LE REGISTRAIRE DES MARQUES DE COMMERCE
THE REGISTRAR OF TRADE-MARKS

Citation: 2017 TMOB 47
Date of Decision: 2017-04-28

IN THE MATTER OF OPPOSITIONS

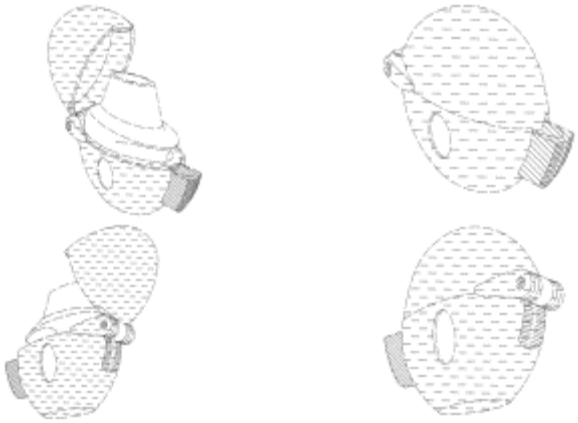
Canadian Generic Pharmaceutical Association	**Opponent**
and	
Boehringer Ingelheim Pharma GmbH & Co. KG	**Applicant**
1,291,973 for Handihaler 3D-II Design **1,291,974 for Handihaler 3D-II Design**	**Applications**

Introduction

[1] On February 28, 2006, the Applicant filed application No. 1,291,973 to register the trade-mark Handihaler 3D-II Design (Mark 1) and application No. 1, 291, 974 to register the trade-mark Handihaler 3D-II Design (Mark 2). Both applications claim priority to German application No. 305 51 046.0/10, filed August 29, 2005.

[2] Both applications cover goods described as "instruments and apparatus for the inhalation of pharmaceutical preparations, namely inhalers for therapeutic purposes; inhalers for the application of drugs for the treatment of respiratory diseases, sold in conjunction with pharmaceutical preparations for the treatment of respiratory diseases" and services described as "conducting clinical studies for pharmaceutical preparations".

[3] The marks are shown below.



Mark 1 Mark 2

[4] Both applications contain the following description: "The trade-mark comprises the colour gray applied to the visible surface of the inhaler device, aside form [*sic*] the circular joint and the rectangular release button which comprise the colour green, as shown in the attached drawings. The two depictions are merely different perspectives of the mark".

[5] At first glance, the main difference between Mark 1 and Mark 2 is that Mark 1 shows the subject inhaler in an open position, whereas Mark 2 shows it in a closed position. However, at the hearing, the Applicant explained that a "lip" was added to its inhalers at one point. Since the "lip" was not present initially, application No. 1,291,974 for Mark 2, which is based upon use in Canada since at least as early as January 15, 2003, shows the inhaler in a closed position. By contrast, application No. 1,291,973 for Mark 1 shows the inhaler in the open position, so that the "lip" can be seen and it is based upon proposed use. Although not discussed in detail in the evidence, this modification was referred to during cross-examination of the Applicant's affiants.

[6] The Opponent has opposed both of the applications. In broad terms, the grounds of opposition may be characterized as being based upon: i) section 38(2)(a) of the Act and various allegations that the applications do not comply with the technical requirements set out in section 30 of the Act; ii) section 38(2)(b) of the Act and various allegations that the marks are not registrable; and iii) section 38(2)(d) of the Act and various allegations that the marks are not distinctive. The grounds of opposition are expansive and extensive in number.

[7] The Opponent need only succeed on one ground in order to be successful and it has succeeded on the ground of non-distinctiveness in both of these cases. Accordingly, for reasons to follow, both oppositions are successful.

File Histories

[8] The applications for both marks were advertised for opposition purposes in the *Trade-marks Journal* of October 20, 2010.

[9] On March 21, 2011, the Opponent filed statements of opposition against both applications. On August 5, 2011, the Applicant served and filed counterstatements in respect of both oppositions and requested that certain paragraphs be struck from the statements of opposition. The Opponent subsequently requested leave to file first amended statements of opposition on October 12, 2011. By way of letter dated November 3, 2011, the Registrar advised that it was satisfied that the grounds of opposition challenged by the Applicant in the first amended statements of opposition were proper grounds of opposition and contained sufficient detail to enable the Applicant to respond thereto. Consequently, the Applicant's request that certain paragraphs be struck was denied and leave to file the first amended statements of opposition was granted.

[10] On February 21, 2012, the Applicant requested leave to file amended counterstatements and leave was granted. A request for leave to file second amended statements of opposition was then filed by the Opponent on March 15, 2012 and, by way of letter dated May 10, 2012, once again, leave was granted. A request for leave to file amended counterstatements was filed on September 17, 2013. In its amended counterstatements, the Applicant requested an interlocutory ruling on the sufficiency of certain paragraphs in the second amended statements of opposition, dated March 15, 2012. By way of letter dated December 6, 2013, the Registrar granted the Applicant leave to file its amended counterstatements and advised that in accordance with the current practice of the Registrar, the sufficiency of the pleadings in respect of the second amended statements of opposition would be considered at the decision stage.

[11] Accordingly, it is the second amended statements of opposition dated March 15, 2012 and the amended counterstatements dated September 17, 2013 which govern these proceedings.

[12] Both parties filed evidence and cross-examinations were held.

[13] Both parties also filed written arguments.

[14] A hearing was held on December 14, 2016 and both parties attended. Notably, the Opponent withdrew grounds of opposition based upon section 30(h) of the Act (paragraph 3(d) of the statements of opposition (as amended)) and section 12(1)(b) of the Act (paragraph 4(b) of the statements of opposition (as amended)).

Overview of the Evidence

[15] In support of its oppositions, the Opponent filed affidavits from the following individuals:

- Dr. Sat Sharma (physician), sworn March 5, 2012 – he discusses respiratory problems, inhalers and what colour and shape indicate to patients, himself and other physicians;

- Mr. Joseph Lum (pharmacist), sworn March 4, 2012 – he discusses the various inhalers that are available in Canada, how they are transferred from manufacturers to pharmacists to patients, and his views with respect to what the shape/colour of inhalers means to pharmacists and patients;

- Mr. Matthew Powell (patent agent), sworn March 5, 2012 – his evidence relates to various patents associated with the Applicant and his opinion with respect to which aspects of the Applicant's "HandiHaler® Drug Delivery Device" are covered by the claims of those patents; and

- Ms. Paulette Howes (law clerk), sworn March 5, 2012 (the first Howes affidavit) – she provides details regarding searches she conducted for inhaler related products in the Compendium of Pharmaceuticals and Specialties (CPS), certified copies of file histories for the applications for Mark 1 and Mark 2, and copies of various industrial design registrations covering inhaler type devices.

Dr. Sharma, Mr. Lum and Mr. Powell were all cross-examined and the transcripts of their cross-examinations, together with answers to undertakings, have been made of record.

[16] In support of its applications, the Applicant filed affidavits from the following individuals:

- Dr. Alan Kaplan (physician), sworn August 9, 2013 – he discusses the drug SPIRIVA®, which is associated with the Applicant's inhalers, its use in the treatment of respiratory problems and what the colour and shape of the device indicate to patients, himself and other physicians;

- Mr. Ywe Looper (Director of Legal Affairs for Boehringer Ingelheim (Canada) Ltd./Lteé – the Canadian affiliate and sub-licensee of the Applicant), sworn August 9, 2013 – he provides background information on the Applicant, its inhalers and its sales and promotional activities in Canada;

- Ms. Michelle Maynard (respiratory therapist), sworn August 8, 2013 – she provides details pertaining to the Applicant's inhalers, describes her interactions with patients and discusses what color/shape mean to her and to patients and other medical professionals, including respiratory therapists and doctors ; and

- Mr. Patrick Zachar (pharmacist), sworn August 8, 2013 – he discusses the Applicant's drug SPIRIVA®, the Applicant's inhalers, their use in the treatment of respiratory problems and what the colour and shape of the device indicate to patients, himself and other pharmacists;

All four affiants were cross-examined and the transcripts of their cross-examinations have been made of record.

[17] In addition, the Applicant also filed a certified copy of its application for Mark 1 in respect of the opposition against application No. 1,291,973 and a certified copy of its application for Mark 2 in respect of the opposition against application No. 1,291,974.

[18] As evidence in reply in both proceedings, the Opponent filed the affidavit of Ms. Paulette Howes, sworn January 12, 2015 (the second Howes affidavit). Ms. Howes was cross-examined and the transcript of her cross-examination has been made of record. Her affidavit provides details regarding a document entitled "What is COPD" and a document entitled "DIN/PIN Detail" obtained from a search she conducted of the Ontario Drug Benefit e-Formulatory website. In addition, she provides details pertaining to documents relating to SPIRIVA® which she obtained from the Patented Medicines Review Board (PMB) website.

[19] I have reviewed all of the evidence. However, I will not summarize it here. Instead, I will discuss those aspects of it which I consider to be most pertinent to the issues at hand in my analysis.

Onus

[20] The applicant in an opposition proceeding bears the legal onus of establishing on a balance of probabilities that its application complies with the requirements of the Act. However, there is an initial evidential burden on an 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* (1990), 30 CPR (3d) 293 (FCTD) at 298].

Analysis

[21] While not identical, the pleadings, evidence and argument concerning both applications are very similar. I will begin by addressing application No. 1,291,974 for Mark 2, which is based upon use in Canada.

Application No. 1,291,974 (Mark 2)

[22] According to the Applicant, the issue at the "deeply buried" heart of this opposition is that of distinctiveness. I agree and I therefore consider it appropriate to begin my analysis with the non-distinctiveness ground of opposition.

Section 38(2)(d) of the Act – Non-Distinctiveness

Pleadings

[23] Generally speaking, the Opponent has pleaded that Mark 2 is not distinctive within the meaning of section 2 of the Act [see paragraph 5 of the statement of opposition (as amended)]. The Opponent goes on to provide the facts upon which it relies in support this allegation in paragraphs 5(a) to (p) of the statement of opposition. As previously discussed, the Applicant challenged the content of a number of these paragraphs in its amended counterstatement filed on September 17, 2013, and requested an interlocutory ruling in this regard. By way of letter dated December 6, 2013, the Applicant was advised that a consideration of the sufficiency of the pleadings would be undertaken by the Registrar at the decision stage of the proceeding, in view of the fact that evidence had already been filed. Since this consideration is being made at the decision stage, I am required to read the pleadings in conjunction with the evidence in order to determine whether the Applicant knows the case it has to meet [*Novopharm Ltd v AstraZeneca AB* (2002), 2002 FCA 387 (CanLII), 21 CPR (4th) 289 (FCA); *Novopharm Ltd v Ciba-Geigy Canada Ltd* (2001), 2001 FCA 296 (CanLII), 15 CPR (4th) 327 (FCA)].

