Canada's Supreme Court abolishes 'promise of the patent'

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“Justice Rowe, writing for a unanimous panel, held that the Promise Doctrine is the wrong yardstick for assessing whether a patent meets the statutory requirement of ‘useful’ ”

The Supreme Court of Canada has done away with the ‘promise of the patent’ doctrine. This doctrine invalidated patents to numerous otherwise useful inventions from 2005 to 2016. The Supreme Court of Canada has clarified that the statutory utility requirement requires only a scintilla of utility related to the subject matter of the invention. This utility must have been demonstrated or soundly predicted as of the Canadian filing date. The decision brings increased certainty to Canada's patent system and more closely aligns it with international norms.

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The notion of the ‘promise of the patent’

Starting in 2005, the Canadian Federal Courts began applying a principle whereby entire patents were often invalidated when a statement(s) in a patent's specification, termed a ‘promise’ or ‘promises’ (or the ‘promise of the patent’), was found to either have not been demonstrated or soundly predicted as of the patent's filing date (the ‘Promise Doctrine’) [1]. The Promise Doctrine required that, in order to meet the Patent Act's requirement that an invention be ‘useful,’ all utilities ‘promised’ in a patent's specification be demonstrated or soundly predicted as of the filing date.

This was an extra-statutory doctrine. The statutory utility requirement is found in Section 2 of the Patent Act. It requires that an invention pertain to a “*new and useful art, process, machine, manufacture or composition of matter*” or a new and useful improvement thereof. No particular quantum of utility is prescribed.

Indeed, the jurisprudence recognized that Canada's Patent Act [2] was ‘fairly forgiving’ in terms of the minimum requirements necessary to satisfy the utility requirement. In particular, only a ‘scintilla’ of utility was required under the Patent Act [3]. However, it likewise became established that “*where the specification sets out an explicit promise, utility will be measured against that promise*” [4]. The state of the law was encapsulated in the Federal Court of Appeal (FCA) decision of *Sanofi v Apotex* as follows:

An inventor whose invention is described in a patent which would otherwise be valid can nonetheless promise more for his invention than required by the Act so as to render his patent invalid. If he does so, so be it; it is a self-inflicted wound [5].

This led to numerous successful patent challenges, often solely on the ground of failing to meet a promise and in situations where the invention otherwise met every other requirement of the Patent Act. Patents to products such as ZYPREXA® (olanzapine), ALTACE® (ramipril), VALTREX® (valacyclovir), STRATTERA® (atomoxetine) and EVISTA® (raloxifene) were successfully challenged based on the Promise Doctrine.

The Promise Doctrine was heavily criticized. Academic writing highlighted that the Promise Doctrine was extra-statutory and unsupportable at law [6]. Furthermore, Canada found itself on the ‘Watch List’ in the United States Trade Representative’s Special 301 Report, in part because of the Promise Doctrine [7].

Case study: latanoprost

The incorporation of the Promise Doctrine into the utility analysis led to strange results, perhaps none more so than in the latanoprost line of cases. In latanoprost, an initial generic, Pharmascience, challenged Pfizer’s Canadian Patent 1,339,132 (the ‘132 Patent’) on the basis of, inter alia, failure to meet its promised utility. The Federal Court (‘FC’) found Pharmascience’s utility allegation to be unjustified, and did not find any particular utility to be promised [8]. The FCA upheld this decision [9].

A second generic, Apotex, also challenged the 132 Patent on the basis of failure to meet its promised utility. The Federal Court dismissed Apotex’s allegation, declining to adopt the promise asserted by Apotex [10].

However, Apotex appealed and the FCA overturned the trial level decision. The FCA found that the Judge from the trial division erred in failing to find that the 132 Patent promised “*treatment of glaucoma and intraocular hypertension on a chronic basis without causing substantial side effects*” [11]. Thus, the same court (the FCA) gave the same question of law (the promise ‘construction’ of the 132 Patent) two different readings in the two cases. The FCA then found that the allegation of lack of soundly predicted utility was justified on the basis that the tests conducted by the inventors, which were single-dose studies, did not provide a basis to predict treatment on a chronic basis. It also found that the inventors did not have a proper line of reasoning connecting single-dose studies to chronic use, nor was there proper disclosure [12].

