

# The Use of Prosecution History for Claim Construction in Canada and the United Kingdom: Is a Patent a Journey or a Destination?\*

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## ABSTRACT

In the last few years, two Federal Court cases have qualified the doctrine of “file wrapper estoppel” to allow prosecution history to be used in the construction of granted patent claims. A third case, while acknowledging that “Canadian law appears quite settled that extrinsic evidence is not relevant to claim construction,” raises the question whether it is time to revisit the rule against using such evidence in claim construction. This article considers Canadian and UK approaches to this issue and argues that the use of file wrapper estoppel remains neither correct nor desirable in Canada.

## RÉSUMÉ

Dans les dernières années, deux affaires entendues par la Cour fédérale ont qualifié la doctrine de « préclusion fondée sur les notes apposées au dossier » afin de permettre l'utilisation de l'historique de demandes dans la construction de revendications concernant des brevets. Dans les conclusions d'une troisième affaire, même si on reconnaît que « la loi canadienne semble résolue; les preuves extrinsèques ne sont pas pertinentes à la construction de revendications », on demande tout de même s'il ne serait pas temps de revoir la règle qui interdit l'utilisation de telles preuves dans la construction de revendications. Cet article porte sur les approches du Canada et du R.-U. à ce sujet, et argumente que l'utilisation de la préclusion fondée sur les notes apposées au dossier demeure incorrecte et indésirable au Canada.

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## 1.0 INTRODUCTION

In 2000, the Supreme Court of Canada established the current framework for claim construction in Canada with the *Whirlpool*<sup>1</sup> and *Free World Trust*<sup>2</sup> cases. These cases adopted the UK practice of purposive construction set out in the *Catnic*<sup>3</sup> and the *Improver*<sup>4</sup> cases.

However, this has not been the last word and, since then, the issue of claim construction has simmered, occasionally boiling over in a dissenting judgment or article. In the last few years there have been two Canadian Federal Court cases, *Distrimed*<sup>5</sup> and *Eli Lilly (Tadalafil)*,<sup>6</sup> in which the same judge for the same reasons has used prosecution history to construe the scope of the granted claims. As acknowledged in the cases themselves, this approach represents a qualification of the established doctrine of excluding the use of “file wrapper estoppel” in the construction of patent claims. In 2016, a third Federal Court case, *Pollard*,<sup>7</sup> while acknowledging that “Canadian law appears quite settled that extrinsic evidence is not relevant to claim construction,” presents a number of arguments for using file history in claim construction and advocates a reconsideration of the issue.

In addition to judicial comment, interested parties have advocated the use of prosecution history when construing claims. For example, in 2015, Lipkus and Frontini<sup>8</sup> argued that Canada was out of step with the rest of the world in using

1 *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067 [*Whirlpool*].

2 *Free World Trust v Électro Santé Inc*, 2000 SCC 66, [2000] 2 SCR 1024 [*Free World Trust*].

3 *Catnic Components Ltd v Hill & Smith Ltd*, [1982] RPC 183 [*Catnic*].

4 *Improver Corp v Remington Consumer Product Ltd*, [1990] FSR 181 (CA) [*Improver*].

5 *Distrimed Inc v Dispill Inc*, 2013 FC 1043 [*Distrimed*].

6 *Eli Lilly Canada Inc v Mylan Pharmaceuticals ULC*, 2015 FC 125 [*Tadalafil*].

7 *Pollard Banknote Ltd v BABN Technologies Corp*, 2016 FC 883 at para 81 [*Pollard*].

8 Nathaniel Lipkus & Matthew Frontini, “Time to Revisit Exclusion of the Prosecution History in Patent Litigation” (2015) 30:2 CIPR 167 [Lipkus & Frontini].

prosecution history, and that the principles underpinning Canadian jurisprudence on this issue were based on a misperception regarding US case law.

These cases and opinions furnish a variety of reasons for using file history when construing claims. The main arguments include:

- more information leads to more accurate results;
- applicants/patentees should be held to what they have said and done in the past;
- Canada should conform to international norms; and
- policy should be updated to reflect current norms and practices.

In contrast, this article will argue that affirming the primacy of the claims within the framework of the patent document alone is a widely accepted and robust principle that provides a fair balance between the rights of the patentee and the rights of third parties.

## 2.0 ESTABLISHING THE PRINCIPLES OF CLAIM CONSTRUCTION IN CANADA

With regard to claim construction in general, and file wrapper estoppel in particular, Canadian courts have rejected the US approach<sup>9</sup> and have adopted UK principles in *Whirlpool*<sup>10</sup> and *Free World Trust*.<sup>11</sup>

In *Free World Trust*, Binnie J recognized that the case raised important questions about the scope and ambit of a patent owner's monopoly, stating:

Too much elasticity in the interpretation of the scope of the claims creates uncertainty and stifles competition. Too little protection robs inventors of the benefit they were promised in exchange for making a full and complete disclosure of the fruits of their ingenuity.<sup>12</sup>

Binnie J went on to consider arguments that prosecution history ought to be admissible in some circumstances in the interest of obtaining consistent interpretation of claims here and in the United States, where many Canadian patents have their origin. However, Binnie J rejected this course, stating:

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9 Lipkus and Frontini (*ibid*) state that the original rationale in *Lovell Manufacturing Co and Maxwell Ltd v Beatty Bros Ltd* (1962), 41 CPR 18 at 38 (Ex Ct) [*Lovell*] for excluding file wrapper estoppel in Canada was based on misperception of an earlier US case. While *Lovell* may have established the general principle of excluding file wrapper estoppel, in *Free World Trust*, *supra* note 2, Binnie J looked specifically to the English courts rather than the US courts to shape the current Canadian principles of claim construction. This UK perspective was overlooked in the Lipkus and Frontini article.

10 *Whirlpool*, *supra* note 1.

11 *Free World Trust*, *supra* note 2.

12 *Ibid* at para 3.

In my view, those references to the inventor's intention refer to an objective manifestation of that intent in the patent claims, as interpreted by the person skilled in the art, and do not contemplate extrinsic evidence such as statements or admissions made in the course of patent prosecution. To allow such extrinsic evidence for the purpose of defining the monopoly would undermine the public notice function of the claims, and increase uncertainty as well as fuelling the already overheated engines of patent litigation. The current emphasis on purposive construction, which keeps the focus on the language of the claims, seems also to be inconsistent with opening the Pandora's box of file wrapper estoppel. If significant representations are made to the Patent Office touching the scope of the claims, the Patent Office should insist where necessary on an amendment to the claims to reflect the representation.<sup>13</sup>

Therefore, to ensure the primacy of the claims, Binnie J elected to follow the UK approach. The principles underpinning the UK approach were set out in the *Catnic*<sup>14</sup> and *Improver* cases.<sup>15</sup>

In *Catnic*, Lord Diplock held that a patent must be read in a "purposive" way that focuses on the essential features of the patent. In particular:

a patent specification is a unilateral statement by the patentee, in words of his own choosing, addressed to those likely to have a practical interest in the subject matter of his invention (i.e. "skilled in the art"), by which he informs them what he claims to be the essential features of the new product or process for which the letters patent grant him a monopoly. It is called "pith and marrow" of the claim. A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge. The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that any variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.<sup>16</sup>

In 1990, in the *Improver* case, Lord Hoffmann, on behalf of the Patents Court, reformulated the test as a series of three questions to establish whether a variant (or allegedly infringing article) infringes the claims of a patent. These are:

1. Does the variant have a material effect on the way the invention works? If yes, the variant is outside the claim. If no:

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13 *Ibid* at para 66.