[24] It is clear in paragraph 5 of the statement of opposition (as amended) that the Opponent is alleging that Mark 2 is not distinctive under section 38(2)(d) of the Act, within the meaning of section 2 of the Act (i.e. in that it does not distinguish, nor is it adapted to distinguish the goods or services of the Applicant from those of others). Although some of the various assertions of fact in support of this ground (see paragraphs 5(a) to (p) of the statement of opposition (as amended)) may be said to be convoluted, extraneous or lacking in detail, it is clear that the Opponent is alleging non-distinctiveness on the basis that relevant consumers would not associate the mark with the source of the goods and services covered by the application and in my view, it has provided sufficient material facts for this allegation in the amended statement of opposition. In this regard, I note the following:

- In paragraph 5(b) of the statement of opposition (as amended), the Opponent alleges that in the normal course, the Applicant's goods are marked and/or labelled with a number of identifiers, including (i) SPIRIVA®, (ii) HandiHaler®, (iii) Boehringer Ingelheim, (iv) the generic name of the medication, and others, such that to the extent that consumers identify the Applicant's goods or services based upon appearance, it is these identifiers

which serve to distinguish the goods and services in question and without these identifiers, the empty or blank goods or offering of services without the name of the Applicant or its licensees does not and cannot distinguish the goods or services of the Applicant from those of others;

- In paragraph 5(c) of the statement of opposition (as amended), the Opponent alleges that the colour, shape and/or size of the Applicant's goods is indicative of the active ingredient, formulation, dose, dosage frequency, therapeutic effect or use, or as a means of delivering, or mechanism for the delivery of an inhaled medication and is not indicative of source;

- In paragraph 5(d) of the statement of opposition (as amended), the Opponent alleges that in the case of patients, colour, shape and/or size is used with the Applicant's goods or services, if at all, to determine when or how the goods and services are to be used, or to indicate their therapeutic effect. The Opponent goes on to provide illustrative examples and asserts that patients do not associate the colour, shape or size of their inhalers with a specific source;

- In paragraph 5(j) of the statement of opposition (as amended), the Opponent alleges that in the ordinary course of trade, the Applicant's goods are or will be placed inside cartons or boxes and as a result, the goods themselves are not visible to consumers at the time of purchase. The Opponent asserts that the boxes are labelled and/or marked with the Applicant's trade-marks, SPIRIVA® and/or HandiHaler® and thus, at the time of transfer, the mark (i.e. the colour/shape and/or size) of the goods will not be visible and cannot serve to identify any particular source. In relation to services, the Opponent asserts that the mark can only be identified with labels and/or markings so that any advertising of clinical studies would have to include the labelling and/or marking and the name of the Applicant or its distributors or licensees in order for consumers to know the source. The Opponent further submits that there is no consumer predisposition to equate any of the features of colour/shape and/or size with the source and therefore, the mark is not and can never be distinctive; and

- In paragraph 5(n) of the statement of opposition (as amended), the Opponent alleges that it is common practice in Canada for pharmaceutical manufacturers to mark or label their goods (including inhalers) and package them in boxes. As such, consumers have grown accustomed to having several pieces of information on the outer box of the goods and/or on the goods themselves, including the brand name of the product, as well as other markings. The Opponent asserts that without assistance from this information, consumers cannot and do not identify source. In support of this assertion, the Opponent indicates in its pleading that it relies upon the pharmaceutical products (including inhalers), listed in the CPS, CNP and CSCP, as listed in Schedules "A" to "D" of the statement of opposition (as amended), to illustrate this practice.

[25] The Applicant has mainly objected to these paragraphs on the basis that the Opponent has not indicated the *why* behind its various assertions. For example, the Applicant asserts that the Opponent has not indicted why consumers would rely on other identifiers and not the mark to distinguish the Applicant's goods or services from those of others, why the mark would be indicative of active ingredients, therapeutic effect, etc., or why material besides that claimed as the trade-mark would be necessary in order to indicate source. To some extent, the *why* appears to me to be implicit in the pleadings, and in my view, it is unnecessary for the Opponent to hypothesize about the reasoning behind its allegations in its pleadings. A proper pleading need only allege the material facts, not the evidence that the party intends to adduce to establish those facts [*Pepsico Inc. and Pepsi-Cola Canada Ltd.* v. *Registrar of Trade-marks*, 22 C.P.R. (2d) 62 (F.C.T.D.)]. In any event, the evidence in this case addresses any deficiencies in the pleadings.

[26] Insofar as the Opponent is alleging non-distinctiveness on the basis that relevant consumers of the Applicant's goods and services would not associate the marks with the source of those goods and services, I am satisfied that it has properly asserted material facts so as to support this ground. I am also satisfied that it has provided sufficient detail to enable the Applicant to respond.

[27] Since I will be focusing on this aspect of the non-distinctiveness ground in my analysis, I will not address the remaining concerns raised by the Applicant with respect to this ground.

Material Date

[28] The material date for assessing a non-distinctiveness ground of opposition has generally been accepted to be the date of the opposition, March 21, 2011 (amended October 12, 2011 and further amended March 15, 2012) [*Metro-Goldwyn-Mayer Inc v Stargate Connections Inc* (2004), 34 CPR (4th) 317 at para 25 (FC)]. Neither party made any detailed submissions with respect to what the relevant material date for assessing this ground is in a case where the statement of opposition has been amended (i.e. the date of filing of the original statement of opposition or the date of filing the amended statement of opposition). However, nothing turns on this difference in dates in the present case. If the correct date is the later date, it would not impact my findings in this case.

The Law

[29] Under section 2 of the Act, "distinctive" in relation to a trade-mark means a trade-mark that actually distinguishes the goods or services in association with which it is used by its owner from the goods or services of others or is adapted to so distinguish them.

[30] Three conditions must be satisfied to establish that a mark distinguishes goods: 1) the mark and the goods and/or services must be associated; 2) the owner uses this association between the mark and his product and is manufacturing and selling the product; 3) the association enables the owner of the mark to distinguish his product from that of others [*Philip Morris Inc v Imperial Tobacco Ltd* (1985), 7 CPR (3d) 254 at 270; aff'd (1987), 17 CPR (3d) 289 (FCA)].

[31] Whether a trade-mark is distinctive is a question of fact to be determined with reference to the message it conveys to ordinary consumers [*Novopharm Ltd v Bayer Inc* (1999) [2000] 2 FC 553 at para 70]. The relevant constituency of consumers of pharmaceutical goods and services includes physicians, pharmacists and patients [*Ciba-Geigy Canada Ltd v Apotex Inc* (1992), [1992] 3 SCR 120 at para 110 (SCC)].

[32] Consumers must relate or associate the trade-mark with the source of the goods or services. To be distinctive, the relevant consumers must distinguish the source's goods or services from those of others, based on the source's trade-mark [*Glaxo Group Limited v Apotex*

Inc 2010 FCA 313 at para 7, affirming *Apotex Inc v Registrar of Trade-marks and Glaxo Group Limited* 2010 FC 291.

[33] In *Apotex* (*supra*), Justice Barnes provides what Justice Russell referred to in *Pfizer Products Inc v Canadian Generic Pharmaceutical Association* 2015 FC 493 CanLII as being highly relevant summaries of the jurisprudence in the pharmaceutical trade-mark area and a telling assessment of the difficulties that arise when the appearance of a product is claimed as a trade-mark in its own right. I consider *Apotex*, as well as the decision in *Pfizer*, which quoted extensively from Justice Barnes' decision in *Apotex*, to be quite instructive in the present case.

[34] In *Apotex* (*supra*), Justice Barnes was assessing the distinctiveness of a purple disc shaped inhaler, which when prescribed for medicinal use, contains a dry-powder medication (fluticasone propionate and salmeterol xinafoate) for the treatment of asthma and chronic obstructive pulmonary disease. Not unlike the present case, when dispensed to the public, the inhaler was contained within a box labelled with the trade-marks "Advair" and "Diskus" and the inhaler was similarly labelled. Also not unlike in the present case, the mark itself (i.e. as applied for), comprising the shape of the inhaler in combination with two complimentary purple colours, had no trade-name or label.

[35] I have reproduced a number of paragraphs from Justice Barnes' decision below:

> [11] In *Kirkbi AG . Ritvik Holdings Inc.,* 2005 SCC 65, [2005] 3 S.C.R. 302, the Supreme Court of Canada again recognized that a mark is a symbol of a connection between source and the product "so that, ideally, consumers know what they are buying and from whom" (para. 39)
>
> [12] I would add to this that s. 2 of the Act defines trade-mark as a mark that is <u>used</u> by a person to distinguish wares. This connotes something more than a passive or indecisive observation of potential provenance
>
> [13] In my view, it is insufficient to show that the appearance of a product may represent a secondary check of product identity or that it may cause a person to wonder whether the expected product was correctly dispensed. What is required is that physicians, pharmacists and patients relate the trade-mark to a single source and thereby use the mark to make their prescribing, dispensing and purchasing choices. An educated guess about source is not enough to constitute distinctiveness and neither is a design that is simply unique in the marketplace and recognized as such: see *Royal Doulton Tableware Ltd. v. Cassidy's Ltée* (1985), [1986] 1 F.C. 357 at 370-371, 1 C.P.R. (3d) 214

(F.C.T.D.). The fact that a physician or pharmacist might make an informal assumption about the provenance of a purple disc-shaped inhaler in the context of a therapeutic discussion with a patient is also insufficient to establish distinctiveness

[14] There is no question that colour and shape can help to distinguish the products of one manufacturer from another. Shape and colour can also be powerful influences on consumer behavior. Nevertheless, a trade-mark which is based on product colour and shape is likely to be weak: see *Novopharm v Bayer Inc.*, above, at para.. 77. Demonstrating that product appearance or get-up has become distinctive is also not easy to satisfy: see *AstraZeneca AB v. Novopharm Ltd.* (2003) FCA at para. 26, 24 C.P.R. (4th) 326.

[16] I agree with GSK that there is nothing inherently objectionable about a trade-mark which applies to a unique combination of product shape and colour. There are, of course, well-known marks that are based on shape and colour combinations. However, in the context of a market where purchasing decisions are usually made by professionals or on the advice of professionals, the commercial distinctiveness of such a mark will be inherently more difficult to establish. That is so because, as the weight of the evidence before me establishes, physicians and pharmacists are not strongly influenced by these attributes and have no obvious reason to associate them with a single trade source or provenance. To the extent that the ultimate consumer enjoys a purchasing choice, they will also be significantly influenced by the prescribing and dispensing advice received (including labelling) and, undoubtedly, by associating products with certain well-known trade-names.