The 132 Patent contains compound claims and use claims. None of the claims relate to chronic or long-term use, and indeed the word ‘chronic’ is not used in the entire specification. The latanoprost cases represent a low-water mark in the jurisprudence and highlight the uncertainty that was imposed on patentees by this extra-statutory doctrine.

The Supreme Court’s NEXIUM® decision

The SCC only grants leave to appeal from the Federal and Provincial Courts of Appeal in cases that are of ‘national importance’. In 2011, a patent covering Sanofi’s blockbuster product PLAVIX® (clopidogrel) was found to be invalid at the trial level for failure to meet the promised utility [13]. This decision was overturned on appeal [14]. Apotex, seeking to impeach the patent, sought and was granted leave to appeal to the SCC. The Promise Doctrine was squarely at issue on this appeal, which was set for hearing in November 2014. However, Apotex withdrew its appeal on the eve of hearing [15].

The SCC again granted leave to hear arguments related to the Promise Doctrine in esomeprazole. At issue in this case was a patent covering AstraZeneca’s NEXIUM product that claimed optically pure salts of the active ingredient esomeprazole (Canadian Patent 2,139,653, the ‘653 Patent’). Apotex had launched a generic version of NEXIUM following its success in a proceeding under the Regulations [16]. AstraZeneca then sued Apotex for infringement of the 653 Patent. Apotex counterclaimed, asserting that the 653 Patent was invalid on several bases, including for lack of demonstration or sound prediction of the promised utility.

Decision of the lower courts

Following a 32-day trial, Justice Rennie of the FC (as he then was) found that the 653 Patent was novel and unobvious [17]. He also found that that the claimed optically pure salt was soundly predicted to be useful as: a proton-pump inhibitor (‘PPI’); a stable enantiomer against chemically mediated racemization; and a stable enantiomer against enzyme-mediated racemization [18].

However, Justice Rennie found that the 653 Patent contained two promises. The first was that the optically pure salt would be useful as a PPI. The second was that it possessed an improved therapeutic profile over the racemate omeprazole such as a lower degree of interindividual variation. He further found that there was no demonstration or sound prediction of this second promise as of the filing date [19]. Consequently, he declared that the 653 Patent was invalid.

The outcome in the esomeprazole trial highlights the failures of the Promise Doctrine. First of all, the entire patent was invalidated based on the failure to meet the promise of ‘improved therapeutic profile’ even though only one of the 29 claims in the 653 Patent actually claimed an improved therapeutic profile (claim 29, a dependent claim). The remaining 28 claims were compound claims to: the optically pure salt (claims 1–8); processes to make

the optically pure salt compounds (claims 9–23); a pharmaceutical preparation (claim 24); and uses of the claimed compound other than use in creating an improved therapeutic profile (claims 25–28). Finally, the disclosure of the 653 Patent used the phrase 'improved therapeutic profile' only once over its 23 pages.

The esomeprazole trial also presents a situation where a patent was found to meet all of the substantive statutory criteria required by the Patent Act (new, useful, inventive, proper subject matter) and yet was found to be invalid. The SCC has, on multiple occasions, made clear that patent law is 'wholly statutory' [20] and thus that an inventor is entitled to a patent "*according to the terms of the Patent Act, no more and no less*" [21]. Decisions invalidating patents solely on the basis of failure to meet a promise seemingly offended this proposition.

AstraZeneca appealed to the FCA. It argued that the trial judge erred by failing to consider promise on a claim-by-claim basis and for failing to find a promise consistent with the inventive concept. The FCA rejected these arguments and upheld Justice Rennie's decision.

AstraZeneca sought and was granted leave to appeal to the SCC. The basis of AstraZeneca's application for leave to appeal was that the clarification of the Promise Doctrine was an issue of national importance.

The Supreme Court's decision

Justice Rowe, writing for a unanimous panel, held that the Promise Doctrine is the wrong yardstick for assessing whether a patent meets the statutory requirement of 'useful' [22]. Rather, the SCC affirmed that only a scintilla of utility is required, and that a failure to have demonstrated or soundly predicted particular statements in a specification will not be fatal to a patent's validity.

