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## Whether the File Wrapper Estops in Canada

File wrapper estoppel, also called prosecution history or extrinsic evidence, is a doctrine that developed in the United States. It is based on the principle that an inventor will not be allowed to make representations to the patent office, including amendments to a patent application, in order to avoid being refused a patent and later, in the context of an infringement action, assert that the patent covers elements or aspects of the subject which were disclaimed or abandoned in discussions with the patent office.<sup>1</sup>

For years, Canadian patent agents have been advising their clients that “there is no file wrapper estoppel in Canada”, but the jurisprudence is more nuanced than this blanket statement may at first suggest. The file wrapper may be relevant for purposes other than claims construction and may also, in certain circumstances, result in estoppel.

### *A Bar to File Wrapper Estoppel*

In the landmark decision of *Free World Trust v Électro Santé Inc.*,<sup>2</sup> Justice Binnie of the Supreme Court of Canada establishes that patent claims must be construed in an informed and purposive way to determine whether elements of the claimed invention are essential or non-essential. 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>3</sup>

At first blush, *Free World Trust* also appears to clearly and succinctly close the door on file wrapper estoppel.

The rejection of file wrapper estoppel relates to Justice Binnie’s rejection of the doctrine of equivalents. Noting that both the U.S. and Canadian approach begin by disaggregating the invention as described in the patent’s claims into its constituent parts, Justice Binnie contrasts the Canadian approach, which characterizes an element as essential or non-essential, with the U.S. approach, which treats all elements as material. The U.S. uses the doctrine of equivalents to introduce a degree of flexibility by asking whether each of the component elements of the invention as claimed is present in the accused device either as literally described in the claim, or by its “equivalent”. The doctrine of equivalents, however, introduces

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<sup>1</sup> *Novartis AG v Apotex Inc*, 2001 FCT 1129, 15 CPR (4th) 417 at para 78 (Fed Ct – TD) aff’d [2001] FCJ No 1546, 15 CPR (4th) 417 [*Novartis*].

<sup>2</sup> 2000 SCC 66, 9 CPR (4th) 168, [2000] 2 SCR 1024 [*Free World Trust*].

<sup>3</sup> *Ibid* at para 31.

considerations extrinsic to the claims themselves by evaluating knowledge of interchangeability at the date of infringement rather than at the date of the patent.<sup>4</sup>

Affirming the primacy of the claims language, Justice Binnie rejects the doctrine of equivalents in Canada.<sup>5</sup> In a purposive construction, the identification of elements as essential or non-essential is made without resort to extrinsic evidence of the inventor's intention.<sup>6</sup> The words chosen by the inventor will be read in a way that is sympathetic to accomplishment of the inventor's purpose expressed or implicit in the text of the claims. Whether an element is essential is to be interpreted at the date of the publication of the patent specification.<sup>7</sup>

That file wrapper estoppel is meant to place a reasonable limit on the doctrine of equivalents, which is not applied in Canada, is taken into consideration by Justice Binnie when reviewing file wrapper estoppel.<sup>8</sup> Justice Binnie notes that the US approach uses the patent claims as a springboard to other considerations, including file wrapper estoppel, some of which are extrinsic to the claims themselves.<sup>9</sup>

Justice Binnie finds that the current emphasis on purposive construction, which keeps the focus on the language of the claims, seems to be inconsistent with opening the Pandora's box of file wrapper estoppel. Allowing extrinsic evidence for the purpose of defining the monopoly would undermine the public notice function of the claims and increase uncertainty in patent litigation. 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>10</sup>

The Supreme Court of Canada's rejection of file wrapper estoppel in *Free World Trust* is limited to defining the scope of protection granted by a patent claim. Prosecution history can still be relevant for other purposes.<sup>11</sup>

### ***Uses of the File Wrapper in Canada***

In its 2001 decision of *Novartis AG v Apotex Inc.*,<sup>12</sup> the Federal Court considers the circumstances in which prosecution history may be relevant. Both the Supreme Court of Canada in *Free World Trust* and the Federal Court in *Novartis* refer to the

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<sup>4</sup> *Ibid* at para 38.

<sup>5</sup> *Ibid* at para 40.

<sup>6</sup> *Ibid* at para 31.

<sup>7</sup> *Ibid* at paras 51-52.

<sup>8</sup> *Ibid* at para 63.

<sup>9</sup> *Ibid* at para 38.

<sup>10</sup> *Ibid* at para 66.