[17] It is also important to remember that the consumer would only ever see the GSK Mark with a label affixed and would be presumed to rely heavily upon the printed information to draw conclusions about source. This was a point expressed by Justice Heery in *Cadbury Schweppes Ltd. v. Darrell Lea Chocolate Shops*, [2008] FCA 470 (Fed. Ct. Australia) at paras. 64-65:

> 64.Use of purple seen to be bound up with the "Cadbury" script – purple never used in isolation [100]. The fact that purple was never used without the "Cadbury" script does not seem to be disputed; see earlier judgment [82]-[87].
>
> 65.The Cadbury experts said that this was irrelevant. I do not agree. Cadbury's expert called at the earlier trial, Professor Roger Layton, Emeritus Professor of Marketing at the University of New South Wales, clearly regarded the association of brand with colour as relevant to consumer perceptions; see earlier judgment at [77]-[78]. For obvious enough reasons, consumers are never presented at the point of sale with a Cadbury product, in purple or not, without the Cadbury name prominently displayed. The ordinary reasonable consumer is to be credited with awareness of this when confronted with the allegedly misleading Darrell Lea product.

> If the consumer of chocolate confectionaries is presumed to have sufficient intelligence to make a product identity decision informed by a label, the consumer of pharmaceutical products must be afforded nothing less.
>
> [ ]…
>
> [19] The distinctiveness of a mark based on colour and shape may also be diminished by its association with a registered trade-name. Where a pharmaceutical product is always used in direct association with a well-known word-mark, the risk of customer confusion will be diminished, if not entirely absent, where a look-alike product is presented for purchase with a different brand name. The problem of association of marks was addressed in the case of *General Motors of Canada v. Décarie Motors Inc.* (2001), 2000 CanLII 16083 (FCA), [2001] 1 F.C. 665 at para. 34, 9 C.P.R. (4th) 368 (F.C.A.) where the consistent use of the claimed word-mark "Décarie" in association with the words "Motors" and "Moteurs" was said to indicate that "Décarie" appearing in isolation represented a "weak, if not absent" use which had not acquired a secondary meaning.
>
> [20] I accept the point made by Justice John Evans in *Novopharm Ltd. v. Bayer Inc.* above, at para. 79 that it is not fatal to a trade-mark registration that consumers may use other means than the mark for identifying the product with a sole source. Nevertheless, Justice Evans qualified this with the statement that there still had to be sufficient evidence that the trade-mark was capable of being so recognized on its own. In other words, a trade-mark based on get-up cannot acquire its distinctiveness by virtue of its use in combination with a distinctive word-mark.

[36] In *Apotex*, Justice Barnes found that the evidence established that no prudent physician or pharmacist would rely upon the colour or shape of an inhaler to exercise a professional judgment about the product and that few patients would make a choice based solely on the appearance of an unlabeled inhaler [*Apotex* supra at para 33]. With a label, he noted, patients are sufficiently equipped to distinguish one product from another and to make informed purchasing choices [*Apotex* supra at para 33]. Colour and shape were held not to be the primary characteristics by which GSK distinguished the *Advair Diskus* inhaler from the goods of its competitors or, more significantly, by which its purchasers made their choices [*Apotex* supra at para 34]. In paragraph 35 of the decision, Justice Barnes concluded that although a few patients may make an association between the appearance of the mark in question and a single source, the evidence was insufficient to support the Respondent's contention that a "substantial body" of patients would do so.

[37] In *Pfizer* (*supra*, at para 71), Justice Russell commented that the wording in paragraph 35 of Justice Barnes' decision suggests that it is not sufficient to establish that "a few patients" or, indeed physicians and pharmacists, make the association between appearance and source. He further noted that there is no definition of "a substantial body" and that whether there is a "substantial body" or not, will always depend on the product and the market for that product.

[38] Commenting again on Justice Barnes' decision in *Apotex*, Justice Russell further noted that the wording in para 5 "to any significant degree", para 12 "something more than a passive or indecisive observation of potential provenance", para 21 "only a secondary check for the identification of a pharmaceutical tablet", para 34 "not the primary characteristics", suggests that while some degree of identification may exist, it must be more than a passive or indecisive observation of potential provenance [*Pfizer, supra,* at para 71].

[39] While appearance does not have to be the "primary characteristic" for identifying a single source for the product, as a matter of first impression, it is still necessary to establish, on a balance of probabilities, that appearance is recognized as an indicator of source [*Pfizer*, *supra,* at paras 72 and 107]. In *Novopharm Ltd v Bayer Inc* (1999), 3 CPR (4th) 305 (FCTD), aff'd at 9 CPR (4th) 304 (FCA), Justice Evans states as follows:

> 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.

[40] In *Pfizer*, Justice Russell confirmed that in assessing distinctiveness in the appearance of a pharmaceutical tablet, one must look at whether the evidence establishes recognition "to any significant degree", among any group or groups of "ordinary consumers" [*Pfizer*, *supra*, at para 82]. In this regard, Justice Russell states "…in order to decide whether a significant degree of distinctiveness has been established, the whole constituency must be examined…I see no clear indication in the cases that the words "and", or any other language requires that distinctiveness must be established separately for each sub-group of that constituency" [*Pfizer*, *supra,* at para 82].

The Evidence

[41] The Opponent has pleaded that the appearance of the Applicant's inhalers (with the absence of any markings or other associated indicia) is not distinctive (i.e. indicative of source), but rather, would be associated with therapeutic use, frequency or type of medication. The Opponent alleges that in the normal course of trade, consumers of the Applicant's inhalers will always rely on other indicia (e.g. name of active ingredient, name of medication (SPIRIVA®), other trade-marks (HandiHaler®), DIN, manufacturer's name, etc.) which appear on the packaging, labelling or inhalers themselves, to identify the product or its source. The Opponent asserts that the same would be true when the services are being provided.

[42] Based upon my review of the evidence (discussed below), the Opponent has adduced sufficient admissible evidence (see, for example, Lum affidavit, paras 10-14, 16-20, 25, 32-36, 59-62 (Exhibit R), 63-66, 70-74 (Exhibits S and T), 75-80, and 82-92) and Sharma affidavit paras 19-22 (Exhibit B), 23-24, 46,53, 57, 59 68, 72-74, 76-77) from which it can reasonably be concluded that the facts alleged to support its non-distinctiveness ground of opposition with respect to the goods exist. I am therefore satisfied that the Opponent has met its initial evidential burden in this case with respect to the goods. Insofar as the services are concerned, since it seems clear on its face that in clinical studies, the mark would be used to deliver the medication, and the same issues arise, it follows that if the Opponent has met its initial evidential burden with respect to the goods, it has also met it with respect to the services.

[43] The issue therefore becomes whether the Applicant, on a balance of probabilities, has established source recognition by appearance amongst patients, physicians and/or pharmacists to any significant degree, bearing in mind the above canvassed principles of law and that distinctiveness need not be established separately for each of these groups within the relevant consumer constituency.

[44] I will begin by first reviewing what the evidence tells us about inhalers in general. I will then review what the evidence tells us about the Applicant's inhalers in particular and how it promotes and uses Marks 1 and 2 in the marketplace. Lastly, I will go on to discuss what the evidence tells us about patients', physicians' and pharmacists' perceptions of the Applicant's inhalers.

Preliminary Matter

[45] At the outset, I would like to acknowledge that both parties have raised concerns with respect to the reliability of some of the witnesses' testimony.

[46] The Applicant takes issue with Mr. Lum's affidavit because he has sworn affidavits in trade-mark pharmaceutical matters before and was compensated for his time in preparing his affidavit. The Applicant submits that he is biased and that his affidavit is suspect because some of the content is repetitive of his past affidavits. I note that during cross-examination, Mr. Lum acknowledged swearing affidavits in proceedings pertaining to Celebrex and Advair. He was asked whether he relied upon either of those affidavits to prepare his current affidavit and he acknowledged that he used his CV and background, which needed some updating, as well as the framework and some information from a chart in an exhibit, which also required some updating, but otherwise started "pretty well fresh" [Lum transcript, Q 13]. He states that the basic information was there that was used for the Advair affidavit, but it generally changed quite a bit [Lum transcript, Q 13].

[47] The Applicant also takes issue with Dr. Sharma's affidavit and asserts that Dr. Sharma is biased. In this regard, the Applicant pointed out that Dr. Sharma was also compensated for his time in preparing his affidavit. In addition, the Applicant directed my attention to Q 147 of the Sharma transcript, where Dr. Sharma indicates that he discourages the practice of writing "do not substitute" on a prescription so that a generic medication cannot be substituted for a particular medication. I note that in *Ciba-Geigy Canada Ltd v Novopharm Ltd* (1994), 56 CPR (3d) 289 (FCTD) at 309-310, Rothstein J. recognized that some physicians and pharmacists may have a loyalty one way or another. Where statements are exaggerated or not reasonably based on the deponent's qualifications, this goes to weight.

[48] The Opponent takes issue with Dr. Kaplan's evidence and in particular, points out that he has been on a speakers' board for Boehringer Ingelheim, served on advisory boards for it, and was involved in clinical trials for SPIRIVA®. This also goes to weight and I acknowledge that as result of his close association with the Opponent, Dr. Kaplan may have a different level of awareness of Mark 1 and Mark 2 than physicians generally [*Pfizer, supra*, at paras 113, 177 and 185].

[49] With respect to Mr. Looper, the Opponent notes that he is an employee of the Applicant. Further, the Opponent notes that during cross-examination, Mr. Looper admitted that the registration of Mark 1 and Mark 2 would be beneficial to his company and to him as an employee of the company. He also admitted to meeting with the Applicant's witnesses for the preparation before their cross-examinations. In view of this, the Opponent submits that his evidence is not unbiased. While that may well be the case for some of his evidence, I am prepared to afford appropriate weight to the factual information provided in his affidavit regarding the Applicant, its sales and promotional activities. However, I will disregard any opinion type evidence.

[50] With respect to Mr. Zachar, the Opponent criticizes his evidence because while he states in his affidavit that his views are "representative of most retail pharmacists who dispense the HandiHaler and Spiriva product", when asked about the careful procedures followed by pharmacists, he advised that he could not "speak for other pharmacists" [Zachar affidavit, para 22; Zachar transcript, page 50]. While the Opponent's criticism is not without merit, I note that this statement appears to have been limited to a discussion on the various checks that he does when dispensing medications, and I note that Mr. Zachar's testimony in this regard appears to be consistent with that of Mr. Lum.

[51] With respect to Ms. Maynard, as a respiratory therapist, the Opponent argues that she is not part of relevant constituency of consumers. While that may be the case, because respiratory therapists may only help patients use inhalers once they have been prescribed, dispensed or purchased, I still consider her evidence to be relevant, to the extent that it offers anecdotal evidence regarding patients' views.

Inhalers

[52] Asthma and Chronic Obstructive Pulmonary Disease (COPD) are the two main conditions patients have when using inhalers Asthma is a reversible airflow obstruction associated with steroid responsive inflammation. COPD is traditionally only a partially reversible airflow obstruction and is most commonly secondary to cigarette smoking [Sharma affidavit, para 20; Kaplan affidavit, paras 19 and 24; Zachar affidavit, para 6].

