its rule 41 evidence, namely the affidavits of Raymond Shelley (a representative of the opponent), Patrick Bolland (a family physician), Benny Masella (a pharmacist), John Miszyn (a pharmacist), Donald A. J. MacDonald (a pharmacist) and Lawrence Eon Ura (a pharmacist), plus two affidavits of Denise West (a legal assistant). The applicant obtained orders for the cross-examination of each of these affiants. Transcripts of the cross-examinations of each of the affiants have been filed and form part of the record.

The applicant filed three affidavits as its rule 42 evidence, namely the affidavits of Stephen Wilton (a representative of the applicant), Clarissa DaCosta (a law clerk) and Adam Pignataro (a pharmacist). The opponent requested and obtained leave to cross-examine these affiants and transcripts of such cross-examinations are included in the record.

On February 22, 2001, the Canadian Intellectual Property Office recorded AstraZeneca AB as the owner of the present application.

Each party filed a written argument and each was represented at an oral hearing.

A few days before the oral hearing was held, the applicant filed a letter with proposed amendments to its application. Three of the amendments referred to the resulting registration not being enforceable in respect of wares not containing omeprazole or omeprazole magnesium. By letter dated December 8, 2003, the Opposition Board informed the applicant that these proposed amendments would not be made of record.

Introduction re Grounds of Opposition

The opponent has pleaded that the application does not comply with section 30 of the *Trade-marks Act* in numerous respects. In addition, it has pleaded that the applicant's alleged mark is not registrable because a) it is not a trade-mark, b) it is clearly descriptive and c) it is a prohibited mark within the meaning of section 10. Finally, the opponent pleads that the mark is not distinctive for several reasons. (The non-entitlement ground of opposition pleaded in paragraph 4 of the statement of opposition was withdrawn by the opponent at the oral hearing.)

The material date with respect to each ground of opposition is as follows: section 30 - the filing date of the application [see *Georgia-Pacific Corp. v. Scott Paper Ltd.*, 3 C.P.R. (3d) 469 at p. 475]; paragraph 12(1)(b) - the date of my decision [see *Lubrication Engineers, Inc. v. The Canadian Council of Professional Engineers*, 41 C.P.R. (3d) 243 (F.C.A.)] or the filing date of the application [see *Fiesta Barbeques Ltd. v. General Housewares Corp.* (2003) 2003 FC 1021 (F.C.T.D.)];

paragraph 12(1)(e) – the date of my decision [see *Allied Corporation v. Canadian Olympic Association* (1989), 28 C.P.R. (3d) 161 (F.C.A.) and *Olympus Optical Company Limited v. Canadian Olympic Association (*1991), 38 C.P.R. (3d) 1 (F.C.A.)]; non-distinctiveness - the date of filing of the opposition [see *Re Andres Wines Ltd. and E. & J. Gallo Winery* (1975), 25 C.P.R. (2d) 126 at p. 130 (F.C.A.) and *Park Avenue Furniture Corporation v. Wickes/Simmons Bedding Ltd.* (1991), 37 C.P.R. (3d) 412 at p. 424 (F.C.A.)].

The applicant bears the legal onus of establishing, on a balance of probabilities, that its application complies with the requirements of the *Trade-marks Act*. However, there is an initial evidential burden on the opponent to adduce sufficient admissible evidence from which it could reasonably be concluded that the facts alleged to support each ground of opposition exist [see *John Labatt Limited v. The Molson Companies Limited*, 30 C.P.R. (3d) 293 at p. 298].

Summary of Evidence

Before turning to the specific grounds of opposition, it is useful to summarize some of the evidence.

The medication with which the applicant claims to have used the applied for trade-mark is marketed under the trade-mark LOSEC. The applicant sells its LOSEC omeprazole magnesium in two dosages. The 20 mg dosage is sold in the form intended to be protected by the present application. The form of the 10 mg dosage is the subject of another trade-mark application. Both dosages have the trade-mark LOSEC written in black on the pill, with 10 or 20 written below depending on the dosage. Prior to 1996, the applicant sold medication under the LOSEC trade-

mark that comprised omeprazole, rather than omeprazole magnesium, and that LOSEC product took the form of a capsule. I note however that some of the affiants refer to the present LOSEC product as simply omeprazole, rather than omeprazole magnesium.

The applicant's LOSEC 20 mg product is most often sold in compliance packs, which consist of an outer cardboard box in which are enclosed sleeves of blister packs of the tablets. The blister packs prominently display the LOSEC trade-mark on the back. The front of the outer box is shown below, magnified for easier reproduction:

When the evidence was filed in these proceedings, omeprazole magnesium was sold only by prescription in Canada and the applicant was the only source of omeprazole magnesium. However, at some point of time, other pharmaceutical companies may be entitled to market omeprazole magnesium. Furthermore, at least under some of the provincial regimes, when a prescription is written for a certain active ingredient, a pharmacist will be entitled, and sometimes

obliged, to dispense the cheapest version, unless the prescription indicates a specific brand and "no substitutions". When generic pharmaceutical products enter the market in Canada, they are often the same colour, size and shape as the original [Masella affidavit, paragraph 13; Miszyn affidavit, paragraph 13; MacDonald affidavit, paragraph 15; Ura affidavit, paragraph 14].

