

# File Wrapper Estoppel in Canada and the United States: What You Say Can and Will Be Used Against You

Alan Macek, DLA Piper (Toronto)

Malaika Tyson, McAndrews, Held & Malloy, Ltd. (Chicago)

Moderator: Yael Bienenstock, Torsys LLP

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## File Wrappers in Canada and the U.S.

- An update on the Canadian amendment and jurisprudence
- The US experience with file wrapper estoppel and what Canada can learn from the US experience
- Significance and use of foreign file wrappers in the US and Canada

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Oh  
Canada!



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## New Era for File Wrappers in Canada

- December 2018, Bill C-86 received Royal Assent
- Budget legislation that made changes to all areas of IP in Canada
- Part of changes that included:
  - College of Patent Agents and Trademark Agents
  - Experimentation use exception
  - Prior user rights
  - Cleaned up some divisional changes
  - Standard Essential Patents

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## Patent Act, s.53.1

53.1 (1) In any action or proceeding respecting a patent, a written communication, or any part of such a communication, may be admitted into evidence to rebut any representation made by the patentee in the action or proceeding as to the construction of a claim in the patent if

(a) it is prepared in respect of

- (i) the prosecution of the application for the patent,  
[and (ii) disclaimers & (iii) re-exams]

(b) it is between

- (i) the applicant for the patent or the patentee; and
- (ii) the Commissioner, an officer or employee of the Patent Office or a member of a re-examination board.

[and (2) divisionals and (3) re-issues]

## *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66:

[66] 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.

## *Free World Trust v. Électro Santé Inc.*, 2000 SCC 66:

[66] ... 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.

## Applications of s.53.1

- “...rebut any representation made by the patentee ...”
- ...it is prepared in respect of (i) the prosecution of the application for the patent...”
- ...it is between (i) the applicant for the patent or the patentee; and [the patent office]”

## *Canmar Foods Ltd. v. TA Foods Ltd.*, 2019 FC 1233

[62] Section 53.1 makes no reference to prosecution histories from other jurisdictions. Representations made by the patentee during prosecution of a foreign patent application should, absent extraordinary circumstances as discussed below, remain inadmissible for the purposes of construing terms used in Canadian patents.

[74] Extraordinary circumstances arise where, as in this case, the patentee acknowledges that the claims have been amended to be substantially the same as claims submitted in another jurisdiction, and the patentee admits that the amendments have limited the scope of the claims in order to make the claims novel and non-obvious. In these circumstances, the Court should be able to refer to the foreign prosecution history for the limited purpose of purposively construing the Canadian claims.

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## *Gemak v. Jempak*, 2020 FC 644

[82] Jempak submits that while, on its face, section 53.1 is applicable only to representations made in the Canadian Patent Office, the language is non-limiting, in that it does not prohibit consideration of foreign prosecution files. I disagree.

[85] ... It is difficult to see how this Court could endorse an interpretation that would render paragraph 53.1(1)(b) completely superfluous or even contradict its plain reading.

[86] ... If Parliament had intended that communications prepared in respect of the prosecution of the application for a foreign patent could be admitted, clearer language would be required to effect that result. In the circumstances, I conclude that section 53.1 did not change the existing rule, as enunciated in *Free World Trust*, that foreign prosecution history is inadmissible.

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## *Janssen Inc. v. Teva Canada Ltd.*, 2020 FC 593

[142] The construction advanced by Janssen during prosecution is consistent with the plain meaning of the claim language, and inconsistent with Janssen's position at trial that only one maintenance dose is essential to claim 1. I find that section 53.1 of the Patent Act is engaged, and the written communication between Janssen and the Commissioner of Patents dated June 26, 2015 is admissible. This evidence supports Teva's position that the maintenance doses referred to in claim 1 are intended to be administered on an ongoing basis.

## *Bauer Hockey Ltd. v. Sport Maska Inc. (CCM Hockey)*, 2020 FC 624

- [65] Although the use of prosecution history is described in terms of estoppel in the United States, section 53.1 squarely makes this a matter of claims construction. When an issue of claims construction arises, the patentee is always making representations to the Court as to the proper construction of the claims and the defendant is always attempting to rebut those representations. Therefore, in my view, as long as the issue is one of claims construction, section 53.1 applies and the prosecution history is admissible. In other words, there is no need to identify a particular representation and rebuttal every time a reference is made to the prosecution history. It is simply integrated in the interpretive process.

*Bauer Hockey Ltd. v. Sport Maska Inc.* (CCM Hockey),  
2020 FC 624

- [105] There was nothing in the application that would have alerted the Patent Office to the interpretation now put forward by [Patentee's expert] Mr. Beaudoin. Neither did Bauer offer any clarification to the Patent Office as to what it meant by "foxing portion." Mr. Beaudoin's interpretation is nothing but an attempt to reclaim ground conceded when the initial claims 1, 2 and 3 were joined and the foxing portion became an essential element. It would effectively reverse the Patent Office's decision by substituting a variety of slits, notches and removal of material, which Mr. Beaudoin admits are within common general knowledge, for the foxing portions that were deemed essential to the patentability of the invention.