[53] In paragraphs 23 and 40 of his affidavit, Dr. Sharma explains that there are two basic types of inhalers that work in different ways to deliver medications for inhalation. The first is a metered dose inhaler (MDI) which usually comes in a boot shape, where the active ingredient is suspended in an aerosol propellant and is pushed out as the patient breathes in, and the second is a dry powdered inhaler which usually comes in a round shape and with which the active ingredient is drawn out of the inhaler and into the patient's lungs when he or she inhales. MDI's can be difficult to operate and sometimes require aerochambers to allow easier co-ordination of breathing and improved timing [Kaplan affidavit, para 34; Lum affidavit, paras 26 and 29].

[54] In deciding which type of inhaler to prescribe to a patient, Dr. Sharma will consider factors such as the age of the patient and lung capacity. In addition, he will consider whether the patient is already on an inhaler and is using it properly. For example, where a patient is using a boot shaped inhaler, he will observe the patient's technique and if it is good, he will continue to prescribe it. If it is not, he will prescribe a dry powdered rounded inhaler instead [Sharma affidavit, para 35]. Likewise, Dr. Kaplan also considers the ability of the patient to use the different types of inhalers when he prescribes a medication [Kaplan transcript, Q 184].

[55] Dr. Kaplan identifies the two types of inhalers mentioned by Dr. Sharma, but also identifies the HandiHaler® containing the SPIRIVA® medication as being a third type of inhaler. He describes it as being a somewhat circular device having an oblong shape, which opens up in the centre for loading a capsule of medication and is levered to open on one side for use by the patient [Kaplan affidavit, para 34].

[56] Both Dr. Kaplan and Dr. Sharma also acknowledge that there are also different categories of inhalers. First, there are "rescue" inhalers ("short acting beta agonists"), which, with one

possible more recent exception (Zenhale), are blue in colour and come in both boot and rounded shapes [Kaplan affidavit, para 33; Sharma affidavit, para 46; Sharma transcript, Q 98]. An example is Ventolin, which Dr. Kaplan confirmed is a short-acting bronchodilator that patients would refer to as their "rescue inhaler" or their "blue inhaler" [Kaplan transcript, Q's 114-115]. They would know that it is the blue inhaler they take for acute symptoms [Kaplan transcript, Q's 120-126]. Although, patients do sometimes get it wrong, this is how they are educated by physicians to distinguish between their inhalers [Kaplan transcript, Q 272]. Mr. Lum provides similar information pertaining to blue inhalers in his affidavit [Lum affidavit, para 32].

[57] Second, there are "maintenance" or "controller" inhalers, which are for long-term maintenance or control therapy. The "controller" inhalers are inhaled steroids that control the condition and can have lasting effects. The "maintenance" inhalers actually improve the underlying disease process. However, their effect gradually wears off following the cessation of use. These "maintenance" and "controller" inhalers typically come in a variety of colours, other than blue (e.g. green, brown, orange or purple) [Sharma affidavit, paras 23 and 46]. During cross-examination, Dr. Kaplan confirmed that a patient could be on SPIRIVA® (a long-acting anticholinergic) and a short acting betaagonist such as Ventolin at the same time and he or she would know that they take the blue inhaler when they are in trouble and the grey-green inhaler once a day, every day, as maintenance [Kaplan affidavit, Q's 129-132; Lum transcript Q 96].

[58] According to Dr. Sharma, maintenance inhalers are green (e.g. Atrovent (boot shaped) and SPIRIVA®) and controller inhalers are brown/orange/red/purple and green (e.g. Serevent, Oxeze, Advair, Symbicort). Serevent and Oxeze are "long acting beta agonists" and are green (e.g. mint green/turquoise). Serevent is delivered in both a boot shaped and a rounded inhaler (boot shaped was discontinued in 2006). Oxeze is delivered in a rounded inhaler. Advair is purple and is delivered in both boot-shaped and rounded inhalers and Symbicort is delivered in a rounded brown/orange/red inhaler. [Sharma affidavit, paras 23 and 46; Kaplan transcript, Q 262]. During cross-examination, Dr. Sharma acknowledged that a green inhaler could be either a controller or maintenance inhaler [Sharma transcript, Q 187].

[59] Dr. Kaplan also acknowledges that Atrovent, Serevent and Salmeterol are green [Kaplan affidavit, para 38], but indicates that he would not describe the SPIRIVA® inhaler as green, but

rather, "mostly gray", with "green portions giving it a unique colour and visual appearance" [Kaplan affidavit, para 38]. During cross-examination, Mr. Lum also confirmed that green inhalers are usually preventative [Lum transcript, Q's 240-242].

[60] Attached as Exhibits C to F of Dr. Sharma's affidavit are copies of pages from the Compendium of Pharmaceutical Specialties (CPS) for the years of 2003, 2005, 2006 and 2011, showing examples of some of the different types of inhalers that were available during those years. The CPS is a general reference that provides information on pharmaceutical products sold in Canada, such dose and other prescribing information. I note that copies of pages from the CPS for the years of 2003, 2005, 2006 and 2011 are also attached as Exhibits A to D of the first Howes affidavit and as Exhibits D to I of the Lum affidavit. Mr. Lum also provides information about the various types of inhalers in his affidavit [Lum affidavit, paras 37-42].

[61] Attached as Exhibit I to Dr. Sharma's affidavit, is a Reference Chart that summarizes some of the orally inhaled devices for the management of COPD and asthma. Dr. Sharma explains that he has this chart on his wall and sometimes uses it to show patients the different types of inhalers and to have patients identify which inhaler they have used in the past. I note that none of the inhalers shown in Exhibit I consist of the same shape/colour combination as SPIRIVA®. Dr. Kaplan indicated in his affidavit that the shape of the SPIRIVA® inhaler was and still is unique [Kaplan affidavit, para 23], and I note that during cross-examination, Dr. Sharma acknowledged that he was not aware of any other inhaler on the market being precisely the same shape as the SPIRIVA® inhaler [Sharma transcript, Q's 168-170].

[62] During cross-examination, Dr. Sharma was also asked what companies he was aware of that make a grey inhaler [Sharma transcript, Q's 139-143]. He mentioned Atrovent, Beclovent, Pulmicort and earlier versions of steroid inhalers, all of which are boot shaped. During cross-examination, Mr. Zachar confirmed that he is aware of at least three grey inhalers used for COPD that are now on the market in addition to SPIRIVA® [Zachar transcript, Q's 224-225].

[63] Based upon my review of the evidence, I am satisfied that "rescue" type inhalers are typically blue in colour and that the "maintenance" and "controller" inhalers typically come in a variety of other shape/colour combinations. While the evidence shows that maintenance inhalers

are green (at least in part), it also shows that some controller inhalers are as well. Thus, unlike the "rescue" inhalers, any emerging pattern with respect to the colour green is less clear.

[64] Despite the fact that there are other green inhalers, gray inhalers, and "roundish" inhalers on the market, overall, I am satisfied that the SPIRIVA® inhaler is unique in terms of its color/shape combination. I am also satisfied that physicians and patients (although not always correctly) use color as a way of distinguishing between which inhaler to use for rescue purposes and which ones to use for longer term control or maintenance purposes. In addition, the evidence before me establishes that in cases where there is a choice between different types of inhalers, shape can be a relevant consideration in determining which type of inhaler to prescribe to a patient (i.e. boot shaped or otherwise).

The Applicant's Activities

[65] Information pertaining to the Applicant and its promotion and use of Mark 1 and Mark 2 in the Canadian marketplace can primarily be found in the Looper affidavit.

[66] Mr. Looper is Director, Legal Affairs for Boehringer Ingelheim (Canada) Ltd./Lteé ("BI Canada"), the Applicant's Canadian affiliate and sub-licensee [paras 1-4]. Mr. Looper explains that BI Canada is sub-licensed by the Opponent (BI) to distribute, promote and market the SPIRIVA® product in Canada [para 5]. He states that BI retains control over the character and quality of the SPIRIVA® product and HandiHaler® devices which are sold in Canada through BI Canada [para 5].

[67] Mr. Looper explains that the HandiHaler 3D-II Design trade-marks (Mark 1 and Mark 2) comprise the surface gray and green colours and shape of BI's inhaler product, known as the branded HandiHaler®, which holds BI's SPIRIVA® product [paras 6-8]. A sample of the marks as applied to the HandiHaler® device as well as all packaging provided therewith to purchasers in Canada is attached as Exhibit A to his affidavit [para 8].

[68] I note that the inhaler itself features the trade-mark HandiHaler® and the name of the Applicant [Looper affidavit, para 8, Exhibit A; Looper transcript, Q 98]. During cross-examination, Mr. Looper confirmed that to his knowledge, no "blank" inhalers (i.e. without these

markings) have been sold in Canada [Looper transcript, Q's 82-85]. All devices sold feature the trade-mark HandiHaler®, the name of the Applicant and its address [Looper transcript, Q's 193-194].

[69] The product packaging (a box) for the inhaler features the trade-mark HandiHaler®, the name Boehringer Ingelheim and the name of the Applicant's sub-licensee. It also features the trade-mark SPIRIVA® and provides the generic name (Tiotropium Bromide Monohydrate) and dosage information for the medication. HandiHaler® is identified as a trade-mark on the inhaler and both HandiHaler® and SPIRIVA® are identified as being trade-marks on the box. Mark 1 and Mark 2 are not identified as trade-marks on the inhaler and neither Mark 1 nor Mark 2 appears on the box, nor can they be seen through it. An insert is also provided with the packaging and it contains detailed information relating to the SPIRIVA® product and the use of the HandiHaler® device. While it shows pictures of the HandiHaler® device, the device is not shown in colour.

[70] Mr. Looper states that the HandiHaler® device was first offered for sale in Canada in association with the SPIRIVA® product in late 2002 and early 2003. According to Mr. Looper, it was the only gray and green inhaler on the Canadian market at that time and remains to be the only one. He states that the colour and shape combination is completely different from all other inhalers on the market now and for at least the past 11 years [para 9]. During cross-examination, Dr. Sharma acknowledged that there are some other gray coloured inhalers in the marketplace, but the shape of the SPIRIVA® inhaler device is unique [Sharma transcript, Q 169].

[71] In paragraph 10, Mr. Looper explains that SPIRIVA® is administered to patients in the form of a capsule containing the tiotropium bromide inhalation powder using the HandiHaler® device. SPIRIVA® is used to treat chronic obstructive pulmonary disease (COPD), a lung disease that includes chronic bronchitis, emphysema, or both conditions. Attached as Exhibit "B" to Mr. Looper's affidavit is a copy of the current SPIRIVA® product monograph. It is divided into three parts. Part III is reproduced in the form of a patient information leaflet, which forms part of the package containing the HandiHaler® device. A copy of the leaflet is attached as Exhibit "C". It contains instructions on how to use SPIRIVA® through the HandiHaler® device,

with pictures. The device in the pictures has no markings and it is shown only in black and white. It is not identified as being a trade-mark.