Based on the evidence before me, I conclude that doctors pay little attention to the appearance of the pharmaceutical preparations that they prescribe [Bolland affidavit, paragraph 9]. Pharmacists are naturally more familiar with the look of various medications given that it is their job to ensure that the drug prescribed is the drug dispensed. When dispensing pharmaceuticals, pharmacists check the drug identification number ("DIN") on the bottle or box and the brand name. The pharmacists who have given evidence differ only slightly about the role that is played by the tablet markings and the tablet colour, shape and/or size. Mr. MacDonald indicates that he looks at the markings on tablets which are not blister-packed; in the case of LOSEC he looks for the name LOSEC printed on the outside of the blister pack. [MacDonald affidavit, paragraphs 21-23] Mr. MacDonald uses the colour as one mechanism to check that he is dispensing the correct product. For example, he would know that the tablets weren't LOSEC if they were blue. [Questions 90-93, MacDonald cross-examination] Mr. Masella's evidence is similar. He opens the box that contains the LOSEC blister packs primarily to check that the right number are in there; he would not dispense them if they were green or blue but would not automatically assume that they were LOSEC if they were the right colour. [Questions 39-53, 96-102, 288-291, Masella cross-examination] Mr. Ura follows the same general procedure, occasionally looking at the actual LOSEC tablets. [Ura affidavit, paragraphs 21-23] On cross-examination, Mr. Ura agreed that he would not dispense a pill that was blue as LOSEC and that colour is one of the checks that he

makes, although his main check is the word LOSEC. [Questions 50-56, 128-133, 203-208] Mr. Miszyn agreed that he would use colour and shape, as well as other things, to confirm that he has the right brand of medication [Questions 332-347, Miszyn cross-examination]. Mr. Pignataro states at paragraph 4 of his affidavit, "During the dispensing process, I rely on the colour, shape and size of the LOSEC brand of omeprazole magnesium tablets as a means to confirm that the correct product, namely the LOSEC brand, is being dispensed." During his cross-examination, Mr. Pignataro confirmed that when dispensing he relies on the trade-mark LOSEC, the tablet's colour, shape and markings and the DIN number [Questions 171-173]. He also stated that if he was given a pill that was the same colour, same shape and same size as the LOSEC pill, which did not say LOSEC on it, he would not dispense it as a LOSEC tablet [Question 181]. [see also Questions 143-144, Wilton cross-examination]

When a patient picks up his/her prescription at a pharmacy, it is typically enclosed in a paper bag and therefore not visible to the purchaser. However, when a new medication has been prescribed for an individual, a pharmacist may show the product to the patient while he or she counsels concerning its use.

Patients become most familiar with the look of their medication through consumption. According to the packaging, LOSEC is typically initially prescribed for 1 to 8 weeks, but the product monograph does refer to some longer maintenance treatments. Dr. Bolland has indicated, at questions 45 through 49 of his cross-examination, that the prescriptions that he writes for LOSEC can commonly be repeated for one year and that these prescriptions are written for patients who have a chronic condition. Messrs. Wilton and Pignataro state that omeprazole magnesium is often

used chronically [Wilton affidavit, paragraph 5; Pignataro affidavit, paragraph 2]. The patients' exposure to the product through consumption does not qualify as use under section 4 but it can help to build the trade-mark's reputation. Patients may be taking more than one type of medication at a time, including more than one type of red-brown tablet.

According to the health professionals who deal with them, patients appear to primarily associate the colour/shape of medication with the therapeutic purpose of the medication. While these professionals admitted during cross-examination that they do not know if patients may also be associating the colour/shape with the source of the medication, there is no evidence that this is in fact the case.

The applicant's sales of LOSEC 20 mg tablets have been substantial. However, circular, red-brown tablets have been in the Canadian market since before the introduction of the applicant's product. I note that what qualifies as red-brown may to some extent depend on the eye of the beholder [see for example paragraphs 7-8 of Masella affidavit]. The sales of the applicant's Red-brown Tablet Design tablets and other's red-brown tablets are discussed in greater detail below.

<u>The Law re Distinctiveness</u>

In *Novopharm Ltd. v. Bayer Inc. et al.* (1999), 3 C.P.R. (4th) 305 (F.C.T.D.), aff'd (2000), 9 C.P.R. (4th) 304 (F.C.A.), Mr. Justice Evans set out some of the legal principles with respect to distinctiveness as applied to pharmaceutical colour/shape/size marks, at pages 321- 323:

> **First, the burden of establishing the distinctiveness of a mark rests on the applicant, both in the opposition proceeding before the Registrar and on an appeal to this Court. Thus, Bayer must establish on a balance of probabilities that in 1992, when Novopharm filed its opposition to the application, ordinary consumers associated**

dusty rose, round extended-release tablets of the size of the 10 mg ADALAT tablet, with Bayer, or a single source of manufacture or supply: *Standard Coil Products (Canada) Ltd. v. Standard Radio Corp.*, [1971] F.C. 106 at p. 123, 1 C.P.R. (2d) 155 (F.C.T.D.), *affirmed* [1976] 2 F.C. iv (F.C.A.).

Second, the "ordinary consumers" to be considered for this purpose include not only physicians and pharmacists, but also the "ultimate consumers", that is the patients for whom ADALAT tablets are prescribed and to whom they are supplied, even though their only access to nifedipine is through a physician's prescription: *Ciba-Geigy Canada Ltd. v. Apotex Inc.*, [1992] 3 S.C.R. 120, 44 C.P.R. (3d) 289.

In *Ciba-Geigy* the Court held that the elements of the tort of passing-off were as applicable to pharmaceutical products as to any other. Accordingly, it was relevant to consider whether the "get-up" of the plaintiff's goods had acquired a distinctiveness that would lead patients to identify that "get-up" with a single source, so that they were likely to be confused into thinking that another's product, with a similar appearance to that of the plaintiff, emanated from the same source as the plaintiff's.

I should also note that, while there are some obvious differences between actions for the tort of passing-off and opposition proceedings to the registration of a trade-mark, there is also a significant link between them. A dismissal of Novopharm's opposition will enable Bayer to prevent competitors from marketing a product that is interchangeable with ADALAT in the form of tablets with a similar appearance to Bayer's nifedipine tablets.

