



## Court Rejects Attempt to “Stretch” Patent Claim Language

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Patent claims are frequently analogized to “fences” and “boundaries”, which delineate the extent of the patent’s monopoly. Placement of those boundaries is critical to a patent’s enforceability, and ultimately its value. As noted by Canada’s Supreme Court, “...if, in order to guard against possible invalidity, some area is left open between what is the invention as disclosed and what is covered by the claims, the patent may be just as worthless as if it was invalid.”<sup>1</sup> A recent decision issued by the Chief Justice of the Federal Court of Canada in *Allergan Inc. v. Sandoz Canada Inc.*, 2020 FC 1189 (“*Rapaflo*”) illustrates this challenge.

In *Rapaflo*, Allergan, Inc. (“**Allergan**”) brought an action against Sandoz Canada Inc. (“**Sandoz**”) under Canada’s *Patented Medicines (Notice of Compliance) Regulations* (the “**Regulations**”). Allergan sought a declaration that Sandoz’s generic silodosin product would infringe Canadian Patent No. 2,507,002 (the “**002 Patent**”). Silodosin is used to treat benign prostatic hyperplasia.

Among other things, the 002 Patent claims a capsule formulation comprising “a granule prepared by wet granulation of a mixture of” silodosin and certain identified excipients. Central to the case was whether “granule” and “prepared by wet granulation” (collectively, the **Wet Granulation Elements**)—both explicitly claimed—are essential elements. It was undisputed that Sandoz’s generic product does not contain granules and is not manufactured with the wet granulation process.

Allergan submitted the Wet Granulation Elements were non-essential, and consequently the Sandoz product would infringe the 002 Patent. The Court disagreed, finding the Wet Granulation Elements essential and noting that “Allergan’s suggestion...is based on a reading of the patent that, if upheld, would undermine the certainty and predictability of the patent system, and chill competition” (*Rapaflo* at 2).

### Essential vs. Non-Essential Claim Elements

The Court stated that the assessment of whether a claim element is essential begins with the presumption that all elements are essential, and that where a party alleges otherwise, it bears the onus of establishing “non-essentiality”. That onus can be met by demonstrating either:

1. “that on a purposive construction of the words of the claim it was clearly not intended that a particular element be essential”; or
2. “that at the date of publication of the patent, the skilled person would have appreciated that the element in question could be substituted without affecting the working of the invention” (*Rapaflo* at 46-47).<sup>2</sup>

The Court held that on a plain reading of the claim language, the Wet Granulation Elements, namely “granule” and “prepared by wet granulation”, were unambiguous, and that there was nothing in the claim language to suggest these elements, which limited the claim’s scope, were not intended to be essential. Accordingly, the Court presumed those elements essential, and proceeded to address the two-prong test above (*Rapaflo* at 67).

On the first prong (*i.e.*, clearly not intended that an element be essential), the Court noted that it must confine the analysis to objective manifestations in the patent claims, as viewed through the lens of the skilled person at the relevant date. With respect to the 002 Patent specifically, the Court’s analysis focused on the 002 Patent’s disclosure, finding that:



- the 002 Patent taught away from the use of a dry process and explicitly towards a wet granulation process (*Rapaflo* at 81-84);
- the use of the limiting terms “granule” and “prepared by wet granulation” in claim 1, when the options of dry mixing and dry granulation were known, suggested that the inventors intended those terms to be essential elements (*Rapaflo* at 102); and
- the fact that the inventors (and the Skilled Person) might have understood that the claimed dissolution profile could also potentially be achieved through dry mixing or dry granulation, as Allergan suggested, did not suffice to provide clear indication that the inventors did not intend the Wet Granulation Elements to be essential (*Rapaflo* at 101).

The Court noted that the absence of details or studies in the 002 Patent pertaining specifically to wet granulation were “at best” a weak indication that the inventors may not have intended the Wet Granulation Elements to be essential (*Rapaflo* at 75, 77).

The Court’s analysis illustrates the hurdle a party is to overcome to demonstrate that an element is not intended be essential:

*“Allergan’s interpretation...required such a subtle reading of the patent that it does not rise to the level of conveying a clear intention that the Wet Granulation Elements are not essential elements. Indeed, permitting such a subtle and unclear indication of intention to displace the unambiguous language in claim 1, as well as the much clearer teachings in the ‘002 Patent away from dry processes, towards wet granulation, would undermine the important objectives of promoting predictability and reducing uncertainty...Rather than clearly disclosing an ambiguity in the language of claim 1, it would introduce an ambiguity by suggesting an intention that is not readily apparent on a purposive reading of the claim 1, having regard to the specification as a whole.”* (*Rapaflo* at 100).