[72] In paragraph 11, Mr. Looper explains that the HandiHaler® device is commercialized in Canada as: i) a device only; ii) a package comprising the HandiHaler® device and 30 capsules of SPIRIVA®; and iii) a package comprising the HandiHaler® device and 10 capsules of SPIRIVA®. A refill package of capsules of SPIRIVA® without the HandiHaler® device is also commercialized, but the capsules must be used with the HandiHaler® device.

[73] The HandiHaler® device and SPIRIVA® are distributed through wholesalers, retail pharmacies, hospital pharmacies and physicians. Mr. Looper explains that wholesalers order/purchase each of items i) to iii) as well as the refill packages of SPIRIVA® directly from BI Canada and they are shipped directly from BI Canada's warehouse to wholesaler warehouses across Canada. Retail pharmacies order/purchase items i) and ii) from BI Canada or from wholesalers and the items are shipped directly from the respective warehouse to the retail pharmacy. Hospital pharmacies order/purchase items i) to iii), as well as the refill packages directly from BI Canada, wholesalers or the Canadian Pharmaceutical Distribution Network (CPDN), a third party distributor and the items ordered are shipped from the respective warehouse directly to the retail pharmacy. Physicians may request items i) or ii) in writing with a copy of the patient's prescription for compassionate use (free good). Item iii) and the refill packages of SPIRIVA® are provided directly to physicians by sales field staff for use as samples. Free goods and physician samples are given by physicians directly to patients [para 11].

[74] Sales figures for the HandiHaler® device and SPIRIVA® in Canada from 2003 to 2012 are provided in paragraph 12 of Mr. Looper's affidavit. I have reproduced the figures below. Mr. Looper indicates that to the extent that the figures include SPIRIVA® capsules without the HandiHaler® device, the HandiHaler® device is always used when the SPIRIVA® capsules are administered. He estimates that some 35% of sales relate to refill packages comprising SPIRIVA® capsules without the HandiHaler® device. It is unclear what portion of the sales, if any, relates to sales of the HandiHaler® device on its own. Notably, during cross-examination, Mr. Zachar indicated that while his pharmacy stocks some HandiHaler® devices in case a

customer breaks one, they do not sell them, they just hand them out [Zachar transcript, Q's 178 to 180].

Year	Approximate Sales (in Canadian dollars)	Market Share (IMS R3 Market)
2003	11.5 million	1.97%
2004	39.0 million	6.03%
2005	57.2 million	7.92%
2006	72.7 million	9.60%
2007	84.7 million	12.54%
2008	137.4 million	14.69%
2009	151.9 million	14.81%
2010	167.3 million	15.85%
2011	179.2 million	16.16%
2012	192.1 million	16.90%

[75] According to Mr. Looper, BI Canada has spent significant resources building up the current demand for and recognition of its HandiHaler® devices as branded with Mark 1 and Mark 2 and used to deliver the SPIRIVA® medication to patients from at least as early as 2004 to present [para 13]. Expenditures related to direct promotion and healthcare professional and patient education for SPRIIVA® and the HandiHaler® devices exceeded $50 million between 2003 and 2012 (annual expenditures have been provided). Mr. Looper states that the appearance of the inhaler is an important feature in promoting the product to healthcare professionals, to whom its advertising in Canada is directed, since direct advertisement to patients is not permitted.

[76] The expenditures referred to above include activities such as funding for education programs for physicians, sponsorship of physician lectures at medical meetings, the cost of development of materials and programs intended to improve patients' understanding and management of COPD, patient material on disease education, funding of COPD spirometry clinics in physicians' offices and more. The promotional activities of the Applicant are outlined in paragraphs 13-14 of Mr. Looper's affidavit. According to Mr. Looper, the figures he provided do not include other promotional costs which would increase the numbers by perhaps 50%. He does not specify what those costs are associated with. However, during cross-examination, he indicated that the big promotional costs would be the overhead and salaries of the sales representatives (the infrastructure) and he also made reference to media-type presentations that may not be captured in the costs [Looper transcript Q's 245-250]. In addition, BI Canada also invests in funding various research projects related to COPD. Figures for its grants/donations for such projects have been provided [para 14].

[77] Attached as Exhibit D, are copies of promotional materials, which according to Mr. Looper, show Mark 1 and Mark 2. He indicates that they are the sort of material that would have been distributed and made available to promote the SPIRIVA® product since it was introduced into Canada in late 2002 and early 2003. Most of the materials show the HandiHaler® device in an open position. While it is difficult to see, in some instances, the device appears to be in white and/or blue colors, rather than green/grey. During cross-examination, Mr. Looper was unable to confirm whether it appeared in these colours in the original copy of the ads [Looper transcript, Q's 159 and d160]. The name of the Opponent and the trade-mark HandiHaler® appear on the device shown in the advertisements. The colour/shape of the device is not identified as being a trade-mark in the advertisements. Mr. Looper confirmed this during cross-examination [Looper transcript, Q's 162-165]. He also confirmed that it is likely that all of the promotional materials of the sort shown in Exhibit D would feature the trade-marks HandiHaler® and SPIRIVA®, and possibly others as well [Looper transcript, Q's 248 and 249].

[78] In paragraph 16 of his affidavit, Mr. Looper reiterates that the HandiHaler® device, to which Marks 1 and 2, comprising the gray and green colours and specific shape as claimed are applied, have been extensively marketed and promoted in Canada. Mr. Looper goes on to say that the colour and shape of the inhaler are unique and that patients, pharmacists and doctors

associate the colour and shape of the inhaler with BI's SPIRIVA® product administered through the HandiHaler® device.

[79] Notably, aside from the fact that Mr. Looper does not indicate how he came to be aware of the association made by patients, pharmacists and physicians, he appears to be saying that the association is between the marks and the product which is administered through the device, not between appearance and a single source.

Evidence from Relevant Consumers

[80] As previously mentioned, the relevant constituency of consumers of pharmaceutical goods includes physicians, pharmacists and patients [*Ciba-Geigy Canada Ltd, supra,* at para 110]. I will discuss the evidence pertaining to each of these categories of relevant consumers below.

Physicians

[81] The evidence with respect to physicians' perceptions is primarily found in the Sharma and Kaplan affidavits.

[82] Dr. Sharma is a physician practicing medicine in Canada. His positions, experience, qualifications, activities, licenses and awards are outlined in paras 1 to 18 of his affidavit. A copy of his curriculum vitae is attached as Exhibit A. Dr. Sharma has an active full time medical respiratory practice as well as an outpatient practice at the St. Boniface General Hospital, in Winnipeg, Manitoba, where he regularly sees patients. From 2003-2011 and at the time he swore his affidavit, Dr. Sharma had approximately 10,000 patients. He sees approximately 1800 patients per year and approximately 80% of the patients he treats use inhalers [Sharma affidavit, paras 26-29; Sharma transcript, Q. 70].

[83] Dr. Sharma states that as a result of his medical experience, including his medical practice, his teaching experience and directorship roles at the Faculty of Medicine, University of Manitoba and the St. Boniface General Hospital, along with the conferences, seminars and workshops that he attends and speaks at and the papers, texts and e-articles that he reviews and

edits, he has frequently had opportunities to interact with other physicians, including respirologists and family physicians [para 19].

[84] According to Dr. Sharma, at these meetings, many topics of discussion arise that are pertinent to patients and their medications and as such, he is familiar with the practices and views of many respirologists and family physicians in Canada [para 19]. He states that as a frequent speaker at conferences, many respirologists and family physicians share their concerns with him about patient care, including concerns about medications, including inhalers (and any concerns/issues that patients may have regarding the different types of inhalers available and how they are used). He further states that this includes both concerns from the physicians themselves and concerns of their patients, as reported by their physicians [para 19].

[85] Dr. Sharma says that he is especially familiar (due to his professional experience) with the practices and views of respirologists and family physicians with regard to asthma and COPD [para 20].

[86] Dr. Kaplan is a physician qualified in and for the Province of Ontario. His extensive professional activities, experience and qualifications are detailed in paragraphs 1 to 17 (and Exhibits A to F) of his affidavit. His current family practice comprises approximately 2500 patients, approximately 20% of which suffer from some sort of breathing disorder including COPD [Kaplan affidavit, para 18]. Dr. Kaplan sees about 500 respiratory patients annually from his own practice, plus another 50 or so consults from other physicians. He prescribes SPIRIVA® about twice daily [Kaplan affidavit, para 22].

[87] When Dr. Sharma writes a prescription, he writes the brand name, never the colour or shape and in deciding which medication to prescribe, the colour and shape of an inhaler is not a factor in his decision, except to the extent that one shape might be easier for a patient to use than another (i.e. boot vs. rounded). The appearance and the manufacturer of a medication are not considerations. Rather, Dr. Sharma takes into account the medical diagnosis, the efficacy, safety and tolerability of the medication, and cost [Sharma affidavit, para 62-64].

[88] According to Dr. Sharma, patients and physicians alike do not associate the colour, shape and/or size of inhalers to a particular manufacturer or source [Sharma affidavit, para 24]. He

states that a physician would never prescribe a blank inhaler based on the appearance of the inhaler without making a reference to the label or packaging (which would have identifying information – including the pharmacologic name of the drug and/or trade-name of the inhaler product and the dosage). If shown a blank inhaler, physicians would not be able to identify this product as coming from any particular manufacturer/source – a label would be required [Sharma affidavit, para 25].

[89] Dr. Sharma states that he cannot identify and will not try to identify any of (a) the medication contained in an inhaler, (b) the inhaler itself, or (c) the manufacturer or source of the inhaler, merely by its appearance (i.e. its colour and/or shape). He states that without the information contained on the label and sometimes on the inhaler, he would not be able to identify the inhaler. In order to identify an inhaler and the medication contained in it, he will always refer to the information found on the label affixed to the inhaler and/or its box, including, for example, the brand name of the dry powder drug (SPIRIVA®), the active ingredient (tiotropium bromide monohydrate), the dosage strength, the drug identification number (DIN) and the manufacturer name (Boehringer Ingelheim) [Sharma affidavit, paras 72,73].

[90] Since he is a specialist, inhalers are not new to most of Dr. Sharma's patients. In most cases, they have already been prescribed inhalers by their primary care physician [Sharma affidavit, para 56]. Dr. Sharma explains that he usually requests that patients bring their inhalers and other medication with them to their appointments. He states that in order to determine the medication contained in an inhaler, he will look at both the pharmacy label and the manufacturer label [Sharma affidavit, para 57].

[91] This evidence is in contrast to Dr. Kaplan's evidence. Dr. Kaplan states that he would associate SPIRIVA® medication with the gray and green colour combination having the shape of the handihaler, even if HandiHaler® was not apparent anywhere on the device or the labelling. He says he would not notice if the reference to HandiHaler® on the device or packaging were absent [Kaplan affidavit, para 27]. According to Dr. Kaplan, colour and shape are the primary means for distinguishing the SPIRIVA® product from others and, in general, appearance is used, along with such indicators as the name of the drug, to identify medications. He views the particular colour and shape as being indicative of the Opponent's SPIRIVA® product and uses

colour and shape to identify the product in the process of prescribing and describing the product to patients [Kaplan affidavit, para 28].

