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PROMISE OF THE PATENT post-PLAVIX:

Three steps forward, one step back

An internationally recognized requirement for patentability is that an invention must be "useful." Typically, the threshold of utility is easily met for inventions that have commercial applicability, such as a drug candidate. Developments in Canadian patent jurisprudence over the last decade; however, have raised the utility requirement for some patents under the so-called "promise of the patent" doctrine. According to this doctrine, if a patent sets out an explicit promise of utility, the patent will be void if it does not meet this promised utility. The Federal Court of Appeal (FCA) in *Eli Lilly Canada v Novopharm*, 2010 FCA 197 describes the heightened utility requirement:

> Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise. The question is whether the invention does what the patent promises it will do. (at 76) [citations omitted].

The promise doctrine has drawn considerable attention, particularly in the context of pharmaceutical patents, where it has served as a basis for the invalidation of a number of patents and given rise to a high profile pharmaceutical company NAFTA challenge against Canada.[1] Critics of the promise doctrine charge that the doctrine unfairly puts at risk many useful patents, because any stray phrase professing a benefit of the invention could be construed as a promise by the courts.

Recently, the FCA in a case involving the drug clopidogrel bisulfate (marketed as PLAVIX®) (*Sanofi-Aventis v Apotex*, 2013 FCA 186 (*'PLAVIX'*)) articulated a more restrained approach to the promise doctrine. The FCA held that it is improper to assume that all patents make a promise of utility and emphasized that a promise should only be construed when "the inventor makes an **explicit promise** of a **specific result**" (at 49) [emphasis added]. Otherwise, a "mere scintilla" of utility is sufficient.

A review of post-*PLAVIX* jurisprudence from the Federal Court confirms a shift towards the restrained approach advocated by the FCA in *PLAVIX*, with one notable exception.[2]

Post-*PLAVIX* Federal Court Decisions

The first post-*PLAVIX* decision by the Federal Court to address the promise doctrine was *Pfizer v Mylan*, 2014 FC 38 (*"Mylan"*), involving Canadian Patent No. 2,177,576 ('576) covering the drug celecoxib (marketed as CELEBREX®). Interestingly, the '576 patent has been the subject of Federal Court decisions before and after the *PLAVIX* case, with differing constructions of the patent's promise. In a pre-*PLAVIX* decision involving the '576 patent, *G. D. Searle v Novopharm*, 2007 FC 81 (*"G. D. Searle"*), Justice Hughes held that the promise of the '576 patent includes "the duality of treatment of inflammation **and reduction of unwanted side effects**" (at 27) [emphasis added].

In *Mylan*, Justice Harrington adopted a different construction of the promise of the '576 patent.[3] Mylan argued that the '576 patent promised significantly reduced harmful side effects in humans compared to other Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), and that this promise was not met. Mylan relied on a statement in the specification to the effect that the "[t]he compounds are useful as antiinflammatory agents, such as for the treatment of arthritis, **with the additional benefit of having significantly less harmful side effects**" (at 30) [emphasis added]. Harrington J. found that the '576 patent made no promise of reduced side effects. Citing *PLAVIX*, Harrington J. held that the statement of "additional benefits" in the specification was not an explicit promise of specific results. Instead, Harrington J. focused on the next paragraph of the specification, which stated that the selectivity of the compounds "**may** indicate an ability to reduce the incidents of common NSAID-induced side effects" [em-

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phasis added], as showing that the reduced side-effects were only a possibility (at 64-65). The case was distinguished from *G. D. Searle* on the basis that in that earlier decision, counsel had conceded the issue of construction of the promise, whereas in *Mylan* no such concession was made (at 74).