14 *Catnic*, *supra* note 3.

15 *Improver*, *supra* note 4.

16 *Catnic*, *supra* note 3 at para 242.

2. If the variant has no material effect, would this have been obvious to a reader skilled in the art at the date of the publication of the patent? If no, the variant is outside the claim. If yes:
3. Would a reader skilled in the art nevertheless have understood from the language of the claims that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

Subsequently, in 2004, in the *Kirin-Amgen* case,<sup>17</sup> Lord Hoffman qualified his previous approach to claim construction (and the approach adopted in Canada) by curtailing the importance of the *Improver* (or “Protocol”) questions, stating:

When speaking of the “*Catnic* principle” it is important to distinguish between, on the one hand, the principle of purposive construction ... , and on the other hand, the guidelines for applying that principle to equivalents, which are encapsulated in the Protocol [or *Improver*] questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others.<sup>18</sup>

Recently, the original *Improver* questions were also reformulated in the 2017 *Actavis* Supreme Court case (discussed further below).

Nevertheless, with *Catnic* reaffirmed and the *Improver* questions still used to a greater or lesser degree, the principles used in Canada and in the United Kingdom are similar and therefore remain comparable. These principles are laid out succinctly in *Free World Trust*:<sup>19</sup>

- (a) The *Patent Act* promotes adherence to the language of the claims.
- (b) Adherence to the language of the claims in turn promotes both fairness and predictability.
- (c) The claim language must, however, be read in an informed and purposive way.
- (d) The language of the claims thus construed defines the monopoly. There is no recourse to such vague notions as the “spirit of the invention” to expand it further.
- (e) The claims language will, on a purposive construction, show that some elements of the claimed invention are essential while others are non-essential. The identification of elements as essential or non-essential is made:
  - (i) on the basis of the common knowledge of the worker skilled in the art to which the patent relates;

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17 *Kirin-Amgen Inc & Ors v Hoechst Marion Roussel Ltd*, [2004] UKHL 46, [2005] RPC 9.

18 *Ibid* at para 52.

19 The *Whirlpool* case, *supra* note 1, affirms that the “purposive construction” approach is adopted for both validity and infringement issues, but does not consider prosecution history specifically.

- (ii) as of the date the patent is published;
  - (iii) having regard to whether or not it was obvious to the skilled reader at the time the patent was published that a variant of a particular element would *not* make a difference to the way in which the invention works; or
  - (iv) according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect;
  - (v) without, however, resort to extrinsic evidence of the inventor's intention.<sup>[20]</sup>
- (f) There is no infringement if an essential element is different or omitted. There may still be infringement, however, if non-essential elements are substituted or omitted.<sup>21</sup>

### 3.0 UK AND CANADIAN CASES ADVOCATING THE USE OF PROSECUTION HISTORY

Since 2004, a number of cases in Canada and the United Kingdom have reconsidered the issue of the use of prosecution history in claim construction. Different conclusions have led Canada and the United Kingdom to evolve in different directions. In both jurisdictions, there have been strong arguments on both sides that can inform the current debate on the use of prosecution history.

#### 3.1 Actavis (UK)

In 2013, the English High Court decided one case<sup>22</sup> of the multi-case *Actavis* dispute.<sup>23</sup> This case was to go via the Court of Appeal all the way to the Supreme Court. In this case, Eli Lilly's patent was granted with both Swiss-type claims and purpose-limited product claims directed to the use of pemetrexed disodium. The Swiss-type claim read:

Use of pemetrexed disodium in the manufacture of a medicament for use in combination therapy for inhibiting tumor growth in mammals, wherein said medicament is to be administered in combination with vitamin B12 or a pharmaceutical derivative

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20 In *Free World Trust*, *supra* note 2, the headings of subsequent explanatory section headings paraphrase these listed principles. It is important to note that the section heading before paragraph 61 in *Free World Trust* paraphrases principle (e)(v) as "Based on the Patent Specification Itself Without Resort to Extrinsic Evidence" [emphasis added].

21 *Free World Trust*, *supra* note 2 at para 32 [emphasis in original].

22 *Actavis UK Ltd & Ors v Eli Lilly & Company*, [2014] EWHC 1511 (Pat) [*Actavis* (High Court)].

23 Other decisions regarding Eli Lilly's pemetrexed disodium product relate to:

- jurisdiction (first instance: *Actavis UK Ltd v Eli Lilly & Company*, [2012] EWHC 3316 (Pat); appeal: *Actavis UK Ltd & Ors v Eli Lilly & Company*, [2015] EWCA Civ 555); and
- how dilution of the product affects infringement (*Actavis UK Ltd v Eli Lilly & Company*, [2016] EWHC 234 (Pat)).

thereof, said pharmaceutical derivative of vitamin B12 being hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin, perchlorate, azidocobalamin, chlorocobalamin or cobalamin.

A question arose as to whether the claim was limited to pemetrexed disodium or whether other pemetrexed salts (for example, pemetrexed potassium) would be a variant encompassed by the claim scope.

In this case, Arnold J relied on the prosecution history, and took account of the fact that the claims had been narrowed to pemetrexed disodium during prosecution at the European Patent Office (EPO) in response to objections of lack of clarity and lack of sufficient disclosure. In particular, he stated:

I accept that, for the reasons explained by Jacob J in *Bristol-Myers Squibb* and Lord Hoffmann in *Kirin-Amgen*, courts should be cautious before relying upon prosecution history as an aid to construction. In the real world, however, anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection) and will consider it to see if it sheds light on the matter. In some cases, perhaps not very many, the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in some broader manner. In such a situation, there is no good reason why the court should shut its eyes to the story told by the prosecution file. On the contrary, consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement. For the reasons discussed below, I consider that the present case provides a good illustration of this.<sup>24</sup>

As discussed later, this is consistent with some of the reasons presented in the Federal Court of Canada in *Distrimedica* and *Eli Lilly (Tadalafil)* when proposing that the use of file wrapper estoppel can and should be used when construing Canadian claims.

Nevertheless, in the United Kingdom, this judgment was overturned on appeal at the Court of Appeal,<sup>25</sup> with Lord Justice Floyd temporarily quashing Arnold J's nascent attempt to introduce file wrapper estoppel.

