PREDICTING PATENT UTILITY FOR A USEFUL DRUG: FEDERAL COURT OF CANADA INVALIDATES PATENT FOR ESOMEPRAZOLE

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On July 2, 2014, the Federal Court of Canada found that ASTRAZENECA AKTIEBOLAG's patent for esomeprazole (registration number 2,139,653, or simply "the '653 patent") was invalid for not meeting the declared promised utility. This is a landmark ruling that clarifies the hot topic issue of "proper disclosure" in the context of patent utility and sound prediction in Canada (*Astrazeneca Canada Inc*. v. *Apotex inc*, 2014 FC 638; ASTRAZENECA AKTIEBOLAG and ASTRAZENECA CANADA INC are collectively referred to herein as "ASTRAZENECA")

Factual Background

Briefly, the '653 patent covers a form of esomeprazole that was being sold in Canada by ASTRAZENECA CANADA INC. as NEXIUM®, a medication recognized as being useful for the treatment of gastrointestinal conditions such as acid reflux. APOTEX INC. ("APOTEX") sought to market a generic form of this drug and applied to the Minister of Health for a Notice of Compliance ("NOC"). As part of the Canadian drug approval process, an Innovator company can apply to the courts to obtain a prohibition order against any generic seeking market approval for a drug for which there is a corresponding patent listed on Health Canada's patent register (known as an "NOC proceeding"). This application for a prohibition order was applied for by ASTRAZENECA for esomeprazole, on account of the '653 patent, which was dismissed. APOTEX therefore obtained its NOC for esomeprazole and started selling the drug in Canada. ASTRAZENECA then sued for direct infringement of the '653 patent.

In its Defence and Counterclaim, APOTEX challenged the validity of the '653 patent for lack of novelty, obviousness and for failing to meet the claimed promise, which ultimately turns on the interpretation of the following statement found in the description of the patent:

> "It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties *which will give an improved therapeutic*

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> *profile such as a lower degree of interindividual variation.* The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole (emphasis added)" [*A*strazeneca *Canada Inc***.** v. *Apotex inc*, 2014 FC 638, para 3.]

ASTRAZENECA contended that the underlined statement was a "hoped for" advantage and that the compound "may" have the improved therapeutic profile described therein. ASTRAZENECA argued that use of the term "will" was not a promise in this context and that, when one looks at the patent as a whole, the expression "improved therapeutic profile" needs to be read as a goal and not a promise. The Court found that ASTRAZENECA's interpretation is inconsistent with the principle of patent utility in Canada, which we will delve into in more detail below.

In response, APOTEX put forward that a simple, plain reading of the patent should be interpreted as making the promise of an improved therapeutic profile. The Court found that, considering the principles applicable in the context of determining utility based on the promise found in the patent, patent '653 promises an "improved therapeutic profile", and that this promise was not kept.

Preliminary Issues

1) Standing of ASTRAZENECA AKTIEBOLAG

Before delving into the interpretation and assessment of the validity of the '653 patent, Apotex argued that ASTRAZENECA CANADA INC. lacked standing and could not act as Plaintiff. As per the *Patent Act* (R.S.C., 1985, c. P-4), a patent infringer is liable "to the patentee" (in this case, ASTRAZENECA AKTIEBOLAG) and to "all persons claiming under the patentee". Apotex argued that there is no express license between ASTRAZENECA CANADA and ASTRAZENECA AKTIEBOLAG, who is the actual patentee. The Court found that ASTRAZENECA CANADA had standing, as it had been selling Nexium® in Canada for 13 years and therefore, there must have been an implied recognition of a right between the two. The Court therefore found that the term "persons claiming under" is to be interpreted broadly and includes ASTRAZENECA CANADA.

2) Preclusion from Contesting Invalidity and Abuse of Process

Interestingly, APOTEX also put forward that what ASTRAZENECA had argued in the previous NOC proceeding should have some bearing, or legal effect, on this impeachment/infringement proceeding. ASTRAZENECA should therefore be precluded from "re-litigating" the same issues that were already examined in the prior NOC case. The Court briefly distinguished NOC proceedings from infringement or impeachment proceedings and confirmed that their status is settled in law: a decision found in an NOC proceeding is not binding in an infringement action. However, prior

caselaw has recognized situations that could give rise to an *estoppel* in order to prevent a party from re-litigating certain factual or legal issues that were already previously decided. Nevertheless, the Court found that, since the evidentiary record was not sufficiently similar between both cases, the *estoppel* doctrine does not apply and the effect of an NOC proceeding is not *res judicata* for an infringement and validity case involving the same patent.

APOTEX also argued that the position taken by ASTRAZENECA in this infringement case was different than the one taken in the NOC proceeding, which is an abuse of process. APOTEX alleged that ASTRAZENECA put forward contradictory arguments with regards to the promise/utility of the patent, and the non-obviousness of the invention. While contradictory, the Court did not consider these arguments "abusive".

Inutility, Promise, Prediction and Proper Disclosure

While the novelty and non-obviousness of the '653 patent was contested by APOTEX, it was the issue of utility, or the promised utility, that became determinative for the evaluation of the validity of the '653 patent; and whether or not the disclosure of this promised utility could be soundly predicted.

The demonstration of utility relies on whether or not, at the date of filing, there is proof that the patent worked as promised. If this utility was not demonstrated before filing of a patent, it can be "soundly predicted" as part of a three part test set out by the Supreme Court of Canada in *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 that is:

> "(1) there must be a factual basis for the prediction of utility, (2) the inventor must have at the date of the patent application an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis, and (3) there must be proper disclosure."

In this context, the court summarized the promises of '653 as being: "(1) use as a PPI (proton pump inhibitor); and (2) an improved therapeutic profile such as a lower degree of interindividual variation." [*Id*, para 214.]

With regards to the first promise, the court found that it was soundly predicted. However, it is the second promise that was found to be neither demonstrated nor soundly predicted.

The Court analyzed the question of proper disclosure under the light of "unsettled" caselaw. The Court's reading of this caselaw suggested that the requirement for proper or "heightened" disclosure should be limited only to cases where the context revolves around "new use" patents. Since the '653 patent is not a new use patent, APOTEX's submissions regarding improper disclosure of studies made by Astra Zeneca were not relevant.

The Court was therefore of the view that:

> "there is no enhanced disclosure requirement in all sound prediction cases. Utility and disclosure are treated separately under the Patent Act, and consequently, should be treated separately in the jurisprudence as well" [*Id,* para 160].

Finding that there was no enhanced disclosure requirement, the Court then proceeded to apply the legal tests relating to the demonstration and sound prediction of utility for the promises made in '653. It concluded that the promise of an "Improved Therapeutic Profile" was still not demonstrated. The evidence presented showed that the studies made by ASTRAZENECA were limited in data and "could not form the basis for a sound prediction of utility that extrapolates across an entire patient population" [*Id*, para 194]. Therefore, these studies did not demonstrate nor soundly predict the promise of an improved therapeutic profile. Patent '653 was invalidated for lack of utility.

CONCLUSION

In conclusion, while this decision is interesting with regards to the assessment by the Court of the promised utility for a drug that was recognized in practice as being useful and effective, the Court's study of the disclosure requirement for an evaluation of sound prediction clarifies, at least for now, what was an ongoing issue for debate: there is no "enhanced disclosure" requirement for the determination of a sound prediction of utility, unless it is for a new use patent. Nevertheless, use of plain words can have plain meanings in the context of identifying this promised utility. It is therefore always prudent to not promise more than you can deliver.

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