<sup>11</sup> *Ibid* at para 67.

<sup>12</sup> *Novartis*, *supra* note 1.

1991 Federal Court decision of *Foseco Trading AG v Canadian Ferro Hot Metal Specialties Ltd.*<sup>13</sup> In *Foseco*, Justice Reed finds that information contained in file wrappers, either domestic or foreign, may be relevant for some purposes on some occasions.<sup>14</sup> Examples include establishing the date of invention (largely irrelevant for patents filed after 1989), convention date, joint inventorship, and even for evidence of what prior art had been before the patent examiner to displace the presumption of validity which is accorded an issued patent.<sup>15</sup> Justice Blais in *Novartis* notes that *Foseco* is a case amongst the few where the Court has seen fit to admit the file wrapper, the reason being that an explanation was required to clarify the facts, and not for the purpose of interpretation.<sup>16</sup>

### **The Duty of Good Faith**

Canada, unlike other jurisdictions such as the United States, does not have an explicit statutory provision directed to issues of fraud. However, Section 53 of the *Patent Act*<sup>17</sup> comes close.<sup>18</sup> Section 53 states:

53. (1) A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

(2) Where it appears to a court that the omission or addition referred to in subsection (1) was an involuntary error and it is proved that the patentee is entitled to the remainder of his patent, the court shall render a judgment in accordance with the facts, and shall determine the costs, and the patent shall be held valid for that part of the invention described to which the patentee is so found to be entitled.

This section prescribes two different grounds on which a patent may be found to be invalid: first, a material allegation in the petition is untrue; and second, the specification and drawings contain more or less than is necessary and such omission or addition is wilfully made.<sup>19</sup> The requirement of wilfulness relates

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<sup>13</sup> *Foseco Trading AG v Canadian Ferro Hot Metal Specialties Ltd* (1991), 36 CPR (3d) 35, 46 FTR 81 (Fed Ct – TD).

<sup>14</sup> *Ibid* at para 29.

<sup>15</sup> *Ibid* at paras 25, 28.

<sup>16</sup> *Novartis*, *supra* note 1 at para 86.

<sup>17</sup> *Patent Act*, RSC 1985, c P4 as amended [*Patent Act*].

<sup>18</sup> *Ratiopharm Inc v Pfizer Ltd*, 2009 FC 711, 76 CPR (4th) 241 at para 197, *aff'd* 2010 FCA 204, 87 CPR (4th) 185 [*Ratiopharm*].

<sup>19</sup> *Rothmans, Benson & Hedges Inc v Imperial Tobacco Ltd/Ltée* (1991), 35 CPR (3d) 417, 42 FTR 68 (Fed Ct) at para 37, *aff'd* (1993), 47 CPR (3d) 188, 61 FTR 239 (Fed CA).

specifically to omissions or additions; generally speaking, untrue allegations, if material, will void the patent even if there is no intent to mislead.<sup>20</sup>

Allegations directed to Section 53 must be pleaded with particularity and a party alleged to have breached the provisions of that section should have ample opportunity to know what is alleged and prepare its defences.<sup>21</sup> An allegation of invalidity under section 53 implicates the notion of fraud and, as such, a party should not merely speculate or make imputations as to motive in a reckless manner or without sufficient evidence so as to have a reasonable belief in its truthfulness.<sup>22</sup>

As stated by Justice Hughes in *G.D. Searle & Co v Novopharm Ltd*<sup>23</sup> and cited in *Ratiopharm Inc v Pfizer Ltd*<sup>24</sup>:

An obligation arises on those seeking to gain a patent to act in good faith when dealing with the Patent Office... [C]ommunications with the examiner must be in good faith. It is to be expected that there will be full, frank and fair disclosure. There is afforded during the prosecution ample opportunity to make further disclosure or to correct an earlier misstatement or shortcoming. It is not harsh or unreasonable, if after the patent issues, and disclosure is found to lack good faith, that the Court deems the application and thus the patent, to have been abandoned.

In *Novopharm*, Justice Hughes, in *obiter*,<sup>25</sup> notes that it is rare to have an opportunity to “look behind” what is said in a patent and compare that with what actually happened and what was actually known to the inventors and others.<sup>26</sup> The requirements imposed by section 27(3) to correctly and fully describe the invention, and section 53(1) not to wilfully provide in the specifications more or less than is

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<sup>20</sup> *Novo Nordisk Canada Inc v Cobal Pharmaceuticals Inc*, 2010 FC 746, 86 CPR (4th) 161 at para 330 [*Nov Nordisk*]; but see *Weatherford Canada Ltd v Corlac Inc*, 2011 FCA 228, 95 CPR (4th) 101 at paras 114, 116 and *Zambon Group SPA v Teva Pharmaceutical Industries Ltd*, 2005 FC 1585 at para 29 where wilfulness is a requirement for allegations of wrong inventorship.