It is important to note that, in the Court of Appeal's view, although Lord Justice Floyd was clear in his rejection of using prosecution history, this did not affect the actual result of the construction of the claims in suit with regard to whether other salts were encompassed. That is, Lord Justice Floyd otherwise confirmed Arnold J's application of the *Improver* questions to similarly find that there was no direct infringement of the claim.

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<sup>24</sup> *Actavis* (High Court), *supra* note 22 at para 111.

<sup>25</sup> *Actavis UK Ltd & Ors v Eli Lilly & Company*, [2015] EWCA Civ 555 [*Actavis* (Court of Appeal)].

Regarding the first *Improver* question, the parties did not dispute that the variants (that is, the different cations/salts in the Actavis product) had no material effect on the way the invention worked. However, it was found that this would not have been obvious to the person skilled in the art (in this case represented by a hypothetical skilled team including a chemist) without resort to information that would not have been “common general knowledge.” In other words, Eli Lilly failed at the second *Improver* question.

Furthermore, in the absence of a doctrine of equivalents, the skilled person would have understood that the claim was clearly limited to the disodium salt. Several parts of the specification supported this inference, including the fact that it referred either to the very broad class of “anti-folates” or to pemetrexed disodium, but not to an intermediate category. So Eli Lilly independently failed to satisfy the third *Improver* question for salts other than pemetrexed disodium.

However, in 2017, the UK Supreme Court heard the case and issued a judgment<sup>26</sup> that significantly changed the law of patent infringement in the United Kingdom. In particular, the court reformulated the *Improver* questions that have underpinned claim construction in the United Kingdom. The reformulated questions are as follows:

- i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?
- ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?
- iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?<sup>27</sup>

In order to establish infringement in a case where there is no literal infringement, a patentee would have to establish that the answer to the first two questions was “yes” and that the answer to the third question was “no.”

Applied to the facts of this case, the second reformulated question assumes that the person skilled in the art knows that the variant achieves substantially the same result as the invention. This change was implemented to address the Supreme Court’s concern that the original second question imposed too high a burden, given that it requires the addressee to figure out for himself whether the variant would

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26 *Eli Lilly v Actavis UK Ltd & Ors*, [2017] UKSC 48 [*Actavis* (Supreme Court)].

27 *Ibid* at para 66.



work.<sup>28</sup> As a result, the Supreme Court concluded that as to the second question, the notional addressee of the patent would appreciate (and would have appreciated at the priority date) that each of the Actavis products would work in precisely the same way as pemetrexed disodium when included in a medicament with vitamin B12.<sup>29</sup>

Regarding the reformulated third question, Lord Neuberger stated that, in his opinion,

the Court of Appeal adopted an approach which places too much weight on the words of the claim and not enough weight on article 2 of the Protocol<sup>[30]</sup> (and it is only right to add that, in doing so, they were, like Arnold J at first instance, following Lord Hoffmann's guidance in *Kirin-Amgen* [2005] RPC 9).<sup>31</sup>

Therefore, this reformulation was recognized as a significant departure and effectively introduced a doctrine of equivalents.<sup>32</sup> The reformulated questions and the new “doctrine of equivalents” overturned the Court of Appeal judgment and it was decided that pemetrexed potassium was covered by a claim that recited “pemetrexed disodium.”

The Supreme Court judgment in *Actavis* is a significant ruling in the United Kingdom, and the effect of these new questions and the new doctrine of equivalents on infringement and validity will be an important and developing topic for some time to come.

In addition to these important changes regarding equivalents, Lord Neuberger also addressed the issue of prosecution history. It is important to note that the discussion above comes from the portion of the judgment where Lord Neuberger addressed the issue of direct infringement while disregarding the prosecution history.<sup>33</sup>

In his conclusions regarding the use of prosecution history, Lord Neuberger stated:

In my judgment, it is appropriate for the UK courts to adopt a sceptical, but not absolutist, attitude to a suggestion that the contents of the prosecution file of a patent should be referred to when considering a question of interpretation or infringement,

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28 *Ibid* at para 61.

29 *Ibid* at para 69.

30 Article 2 of the Protocol on the Interpretation of Article 69 of the European Patent Convention of 5 October 1973, as revised by the Act revising the EPC of 29 November 2000, which reads: “For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.”

31 *Actavis* (Supreme Court), *supra* note 26 at para 71.

32 For a fuller discussion of the doctrine of equivalents aspect, see Gordon D Harris, “Actavis v Eli Lilly—Should We Have Seen It Coming?” (2017) 10:10 CIPA J 29.

33 *Actavis* (Supreme Court), *supra* note 26 at para 67.

along substantially the same lines as the German and Dutch courts. It is tempting to exclude the file on the basis that anyone concerned about, or affected by, a patent should be entitled to rely on its contents without searching other records such as the prosecution file, as a matter of both principle and practicality. However, given that the contents of the file are publicly available (by virtue of article 128 EPC 2000) and (at least according to what we were told) are unlikely to be extensive, there will be occasions when justice may fairly be said to require reference to be made to the contents of the file. However, not least in the light of the wording of article 69 EPC 2000, which is discussed above, the circumstances in which a court can rely on the prosecution history to determine the extent of protection or scope of a patent must be limited.

While it would be arrogant to exclude the existence of any other circumstances, my current view is that reference to the file would only be appropriate where (i) the point at issue is truly unclear if one confines oneself to the specification and claims of the patent, and the contents of the file unambiguously resolve the point, or (ii) it would be contrary to the public interest for the contents of the file to be ignored. The first type of circumstance is, I hope, self-explanatory; the second would be exemplified by a case where the patentee had made it clear to the EPO that he was not seeking to contend that his patent, if granted, would extend its scope to the sort of variant which he now claims infringes.<sup>34</sup>

This approach represents a qualification of previous practice in which using prosecution history was not permitted. Despite this qualification, it is important to note that, in this case at least, Lord Neuberger did not consider that the contents of the prosecution file justified departing from the provisional conclusion he reached without considering the prosecution history.<sup>35</sup>

To what extent this judgment will open the way to using prosecution history remains to be seen. In adopting a “skeptical” attitude and limiting access to issues that are truly unclear and contrary to public interest, Lord Neuberger appeared to be attempting to reach a cautious compromise on the issue. However, in contrast to absolutist positions, a compromise position is typically more difficult to define. Therefore, it is likely that how and when prosecution history can be used will be argued for months and years to come in blogs, in academia, and in the courts.

### 3.2 **Distrimedic (Canada)**

The patent at issue in the Canadian Federal Court case of *Distrimedic* described a system for preparing a pill dispenser. The system comprised a tray having a number of evenly spaced recesses that was used to support a container-defining sheet made of clear plastic and itself having a corresponding number of evenly spaced cavities embossed therein. The idea was to make a series of containers for holding pills to be

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<sup>34</sup> *Ibid* at paras 87-88.