Thus, in any enforcement proceedings that Bayer were to bring for trade-mark infringement, it would not be required to prove that the colour, shape and size of its product had a secondary meaning, as it would in a passing-off action if it were not the holder of valid trade-mark. By virtue of the statutory definition of a trade-mark, the valid registration of the mark at issue in this proceeding in effect irrefutably establishes that the appearance of ADALAT tablets is associated by consumers with a single source.

Third, while I accept that the colour, shape and size of a product may together be capable in law of constituting a trade-mark, the resulting mark is, as a general rule, likely to be weak: *Smith Kline & French Canada Ltd. v. Canada (Registrar of Trade Marks)* (1987), 9 F.T.R. 129 (F.C.T.D.), 131.

In this case, pink round small tablets are commonplace in the pharmaceutical market. This means that Bayer has a heavy burden to discharge in proving on the balance of probabilities that in 1992 those properties had a secondary meaning, so that ordinary consumers associated the tablets with a single source: *Standard Coil*, *supra*, at p. 123. The fact that, when Novopharm filed its objection, ADALAT were the only extended-release nifedipine tablets on the market is in itself insufficient to establish a secondary meaning: *Cellular Clothing Co. v. Maxton & Murray*, [1899] A.C. 326 (H.L.), 346; *Canadian Shredded Wheat Co. v. Kellogg Co. of Canada Ltd.*, [1939] S.C.R. 329.

Fourth, it is not fatal to an application that consumers may also use means other than the mark for identifying the product with a single source. Thus, while pharmacists rely mainly on the brand name and other identifying indicia on the stock bottles and packaging containing the product, or the inscription on the tablets, which is not part of the mark, if there is evidence that to any significant degree they also recognized the product by its appearance (excluding the markings on the tablet because they are not part of the mark), this may be sufficient to establish the distinctiveness of the mark.

In addition, Madam Justice Dawson made the following observations concerning the issue of distinctiveness in proceedings of this nature in *Novopharm Ltd. v. AstraZeneca AB*, [2003] F.C.J. No. 1535 (F.C.T.D.) (hereinafter "AstraZeneca 2") at paragraphs 5 through 8:

It follows that what is to be determined in this proceeding is whether Astra has met its burden to establish that the proposed trade-marks were distinctive as of the date of opposition. This turns upon the factual question as to whether as of the date of opposition, tablets marketed in an appearance similar to Astra's 5 mg and 10 mg tablets render Astra's marks non-distinctive and thereby preclude registration of the trade-mark.

The term "distinctive" is defined in section 2 of the Act in the following terms:

"distinctive", in relation to a trade-mark, means a trade-mark that actually distinguishes the wares or services in association with which it is used by its owner from the wares or services of others or is adapted so to distinguish them.	**« distinctive » Relativement à une marque de commerce, celle qui distingue véritablement les marchandises ou services en liaison avec lesquels elle est employée par son propriétaire, des marchandises ou services d'autres propriétaires, ou qui est adaptée à les distinguer ainsi.**

As the Court of Appeal wrote in *AstraZeneca AB v. Novopharm Ltd.*, 2003 FCA 57 at paragraph 16:

[...] A mark actually distinguishes by acquiring distinctiveness through use, resulting in distinctiveness in fact. A mark that is "adapted so to distinguish" is one that does not depend upon use for its distinctiveness because it is inherently distinctive. A coined or invented word mark falls into this category: Standard Coil Products (Canada) Ltd. v. Standard Radio Corp., [1971] F.C. 106 (T.D.), at 115;

The Molson Companies Limited v. Carling O'Keefe Breweries of Canada Limited, [1982] 1 F.C. 175 (T.D.), at 278-79.

Principles to be applied when considering this issue are:

1. The trade-mark applicant must satisfy the tripartite test enunciated in *Phillip Morris v. Imperial Tobacco Ltd.* (1985), 7 C.P.R. (3d) 254 (F.C.T.D.) at page 270. See: *AstraZeneca v. Novopharm, supra* at paragraph 19. The third part of the tripartite test requires that the association between the mark and the product enables the owner of the mark to distinguish his product from that of others.

2. Colour alone has not been viewed as being inherently distinctive. See: *AstraZeneca v. Novopharm,* at paragraph 18.

3. Proof of actual distinguishment is not an easy burden to discharge. See: *AstraZeneca v. Novopharm,* at paragraph 20.

4. Where the active ingredient in the pharmaceutical product is not claimed as the trade-mark, and the trade-mark sought to be registered is the colour and shape of the tablet, the applicant must show that the colour and shape distinguishes the tablet from the tablets of other manufacturers. See: *AstraZeneca v. Novopharm,* at paragraph 22.

5. It is incumbent on the trade-mark applicant to show that physicians, pharmacists or patients can and do use the proposed trade-mark in choosing whether to prescribe, dispense or request the product. See: *Novopharm Ltd. v. Astra Aktiebolag* (2000), 6 C.P.R. (4th) 16 (F.C.T.D.); aff'd (2001) 15 C.P.R. (4th) 327 (F.C.A.).