[92] During cross-examination, Dr. Kaplan was asked whether he would ask to see his new patients' inhalers to see what they are already taking [Kaplan transcript, Q 143]. He confirmed that he would. He was then asked whether he would look at the label on the inhaler to see what the drug is [Kaplan transcript, Q 145]. His response was as follows:

> A I look at the inhaler sort of all in one big picture. It's going to be a combination of the shape, the colour, which kind of device it is, whether it's a metered-dose inhaler or a dry powder device. Because I'm fairly familiar with all these medications, especially the older ones, I don't necessarily look at the label directly other than maybe to look at the instructions because I didn't prescribe them. And even sometimes when I do prescribe them, I look at the pharmacy label to make sure that the pharmacy instructions are correct.

[93] He was then asked the following question and replied as follows:

> 147.
>
> Q And as a careful physician, you'd want to see some sort of marking on that inhaler to know what was in it?
>
> A Again, because these are medications we use every day all the time and I've been so -- I've been teaching them, I've been showing devices, I've been teaching devices to doctor, it's generally just the colour and the shape so it jumps out at me and I recognize them from that.

[94] During cross-examination, Dr. Kaplan was asked about his practice when a patient does not bring his or her inhaler to an appointment and how he determines what medication they are taking. He indicated that he makes an educated guess based upon colour. He then tries to make an effort to look at pharmacy records [Kaplan transcript, Q 155]. When asked if he would prescribe based upon a patient's imperfect recollection, he replied as follows:

> 156
>
> A I can't say I've never done it based upon their recollection. If the person is trustworthy, I describe the shape of the inhaler as well as the colour. Since

> these colours are all different for different inhalers. So if the shape and colour match and it makes sense, I might – in the setting of an acute situation where I don't have the opportunity to find out exactly what they're taking, I might well base it on the colour and shape

[95] This evidence is inconsistent with Dr. Sharma's evidence and I query whether all of it would be representative of physicians (specialists or otherwise) in general, when one considers the standard of care that would ordinarily be expected from such a profession. I note that it also appears to be inconsistent with some of Dr. Kaplan's own later testimony regarding the SPIRIVA® inhaler [Kaplan transcript, Q 279], which I have reproduced below:

> 279.
>
> Q Now, we've discussed the fact that you are quite familiar with this device and you see it with HandiHaler and Boehringer Ingelheim written on it. If you were provided with this device and it had the same colour and the same shape and it said Apotex Inc. and it did not say HandiHaler, where would you think the device came from?
>
> A Apotex.

[96] Given the emphasis Dr. Kaplan purports to place on colour/shape, rather than labels and markings when identifying medications, the above response is somewhat surprising. It is difficult to understand how, upon seeing an inhaler with Boehringer Ingelheim written on it, he would not notice it and would assume Boehringer Ingelheim to be the source based upon the appearance of the inhaler, but when faced with an inhaler having the same appearance and Apotex written on it, he would make his assumption as to source based upon the name written on the inhaler.

[97] Dr. Kaplan's close ties to Boehringer Ingelheim also cause me to query how representative his views are of other physicians. During cross-examination, he acknowledged that he has had extensive experience with SPIRIVA® and the HandiHaler device because he was involved in clinical studies for the drug and was compensated for his participation by the Opponent [Kaplan transcript, Q 168]. As noted previously, he has also been compensated for speaking engagements and received program funding from Boehringer Ingelheim in the past [Kaplan transcript, Q's 51-71]. In addition, he has served on advisory boards for the company and been compensated for doing so [Kaplan transcript, Q's 72-76]. Consequently, he is quite familiar with the manufacturer of SPIRIVA® [Kaplan transcript, Q 169].

[98] During cross-examination, Dr. Kaplan also stated that he works with many different pharmaceutical companies, virtually every one that has a respiratory product, and because of his intimate relationships with these companies he is able to keep straight the different companies and what they make [Kaplan transcript, Q 171]. In view of Dr. Kaplan's association with pharmaceutical companies, and in particular, the Opponent and its SPIRIVA® inhalers, it seems likely that he would have had a different level of awareness of Marks 1 and 2 than physicians generally.

[99] With respect to Dr. Sharma, I note that during cross-examination, he was asked to describe the color/shape of a number of different inhalers (e.g. Flovent, Serevent, Advair, etc.). For the most part, he was able to identify what colour they are and who they are made by [Sharma transcript, Q's 198-207]. He was then asked the following question:

> Q So paragraph, 52, please. You say, "In my experience, neither doctors nor patients consider inhalers to relate to any particular manufacturer or source. Instead inhalers are considered to be functional devices for delivery of medicine into the lungs". I'm just not entirely certain as to how the fact that they are functional devices relates to whether a doctor would know what company manufactures a particular inhaler. When I asked you those questions a moment ago, you seemed to have no difficulty in ascertaining the manufacturer of a particular…
>
> A Well, because in my case I do research and I'm, I know them quite a bit more. But as a general physician or even a lot of my colleagues in specialty may not be aware or may not be in contact with the company people, like the detail people or companies that much. So they would only know what drug is out there available for what disease process and how it works and what the data is about it. And I'm sure if you want to look at it, there are the names on the, the manufacturer name of the company on the product.

[100] I note that Dr. Kaplan also acknowledged that some physicians will not see pharmaceutical representatives [Kaplan transcript, Q 182], and according to Dr. Sharma, only a small number of physicians would use samples. Most hospitals are not allowing samples at all and some clinics have policies about not keeping samples available. In view of this, Dr. Sharma states that many would only know what the inhaler is used for, what disease algorithm it fits, write a prescription and rely on the pharmacist to educate the patient. They would not necessarily be familiar with the colour/shape of SPIRIVA® [Sharma transcript, Q's 209-218].

[101] Thus, it seems that both Dr. Kaplan and Dr. Sharma, for one reason or another, may possess a higher degree of knowledge than some other physicians regarding the appearance of the various inhalers which are available to patients, including the SPIRIVA® inhaler.

[102] In any event, it is their testimony that is before me in this case, and all in all, I am of the view that the evidence falls short of establishing that, for physicians, the appearance of the inhalers, and in particular, the SPIRIVA® inhaler, is indicative of source to a significant degree.

[103] While both Dr. Sharma and Dr. Kaplan may well be familiar with the appearance of various inhalers, including the SPIRIVA® inhaler and who makes them, this does not in and of itself, demonstrate that they recognize or associate the appearance as being indicative of source.

[104] Dr. Sharma states that he cannot identify and will not try to identify the medication contained in an inhaler, the inhaler itself, or the manufacturer or source of the inhaler, merely by its appearance (i.e. its colour and/or shape) [Sharma affidavit, para 72]. In order to identify an inhaler, he will always refer to the information found on the label affixed to the inhaler and/or its box, including, for example, the brand name of the dry powder drug (SPIRIVA®), the active ingredient (tiotropium bromide monohydrate), the dosage strength, the drug identification number (DIN) and the manufacturer name [Sharma affidavit, para 73].

[105] When asked during cross-examination whether he would associate a two-toned purple inhaler with a particular product, he said that he would not- he would need to look at what it is [Sharma transcript, Q 105].

[106] When writing a prescription, he writes the brand name, never the colour or shape and in deciding which medication to prescribe, the colour and shape of the inhaler is not a factor in his decision, except to the extent that one shape might be easier for a patient to use than another (i.e. boot vs. rounded). The appearance and the manufacturer of a medication are not considerations. Rather, Dr. Sharma takes into account the medical diagnosis, the efficacy, safety and tolerability of the medication, and cost [Sharma affidavit, para 62-64].

[107] Even if physicians do not make use of appearance in their prescription practices, this does not mean necessarily, that appearance has no distinctiveness for them. As noted by Justice Evans in *Novopharm*, [*supra* at para 82], even though physicians and pharmacists are regulated

professionals who must make prescribing and dispensing decisions within the bounds of their professional obligations, and so rely upon other indicia, if there is evidence that to any significant degree they also recognized the product by its appearance (excluding markings), this may be sufficient to establish the distinctiveness of the mark.

[108] Dr. Sharma's evidence suggests that physicians do not rely upon appearance to a significant degree to recognize or identify a particular pharmaceutical product or inhaler.

[109] While Dr. Kaplan appears to place more emphasis on appearance, for reasons previously discussed, I have some concern with respect to how representative his evidence would be of physicians in general, given the degree of care one would reasonably expect a physician to exercise when prescribing or identifying medications and given his close association with Boehringer Ingelheim. In addition, as mentioned previously, his evidence is not without inconsistencies.

[110] Overall, I am not satisfied that the evidence establishes that physicians would likely associate, to a significant degree, an unmarked inhaler having the gray/green colour and shape combination of the SPIRIVA® inhaler with a single source, either as part of their prescription practices or otherwise.

Pharmacists

[111] The evidence from pharmacists in this case comes from Mr. Lum and Mr. Zachar.

[112] Mr. Lum is a registered and active member of the Ontario College of Pharmacists [Lum affidavit, para 2]. He has been practicing as a pharmacist since 1979. Since 1997, Mr. Lum has been an associate owner of and working as a pharmacist at a Shoppers Drug Mart located in Oakville, Ontario. The pharmacy dispenses approximately 60 inhalers per week [Lum affidavit, paras 3-6]. Mr. Lum states that based on many discussions he has had with a large number of patients, he is familiar with the general perceptions of patients [Lum affidavit, para 12]. In addition, he states that as a result of his experience over the past 30 years, he also has a good understanding of the general views and perceptions of other pharmacists [Lum affidavit, para

13]. Mr. Lum outlines his professional experience, qualifications and education in detail in paragraphs 1 to 15 of his affidavit. Attached as Exhibit A to his affidavit, is copy of his CV.

[113] Mr. Zachar is a qualified pharmacist as well. He has practiced as a retail pharmacist and pharmacy manager since 2006. He currently works as a Regional (Northern and Central Alberta) Pharmacy Manager for Rexall. He oversees pharmacy operations in 21 stores. His professional experience, qualifications and education are outlined in detail in paragraphs 1 to 5 of his affidavit.

[114] Both Mr. Lum and Mr. Zachar follow a similar dispensing process for inhalers, which involves several verification steps [Lum affidavit, paras 75-81; Zachar affidavit, paras 17-18; Zachar transcript, Q's 79-96. The process begins with a prescription and involves the following steps:

- the patient's information and prescription information is entered into a computer;
- a pharmacy label is generated, which is checked against the prescription
- the medication is compared to the prescription/pharmacy label – the pharmacist checks that the medication is correct by checking the box (active ingredient, DIN, dosage)
- the pharmacist will then open the box and look at the inhaler and the capsules to check the inhaler, including markings, colour, shape and to ensure the proper capsules are in the box
- the pharmacy label is applied to the box

[115] Thus, by the time a pharmacist checks an inhaler, he or she has already conducted numerous checks to identify the product [Zachar transcript, Q's 96-97].