<sup>35</sup> *Ibid* at para 89.

taken four times per day (breakfast, lunch, dinner, and bedtime) over seven days.<sup>36</sup> Alignment of the container-defining sheet with the tray and recesses was ensured using a “positioning means.”

In order to overcome prior art, the claim was amended during prosecution to introduce a “wherein” clause reciting that

the positioning means comprises at least one upwardly projecting protuberance provided on the top surface of the recessed support, at least one hole provided into the container-defining sheet and at least one other hole provided in the container-sealing sheet, said at least one hole and one other hole being sized and positioned to correspond to and be engaged by said protuberance.

The question raised was whether the “wherein” clause should be construed as an essential feature of the claim.

Relying on the prosecution history, the Federal Court determined that this feature, because it was added, must be an essential feature. The plaintiff objected to the use of file history (or “file wrapper”), “arguing on the basis of the Supreme Court decision in *Free World Trust* that such use of extrinsic evidence has been rejected.”<sup>37</sup> However, de Montigny J drew a distinction between claim amendments and other representations made to the Patent Office, stating,

I am not convinced that the letter referred to by the Defendants to the Counterclaim falls squarely within the compass of that exclusion. While statements or admissions made in the course of patent prosecution shall not be used for the purpose of interpreting a claim, this is not what the Court is called upon to do in the case at bar. A change in the wording of a claim as a result of an objection from the Patent Office is an objective fact from which an inference may be drawn, and is not the same as representations made to the Patent Office. A purposive construction should obviously focus on the wording of a claim, obviously, but this is a far cry from saying that nothing else should be considered.<sup>38</sup>

However, even under conventional purposive construction, it seems that in this case this feature should be considered an essential feature because it was explicitly recited in the claim and nothing suggested that it was not essential. That is, the inclusion of this feature in the claim was an express indication of the inventor’s intent, from which the skilled person would understand that this particular element was essential, irrespective of its practical effect.<sup>39</sup>

Although it is true that purposive construction can result in a recited feature in a claim being deemed non-essential, or construed more broadly than simply a literal

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36 *Distrimedica*, *supra* note 5 at para 22.

37 *Ibid* at para 209.

38 *Ibid* at para 210.

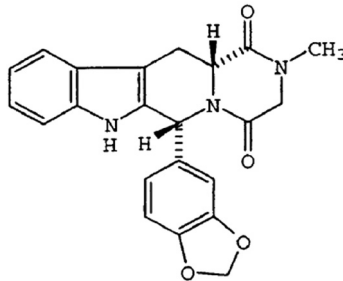
39 *Free World Trust*, *supra* note 2 at para 31.

construction, the principles of purposive construction would indicate that the expression in the claim is to be considered essential unless the context of the claim language dictates otherwise. That is, in order to ensure fairness, the principles of purposive construction demand that the claim be construed through the eyes of a skilled person. Therefore, what is determinative is not what the inventor intended, but what the skilled person understands the inventor to have intended. Thus, even if the “inventor has misspoken [that is, said something other than what was intended] or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound.” That is, the “public is entitled to rely on the words used *provided* the words used are interpreted fairly and knowledgeably.”<sup>40</sup>

### 3.3 Eli Lilly (Tadalafil) (Canada)

The patent in the *Eli Lilly (Tadalafil)* case related to pharmaceuticals and in particular to dosage regimes. The patent included the following claim:

1. A pharmaceutical unit dosage form comprising about 1 to about 20 mg of a compound having the structural formula:



said unit dosage form being suitable for oral administration.<sup>41</sup>

The question arose as to whether a maximum daily dosage of 20 mg should be considered an essential element of the claims.

It is important to note that, although the claim recited a dosage form of up to about 20 mg, the claim did not recite the maximum daily dose. For example, a patient could potentially take multiple units of 20 mg at a time or at intervals throughout the day.

Relying in part on the file history, the court deemed that the daily dosage was not essential. In doing so, de Montigny J did not provide further arguments or reasons why this approach was desirable or consistent with the Supreme Court cases on claim construction.

<sup>40</sup> *Ibid* at para 51 [emphasis in original].

<sup>41</sup> *Tadalafil*, *supra* note 6, annex.

Regarding the specific prosecution history in this case, the application as originally filed included claims reciting the method of treating sexual dysfunction as comprising the administration of about 1 to 20 mg tadalafil, up to a maximum total dose of 20 mg per day. These claims were rejected for claiming a method of medical treatment. In response, Lilly redrafted these claims as “use” claims and removed the reference to a maximum total dose per day. Citing his own prior decision in *Distrimedic* (discussed above), de Montigny J held that it was proper to use this file history in interpreting the claims. The removal of the maximum total dose was used to determine that this feature was not an essential feature.

However, even under conventional purposive construction, it seems that this feature should not be considered an essential feature simply because it was not part of the language of the claims. That is, the claim made no explicit or implicit reference to a maximum daily dosage. Therefore, the prosecution history did not need to be considered in order to arrive at the correct conclusion that the maximum daily dosage was not part of the scope of the claim.

### 3.4 Pollard (Canada)

Unlike in the other Canadian cases, the judge in *Pollard Banknote Ltd v BABN Technologies Corp* did not use prosecution history to construe the claims. Nevertheless, he considered that using prosecution history would have changed the findings in this impeachment proceeding.

The patent in the *Pollard* related to instant lottery tickets. Specifically, the application disclosed embodiments that incorporated a bar code (for ticket validation) and game data (to indicate whether or not the player has won) hidden under one or more scratch-off layers. In one embodiment, the game data and the bar code were hidden under separate scratch-off layers; in another embodiment, both game data and bar code were hidden under a single scratch-off layer. Claim 1 recited:

1. A scratch-off lottery ticket comprising:

- (a) a substrate;
- (b) a play area on the substrate comprising printed indicia, said printed indicia when present in a desired format may result in a prize being won;
- (c) a non-play area on the substrate spaced apart from the printed indicia of the play area and including an authentication means comprising a two dimensional (2D) bar code, said 2D bar code containing all information necessary to authenticate the lottery ticket, said 2D bar code being readable by a reading device by an agent of the lottery ticket, such that when the 2D bar code is read by the reading device, the lottery ticket may be authenticated without the input of additional information provided by the agent of the lottery ticket or directly from the printed document;
- (d) a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area, wherein the absence or

alteration of the scratch-off coating covering the bar code may be a determining factor as to whether the lottery ticket is authentic.