Ultimately, the Court concluded that Allergan’s proposed construction was “an attempt to stretch the language of claim 1 to encompass anything that achieves the same desired result as what was actually claimed”, which “is not permissible” (*Rapaflo* at 103).

On the second prong of the test (*i.e.*, whether the element could be substituted without affecting the working of the invention), the Court found that given the manner in which the 002 Patent taught away from the use of dry processes, and the evidence regarding the Skilled Person’s understanding of silodosin’s properties and their implications for a dry process, the Skilled Person would not have understood that a dry process could be substituted for the wet granulation process without materially affecting the working of the invention. Put differently, the Skilled Person would not have appreciated that the invention “would obviously work in the same way” (*Rapaflo* at 111).

### **Section 53.1 Patent Act: Prosecution History & Licensees**

To support its argument that the Wet Granulation Elements were essential, Sandoz sought to introduce into evidence statements made during the prosecution of the 002 Patent. Section 53.1 of the *Patent Act* permits the introduction of a patent’s prosecution history into evidence to rebut any representation made by the “patentee” in an action as to the construction of a claim in certain limited circumstances.

It was admitted in the proceeding that the defendant Kissei Pharmaceutical Co., Ltd. (“**Kissei**”) was the “patentee”, Allergan being the exclusive licensee. The Court found that since the patentee Kissei had not made any representations to the Court with respect to the construction of the 002 Patent, Sandoz could not invoke and rely on s. 53.1 to introduce the 002 Patent prosecution history into evidence. The Court also held the plain and ordinary meaning of the language in subsection 53.1(1), together with a contextual reading of the *Patent Act* and the relevant jurisprudence supported the view that the word “patentee” in subsection 53.1(1) does not include a “licensee”.

Notwithstanding, the Court took notice of the “loophole” this interpretation of s. 53.1 creates, namely permitting a patentee to circumvent the operation of the section by acting through a licensee, and found that the prosecution history in question provided a “glaring example of the mischief that is implicitly permitted by the current wording of subsection 53.1(1)” (*Rapaflo* at 131-135).

While the Court found that s. 53.1 did not apply as the patentee Kissei had not made any representations with respect to the construction of the 002 Patent, the decision does not address the fact that Kissei did take a position on validity, namely denying “that any of the claims of the ‘002 Patent are invalid, void or of no force or effect” and adopted and relied on



Allergan's submissions in this regard (*Rapaflo* at 7). Although the same interpretation of the claims must apply to both infringement and validity and construction of the claims must precede an evaluation of infringement or validity, the decision does not reconcile how the patentee in this instance could adopt and rely on the licensee's validity submissions, yet be found to have not made representations with respect to construction.

### **Unknown Problems Not Obvious To Solve**

By way of counterclaim, Sandoz also challenged the validity of the 002 Patent on the ground of obviousness. The Court's analysis centered on the "obvious to try" test, namely was it more-or less self-evident to a Skilled Person reading the prior art that the improvements sought and claimed in the 002 Patent ought to work.

The Court found that the 002 Patent addressed for the first-time silodosin's very low solubility in water and its potent adhesive and electrostatic properties, and provided a solution to these problems. While Sandoz conceded that the problems of low solubility and potent adhesive/electrostatic properties of silodosin had not been disclosed prior to the claim date, it asserted that those problems would have been readily identified through routine testing and upon identification of those problems, the Skilled Person would have known that those problems could be overcome by pursuing straightforward testing involving a small number of known options (*Rapaflo* at 182).

The Court disagreed with Sandoz's submissions, concluding that absent the knowledge of silodosin's problematic properties, it would not have been obvious to solve them. In other words, before knowing of the existence of the problems that were solved by the claimed invention, it would not have been more or less self-evident to try to obtain the invention. This remains true even if, in theory, there were a small number of known potential solutions to those problems (*Rapaflo* at 192). While the Court held this finding determinative of the "obvious to try" test, it nevertheless also concluded that based on the evidence, the inventors likely engaged in a significant amount of difficult, non-routine work and overcame several unexpected obstacles to achieve the claimed invention, all which weighed in favour of a negative finding in the "obvious to try" analysis.

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<sup>1</sup> *Burton Parsons Chemicals, Inc. v. Hewlett-Packard (Canada) Ltd.*, [1976] 1 SCR 555 at 565.

<sup>2</sup> While the Court recognized prior jurisprudence suggesting the disjunctive test (above) was intended to be conjunctive (*Shire Canada Inc v Apotex Inc*, 2016 FC 382 at para 137), it concluded nothing turned on the issue.

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