In coming to this decision, the SCC set out the relevant background and framed the appeal as relating to the following issues:

- Is the Promise Doctrine the correct approach for the requirement in s 2 of the Act that an 'invention' be 'useful'?
- Was the drug for which the 653 Patent was granted 'useful' within the meaning of s 2 of the Act at the filing date [23]?

The SCC traced the roots of Canada's Promise Doctrine to the 'False Promise Doctrine' from early 20th century UK's law and the cases of *Hatmaker v Joseph Nathan & Co.* [24] and *Alsop's Patent Re* [25]. The SCC cited the scholar Norman Siebrasse who explained that the False Promise Doctrine was based on the notion that patents in the UK at that time were granted from the Crown as a discretionary exercise of the Royal prerogative based on the entirety of the applicant's representations, and that any false or deceptive representation could result in the revocation of the patent grant [26]. The False Promise Doctrine of the UK was specifically repealed from the UK's Patent Act in 1977, and it was subsequently recognized by UK courts that false promise was no longer a means of invalidating a patent [27].

Justice Rowe went on to find that the Promise Doctrine is incongruent with both the words and scheme of Canada's Patent Act [28]. In particular, he first held that the Promise Doctrine is incorrect as it requires a determination of utility based on reference to the promises expressed in the patent at issue. Justice Rowe held that the Promise Doctrine improperly conflates the Patent Act's s 27(3) sufficiency of disclosure requirements with the s 2 utility requirement. He held that s 2 does not require that all uses disclosed in the specification (by virtue of the necessity to satisfy the s. 27(3) disclosure requirement) be demonstrated or soundly predicted. All that is required is that, as a condition precedent to satisfying the definition of 'invention', there must have been 'utility' [29]. 'Overpromising' was said to be dealt with in other ways in the Patent Act: by virtue of s 27(3), if the requirements of that section are not met; through the prohibition on overly broad claims (i.e., if the claim itself is inoperable); and through the fraud provision, s 53, if the 'overpromise' was an omission or addition willfully made for the purpose of misleading [30].

Justice Rowe went on to find that the Promise Doctrine is incompatible with the Patent Act because it requires all promises to be met as of the filing date. He noted that this requirement is inconsistent with the s 2 requirement, which only requires an invention to be 'useful' [31]. The law requiring all promises to be met was said to have 'unfair consequences' [32]; this is a recognition by the SCC that invalidating an entire patent simply because each and every statement in its specification may not have been established as of the filing date is disproportionate and draconian.

The SCC set the new test for utility as follows:

- First, courts must identify the subject-matter of the invention as claimed in the patent;

- Second, courts must ask whether that subject matter is useful – is it capable of a practical purpose (i.e., an actual result) [33]?

No particular degree of usefulness is required; a ‘scintilla’ of utility is satisfactory. In other words, an invention that is not devoid of utility meets the statutory requirement. Furthermore, consistent with its position that it is inconsistent with the scheme of the Act to require that every promise be met, the SCC held that s 2 will be satisfied if any one use related to the invention’s subject matter is demonstrated or soundly predicted as of the patent’s filing date [34].

Applying this test, the 653 Patent was declared useful and valid on the basis of the finding that its use as a PPI to reduce the production of gastric acid was soundly predicted [35].

Anticipated impact/future perspective

Utility attacks should no longer succeed in Canada except in exceedingly rare cases where a patentee had no basis to predict any use related to his or her invention as of the filing date (i.e., entirely speculative applications). The SCC’s decision should comfort patentees that their invention will be given the protection they ‘bargained for’. By doing away with the Promise Doctrine, esomeprazole SCC should bring about a returned focus to the traditional validity attacks of novelty and obviousness in the years to come.

Executive summary

- Canada’s unique ‘Promise Doctrine’ abolished by the Supreme Court.
- Test for utility to require any scintilla of utility related to the subject matter of the invention.
- Increased certainty that useful inventions will not be invalidated on unpredictable grounds.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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