The issue of using prosecution history arose around the feature of “a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area.” The key to the parties’ difference concerning this element was the meaning of the word “continuous.” Pollard argued that this feature “indicates that a single scratch-off coating covers both the printed indicia and the bar code.”<sup>42</sup> In contrast, the co-defendant SG (Scientific Games Products (Canada) ULC) argued that

the word “continuous” does not suggest that there is a single scratch-off coating, but rather that the coating, whether there is only one or more than one, completely hides (is continuous over) each of the printed indicia and the bar code. In support of this argument, SG cites several places in the 551 Patent that refer to the bar code being entirely covered: “entirely covered,” “the entire bar code could be hidden from view,” “completely covered,” “the entire bar code is covered,” “covered in its entirety.”<sup>43</sup>

Locke J found SG’s construction reasonable but somewhat counterintuitive, saying,

[i]f the inventor’s intent had been simply to indicate that each of the printed indicia and the bar code are to be completely covered, I would have expected him to use words like those cited by SG from the disclosure portion of the 551 Patent. If I were to construe the word “continuous” only in the context of the phrase “a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area,” I would conclude that it suggests a single coating covering both the bar code and the printed indicia.<sup>44</sup>

Despite this difficulty, Locke J found that, without the benefit of prosecution history, the construction argued by SG was more consistent with the inventor’s intent as described in the 551 Patent. Accordingly, he concluded that the description “a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area” indicated that each of the printed indicia and the bar code must be completely hidden. There may be more than one scratch-off coating involved in doing this.

In arguing for the use of file history in claim construction, Locke J provided the following comments:

The SCC did not address the possibility that the Patent Office may fail to insist on amendments to claims to reflect representations made by the applicant. The SCC also did not explain how the patent gives public notice of the claims, but the prosecution

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42 *Pollard*, *supra* note 7 at para 109.

43 *Ibid* at para 111.

44 *Ibid* at para 112.

history, which is likewise available to the public, does not. I note also that, unlike in 2000, when the *Free World Trust* decision was released, prosecution histories in many jurisdictions (including Canada) are now available on the internet. This raises the question whether it is time to revisit the rule against using extrinsic evidence in claim construction.<sup>45</sup>

and

I would expect that SG's argument would never have made it to a trial in the US where the principle of file wrapper estoppel applies. There, SG would likely not have been allowed to argue a claim construction that attempts to recapture ground conceded during prosecution of the patent application to avoid prior art.<sup>46</sup>

Although SG's argument won the construction battle, the defendants lost the infringement war. Locke J's analysis resulted in the granting of Pollard's request for a declaration impeaching the 551 Patent for lack of obviousness in light of a prior art document.<sup>47</sup> The prior art document disclosed a lottery ticket that, optionally, was of the scratch-off type. The ticket comprised a play area with printed indicia that indicated whether or not a prize had been won and that were completely covered, as well as a separate non-play area including authentication means (control number 142 in the form of a 1D bar code), which likewise was completely covered.

Two points may be made here. The first is that the claims could legitimately have been construed to be consistent with the judge's desired interpretation. In this case, it is worth noting that the judge's initial reaction was to follow Pollard's suggested construction,<sup>48</sup> which suggests that this construction was the more natural one. In particular, the issue was apparently to construe the phrase "a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area." However, the discussion is focused on the word "continuous." In the narrow context, SG may well have been correct in arguing that an essential feature of the claim was that the barcode and the printed indicia were entirely covered, because the purpose of the coating was to conceal the information beneath. However, once we move our focus from the word "continuous" to the phrase as a whole, this aspect of the coating does not appear to fully define the claimed feature. That is, the claim recited "*a removable continuous scratch-off coating covering both the printed indicia in said play area and the bar code in said non-play area*" (emphasis added). That is, the covering of the printed indicia and the bar code must be performed by a single continuous scratch-off coating.<sup>49</sup> This is only emphasized

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45 *Ibid* at para 80.

46 *Ibid* at para 238.

47 This decision is under appeal.

48 *Pollard, supra* note 7 at para 112.

49 I appreciate that the indefinite article may refer to one or more objects. However, for multiple objects to fall within the scope of a claimed feature, each must satisfy the requirements of that

by the use of the word “both” in the claim. Therefore, prosecution history is not necessary to arrive at the conclusion that a single coating covered both the indicia and the bar code.

The second point that may be made is that even if a patentee can successfully argue for a different construction of the claim in an infringement case, this would not necessarily benefit the patentee. Because the demands of novelty and inventive step (among others) apply to the patent as well as to the application, arguing for broader construction during an infringement proceeding can lead to an undermining of the patent. In this case, the co-defendants BABN Technologies and SG argued for a narrow construction during prosecution to overcome prior art. When they attempted to recapture the abandoned scope during the infringement counterclaim, they once again brought into play this prior art, which rendered the patent invalid.

It is not uncommon for judgments to express a view on the outcome of a case with different constructions. In *Pollard*, the Locke J noted:

I have concluded that the claims of the 551 Patent are invalid. Therefore, I grant Pollard’s request for a declaration impeaching the 551 Patent. In the event that I am wrong, and the claims of the 551 Patent are valid, I conclude that said claims are not infringed by Pollard. In either case, I dismiss SG’s counterclaim for infringement.<sup>50</sup>

These alternative scenarios are not the same, but they are consistent in that in neither case is the alleged infringer liable for the acts carried out. The main difference is the effect on the patent. That is, patent rights are put at risk if the patentee tries to assert an overly broad construction. This in itself should limit the cases in which a patentee tries to circumvent the system as it currently is.

#### 4.0 ARGUMENTS FOR AND AGAINST

There are a number of factors to consider in deciding whether the Canadian Federal Court was correct to use prosecution history to interpret the claims in *Distrimedica* and *Eli Lilly (Tadalafil)*. First, there is the question whether these cases are contrary to the prohibition within the text of the leading Supreme Court of Canada cases. This aspect relates to whether the Supreme Court definition of extrinsic evidence covers all evidence outside the patent document or whether, in the words of de Montigny J, extrinsic evidence does not cover “objective fact[s] from which an inference may be drawn.”<sup>51</sup> Second, we should consider whether the Federal Court adequately addressed the reasons provided by the courts in prohibiting file wrapper estoppel. These reasons include such considerations as ensuring fairness for the

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feature. For example, a person has two cars: one has a tow bar and no sunroof, and the other has a sunroof but no tow bar. The person could legitimately answer “yes” to the question, “Do you have a car?” However, the person could not answer “yes” to the question, “Do you have a car comprising both a tow bar and a sunroof?”

50 *Pollard*, *supra* note 7 at para 2.

51 *Distrimedica*, *supra* note 5 at para 210.



patentee and third parties and helping reduce burdens on the courts and other interested parties. Proponents of using prosecution history have tended to downplay the additional burden, and have construed fairness to mean that justice is best served by ensuring that the patentee has maintained a consistent view of the scope of the claimed features. Conversely, opponents of using prosecution history have tended to emphasize the additional burden, and have construed fairness to mean that the patent document should be easily and simply understandable in its own right.