[116] According to Mr. Lum, neither patients, nor pharmacists consider the appearance (i.e., colour, shape and size) of inhaler drug delivery devices to mean that they come from any particular source. Rather, they associate it with their drug's therapeutic use. For example, blue inhalers are used as rescue inhalers, whereas others are used for preventative therapy [Lum affidavit, para 18].

[117] Mr. Lum states that if he saw a SPIRIVA® inhaler with no labelling or markings, he would not know what, if any, drug was intended to be delivered by such inhaler, nor would he know the manufacturer that had made the device. He says the same would be true for customers/patients [Lum affidavit, para 20]. Mr. Lum states that he has never seen or received any inhaler from a manufacturer that was free of markings or labels. If any labels or markings were absent on an inhaler, he would never try to identify it and/or its source based solely on the shape, size or colour of the inhaler [Lum affidavit, para 73].

[118] Mr. Lum states that he would only identify an inhaler by checking the labels for the brand-name of the inhaler, the name of the active ingredient, the dosage strength, the DIN and any manufacturer name. He also checks the inhaler box for the same information [Lum affidavit, para 82]. Where there is incomplete information, for example, an inhaler with no labels, he would never take a risk and attempt to identify the inhaler based on shape, colour and/or size alone. In the case of SPIRIVA®, the only inhalers he dispenses are those which come into the pharmacy in sealed boxes which contain the brand-name of the inhaler, the name of the active ingredient, the dosage strength, the DIN and the manufacturer name [Lum affidavit, Q's 82-85].

[119] During cross-examination, Mr. Lum stated that colour, shape and size are secondary checks that a pharmacist might make when dispensing an inhaler, but the primary checks are more objective checks, such as DIN number, actual name, on the rare occasion, UPC number [Lum transcript, Q 154]. However, during cross-examination, he did state that in the event of a disconnect in terms of color, he would call the manufacturer to inquire because he would want to ensure accuracy [Lum transcript, Q's 154-162].

[120] By contrast, Mr. Zachar, states that colour and shape are one of the primary checks when dispensing the SPIRIVA® Handihaler product. He states that if SPIRIVA® was prescribed and the actual device located on the shelf by the pharmacist was not the gray and green colour and/or the ovaloid shape, this would immediately signal, for example, that the wrong medication might have been taken from the shelf [Zachar affidavit, para 18]. He states that the appearance, the label, the name on the prescription, the information entered into the computer, the DIN, the dosage, etc. must all be consistent. If any one factor suggests a product other than what was prescribed, the entire process must be scrutinized.

[121] According to Mr. Zachar, of the factors used to ensure the correct medication is dispensed, colour and shape of an inhaler is the first and most obvious check a pharmacist performs to ensure the correct medication is given to a patient [Zachar affidavit, para 19].

[122] During cross-examination, Mr. Zachar confirmed that every SPIRIVA® inhaler he has dispensed has come in a box having SPIRIVA® on it, along with the chemical name "tiotropium bromide", and the name of the manufacturer [Zachar transcript, Q's 70-75]. He also confirmed that every SPIRIVA® inhaler has Handihaler® on it, along with "Boehringer Ingelheim".

[123] When asked if part of his checks include ensuring that the inhaler has all the proper markings on it, such as "HandiHaler®" and "Boehringer Ingelheim", he stated that more than anything, he looks at the distinctive shape and the colour [Zachar transcript, Q's 99-102], but that the other markings would "come up", as he is checking the shape and colour [Zachar transcript, Q's 101-102].

[124] Mr. Zachar and Mr. Lum appear to take a different view on whether the colour/shape of an inhaler is something they would do as a "primary" check or a "secondary" check when identifying an inhaler. However, it does appear to be something both of them would take into consideration when attempting to identify an inhaler to ensure that it is the correct medication.

[125] That said, they both most definitely also look to other indicators as well, such as the name of the active ingredient or the brand name associated with the drug. Both confirmed that they would never use colour and shape as the only way of identifying SPIRIVA® [Zachar transcript, pages 50-51; Lum affidavit para 73].

[126] While both Mr. Lum and Mr. Zachar may rely on colour and shape to identify an inhaler to some extent, it is not clear from the evidence before me that either of them does so significant degree. Rather, it seems as though more reliance is placed on other indicia.

[127] During cross-examination Mr. Zachar was asked if he would go ahead and fill a prescription for "tiotropium", if the SPIRIVA® inhaler had "salbutamol" on it and he said that it would be a strange thing to be written on the device and that he would have to double check his other stock [Zachar transcript, Q 102].

[128] During cross-examination, Mr. Zachar was also asked:

> 113.
>
> Q If you got a box and you pulled it out of your cabinet and it said Apo-tiotropium on it and you opened it up and the HandiHaler said not "HandiHaler", but "Apotex Inc.", where would you think the HandiHaler came from even if it looked exactly the same as the Boehringer device.
>
> A The first indication is it's the Boehringer Spiriva HandiHaler device.
>
> 114
>
> Q But is says "Apotex" on it.
>
> A If it says "Apotex", I guess it would be Apotex.

[129] This suggests that, even for pharmacists, other indicia such as the name of the manufacturer would trump the appearance of the SPIRIVA® inhaler for source identification purposes, which in turn suggests that colour and shape are less indicative of source. Justice Barnes came to this same conclusion when faced with similar evidence in *Apotex* [*supra*, at para 26].

[130] During cross-examination, Mr. Zachar was also referred to paragraph 18 of his affidavit. In paragraph 18, he states that if another inhaler was prescribed and the device located to fill the prescription was grey, green and ovaloid, it would immediately signal that the wrong medication might have been taken from the shelf. He was asked if what he meant by this is that if he was looking, for example, for salbutamol and he pulled out the SPIRIVA® inhaler, he would know the wrong drug had been pulled from the shelf. He confirmed that this was what he meant [Zachar transcript, Q 122].

[131] At the hearing, the Opponent submitted that this suggests that colour and shape are more indicative of the medication, not the source of the medication. In other words, when pharmacists see a different colour/shape than what they are expecting to see, they are concerned that they have the wrong drug, not the wrong brand. I agree, and I once again, I note that it is not even clear from the evidence that colour/shape are relied upon to a significant extent to identify a particular product. Rather, it seems from the evidence before me, that for pharmacists, the name

of the manufacturer or on the drug may prevail when any assumptions about what the product is are being made.

[132] In *Pfizer* [*supra*, at para 197], Justice Russell commented that "it is not enough to say that pharmacists know what Viagra looks like. You have to prove that pharmacists connect the product's appearance (without the markings), to a significant degree, to a single source. It seems to me that taken overall, this evidence confirms that if confronted with a blank, blue-diamond-shaped tablet, a pharmacist would not know what it was. In my view, if you do not know what it is, you cannot connect it with a single source".

[133] This same issue arises in the present case.

[134] Overall, the evidence before me is insufficient to establish that as a matter of first impression, pharmacists relate or associate the color and shape of the SPIRIVA® inhaler (without markings or other indicia) to either the product or the source of the product, to any significant degree.

Patients

[135] None of the evidence before me originates directly from patients. I am therefore left to rely primarily upon anecdotal evidence from physicians and pharmacists in order to assess what patients' perceptions might be.

[136] Dr. Sharma states that he has never had a patient associate their delivery device with a particular manufacturer or source. According to Dr. Sharma, patients are not concerned about the manufacturer or source of their medications or even if there is a single source for them [Sharma affidavit, paras 53 and 66]. Mr. Lum also states that he doesn't recall patients ever talking about the manufacturer of their inhalers, including Boehringer Ingelheim, within the context of receiving a prescription for SPIRIVA® [Lum transcript, Q's 128-130 and 262].

[137] What patients are typically concerned about, is how long they have to take a medication for, if there are side effects, if it will help their condition, how often they need to take it, if it should be taken before or after another inhaler, can it be taken with other medications, etc. [Zachar transcript, Q 156; Lum affidavit, paras 86 and 92; Lum transcript, Q's 78-83]. During

cross-examination, Mr. Zachar confirmed that most patients don't care who makes their inhalers and a busy pharmacist may not even talk about the manufacturer of the product [Zachar transcript, Q's 198-199]. Mr. Lum also states that in his experience, most patients are rarely concerned or know about the sources of manufacture for their medications or inhalers [Lum affidavit, para 91].

[138] According to Dr. Sharma, to the extent that patients are familiar with the appearance of their inhalers, they associate the appearance with scheduling and therapy (e.g. the gray once a day inhaler and the blue rescue inhaler) or blue vs non-blue [Sharma affidavit, para 77; Sharma transcript, Q 237]. Dr. Sharma believes that if anything, patients use colour to distinguish the inhaler they should take when they have symptoms from the one they need to take on a regular basis [Sharma transcript, Q 237]. Other than that, he states, they are not taught anything else about shape or colour. Dr. Kaplan and Mr. Zachar also confirmed that this is how patients are educated and that this is how they sometimes distinguish between their inhalers [Kaplan transcript, Q 272; Zachar transcript, Q 141]. Mr. Lum says that many of his patients have also come to associate the appearance of their inhalers with therapeutic effect or type of inhaler (i.e. control vs rescue) [Lum affidavit, paras 88-89].

[139] During cross-examination, Mr. Zachar indicated that some patients don't even know the names of the medications they are taking. For example, some think SPIRIVA® is the name of the drug [Zachar transcript, Q's 146-147]. Ms. Maynard confirmed this during her cross-examination as well [Maynard transcript, Q's 113-114]. Patients will sometimes refer to their SPIRIVA® inhaler as being their grey, green inhaler [Zachar transcript, Q's 148 to 149], which suggests that patients relate the appearance of their SPIRIVA® inhaler to the medication they take, not what brand it is or where it came from.

[140] For some patients, even the brand name associated with the product does not indicate source. There is evidence, (at least with respect to the blue rescue inhalers), that patients will sometimes associate the brand- name of their medication with the medication itself, rather than the source. For example, patients will refer to their Ventolin (salbutamol made by GSK) when in fact they are taking salbutamol made by Apotex.

[141] Dr. Kaplan states that his conversations with patients lead him to conclude that colour and shape is the foremost means used by patients of differentiating various inhaler products [Kaplan affidavit, para 29]. In paragraph 32 of his affidavit, Dr. Kaplan indicates that when choosing to continue on existing medication, patients rely on the gray and green colouring and shape of the SPIRIVA® inhaler to request their medication. During cross-examination, he confirmed that what he meant by this is that patients sometimes come in when they are running out of medication and they might not know the name of the medication, so they might say it's the "green and grey one, the one I take once a day" [Kaplan transcript, Q193]. Again, this suggests that patients are associating the appearance of their inhalers with the medication they take or its scheduling or therapeutic effect.