6. It is not fatal to an application that consumers may also use means other than the mark for identifying the product with a single source. As Mr. Justice Evans, as he then was, wrote in *Novopharm Ltd. v. Bayer Inc.* (1999), 3 C.P.R. (4th) 305 at paragraph 79; aff'd (2000) 9 C.P.R. (4th) 304 (F.C.A.):

> **[...] Thus, while pharmacists rely mainly on the brand name and other identifying indicia on the stock bottles and packaging containing the product, or the inscription on the tablets, which is not part of the mark, if there is evidence that to any significant degree they also recognized the product by its appearance (excluding the markings on the tablet because they are not part of the mark), this may be sufficient to establish the distinctiveness of the mark.**

Relevant Market to be Considered re Distinctiveness

***AstraZeneca AB v. Novopharm Ltd. et al.* (2003), 24 C.P.R. (4th) 326 (F.C.A.) [hereinafter "AstraZeneca 1"] and AstraZeneca 2 both dealt with an opposition to an application to register a**

trade-mark consisting of the shape and colour of a pharmaceutical tablet. The oppositions succeeded on the basis of non-distinctiveness and one of the issues discussed by the courts was the relevant market to be considered. The applicant argued that the relevant market should be restricted to the active ingredient listed in its statement of wares. The opponent argued that the relevant market is all pharmaceutical pills. At page 338 of AstraZeneca 1, Mr. Justice Stone stated, "However, it is to be noted that the active ingredient as such is not claimed by the appellant as the trade-mark. The trade-mark sought to be registered is the colour and shape, or appearance, of the 2.5mg tablets that happen to contain the active ingredient. In order to bring its application within this branch of the 'distinctive' test in s.2, the appellant had, therefore, to show that through use over time the colour and shape of its tablets actually distinguishes them from tablets of other manufacturers."

In AstraZeneca 2, Madam Justice Dawson began her discussion of "acquired distinctiveness" as follows, at paragraphs 15 through 18, by referring to AstraZeneca 1:

> **At the outset, it is necessary to consider whether the trade-mark must distinguish Astra's 10 mg felodipine from:**
>
> > **(i) the felodipine of its competitors that are interchangeable with Astra's felodipine;**
> >
> > **(ii) all pharmaceuticals in the same therapeutic class, that is all tablets used to treat hypertension; or**
> >
> > **(iii) all pharmaceutically active ingredients available, even non-competing ones.**
>
> **Astra argues that the relevant market is limited to tablets containing felodipine that are interchangeable with Astra's felodipine.**
>
> **This issue was considered by the Court of Appeal in *AstraZeneca v. Novopharm, supra* where the Court of Appeal rejected Astra's submission that the relevant market place was felodipine tablets. At paragraph 22, Mr. Justice Stone, for the Court, wrote that:**

> **Nor would the evidence appear to establish that the combination of colour and shape of the appellant's tablets had the effect of "actually distinguishing" the appellant's wares from those of others. Counsel points out that as the appellant's tablets were the only hypertensive prescription drug in the Canadian market place that contained the active ingredient "felodipine", it readily distinguishes that drug from other prescription drugs because none of the others relied upon contained that active ingredient. There was thus no possibility of some other drug being substituted for the PLENDIL 2.5 mg tablet. Indeed, "felodipine" is identified in the trade-mark application as the "wares" in association with which the trade-mark had been used in Canada since 1994. The appellant maintains from this that both the Registrar and Kelen J. erred in this respect by expanding the relevant market to all round and yellow tablets for the treatment of hypertension rather than restricting it to "felodipine" wares. Indeed, the respondent adduced some evidence of other non anti-hypertensive yellow and round tablets in the Canadian pharmaceutical market, and asserts that the relevant comparison market is all pharmaceutical pills including other yellow and round anti-hypertensive tablets. However, it is to be noted that the active ingredient as such is not claimed by the appellant as the trade-mark. The trade-mark sought to be registered is the colour and shape, or appearance, of the 2.5 mg tablets that happens to contain the active ingredient. In order to bring its application within this branch of the "distinctive" test in section 2, the appellant had, therefore, to show that through use over time the colour and shape of its tablets actually distinguishes them from tablets of other manufacturers.**

Astra argues that a different conclusion should be reached in this case because distinctiveness is an issue of fact and because the analysis of the Court of Appeal "was flawed, in confusing the 'wares' with the 'trade-mark'". I am not prepared to depart from the conclusion of the Court of Appeal. While distinctiveness is essentially an issue of fact, the conclusion of the Court of Appeal in the above quoted paragraph, in my view, is not simply a conclusion of fact.

Where the active ingredient as such is not claimed in a trade-mark, the Court of Appeal has held that the applicant must show that through use over time the colour and shape of its tablet actually distinguishes it from other manufacturers' tablets. This conclusion is, in my view, binding upon me.

Given Madam Justice Dawson's holding that Mr. Justice Stone's statement is a conclusion of law, I am clearly bound to consider all other pharmaceutical tablets in my consideration of the issue of distinctiveness, in the absence of the active ingredient being claimed in the applicant's trade-

mark. It is not clear to me how an applicant claims an active ingredient in a trade-mark but it is clear to me that the trade-mark in the present case no more includes the active ingredient than did those being considered in AstraZeneca 1 and AstraZeneca 2.

I note that AstraZeneca 2 is currently being appealed to the Federal Court of Appeal. Leave to appeal AstraZeneca 1 has been dismissed by the Supreme Court of Canada.

Before proceeding, I will comment that had the applicant succeeded with the amendments that it proposed with respect to its application last November, this would not have affected the impact of Mr. Justice Stone's statement, as interpreted by Madam Justice Dawson. By submitting that the proposed amendments should be allowed because they do not change the trade-mark, the applicant appears to be conceding that the amendment would not result in the active ingredient being claimed in the trade-mark. In any event, Mr. Justice Stone was not the first to treat the general pharmaceutical marketplace as the proper comparison market [see *Novopharm Ltd. v Astra Aktiebolag* (2000), 6 C.P.R. (4th) 16 (F.C.T.D.) at 25, affmd. (2001), 15 C.P.R. (4th) 327 (F.C.A.), leave to appeal dismissed [2001] S.C.C.A. No. 646 (S.C.C.); *Apotex Inc. v. Searle Canada, Inc.* (2000), 6 C.P.R. (4th) 26 (F.C.T.D.) at 35; *Novopharm Ltd. v. Ciba-Geigy Canada Ltd.* (2000), 6 C.P.R. (4th) 224 (F.C.T.D.) at 233, affmd. (2001), 15 C.P.R. (4th) 327 (F.C.A.), leave to appeal dismissed, [2001] S.C.C.A. No. 646 (S.C.C.)].

