# SOUND PREDICTION OF THE UTILITY OF PATENTABLE INVENTIONS IN THE LIFE SCIENCES

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On December 5th, 2002 the Supreme Court of Canada ordered two generic drug manufacturing companies to pay Glaxo Wellcome Foundation Inc. damages of $200 million. Glaxo Wellcome suffered the losses because it had to lower the price of AZT to remain competitive with the generic made drug.

The decision, known as *Apotex* v. *Wellcome Foundation Inc.*, is particularly important for the life sciences industry in Canada for at least two reasons. First, it sets the standard of what a patentee may legitimately claim based on *sound prediction* of utility as opposed to *bona fide* proven or demonstrated utility. Second, examiners at the Canadian Patent Office will invoke this decision against patent applications that fail to meet the standard set out in the Supreme Court decision.

There are three basic criteria for patentability in Canada : novelty, non-obviousness, and utility. What all potential patent applicants should also know is that, according to Canadian law, in the absence of demonstrated utility they are expected, at the very least, to be able to make a « sound prediction » of the utility of their invention as of the claim date. But just what is it that makes a prediction of utility a *sound* one?

Briefly, the patent at issue claimed that AZT would be useful in the treatment and prevention of HIV infections and full blown AIDS in human beings. It is important to remember that the period of time relevant to the case was early 1985. In short, the Court had to decide whether or not that particular

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prediction of utility of AZT was in fact a *sound prediction* at the time of the claim date.

It is interesting to note that the doctrine of sound prediction originated in England well before it was first admitted into Canadian law by the Supreme Court in its abundantly cited decision *Monsanto Co.* v. *Commissioner of patents*. The underlying principle of the doctrine of sound prediction is the so-called *honest foundation*. Stated in other words: if a patentee can formulate an *honest* prediction as to the utility of the invention, he or she should in all fairness be entitled to base a claim on it. The doctrine of sound prediction should not be abused or diluted, the Court warned, for patents are not to be issued in exchange for misinformation, mere speculations, or lucky guesses. However, a sound prediction is not a certainty either.

So, just what is it? The Supreme Court said the recipe for a sound prediction contains the following three indispensible ingredients: (1) a solid factual basis, (2) a clear reasoning at the claim date permitting to infer the predicted result from the factual basis, and (3) a sufficient description in the patent application itself. In the case at hand, as of the claim date, Glaxo had only tested AZT against mouse retroviruses in mouse cell lines and actually had to ask two scientists at the NCI/NIH to conduct the necessary testing against HIV in a human cell line.

The results of those tests showed that AZT did indeed inhibit HIV replication in human cells. The solid factual basis was the sum of Glaxo's and the NIH's test results. Therefore, without the NIH's testing there would have been no solid factual basis (ingredient 1) to Glaxo's prediction that AZT would be useful in the treatment and prevention of HIV infections and full blown AIDS in human beings. Because Glaxo understood, even before the claim date, what the mechanism of action of AZT was (AZT is a nucleoside analogue, a fake DNA base, that blocks the elongation of the DNA strand that is reverse transcribed from the viral RNA), the Court found that it had in effect the necessary clear reasoning (ingredient 2) to infer the usefulness of AZT in the treatment and prevention of HIV/AIDS. Finally, the sufficiency of the description (ingredient 3) wasn't really at issue because both elements 1 and 2 were detailed therein. Therefore, the Court held that Glaxo had in fact formulated a sound prediction of utility at the claim date of its patent and was consequently entitled by law to frame a claim on it.

Even though Glaxo showed « precious little consideration », in the words of the Court, to the two NIH scientists who provided it with the crucial testing, the fact that these NIH scientists were not named as inventors in the patent application did not invalidate Glaxo's patent, as the generic companies contended. The Court found that since the NIH scientists hadn't conceived

of the original idea, but had merely verified it, they were not to be considered as genuine inventors or co-inventors as understood in Canadian law.

The message here is that in order to be entitled by law to claim the object of a prediction, the factual information and expertise at hand at the claim date had better be on the patentee's side. Therefore, especially in the absence of clinical trial data, patent applicants are well advised to put forth results of tests in human models in order to have a legitimate claim to the object of the predicted utility of their invention.