#### 4.1 The Scope of the SCC Prohibition

*Free World Trust*, in its canons of claim construction, stated that the claim should be construed “based on the patent specification itself without resort to extrinsic evidence.”<sup>52</sup> A straightforward reading of this suggests that the specification is all that should be considered, and that anything that is not the specification is extrinsic evidence (that is, outside the patent specification itself). Binnie J clarified this view by giving examples of extrinsic evidence as “statements or admissions made in the course of patent prosecution.”<sup>53</sup> It was with these examples of extrinsic evidence that de Montigny J in *Distrimed* drew a distinction, stating,

[w]hile statements or admissions made in the course of patent prosecution shall not be used for the purpose of interpreting a claim, this is not what the Court is called upon to do in the case at bar.<sup>54</sup>

However, as noted above, statements or admissions made in the course of patent prosecution are *examples* of extrinsic evidence, not an exhaustive list. Therefore, simply because amendments were not listed as examples of extrinsic evidence does not mean that they are not extrinsic evidence.

Indeed, because amendments are not part of the patent specification itself, it seems clear that they *are* extrinsic evidence. Therefore, it appears that the Federal Court in *Distrimed* and *Eli Lilly (Tadalafil)*, by using amendments to the claims made during prosecution to interpret the claims, did not act in accordance with the principles of purposive claim construction set down in *Free World Trust*.

#### 4.2 Policy Considerations

Regardless of whether the *Distrimed* and *Eli Lilly (Tadalafil)* cases did in fact undermine the Supreme Court of Canada’s direction, there remains the objective question whether using prosecution history is sound policy when construing claim scope.

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52 *Free World Trust*, *supra* note 2, header of section starting at para 61.

53 *Ibid* at para 66.

54 *Distrimed*, *supra* note 5 at para 210.

#### 4.2.1 Public Notice Function

The reasons given in *Distrimedic*, and reused in *Eli Lilly (Tadalafil)*, for using prosecution history rely mainly on the argument that more information makes for better judgments. De Montigny J appeared to consider claim amendments to be particularly useful, arguing that each amendment is “an objective fact from which an inference may be drawn.”<sup>55</sup>

The UK *Actavis* High Court and Supreme Court judgments bolster this type of argument by emphasizing the accessibility of the information relating to prosecution history. The High Court noted that “anyone who is interested in ascertaining the scope of a patent and who is professionally advised will obtain a copy of the prosecution file (most, if not all, of which is generally open to public inspection),” and that where “the prosecution history is short, simple and shows clearly why the claims are expressed in the manner in which they are to be found in the granted patent and not in some broader manner,” there is “no good reason why the court should shut its eyes to the story told by the prosecution file.”<sup>56</sup> The Supreme Court reiterated these points, noting that “the contents of the file are publicly available (by virtue of article 128 EPC 2000) and (at least according to what we were told) are unlikely to be extensive.”<sup>57</sup> Similar arguments were made in *Pollard*, in which the judge highlighted the availability of the prosecution histories on the Internet.<sup>58</sup>

However, these arguments were anticipated by *Kirin-Amgen* and *Free World Trust*, and refuted (ultimately unsuccessfully) in the *Actavis* appeal. In *Kirin-Amgen*, Lord Hoffmann noted that “file wrapper estoppel means that the true scope of patent protection often cannot be established without an expensive investigation of the patent office file.”<sup>59</sup> Lord Hoffmann also argued that “the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide.”<sup>60</sup>

In the appeal of *Actavis*, Arnold J stated, “firstly [file wrapper estoppel] assumes that the skilled reader will always read the prosecution history. I do not see why this should be so, given the limited value which, at least before the judgment in this case, it was generally recognised to have.”<sup>61</sup>

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55 *Ibid* at para 210.

56 *Actavis* (High Court), *supra* note 22 at para 57.

57 *Actavis* (Supreme Court), *supra* note 26 at para 87.

58 *Pollard*, *supra* note 7 at para 80.

59 *Kirin-Amgen*, *supra* note 17 at para 39.

60 *Ibid* at para 35.

61 *Actavis* (Court of Appeal), *supra* note 25 at para 58.

The court in *Free World Trust* echoed this sentiment, noting that “to allow such extrinsic evidence would undermine the public notice function of the claims.”<sup>62</sup> This reference to the “public notice function” appears to limit what should be used in claim construction in two ways: the information should form part of a single “notice,” and the information should be accessible (public).

Regarding the first limitation, it has been argued that, by using what the skilled person would do, the court has full freedom to decide what can be considered because the skilled person must have some legal awareness.<sup>63</sup> That is, the hypothetical skilled person will use the prosecution history if he is given licence to do so by the courts, just as he is now imagined as reviewing the description to clear up ambiguities in the claims. Nevertheless, because the claims are published as part of a patent, complete with description and drawings, it seems reasonable to allow those unified aspects to be used in construing the claims, but nothing more. This “public notice” concept is analogous to the discussion in the UK *Telsonic* case,<sup>64</sup> where, in expressing reluctance to accept that file wrapper estoppel has any part to play in construing a patent and its claims, Laddie J held that patents and their claims are meant to be statements made by the patentee to the relevant public, and that their meaning and effect should be discernible from the face of the (single) document. The fact that other information relating to the patent is publicly available or accessible, as argued in the *Actavis* High Court case and in *Pollard*, addresses the second “publicly accessible” aspect of what should be used, but it does not address the first unified “notice” limitation.

Norman Siebrasse takes a different tack on the public notice function, arguing in his blog, *Sufficient Description*, at the time of the earlier *Distrimedic* case that file wrapper estoppel “would not undermine the notice function, because it operates purely as an estoppel” because “[t]he use of prosecution history can only narrow the claims, not expand them.”<sup>65</sup> In other words, because file wrapper estoppel can only narrow the claims, a person operating outside the claim construed without the file wrapper would necessarily be outside the claim construed with the file wrapper.

Using an “estoppel” approach like this (where prosecution history can only narrow the claims) would prevent the problem identified: that of third parties mistakenly believing they are safe when they are operating outside the scope of the

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62 *Free World Trust*, *supra* note 2 at para 66.

63 J Turner, “Purposeful Construction: Seven Reasons Why Catnic Is Wrong” [1999] EIPR 531. Turner argued that “[i]t is circular for patent law to refer the interpretation of patent claims to the person skilled in the art” because the “skilled person has to refer back to the lawyer to find out what the claims are for” (reason 1).

64 *Telsonic’s Patent*, [2004] RPC 38.

65 Norman Siebrasse, “Use of Prosecution History in Claim Construction: The First Crack in the Free World Wall?” (14 February 2014), *Sufficient Description* (blog), online: <[www.sufficientdescription.com/2014/02/use-of-prosecution-history-in-claim.html](http://www.sufficientdescription.com/2014/02/use-of-prosecution-history-in-claim.html)>.

claims as construed in light of the specification alone. However, this argument itself appears to acknowledge that the patentee may gain an unfair advantage by encouraging third parties to act outside a broader claim scope than is actually warranted.