<u>Other "Red-brown Tablets"</u>

In its statement of opposition, the opponent alleges "red-brown tablets were and are, at all material times, common to the pharmaceutical trade." The opponent specifically refers to 5 red-brown tablets.

At paragraphs 7 and 8 of his affidavit, Mr. Masella attests to having sold seven types of red-brown tablets (other than the applicant's) from 1996 to 1999. The seven do not include the five listed in the statement of opposition. He adds that he knows of numerous patients who take one of these other red-brown tablets as well as the applicant's red-brown tablet.

Mr. Miszyn attests that he has dispensed or sold four other types of red-brown tablets from 1996 to 1999. Two of these were listed in the statement of opposition. None of them were mentioned by Mr. Masella.

Mr. MacDonald attests "that there are many other red-brown tablets in the pharmaceutical market place in Canada" and lists as an example 9 prescription drugs and two types of non-prescription drugs. He attests to having dispensed or sold all of them from 1996 to 1999. He further adds that some of these other red-brown tablets are used in the treatment of conditions that are concurrent or associated with the conditions treated by omeprazole magnesium and also that numerous patients who take LOSEC tablets also take one of these other red-brown tablets. [paragraphs 7-11, MacDonald affidavit] None of the red-brown tablets referred to by Mr. MacDonald were listed in the statement of opposition; nor do any of them overlap with those mentioned by Mr. Miszyn. Six of them were however included in Mr. Masella's seven.

Mr. Ura lists five prescription drugs and two types of non-prescription drugs that take the form of red-brown tablets and that he has sold or dispensed from 1996 to 1999. One of these (famotidine) is often dispensed by him for gastric ulcers and in his experience there are patients who take

LOSEC along with one of four other red-brown drugs. [paragraphs 6-10, Ura affidavit] None of the red-brown tablets referred to by Mr. Ura were listed in the statement of opposition. However, one of the prescription drugs (Voltaren SR) was also mentioned by both Messrs. Masella and MacDonald and both of the non-prescriptions drugs were mentioned by Mr. MacDonald.

Mr. Shelley provides evidence concerning the opponent's Apo-Imipramine product, which is one of the "red-brown" tablets referred to in the statement of opposition. Mr. Shelley provides the annual sales figures for 1995 through 1998 for the Apo-Imipramine product. He also provides excerpts from the 1999 Compendium of Pharmaceutical Specialties, which describe the Apo-Imipramine product as "light-brown" round tablets. However, Ms. West has provided samples of the Apo-Imipramine tablets and I am satisfied from these that they are of a colour similar to that of the applicant's 20 mg LOSEC tablets and might be described by some as "red-brown".

Ms. West has also provided a colour copy of six pages from the 1997 Compendium of Pharmaceuticals and Specialties, which display various pills including four of the pleaded pills and many of the red-brown tablets referred to by the other affiants. Only a handful of these are not round.

Overall, we have evidence of there being approximately twenty other "red-brown" tablets on the market as of the material date. It matters not that all of these tablets were not listed in the statement of opposition. [see *Novopharm Ltd. v. AstraZeneca AB et al.* (2002), 21 C.P.R. (4th) 289 (F.C.A.); *Novopharm Ltd. v. Ciba-Geigy Canada Ltd.; Novopharm Ltd. v. Astra Aktiebolag* (2001), 15 C.P.R. (4th) 327 (F.C.A.)]

I conclude on the basis of this evidence that the opponent has met its evidential burden to show that red-brown tablets were common to the pharmaceutical trade as of the material date.

Evidence of Use of Applicant's Mark as of Date of Opposition

Sales of the applicant's LOSEC 20 mg Red-Brown Tablet Design tablets began in Canada at least as early as February 1996. In 1997, the applicant sold approximately 234 million LOSEC 20 mg tablets or about $106 million worth. The sales figures for 1998 have also been provided but as they have not been broken down as of the date of filing of the opposition, they are not useful to the assessment of distinctiveness as of that date. [Wilton affidavit, paragraphs 6 and 26]

Even if we distil the applicant's numbers down by factoring in the number of pills taken by a single patient during treatment with this medication, we are still left with a significant number of Canadians who have consumed the applicant's LOSEC 20 tablets.

Mr. Wilton has attested that "[t]he LOSEC brand of omeprazole magnesium is the best selling prescription pharmaceutical preparation in Canada based on dollar sales." [paragraph 26, Wilton affidavit] However, Mr. Wilton's statement is clearly referring to the combined sales of all dosages of the LOSEC product. Also, he is not saying that the LOSEC brand is the best selling prescription pharmaceutical preparation in Canada based on number of pills sold. Finally, Mr. Wilton is speaking in the present tense, which is after the material date. In any event, in *Novopharm Ltd. v. Astra Aktiebolag* (2000), 6 C.P.R. (4th) 16 (F.C.T.D.), affirmed 15 C.P.R. (4th) 327, Mr. Justice Rouleau indicated that impressive sales do not by themselves satisfy the

applicant's burden, as explained at page 25 of his decision:

> **[15] The Registrar of Trade-marks appears to have relied upon the sales of LOSEC in finding that Astra's mark was distinctive. However, impressive sales figures alone do not satisfy the burden on an applicant for a trade-mark of proving distinctiveness. Furthermore, there was evidence before the Registrar here to suggest that the sales numbers did not give a precise picture of the marketplace. For example, Dr. Joseph's evidence was that only ten to fifteen percent of her patients suffering from gastrointestinal disorders would be taking LOSEC. Similarly, Dr. Shulman's evidence was that only fifty of several thousand patients were taking LOSEC, while Mr. Droznika stated that LOSEC was not one of the most popular drugs used for gastrointestinal indications in his area. And while Mr. Dixon swore in his affidavit that "a significant number of patients prescribed LOSEC brand of omeprazole have taken the brand chronically", he admitted in cross-examination that he did not know what that "significant number" was.**

In the present case, Dr. Bolland says that generally he writes new prescriptions for LOSEC about 2 or 3 times a month but might have between forty to fifty patients on LOSEC at any one time. [paragraph 5, Bolland affidavit; Questions 37-43, Bolland cross-examination]. However, for gastric ulcers Dr. Bolland tends to prescribe PANTOLAC a bit more than LOSEC (Questions 65-67). Mr. Masella stated during his cross-examination that LOSEC tablets are frequently dispensed and are a big seller. [Question 36] He dispenses about 3000 LOSEC prescriptions a year, which makes it about the second or third highest of any product that he dispenses. [Questions 133-134] Mr. Ura says that the 20 mg LOSEC tablets are possibly among the top ten most frequently dispensed products in his pharmacy [Questions 200-202, Ura Cross-examination]. Mr. Miszyn states that LOSEC is a product that is dispensed moderately, compared to penicillins [Questions 124-126, Miszyn cross-examination].

While large sales clearly do not hurt the applicant's case, they do not make its case in the absence of evidence that shows that the combination of the colour and shape of the LOSEC 20mg product serves a trade-mark function in the minds of the public.

Mr. Wilton attests to the applicant having spent in excess of two and five million dollars annually in Canada in 1997 and 1998 respectively in respect of the promotion "of the LOSEC brand of omeprazole magnesium, including the colour, shape and size of the tablets." [Wilton affidavit, paragraph 28] However, it is difficult to tell to what extent, if any, those efforts promoted the mark that is the subject of the present application. Mr. Wilton provides as Exhibit "F" black and white copies of promotional material. The first page appears to be promoting LOSEC 20 mg to either physicians or pharmacists as part of a triple therapy regimen. The photocopy is not completely legible but there is a trade-mark notice that reads: "LOSEC® 1-2-3 M ™ and LOSEC® 1-2-3 A ™ are trademarks of Astra Pharma Inc." I do not see how that item is promoting the applied for mark. The second item appears to be a partial monograph for LOSEC, which reads near the end: AVAILABILITY OF DOSAGE FORMS: LOSEC (omeprazole magnesium) 20 mg tablets are red-brown, circular and biconvex, printed LOSEC 20 on both sides. The third item appears to be a brochure targeted at consumers. It includes pictures of the 20 mg LOSEC tablet as well as its packaging and states, "LOSEC is provided in two strengths: a reddish-brown (20 mg) or a pink (10 mg) tablet." At the end of the brochure the following trade-mark notice appears: "LOSEC® (omeprazole magnesium) is a registered trademark of the AstraZeneca group of companies. The AstraZeneca logo is a trademark of AstraZeneca PLC and is used under license by Astra Pharma Inc. and Zeneca Pharma Inc." Overall, it does not appear to me that any of these promotional materials would serve to educate doctors, pharmacists or patients that the colour and shape of the LOSEC 20 tablet is a trade-mark or indicates a single source. If anything, the materials suggest that the colour serves to distinguish a certain dosage of omeprazole magnesium and the trade-mark notices, which are directed only to other marks

associated with the product, suggest that the source of the product is neither AstraZeneca AB, nor its predecessor Astra Aktiebolag.

In support of its claim that it has educated the public concerning the trade-mark status of the colour and shape of its tablet, the applicant points to the notice that appears on the front of its packaging, to the right of a coloured picture of its tablet with the abbreviation TM/MC and the words "Actual size Grosseur réelle", as shown above earlier under the heading "Summary of Evidence". The wording reads, "If your omeprazole magnesium tablets look like that shown, it is your assurance that they come from Astra Pharma Inc." I however have some difficulty accepting that this notice educates the public that the colour and shape of the tablet on their own is an assurance that they come from Astra Pharma Inc., for the simple reason that the picture does not show simply a red-brown tablet, but rather a red-brown tablet bearing the words LOSEC 20 thereon. There is no evidence that doctors, pharmacists or patients interpret the wording on the packaging as meaning that red-brown tablets only come from one source and in the absence of such evidence I am not prepared to conclude that this would be the understanding. For whatever reason, the applicant considered it appropriate to display the tablet with the marking LOSEC 20 thereon, with the consequence that its message becomes interpretable as requiring that feature to be present in order to conclude that the pharmaceutical preparation comes from Astra Pharma Inc. I tend to agree with the applicant that if someone can read the notice on the packaging then that same person can read the marking that appears on the representation of the pill. In any event, it seems unlikely that members of the public would simply accept an assertion that red-brown tablets indicate the applicant given the existence of other red-brown tablets in the marketplace.

Conclusion re First Distinctiveness Ground of Opposition

Paragraph 5 of the statement of opposition pleads that the applicant's trade-mark does not and cannot distinguish the applicant's wares from the wares of others, namely red-brown tablets manufactured by others.

Based on the evidence, I conclude that when a pharmacist sees pills bearing the trade-mark LOSEC, he knows that they come from a single source, namely the applicant. When he sees a red-brown tablet bearing the marking LOSEC 20, he also knows that it comes from this single source. If he were to see LOSEC 20 marked on a tablet that was not red-brown, then he would check to make sure that it was in fact the correct medication. However, if a pharmacist sees a red-brown, circular tablet without any markings thereon, he understands that it might be from one of a number of sources, because this look is not unique to a single source, and he requires other means to identify the source of the tablet. In AstraZeneca 2, Madam Justice Dawson stated at paragraph 22, "The proper question is what does a red-brown pill mean to a pharmacist?" It is clear to me that in the present case, the answer is not "medication from one particular source". The applicant does not satisfy its legal burden by showing that pharmacists know that its omeprazole magnesium is not, for example, green.