In *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061 (*"Bayer"*), the promise of the patent was raised in an allegation of inutility in relation to Canadian Patent Nos. 2,382,426 ('426) and 2,179,728 ('728) covering oral contraceptives with the active ingredient drospirenone. Cobalt argued that the '426 patent contained a promise of rapid absorption of drospirenone *in vivo*, which was not soundly predicted or demonstrated. Specifically, Cobalt relied on a passage suggesting that rapid dissolution *in vivo* caused enhanced bioavailability of drospirenone. Cobalt argued that this constituted a promise, despite the fact that it was explicitly phrased as providing a possible mechanism and prefaced by a statement that the applicant did not intend to be "limited to any particular theory" (at 97).

Justice Hughes rejected Cobalt's argument, citing the restrained approach to promise of the patent advocated in *PLAVIX* and emphasizing that "[c]ourts should not strive to defeat otherwise valid patents" (at 93). The passage relied on by Cobalt was described as a non-binding effort to explain why rapid dissolution works to increase bioavailability *in vivo* (at 98). Hughes J. did find that the '426 patent contained a more limited promise of rapid dissolution but allegations of inutility were not justified in relation to the more limited promise.

Regarding the '728 patent, Hughes J. held that a list of advantages provided in the specification was not to be construed as a promise, despite the fact that the listed advantages appeared to be both specific and explicitly stated. Hughes J. held that the list was simply an "observation as to advantages expected to be achieved" (at 152), noting that "in alluding to a possibility, an inventor is not promising a result to be achieved; a goal is not necessarily a promise" (at 152). Although unstated, the holding that the asserted advantages were merely a possibility was presumably influenced by the fact that the advantages were couched in language such as "**can** be characterized" and "**can** provide".

In sharp contrast to the foregoing decisions stands the Federal Court's decision in *Alcon v Cobalt Pharmaceuticals*, 2014 FC 149 (*"Alcon"*), which suggests that an inferred promise may still be a basis for invalidity post-*PLAVIX*. In *Alcon*, Cobalt alleged invalidity of Canadian Patent No. 2,447,924 ('924).

The '924 patent claims solutions comprising olopatadine and an amount of polyvinylpyrrolidone (PVP) "sufficient to enhance the physical stability of the solution", wherein the composition does not contain five listed excipients (the 'excluded excipients'). Justice Gleason construed the promise of the '924 patent to include the promise that PVP "will enhance the physical stability of the relevant olopatadine solutions **but that the five excluded excipients will not do so**" (at 61) [emphasis added]. While the specification taught that two of the excluded excipients would not enhance the stability of the olopatadine solutions, the specification was silent concerning the remaining excipients. Gleason J. appears to have been influenced in part by an inference drawn from the fact the two excipients that would not enhance stability were "listed in the same fashion as the other three excluded excipients" in the claims (at 63).

Conclusion

While the early jurisprudence suggests that there is a shift towards a more restrained approach to the promise doctrine in the Federal Court following *PLAVIX*, many aspects of the doctrine remain unsettled. *Alcon* serves as a reminder that courts may yet infer a promise from a patent. Moreover, the promise doctrine itself remains a contentious issue. On January 30, 2014, the Supreme Court of Canada granted leave for Apotex to appeal the *PLAVIX* decision. The appeal, expected to be heard later this year, promises to bring some clarity to this issue.

References

1. Eli Lily and Company, Notice of intent to submit a claim to arbitration under NAFTA chapter eleven (June 13, 2013), online: Foreign Affairs, Trade and Development Canada < http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-02.pdf>.
2. Of the four Federal Court decisions to consider the promise doctrine post-*PLAVIX*, three have generally followed a restrained approach (*Pfizer v Mylan*, 2014 FC 38; *Bayer v Cobalt Pharmaceuticals*, 2013 FC 1061; and *Pfizer v Apotex*, 2014 FC 314), and one has not (*Alcon v Cobalt Pharmaceuticals*, 2014 FC 149).
3. Also see *Pfizer v Apotex*, 2014 FC 314, a second post-*PLAVIX* proceeding concerning the same '576 patent, in which Harrington J. reached the same conclusion as in *Mylan* regarding promised utility, for substantially the same reasons.

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