<sup>21</sup> *Ratiopharm*, *supra* note 18 at para 197.

<sup>22</sup> *Novo Nordisk*, *supra* note 20 at para 328; *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142, 63 CPR (4th) 406 at para 62, *aff'd* 2009 FCA 97.

<sup>23</sup> *G D Searle & Co v Novopharm Ltd*, 2007 FC 81, *rev'd* on other grounds 2007 FCA 173.

<sup>24</sup> *Ratiopharm*, *supra* note 18 at para 204.

<sup>25</sup> See *G D Searle & Co v Novopharm Ltd*, 2010 FCA 204 at para 2. It should also be noted that, in affirming Justice Hughes' decision, the Federal Court of Appeal states in para 34 that “Pfizer expressed concern that the trial judge's determination pursuant to subsection 53(1) of the Act was based on an overly broad interpretation of that subsection. I am of the view that the determination is confined to the unique and particular circumstances of this matter. It has limited, if any, value as a precedent.”

<sup>26</sup> *Ibid* at para 114.

necessary so as to mislead, are two grounds to “look behind” what is said in a patent.<sup>27</sup> As stated by Justice Hughes:

In considering whether the specification is misleading the Court must look at the specification, the nature of the alleged misleading material to determine if it would be likely to mislead a person skilled in the art, and whether, taking the evidence as a whole, whether an intention to mislead can be determined directly or by reasonable inference.<sup>28</sup>

It must be shown that there was an intention to mislead in the drafting of the patent application itself.<sup>29</sup>

Justice Tremblay-Lamer of the Federal Court in *Litebrook Co v Apollo Light Systems Inc*<sup>30</sup> looks into a nuance in the application of section 53(1). She notes that there is a bar to the use of prosecution file history for the purpose of determining the validity of claims.<sup>31</sup> Justice Tremblay-Lamer refers to *Eli Lilly & Co v Apotex Inc*,<sup>32</sup> where it was found that there is no provision in the Patent Act that an untrue allegation, even amounting to a misrepresentation, made in the course of a prosecution of the application for the patent in the Canadian Patent Office has any effect on the validity of the patent.<sup>33</sup>

Thus a fine line seems to emerge with respect to the relevance of the file wrapper to section 53(1). While the file wrapper is generally not relevant as an interpretive tool, it may become relevant when determining whether disclosure was in good faith and whether there was an intention to mislead. It may therefore be necessary to first show that the specification and drawings contain more or less than is necessary before wilfulness, and by implication the file wrapper, becomes relevant.

While Justice Tremblay-Lamer upholds *Free World Trust* in that the file wrapper cannot be used for the purpose of determining the validity of claims, she finds that the file wrapper is relevant when determining, under an equitable defence claim, whether the defendant’s allegations of inequitable conduct are true.<sup>34</sup>

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<sup>27</sup> *Ibid* at para 115.

<sup>28</sup> *Ibid* at para 158

<sup>29</sup> *Novo Nordisk, supra* note 20 at para 333; *Corning Glass Works v Canada Wire & Cable Ltd* (1984), 81 CPR (2d) 39 at para 64.

<sup>30</sup> 2006 FC 399, 50 CPR (4th) 445 [*Litebrook*].

<sup>31</sup> *Ibid* at para 15.

<sup>32</sup> (1998), 145 FTR 277, 80 CPR (3d) 80 (Fed Ct), *aff’d* (2000), 259 NR 225 (Fed CA).

<sup>33</sup> *Litebrook, supra* note 30 at para 12.

<sup>34</sup> *Ibid* at para 21.

## ***Opening Pandora's Box***

In the recent Federal Court decision of *Distrimed Inc v Dispill*,<sup>35</sup> a case dealing with allegations of patent, copyright and trade-mark infringement, Justice Yves de Montigny refers to the file wrapper in determining whether an element is essential to a claim.