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*Seedlings Life Science Ventures, LLC v. Pfizer Canada ULC*, 2020 FC 1

[77] ... It appears that the examiner initially rejected the application on the basis that it was anticipated by the Farrugia 2001 patent, which describes an auto-injector with a flat shape. Seedlings then amended its claims so that references to the "retracted position" became references to a "retracted storage position." It is difficult, however, to draw any firm conclusions from this exchange, because of a peculiarity of the Farrugia device. ... In this context, the addition of the word "storage" to the phrase "retracted position" was certainly meant to differentiate the Seedlings device from the Farrugia device, but not by insisting on the position of the syringe relative to the housing in the storage position.

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## Other references

- Evolution Technologies Inc. v. Human Care Canada Inc., 2019 FCA 209
  - s53.1 was raised but not considered by the court
- Intercontinental Exchange Holdings Inc (Re), 2020 CACP 27
  - “We note that subsection 53.1(1) of the Patent Act applies to actions or proceedings regarding issued patents, such as infringement or invalidity proceedings, and not to claim construction of patent applications during prosecution.”
- Actavis UK Ltd v Eli Lilly & Co [2017] UKSC 48
  - “...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.”

Learning  
from our  
neighbours  
to the  
south



## Doctrine of Equivalents (DOE) and US File Wrapper Estoppel

The DOE is a judicial doctrine that permits a court to find infringement when an accused product or process falls outside of the literal language of the claims but is equivalent to and differs only insubstantially from the claimed invention.

Claims for infringement will be barred by prosecution history estoppel under the doctrine of equivalence if patentee:

- (i) Amended claims, surrendering broader claim scope (amendment-based estoppel) and/or
- (ii) Clearly and unambiguously disclaimed such claim scope in office action responses, in an apparent effort to achieve patentability (argument-based estoppel).

## US File Wrapper Estoppel: Applicability

Focused on surrendered subject matter - all scope between original claim limitation and amended claim limitation

The file wrapper estoppel can be extended to other patents in the family.

- Claim terms “cannot be interpreted differently in different claims because claim terms must be interpreted consistently.”

However - It is the patentee's response to a rejection – not the examiner's ultimate allowance of a claim – that gives rise to prosecution history estoppel.

## Findings of File Wrapper Estoppel

### Narrowing claims and statements

- Consolidating dependent claims into independent claims
- However, as-filed narrow claims don't bring rise to FWE.
- Claims limited in an Examiner interview

### Clear and unambiguous distinguishing over the prior art

- Stressing the importance of certain steps/elements/components
- Arguing specific combinations (e.g., synergy) or disavowing elements
- Criticizing the prior art (e.g., teaching away) including criticizing the art in the specification.
- Declarations are also evidence of surrendered claim scope

### Remarks made after allowance

- Statements made after claims are found allowable may bring rise to PHE.

### Failure to continue prosecution

- By limiting claims to single species without pursuing broader claims, patentee surrendered other subject matter disclosed

## Findings of No File Wrapper Estoppel

Generally file wrapper estoppel will be found unless patentee can identify an objectively apparent reason for the narrowing amendments that is discernible from the prosecution history.

- Cancelled claims, with no arguments, are not deemed narrowing amendments (e.g., restriction requirement)
- Claims are amended but do not narrow the claim or add a new limitation
- Amendments are only tangentially related – very narrow rebuttal

## Tangentially Related

May rebut the presumption of surrender by showing that “the rationale underlying the narrowing amendment [bore] no more than a tangential relation to the equivalent in question.

### Ajinomoto Co., Inc. v. ITC, 932 F.3d 1342 (Fed. Cir. 2019)

- Claim limitation had parts A and B, the applicant amended part B and sought to assert an equivalent to part A
- Court held that the assertion of equivalents to part A of the claim limitation was unrelated to the amendment of part B of the claim

### Eli Lilly and Co. v. Hospira, Inc., 933 F.3d 1320 (Fed. Cir. 2019)

- Amendment made to narrow genus (“antifolate”) to species (“pemetrexed disodium”)
- Patentee argued prior art did not disclose the combination of genus with other claim elements
- Court held – Amendment was not made to “cede other, functional identical, pemetrexed salts “

## Foreign Prosecution Estoppel: US

No foreign prosecution estoppel

- Instructions to foreign counsel on its face are not estoppel

But, foreign prosecution may be considered when it comprises relevant evidence

- Statements made to foreign patent offices that a particular chemical compound was not interchangeable with the claimed chemical was relevant to infringement analysis under DOE - proof that accused infringer's chemical was not interchangeable with patented process

Therefore, having a consistent worldwide approach is a recommend strategy.

# Questions?