[142] According to Dr. Sharma, patients would not be able to identify a blank inhaler as coming from any particular manufacturer/source and would either look for labelling information or contact a physician or pharmacist [Sharma affidavit, para 25]. During cross-examination, Mr. Zachar confirmed that if a patient taking SPIRIVA® took it home and opened it and saw that it was red, they would bring it back to the pharmacist because they would be concerned that they got the wrong drug [Zachar transcript, Q 176]. Colour helps to make sure that patients are getting the right medication [Zachar transcript, Q 177]. Ms. Maynard gave similar evidence on this point [Maynard transcript, Q's 111-112].

[143] According to Dr. Sharma, patients understand that a change in colour or shape of inhaler may mean a different drug has been given to them, but they don't believe that a colour or shape change means a change in the manufacturer or source [Sharma affidavit, para 76]. Ms. Maynard's anecdotal evidence supports this conclusion [Maynard affidavit, para 18] and I note that during cross-examination, Ms. Maynard also confirmed that the wrong colour can indicate the wrong medication or the wrong dose [Maynard transcript, Q's 129-131]. Mr. Lum says that if the appearance (i.e. colour, shape and/or size) of the patient's medication or inhaler were changed, the patient would ask him if there has been a mistake or to clarify that a new drug (i.e. new active ingredient) has been prescribed [Lum affidavit, para 90].

[144] Overall, the evidence suggests that patients are not concerned with the source of their inhalers. They are mostly concerned with what they are for, how well they work, dosage, side

effects, etc. To the extent that patients attribute any significance to the appearance (i.e. colour, size or shape) of their inhalers, they associate it with their medication or its therapeutic effect. The evidence does not establish that patients associate the appearance of their SPIRIVA® inhalers with source to any significant degree.

Conclusion

[145] The burden of establishing the distinctiveness of a mark rests on the applicant in an opposition proceeding. To succeed in this case, the Applicant needed to adduce sufficient evidence to establish that at the relevant material date, on a balance of probabilities, and as a matter of first impression, a substantial body of consumers (physicians, pharmacists and patients) associate the SPIRIVA® inhaler (without markings) with a single source of manufacture to a *significant* degree. Again, it is not necessary to establish distinctiveness within all three of these groups- recognition within a substantial body consisting of one or a combination of these groups is sufficient [*Pfizer* supra at para 97]. In this case, I am not satisfied by the evidence that the Applicant has met its burden.

[146] The evidence suggests that the Applicant has enjoyed substantial sales and expended a fair bit on promotion and advertising. However, impressive sales figures alone do not satisfy the burden on an applicant for a trade-mark of proving distinctiveness [*Novopharm Ltd v Astra Aktiebolag* (2000), 6 CPR (4th) 16 at 25 (FC); aff'd 2001 FCA 296]. Furthermore, advertising does not *per se* establish distinctiveness of appearance [*Pfizer*, supra at para 167].

[147] There is no evidence that HandiHaler® devices have ever been sold in Canada without markings. All devices sold feature the trade-mark HandiHaler®, the name of the Applicant and its address. Likewise, the packaging for the HandiHaler® devices consists of a box which features the trade-mark HandiHaler®, the name Boehringer Ingelheim, the name of the Applicant's sub-licensee, the trade-mark SPIRIVA®, the generic name (Tiotropium Bromide Monohydrate) and dosage information for the medication. HandiHaler® is identified as a trade-mark on the inhaler and both HandiHaler® and SPIRIVA® are identified as being trade-marks on the box. However, Mark 1 and Mark 2 are not identified as trade-marks on the inhaler and neither Mark 1 nor Mark 2 appears on the box.

[148] There is nothing on the HandiHaler® device itself, its packaging or its accompanying insert, which indicates that the appearance of the inhaler is indicative of source. Nothing suggests that the appearance of the inhaler is indicative of anything more than just what the device is or looks like.

[149] The same is true for the Applicant's advertising and promotional materials. Mr. Looper confirmed that it is likely that all of the promotional materials of the sort shown in the exhibits attached to his affidavit would feature the trade-marks HandiHaler® and SPIRIVA®, and the colour/shape of the Applicant's inhalers is not identified as being a trade-mark in the advertisements. Moreover, I note that the exhibit materials primarily provide instructions for using the HandiHaler® device with SPIRIVA® medication or make reference to the therapeutic benefits associated with using the HandiHaler® device and SPIRIVA® medication, the focus is not on the source of the SPIRIVA® inhaler.

[150] I am not satisfied that the Applicant's sales and advertising in this case have resulted in distinctiveness given that the goods have always been associated with other trade-marks and given that the relevant public does not appear to have been educated as to the trade-mark status of the applied for marks. I note that almost no evidence has been provided with respect to the Applicant's services.

[151] While I acknowledge that the appearance (i.e. colour/shape combination) of the SPIRIVA® inhaler is unique, it has been held that a design that is simply unique in the marketplace and recognized as such is not enough to constitute distinctiveness [*Royal Doulton* supra at 370-371].

[152] In *Royal Doulton*, *supra*, at 225 (FCTD), the Federal Court explains that a trade-mark may be recognized as unique but not distinctive:

> It is to be noted that a distinctive trade mark is one which links, e.g., goods with a vendor so as to distinguish them from the goods of other vendors. It is not distinctive if it simply distinguishes one design of goods from another design of goods even though if one had special trade knowledge one might know that these two kinds of goods are sold respectively by two different vendors. Such a concept of distinctiveness would run counter to a basic purpose of the trade mark which is to assure the purchaser that the goods have come from a particular source in which he has confidence…

[153] In *Apotex, supra*, at para 16, Justice Barnes noted that in the context of a market where purchasing decisions are usually made by professionals or on the advice of professionals, the commercial distinctiveness of such a mark will be inherently more difficult to establish. That is so because, physicians and pharmacists are not strongly influenced by these attributes and have no obvious reason to associate them with a single trade source or provenance. To the extent that the ultimate consumer enjoys a purchasing choice, they will also be significantly influenced by the prescribing and dispensing advice received (including labelling) and undoubtedly, by associating products with certain well-known trade-marks.

[154] This can be seen in the evidence before me. When a physician writes a prescription, he writes the brand name, never the colour or shape, and in deciding which medication to prescribe, the colour and shape of an inhaler is not a factor in his decision, except to the extent that one shape might be easier for a patient to use than another (i.e. boot vs. rounded). The appearance and the manufacturer of a medication are not considerations. It is the medical diagnosis, the efficacy, safety and tolerability of the medication, and cost which are taken into account. Likewise, pharmacists are not concerned with colour and shape in making their dispensing choices and patients primarily care about what the medication is, how it works, side effects, etc. and are undoubtedly heavily influenced by their physicians' and pharmacists' choices.

[155] I acknowledge that the distinctiveness assessment is not limited to prescribing, dispensing and purchasing choices. However, even a broader assessment of the evidence, including identification in general, does not result in a finding of distinctiveness amongst consumers in this case.

[156] It is difficult to reliably assess what patients were saying, referring to or thinking with respect to the Applicant's SPIRIVA® inhaler at the material date, since no patient records have been produced, and none were consulted or referred to by witnesses. However, based on the evidence that is before me, to the extent that patients may attach any significance to the appearance of the Applicant's SPIRIVA® inhaler, they appear to associate it with the medication itself and/or its therapeutic use. The evidence suggests that to patients, the appearance of the SPIRIVA® inhaler is not indicative of a single source. As for physicians, the evidence suggests that even those who are well aware of the colour/shape of the SPIRIVA® inhaler and who

manufacturers it, do not associate the appearance of the inhaler with source to a significant degree and other indicia (for example, active ingredient, trade name, name of manufacturer, DIN, etc.) seem to be more heavily relied upon for the purposes of identification as a matter of first impression. The same holds true for pharmacists.

[157] The following passage from Justice Russell in *Pfizer* [supra, at para 182] is relevant to the case at hand:

> As Justice Barnes pointed out in *Apotex*, above, at paragraph 13, "it is insufficient to show that the appearance of a product may represent a secondary check of product identity or that it may cause a person to wonder whether the expected product was correctly dispensed. Furthermore, an educated guess about source is not enough to constitute distinctiveness and neither is a design that is unique in the market place and recognized as such: "The fact that a physician or pharmacist might make an informal assumption about the provenance of a [blue, diamond-shaped pill] in the context of a therapeutic discussion with a patient is also insufficient to establish distinctiveness".

[158] The evidence in the present case simply does not establish that a substantial body of patients, physicians and/or pharmacists associate the appearance of the SPIRIVA® inhaler (without markings) with source to any significant degree.

[159] In *Apotex* [*supra* at para 42], Justice Barnes concluded his decision by paraphrasing from an earlier of decision of Justice Dawson in *Novopharm Ltd v AstraZeneca AB* (2004), 2003 FC 212, where the distinctiveness of a red-brown pill was at issue. Within the context of Advair inhalers, Justice Barnes posed the question: What does an unlabeled two-tone purple circular inhaler mean to a physician, pharmacist or patient? The answer: not enough for a finding of distinctiveness. A similar question was posed by Justice Russell in *Pfizer* [*supra* at para 210] with respect to Viagra, where he asked: What does an unmarked blue, diamond-shaped pill mean to a physician, pharmacist or patient. Justice Russell came to the same conclusion as Justice Dawson and Justice Barnes. Posing the same question regarding the Applicant's green/grey spherical shaped inhaler in the present case, I am unable to come to any different conclusion based upon the evidence before me. I am therefore unable to conclude on a balance of probabilities that Mark 2 was distinctive of either its associated goods or services at the material date.

[160] Accordingly, the non-distinctiveness ground of opposition is successful.

Remaining Grounds of Opposition

[161] Since the Opponent has succeeded on the basis of non-distinctiveness and it need only succeed on one ground to be successful in its opposition, I will not be addressing any of the remaining grounds of opposition in this decision.

Application No. 1,291,973 (Mark 1)

[162] My analysis with respect to the distinctiveness of Mark 1 does not differ significantly from that which applies to Mark 2. In view of this, the distinctiveness ground of opposition in relation to Mark 1 succeeds for reasons similar to those set out with respect to Mark 2. As a result, I am also refusing application No. 1,291,973 on the basis that the Applicant has not met the legal burden upon it to show that Mark 1 was distinctive as of the relevant material date.

Disposition

[163] In view of the foregoing, pursuant to the authority delegated to me under section 63(3) of the Act, I refuse application Nos. 1,291,973 and 1,291,974 pursuant to section 38(8) of the Act.

_____

Lisa Reynolds
Member
Trade-marks Opposition Board
Canadian Intellectual Property Office

TRADE-MARKS OPPOSITION BOARD
CANADIAN INTELLECTUAL PROPERTY OFFICE
APPEARANCES AND AGENTS OF RECORD

HEARING DATE: 2016-12-14

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