Overall, I do not find that the evidence from the health professionals in this case differs significantly from many previous cases where a colour/shape mark was held to not distinguish one source's pharmaceutical preparation. Regarding patients, for the reasons set out earlier, I am not satisfied on a balance of probabilities that a significant number of patients associate the look of a

red-brown, circular tablet with a single source. As stated by Mr. Justice Evans in *Novopharm Ltd. v. Bayer Inc.* (*supra*) at p. 331, it is not necessary to file direct evidence to show that patients associate the applied-for mark with a single source, but the absence of such evidence "is damaging when there is evidence from pharmacists and physicians to the effect that patients typically do not associate the appearance of a medication with a single source."

The fact that the applicant has sold a very large amount of its Red-brown Tablet Design tablets does not negate the fact that it is not the only party selling medication with this general appearance in Canada, nor was it the first to do so. Accordingly, the fact that others use a similar look for products in the same general class of wares, *i.e.* pharmaceutical preparations, means that the applicant ought not to be given the exclusive right to monopolize this look through registration. The applicant has not satisfied the burden on it to show that, on a balance of probabilities, the applied for trade-mark was distinctive of its wares as of the material date. The first non-distinctiveness ground of opposition therefore succeeds.

Distinctiveness is essentially an issue of fact. The applicant has argued here that the facts differ significantly from previous oppositions concerning colour/shape pharmaceutical tablet marks and that the outcome should therefore be in its favour. In particular, it submits that there are two important differences in the present case: 1. a representation of the tablet appears on the outside of the packaging; and 2. a message appears on the packaging that aims to educate the public as to the nature of the trade-mark. However, for the reasons discussed above, I have not found that these two changes in the way that the applicant has marketed this particular pharmaceutical

product have been shown to have the desired effect of causing patients to associate this particular colour/shape with a single source.

Second Distinctiveness Ground of Opposition

Paragraph 6 of the statement of opposition pleads that the applicant's mark cannot be distinctive since the applicant's patents prevent anyone else from manufacturing omeprazole magnesium. As I have already ruled that the proper comparison market is all pharmaceuticals, this ground of opposition lacks merit. In any event, both the Federal Court and the Opposition Board have declined to accept such an argument [see *Novopharm Ltd. v. Bayer Inc. (supra)* at p. 323-4 (F.C.T.D.) and *Novopharm Ltd. v. Astra Aktiebolag* (2000), 6 C.P.R. (4th) 101 at p. 114 (T.M.O.B.)]

Third Distinctiveness Ground of Opposition

Paragraph 7 of the statement of opposition reads as follows:

> **The Applicant has not properly licensed the alleged trade-mark to Astra Pharma. Any licenses between the Applicant and Astra Pharma relating to omeprazole magnesium do not cover the alleged trade-mark. Any use of the alleged trade-mark by Astra Pharma does not therefore enure to the benefit of the Applicant. The alleged trade-mark is therefore not distinctive of the Applicant.**

This ground of opposition was added after the opponent cross-examined Mr. Wilton and found his answers concerning the licensing of the mark to be unsatisfactory.

In his affidavit, Mr. Wilton attested that Astra Pharma Inc. ("Astra Pharma") "has sold pharmaceutical preparations containing omeprazole magnesium, in Canada, …since at least as early as February 1996 in the form of red-brown tablets containing 20 mg of omeprazole magnesium." [paragraph 6, Wilton affidavit] He further stated that the red-brown tablets "have

always been round and biconvex in shape, of a consistent size, and always sold under the brand name LOSEC."

Paragraph 7 of Mr. Wilton's affidavit reads as follows:

> **Astra Pharma is a wholly owned subsidiary of Astra AB the owner in Canada of the trade-mark LOSEC and the trade-marks that are the subjects of Canadian Applications 815,151, 815,153 and 815,155 ("the Trade-marks"). Astra Pharma has the permission of Astra AB to use the Trade-marks in association with pharmaceutical preparations containing omeprazole magnesium. Astra AB has direct control of the character and quality of the LOSEC products (the words "product" and "brand" are used interchangeably herein and have the same meaning) sold by Astra Pharma in Canada, including the colour, shape and size of the products and the omeprazole magnesium therein. Indeed, any omeprazole magnesium tablets sold in Canada by Astra Pharma have been made by Astra AB.**

According to Mr. Wilton's affidavit, Astra Pharma Inc. was a wholly owned subsidiary of Astra Aktiebolag until the end of 1999. Effective January 2000, Astra Pharma Inc. and Zeneca Pharma Inc. merged to form AstraZeneca Canada Inc., a wholly owned subsidiary of the current owner of this application, AstraZeneca AB. Mr. Wilton provides packaging of the type used by the applicant. On the side of the packaging there is the message "TM Trademark of Astra AB used under license by Astra Pharma Inc."

In support of its allegation that the mark is non-distinctive due to licensing, the opponent relies on Questions 92-96 of Mr. Wilton's cross-examination, wherein Mr. Wilton stated that he assumed that there was a written license and the applicant's counsel refused to produce any such document. The opponent asks that an adverse inference be drawn that this license does not cover the applied-for mark. At the oral hearing, the opponent argued that the issue is what is being licensed, *e.g.* 2D or 3D, with or without markings, not whether the trade-mark owner controls the

character or quality of the wares. This is a reasonable concession since the trade-mark owner appears to be in control of the character and quality since it manufactures the wares.