#### 4.2.2 Patent Office Prosecution

A common complaint about excluding prosecution history from the construction of claims is that it allows patentees to present very different arguments post-grant from those presented during prosecution of the application. The motives for this are clear. In its interaction with the patent office in the application stage, the applicant is mainly trying to establish validity (for example, by overcoming prior art), and so a narrower construction may aid the issuing of a patent. In contrast, after grant, the patentee generally wants its monopoly to be as big as possible and so would like as broad a construction of its claims as possible.

In the United Kingdom, Lord Justice Jacob memorably drew attention to this validity–infringement dichotomy by referencing the vivid simile of another intellectual property professor, saying, “Professor Mario Franzosi likens a patentee to an Angora cat. When validity is challenged, the patentee says his patent is very small: the cat with its fur smoothed down, cuddly and sleepy. But when the patentee goes on the attack, the fur bristles, the cat is twice the size with teeth bared and eyes ablaze.”<sup>66</sup>

In *Pollard*, Locke J looked enviously to the United States, where, he said, the patentee “would likely not have been allowed to argue a claim construction that attempts to recapture ground conceded during prosecution of the patent application to avoid prior art.”<sup>67</sup> Likewise, in the *Actavis* High Court case, Arnold J noted that

consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement.<sup>68</sup>

These arguments were anticipated in the Canadian *Free World Trust* case, where Binnie J noted:

If significant representations are made to the Patent Office touching the scope of the claims, the Patent Office should insist where necessary on an amendment to the claims to reflect the representation.<sup>69</sup>

That is, the onus is on the Patent Office to ensure that the claims are patentable. Locke J noted in *Pollard*<sup>70</sup> that errors of the Patent Office were not considered by the

<sup>66</sup> *European Central Bank v DSS*, [2008] EWCA Civ 192 at para 5.

<sup>67</sup> *Pollard*, *supra* note 7 at para 238.

<sup>68</sup> *Actavis* (High Court), *supra* note 22 at para 111.

<sup>69</sup> *Free World Trust*, *supra* note 2 at para 66.

<sup>70</sup> *Pollard*, *supra* note 7 at para 80.

Canadian Supreme Court. However, even in cases where the Patent Office errs and the patentee is attempting to abuse the system, this can be corrected in a post-grant invalidity action.

In the *Actavis* appeal, Lord Justice Floyd also noted that it will be a rare case where using prosecution history will assist the court in preventing abuse in this way.<sup>71</sup> For example, under the current *Free World Trust* system, in order to allow a patentee to reclaim scope abandoned during prosecution,

- the claim language must support multiple constructions, including a narrower scope and a broader scope;
- the applicant must have indicated that the narrower scope was sought during prosecution; and
- the broader scope argued post-grant must satisfy the requirements of the *Patent Act* (regarding novelty, obviousness, double patenting, etc.) to avoid being invalidated.

If these conditions are satisfied, the patentee may be able to expand the scope of protection. It is arguable, however, that the patentee may have been entitled to this additional scope had the patentee recognized it earlier (for example, during prosecution or even reissue proceedings).<sup>72</sup>

Furthermore, introducing a construction practice that allows for errors in Patent Office practice rather than one that simply corrects Patent Office errors when they occur may implicitly encourage such errors. For example, in any case where claim construction is an issue, a claim may appear to support more than one construction. If this ambiguity is recognized during prosecution, under the current system the Patent Office should remedy the situation by requiring the applicant to clarify the claim. However, if admissions made during prosecution were binding on future constructions, an examiner could legitimately rely on admissions made during prosecution to resolve such apparent ambiguous constructions. This may lead to the granting of claims that have a different scope from what might be expected on the basis of the patent document alone. This would be unfair for third parties.

#### 4.2.3 Increases in Uncertainty and Effects on Litigation

Other arguments provided against the use of prosecution history are not addressed in those cases that promote the use of prosecution history. For example, *Free World Trust* and *Kirin-Amgen* were both concerned with the effect on the court system. In *Kirin-Amgen*, Lord Hoffman quoted his counterpart Lourie J in the United States (where prosecution history is used) in saying that

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<sup>71</sup> *Actavis* (Court of Appeal), *supra* note 25 at para 58.

<sup>72</sup> Section 47(1) of the *Patent Act*, RSC 1985, c P-4.

the only settled expectation currently existing is the expectation that clever attorneys can argue infringement outside the scope of the claims all the way through this Court of Appeals.<sup>73</sup>

In *Free World Trust*, the more general comment was made that using extrinsic evidence would “increase uncertainty as well as fuelling the already overheated engines of patent litigation.”<sup>74</sup>

There are, of course, a variety of ways in which uncertainty in claim construction might affect the courts. Uncertainty may result in more cases being brought to court because each side may believe it has an arguable case. Likewise, as alluded to in the quotation from *Lourie J* above, uncertainty may result in more cases being appealed. The other effect of introducing additional matter to be considered when construing the claims is that each case will take longer and the costs for each party will be greater. These additional costs would apply to all cases where the claims are construed, not just those in which patent prosecution might adjust the scope of a claim. Therefore, even if the additional cost for an individual case were incremental, the cumulative cost for all such cases would represent a significant extra burden in exchange for limited benefit.

Increasing the burden and uncertainty on claim construction also affects normal business transactions. For example, due diligence exercises on assignments and licence agreements would necessarily become more arduous if the file history had to be routinely considered when construing the scope of a patent. *Free World Trust* also highlights the risk of potential competitors being deterred from lawfully working in areas that are not in fact covered by the patent. This means that competition is “chilled” and the patent owner gets more of a monopoly than the public bargained for.<sup>75</sup>

#### 4.2.4 International Consistency

Lipkus and Frontini have argued Canada is “out of step with how the rest of the world treats patent prosecution histories.”<sup>76</sup> Their argument was based on a 2003 survey of intellectual property professionals representing 40 countries, which, the authors claim, illustrates that Canada is also an outlier with respect to its exclusion of the prosecution history in interpreting the scope of the patent.<sup>77</sup> Lipkus and Frontini state:

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73 *Kirin-Amgen*, *supra* note 17 at para 39.

74 *Free World Trust*, *supra* note 2 at para 66.

75 *Ibid* at para 42.

76 Lipkus & Frontini, *supra* note 8 at 168.

77 “Summary Report Q175: The Role of Equivalents and Prosecution History in Defining the Scope of Patent Protection” (2003 Executive Committee Meeting of the International Association for the Protection of Intellectual Property [AIPPI], Lucerne, Switzerland, 25-29 October 2003) at 4-6, online: AIPPI <<https://aippi.org/download/committees/175/SR175English.pdf>> [Q175 Report].