In *Distrimed*, the applicant had, in prosecution, added “upwardly projecting protuberance(s) and holes” elements to the claims at issue in order to overcome a rejection from the Patent Office.<sup>36</sup> Regardless of what appears to be clear guidance to the contrary from the Supreme Court in *Free World Trust*, it was submitted by the Defendants to the Counterclaim that it would be difficult to imagine a clearer indication of the essentiality of a claim element than its addition to a claim in order to overcome an objection from the Patent Office.<sup>37</sup> Despite the applicant’s counsel’s vigorous objections to the use of the file wrapper, Justice Yves de Montigny nonetheless accepts the file wrapper as evidence, 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>

As noted in *Free World Trust*, 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>39</sup> By amending the claims to reflect the representation, the claims are able to stand on their own and there is no need to have recourse to the prosecution history.

Justice Yves de Montigny’s use of the amendment as a fact from which an inference may be drawn seems to reverse this reasoning. Instead of relying on the fact that any significant representations would be reflected in the claims, Justice Yves de

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<sup>35</sup> 2013 FC 1043.

<sup>36</sup> *Ibid* at para 207.

<sup>37</sup> *Ibid* at para 208.

<sup>38</sup> *Ibid* at paras 209-210.

<sup>39</sup> *Free World Trust*, *supra* note 2 at para 66.

Montigny uses the fact that the Patent Office insisted on an amendment to identify the contents of that amendment as significant and therefore essential.

It is not clear how to reconcile the public notice function of the claims highlighted by the Supreme Court of Canada in *Free World Trust* and the distinction Justice Yves de Montigny draws between reliance on amendments to a claim as a result of an objection to determine whether an element is essential and use of statements or admissions made in the course of patent prosecution to interpret the claim. Indeed, a reliance on the prosecution history of a patent seems to run completely counter to the principle of primacy of the claims language that underlies the Supreme Court of Canada's rejection of file wrapper estoppel.

The Supreme Court of Canada in rejecting the doctrine of file wrapper estoppel in *Free World Trust* defines the doctrine as precluding a patent owner from claiming the benefit of the doctrine of equivalents to recapture ground conceded by limiting argument or amendment during negotiations with the Patent Office.<sup>40</sup> *Distrimedic*, however, seems to preclude a patent owner from claiming an element as non-essential, and thus substitutable with a variant that performs substantially the same function in substantially the same way<sup>41</sup>, as a result of an amendment during negotiations with the Patent Office.

The *Distrimedic* type argument also appears in a Decision of the Commissioner of Patents. In *Re: Patent Application 2,237,438*, the Patent Appeal Board summarizes the Applicant's argument and states that:

considering the specification as a whole and the fact that the Applicant amended its claims to introduce the electronic components, it would seem difficult to conclude that it did not intend to make these elements essential.<sup>42</sup>

The Patent Appeal Board, however, states that such an argument would result in the unpatentable being rendered patentable simply because an inventor intends an element to be essential.<sup>43</sup> The Board goes on find that the inventor's intent is not determinative of essentiality and that essentiality will be determined on the basis of "material effect".<sup>44</sup> With this reasoning, the Patent Appeal Board seems to say that an amendment to a claim shows an Applicant's intent to make an element essential, but that, when purposively construing a claim, the Applicant's *intent* to make an element essential does not make the element essential. While this

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<sup>40</sup> *Ibid* at para 63.

<sup>41</sup> See *ibid* at para 55 where Justice Binnie discusses substitutability.

<sup>42</sup> *Re Application No. 2,237,438*, (20 Jun 2013) CD1346 at para 31.

<sup>43</sup> *Ibid*.

<sup>44</sup> *Ibid* at para 33.

reasoning seems to avoid applying file wrapper estoppel in a purposive construction, it does not seem possible to reconcile this reasoning with the principles laid out by the Supreme Court in *Free World Trust* which states that, amongst other things, the identification of elements as essential or non-essential is made according to the intent of the inventor, expressed or inferred from the claims, that a particular element is essential irrespective of its practical effect.<sup>45</sup>

It is important to note that *Distrimedic* only considers circumstances where amendments to the claims are made in prosecution to overcome an objection of the Patent Office, and should not (yet) extend to file wrapper estoppel based on arguments made in responses.

The Federal Court in *Distrimedic* is opening the pandora's box of file wrapper estoppel which the Supreme Court of Canada sought to keep closed.<sup>46</sup> It will be for future cases to decide whether to reverse, limit or further define how much the box is opened.

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<sup>45</sup> *Free World Trust*, *supra* note 2 at para 31.

<sup>46</sup> *Ibid* at para 66.