Subsection 50(2) of the *Trade-marks Act* states, "to the extent that public notice is given of the fact that the use of a trade-mark is a licensed use and of the identity of the owner, it shall be presumed, unless the contrary is proven, that the use is licensed by the owner of the trade-mark and the character or quality of the wares or services is under the control of the owner." The notice on the side of the packaging presumably aims to bring this subsection into play. However, I am troubled by the fact that it is not clear on the packaging what trade-mark TM is meant to refer to, given that it appears to the right of a picture of a red-brown tablet bearing the marking LOSEC 20.

The question is complicated somewhat by the fact that the applicant's counsel indicated that he was not prepared to produce the licence agreement because there was no ground of opposition that raised the issue. The opponent subsequently amended its statement of opposition to plead such a ground but given that it was not pleaded at the time that the applicant's counsel made its refusal, I find it difficult to make an adverse inference based on the refusal.

The opponent is here relying on the applicant's evidence to satisfy its initial burden. However, I find that the applicant's evidence does not satisfy the opponent's initial burden. Mr. Wilton has attested to there being a license from the trade-mark owner to the party whose name appears on the product. He has attested that the license covers the trade-mark covered by this application and it is clear that the trade-mark owner controls the character and quality of the associated wares. It is not necessary that a trade-mark license be in writing. Mr. Wilton's evidence, both in his

affidavit and during his cross-examination, certainly does not lead me to conclude that, on a balance of probabilities, any use of the trade-mark by the owner's Canadian subsidiary does not accrue to the benefit of the owner pursuant to subsection 50(1) of the *Trade-marks Act*. I therefore dismiss this ground of opposition.

Section 30 Grounds of Opposition

The opponent has pleaded four paragraphs with respect to section 30.

Non-compliance with Subsection 30(a)

The opponent has pleaded that the application does not comply with subsection 30(a) because the applicant has failed to specify the dosage strength in respect of the wares. As I see no basis on which to conclude that the dosage is required in order to satisfy the requirement that the specific wares be stated in ordinary commercial terms, the subsection 30(a) ground of opposition fails.

Non-compliance with Subsection 30(h)

The opponent pleads that the applicant has failed to provide an accurate representation and/or drawing of the alleged trade-mark because the wares also contain markings on the visible surface of the tablets, specifically "Losec" and a number. Markings, namely LOSEC 20, do appear on the applicant's tablets in the marketplace. However, I do not find that their lack of appearance in the drawing of the applied for trade-mark results in this application not complying with subsection 30(h). It is clear to me that the applicant believes that the look of its tablet, without consideration of the markings that appear thereon, can serve to distinguish it wares. Whether or not the applicant has proved this to be the case in the marketplace, I consider it acceptable that the

applicant has taken this position as a preliminary matter as it is the colour and shape in which the applicant wishes to claim a monopoly. By way of analogy, I would note that specimens of design marks may often show another trade-mark appearing on the label or packaging but this does not mean that the drawing of the trade-mark is therefore inaccurate. [see *Nightingale Interloc Ltd. v. Prodesign Ltd.*, 2 C.P.R. (3d) 535 (T.M.O.B.) at p. 538-9] I do not mean by this to say that the marking will be of no consequence in the marketplace.

Non-compliance with Subsection 30(i)

Two grounds have been pleaded under subsection 30(i). The first claims that the applicant could not have been satisfied that it was entitled to use the mark because it did not intend to use the mark to distinguish its wares. The facts do not support such a conclusion. The second claims that the applicant could not have been satisfied that it was entitled to use the mark because the mark is functional in nature, indicative of a pharmaceutical product, and confusingly similar to other pharmaceutical products. The opponent must first put forth evidence that supports its allegations and it has not done so with respect to the first two arms of this claim. Regarding the third arm, the opponent has not pleaded that the applicant was aware of the allegedly confusing red-brown tablets. The subsection 30(i) grounds therefore all fail.

<u>Registrability Grounds of Opposition</u>

The opponent has pleaded three paragraphs under paragraph 38(2)(b).

Section 2

The opponent pleads that the applicant's mark is not a trade-mark within the meaning of section 2 of the *Act*. There is no substance to this claim as the case law clearly holds that marks of this nature can function as trade-marks. [see *Smith, Kline & French Canada Ltd. v. Registrar of Trade Marks*, [1987] 2 F.C. 633 (F.C.T.D.)]

Paragraph 12(1)(b)

The opponent pleads that the mark is clearly descriptive of the character of the wares, specifically a pharmaceutical preparation in the form of a tablet. However, the wares are pharmaceutical tablets containing omeprazole magnesium and there is no evidence that such active ingredient is red-brown by nature. Instead there is evidence that the applicant sells this active ingredient in two colours, pink and red-brown, which suggests that it is not red-brown by nature. In addition, there is evidence that the shape of the LOSEC product is arbitrary (Wilton affidavit, paragraph 20). The paragraph 12(1)(b) ground of opposition accordingly fails, regardless of the material date.

Paragraph 12(1)(e)

The opponent pleads that Red-brown Tablet Design has by ordinary *bona fide* commercial usage become recognized in Canada as designating the kind of wares, specifically pharmaceutical preparations. Although there is evidence of many pharmaceutical preparations on the market in the form of red-brown tablets, that is not evidence that the look of a red-brown circular tablet has come to be recognized as designating pharmaceutical preparations. The ground is therefore dismissed.

Disposition

Having been delegated by the Registrar of Trade-marks by virtue of subsection 63(3) of the *Trade-marks Act*, I refuse the applicant's application pursuant to subsection 38(8) of the *Act*.

DATED AT GATINEAU, QUEBEC, THIS 20th DAY OF JANUARY 2004.

Jill W. Bradbury
Member
Trade-marks Opposition Board