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Supreme Court Clarifies Patent Doctrine of Sound Predictions

On December 5, 2002, the Supreme Court of Canada delivered its reasons in *Apotex Inc. et al. v. The Wellcome Foundation Ltd. et al.*, a case involving the validity of a patent claiming the compound AZT for use in the treatment and prophylaxis of HIV in human beings. This case raised the question of whether a valid patent can issue for an "invention" that is a mere speculation or guess at the time it is made. In its decision, the Court confirmed that the utility of a patentable invention must either be known at the time the patent application is first filed (e.g. by constructing the invention and observing its utility) or be soundly predictable in the then state of the art. Mere speculations or guesses, no matter how prophetic, are not patentable even if they turn out to have been correct.

The ruling marked the end of a lengthy legal battle. In 1983, scientists at the U.S. National Institutes of Health (NIH) learned that AIDS was caused by infection with a new retrovirus then known as HTLV-III (HIV) and began designing the assay systems necessary to test potential anti-HIV compounds In 1984, scientists at Wellcome began a similar effort, but chose to construct assays involving mouse cells and mouse retroviruses. The Wellcome scientists were not equipped to work with human cells or HIV. In the fall of 1984, the Wellcome scientists identified AZT as a compound effective to eradicate the murine retroviruses from the mouse cells in the lab dish. While these results were considered encouraging, their actual relevance to HIV treatment was unknown. HIV did not infect mouse cells and was far more complex and mutable than the murine retroviruses. In addition, the conditions of the laboratory were very different from those in a living human being where any potential HIV treatment would need to be ingested, absorbed, metabolized, and delivered to the specific human T-cells that are the target of HIV. Though the scientists at Wellcome were hopeful that AZT would be effective against HIV in a living human being, they recognized that it was impossible to predict human response from their murine results.

By the fall of 1984, NIH and Wellcome were cooperating to find anti-HIV drugs. Wellcome was sending its promising compounds to NIH and NIH scientists would examine the compounds in the human HIV assays they were continually developing and improving. Wellcome sent NIH some AZT under code.

Before any results from NIH were received, Wellcome prepared a draft patent application claiming AZT for use in treating HIV. At this point, this utility was a mere guess. In mid-February, AZT was found by NIH to effectively inhibit the replication of HIV in human cells in the laboratory. However, it was still unknown whether AZT would survive ingestion and metabolism and serve as a functioning drug. On March 16, 1985, Wellcome filed a patent application in the United Kingdom from which the Canadian patent claimed priority.

Confirming the existence of the doctrine of sound prediction in Canada, the Supreme Court ruled that utility of a patent must be established by the inventor at the date of the priorty patent application, either by demonstration or by sound prediction. Sound prediction exists when three factors are combined. First, there must be a factual basis for

the prediction. Secondly, there must be an "articulable and 'sound' line of reasoning" linking the facts to the prediction. Finally, the Court states that, in order for sound prediction to establish the utility of an invention, there must be proper disclosure.

The soundness of a prediction will be a question of fact to be determined on the facts of each case. It must not, in any case, be diluted to "a lucky guess or mere speculation". To be fair to the public, there must be more than speculation. Conversely, to be fair to the inventor, absolute certainty should not be required in all cases. The doctrine of sound prediction is an attempt to strike a balance between both interests. The Court nonetheless cautioned that, since sound prediction is not tantamount to certainty, there will always exist a risk that the prediction will not materialize. Should that occur, the Court added, the patent could then be invalidated for want of utility.

Reinstating the facts as found by the trial judge, the Supreme Court found that Wellcome had no invention before it received NIH's results. The statements contained in the draft patent application constituted mere unpatentable speculation. However, with the NIH results in hand, the Court held that Wellcome had sufficient information to form a sound prediction. As a result, the patent was not invalidated as related to a mere speculation.

The appellants also argued that if the invention was not complete without the input of the NIH scientists, then the NIH scientists must be joint inventors of the invention and Wellcome's failure to name the NIH scientists as joint inventors invalidated the Canadian patent. The Court disagreed with this approach on the basis that the conception of the use of AZT to treat HIV infection arose only in the minds of the Wellcome scientists, and the not the minds of the NIH scientists. Without contributing to the conception, the NIH scientists could not be considered joint inventors.

Further, in a novel reading of subsection 53(1) of the *Patent Act*, the Court found that a failure to name joint inventors would not invalidate a patent unless there had been wilful intention on the part of Wellcome to mislead the Patent Office, a fact not found on the evidence.

As a result, the validity of the AZT patent was upheld.

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