Some countries have a formal doctrine of file wrapper estoppel; members of another group of countries indicated that the prosecution history may be relevant in interpreting claims, while members of a third group regularly resort to the prosecution history for interpreting claims. Canada was the sole country in which the prosecution history was described as “irrelevant and inadmissible for the purposes of determining the scope of protection granted by a patent.”<sup>78</sup>

However, this may oversimplify the results of this survey. That is, those who performed the survey recognized that there was “a wide range of answers” to the question, “Does the prosecution history play a role in determining the scope of patent protection?”<sup>79</sup>

Among the wide range of answers:<sup>80</sup>

1. About 17 countries (including the United States and Japan) indicated that prosecution history did play a role. It should be noted that this group is by no means monolithic in its use of prosecution history.<sup>81</sup>
2. For about 13 countries (including India, Brazil, and Australia), it was not clear whether they would use prosecution history or not. This lack of clarity arose for a variety of reasons, including a lack of a precedential case touching on this issue, and prosecution history not being used for interpretation because it is not publicly available. For those countries that indicated a lack of a precedential case (around 8 countries), 5 indicated that they believed that prosecution history could be used, 1 indicated that it believed that prosecution history could not be used, and 2 were unwilling to speculate.
3. About 7 countries (including Canada, the United Kingdom,<sup>82</sup> and Germany) indicated that prosecution history would not play a role in claim construction.
4. About 2 countries (Belgium and Italy) indicated that, for national filings, prosecution history would not be used because substantive examination did not take place.

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78 Lipkus & Frontini, *supra* note 8 at 169-70.

79 Q175 Report, *supra* note 77 at 4-6.

80 The Q175 Report was a free-text survey. Therefore, the numbers given here are approximate because there appeared to be some discrepancies in how the questions were interpreted. For example, some respondents appeared to be considering prosecution history in general, whereas others appeared to be considering US-style file wrapper estoppel specifically.

81 For example, some countries stated that they do not have “file wrapper estoppel,” but went on to say that prosecution history would play a part in construing claims.

82 With the *Actavis* (Supreme Court) decision discussed above, the UK approach may be more accepting of prosecution history in certain limited cases, although even this possibility is contested: see “An Improved Improver?—Part 2” (17 July 2017), *The IPKat* (blog), online: <[ipkitten.blogspot.ca/2017/07/an-improved-improver-part-2.html](http://ipkitten.blogspot.ca/2017/07/an-improved-improver-part-2.html)>

Taken together, the survey results indicate that Canada is in fact well within the global spectrum of responses to this issue. A significant minority of countries do not allow prosecution history to be used in construing claims. Indeed, as noted in *Free World Trust* in 2000, the principles of the UK *Catnic* case had already been adopted in New Zealand, Australia, South Africa, and Hong Kong.<sup>83</sup>

Furthermore, because of the wide range of responses, it is unclear what changes in claim construction Canada could make in order to help achieve a global consensus. Indeed, de Montigny J's view in *Distrimedica* that the use of prosecution history should be restricted to changes in claim wording (as opposed to, for example, representations to the Patent Office) would result in Canada occupying a more isolated (albeit more intermediary) position on the file wrapper estoppel spectrum.

In the UK *Actavis* Supreme Court case, Lord Neuberger directly addressed international consistency within the European context, stating,

[w]hile the French courts appear to be more ready to refer to the prosecution file on issues of interpretation or scope than the German or Dutch courts, it is unclear how much, if any, difference there is in outcome. The position in relation to the Italian courts is more unclear, and it may well be that the effect of the approach of the Spanish courts is the same in outcome as that of the German and Dutch courts. In those circumstances, particularly as it may be inevitable that there is a degree of difference in the approach of different national courts on such an issue, there is nothing in the French, Italian, or Spanish jurisprudence which causes me to depart from the conclusion expressed by Lord Hoffmann.<sup>84</sup>

That is, although the Supreme Court recognized that different European jurisdictions approach the issue of using prosecution history differently, the differences can be subtle and the outcome is, in any case, more or less the same.

Another issue touching on harmonization is that each patent system may have one or more counterbalances to curb some of the effects of a particular principle or doctrine. With respect to claim construction, in the United States, for example, as recognized in *Free World Trust*,<sup>85</sup> flexibility on claim construction is achieved using a doctrine of equivalents that counteracts the effects of considering all elements as "material" (as opposed to considering the "essentiality" of each element). In this context, it is interesting to note that, in the *Actavis* case, the UK Supreme Court opened the door for a doctrine of equivalents and the use of prosecution history simultaneously. Therefore, if Canada were to adopt certain principles from our international neighbours in a piecemeal manner, although we may achieve consensus in the narrow sense regarding those principles adopted, it may lead to a

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83 *Free World Trust*, *supra* note 2 at para 39.

84 *Actavis* (Supreme Court), *supra* note 26 at para 86.

85 *Free World Trust*, *supra* note 2 at para 38.



divergence of practice when taken as a whole, as the adopted principles may operate unfettered by any non-adopted counterbalances.

## 5.0 CONCLUSIONS

It is my view that in *Distrimed* and *Eli Lilly (Tadalafil)* the Federal Court of Canada has erred in using file wrapper estoppel because the prosecution history is extrinsic evidence.

Regarding the Federal Court's reasons for doing so, and for advocating a reconsideration of the issue in *Pollard*, there appears to be an emphasis on the view that more information leads to more correct decisions. While this is a tempting argument, it ignores other mediating influences, such as limiting the burden on third parties in determining what a patent covers, and facilitating speedy and efficient trials.

Furthermore, in *Distrimed* and *Eli Lilly (Tadalafil)*, as well as in the UK Supreme Court *Actavis* case, the use of file wrapper estoppel did not mean that the construction of the claim was any different from what it would have been if file wrapper estoppel had not been used. In *Pollard*, the patentee faced the same dilemma that it had faced during prosecution: it could pursue a narrow valid scope or a broader invalid scope. In prosecution, the patentee argued for a narrow claim, which resulted in the patent issuing; in court, it argued for a broader scope and the patent was duly invalidated. Regardless of which option the patentee chose, the infringement action would have foundered. Although not a definitive proof, this lends credence to the claim that file wrapper estoppel is of limited use when construing claims and establishing claim scope.

Reasons against using file wrapper estoppel such as these can be found in cases in both the United Kingdom and Canada and suggest that the current practice as set out in *Free World Trust* represents a fair and consistent balance between the competing interests of patentees, third parties, and other interested parties (for example, the judiciary and the Canadian Intellectual Property Office). Practice regarding the use of prosecution history in other jurisdictions and at other times indicates that there may be other compromise positions available that represent different ways of providing balance in the patent system. Given that claim construction underpins many other aspects of patent law, such as statutory subject matter,<sup>86</sup> infringement, and validity, the use of prosecution history is an issue that should be discussed widely, considered carefully, and, in my view, not introduced lightly. Given that the prohibition on using prosecution history comes from the Supreme Court, any attempt to introduce such use in Canada could and should come only through legislation or another Supreme Court decision.

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86 Two patent notices, "Examination Practice Respecting Medical Diagnostic Methods—PN 2015-02" (29 June 2015) and "Examination Practice Respecting Computer-Implemented Inventions—PN 2013-03" (8 March 2013), apply a problem-solution approach to purposive claim construction to determine subject-matter eligibility.

