

This newsletter does not constitute legal advice

Harvard Onco-Mouse NOT Patentable in Canada

The Supreme Court of Canada in the recently decided *Harvard Mouse* case ruled that patent claims to higher life forms are not patentable in Canada, although methods of genetic modification of higher life forms may be patentable, and genetically modified eggs from which higher life forms would grow may be patentable. By implication, the Court endorsed the continuing practice of the Patent Office to allow claims for lower life forms; the boundary between higher and lower life forms has not been precisely defined. Our firm sent out a special Newsletter on this case on the day that the Court released its judgment. That Newsletter can be viewed on our website (www.barrigar.com) and downloaded.

Valid Claims can be Based on Sound Prediction, but not Speculation

The Supreme Court of Canada in the recently decided case *Apotex v. Wellcome Foundation* upheld as valid patent claims based on the sound prediction, prior to testing, that the pharmaceutical compound active in the drug known as AZT would be useful for the treatment of HIV. In so doing, the Court distinguished between claims based on speculation, which would be invalid, and those based on sound prediction, which, with qualifications, would be valid. The “sound prediction” doctrine in general terms resembles the U.S. “prophetic example” doctrine.

The appellants, generic drug manufacturers, challenged the validity of the respondent Glaxo/Wellcome's patent, contending that the necessary utility had not been established as of the priority date of the patent (because testing on humans had not then been done, and consequently there was no factual basis for a sound prediction), and that the claims covered more than the invention made (because there were claims to prophylactic as well as treatment methods). The Court rejected these contentions.

IN THIS ISSUE:

Two patent decisions by the Supreme Court of Canada;

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for further information.

An inventor must be able to establish utility of the claimed invention as of the filing date of the patent application.

The appellants also argued that because the U.S. National Institutes of Health (NIH) scientists who tested the compound and confirmed the anti-HIV activity of AZT were not named as co-inventors, the patent was invalid also for erroneous inventorship. The Court also rejected this attack, holding that verification of the inventive concept does not make the verifiers co-inventors, and that in any event, there was no deliberate attempt by the respondents to mislead.

Glaxo/Wellcome had identified a new use, *viz* treatment of HIV, for a previously known compound. Since the Glaxo/Wellcome scientists were not equipped to test their idea, they retained NIH to perform blind testing on the active compound of AZT and some other compounds that they supplied to NIH (none of which was identified by Glaxo/Wellcome to NIH). Testing the AZT compound *in vitro*, the NIH scientists found that AZT inhibited HIV replication. About a month later, Glaxo/Wellcome filed in Britain the patent application from which the Canadian patent derived Convention priority.

The appellants contended that because AZT had not, at the time that the British patent application was filed, been administered to patients with HIV or AIDS, crucial information regarding its bioavailability, pharmacokinetics, metabolic characteristics, activity and toxicity was not known. Before it could be known whether AZT could be used as a treatment for HIV in humans, the appellants argued that Glaxo/Wellcome needed to know if AZT would be absorbed into the human blood stream, reach and enter T-cells infected with HIV, and inhibit the reproduction of the HIV infection without proving toxic to other cells, and demonstrate clinical improvement in the patient. The Court rejected those contentions and held that by the date of filing the initial British patent application, Glaxo/Wellcome had enough information about AZT and its anti-HIV activity in human cells to make a sound prediction that AZT would be useful in the treatment of HIV. Some claims covered use of AZT for treating retroviruses other than HIV. The trial judge held these invalid as being beyond sound prediction; this finding was not appealed.

The Court pointed out that the doctrine of sound prediction balances the public interest in early disclosure of inventions, even before their utility has been fully verified by tests, and the countervailing public interest in avoiding the grant of useless patents in exchange for speculation or misinformation. While allowing a patent based on speculation would be unfair to the public, requiring Glaxo/Wellcome to demonstrate AZT's efficacy through the clinical tests required for approval of a new drug would have been unfair to Glaxo/Wellcome. The Court held that the patent disclosure was, as filed, of use and benefit. Glaxo/Wellcome, by making the disclosure, fulfilled its side of the bargain with the public, and was properly granted a patent.

The Court held that an inventor must be in a position to establish utility of the claimed invention as of the filing date of the patent application, either by testing or by way of sound prediction based on the information and expertise then available.

Where the patent protects a new use for a previously known chemical compound, it is not enough to formulate a description of the invention. On this point, the Court spoke as follows:

Glaxo/Wellcome argues that where the subject matter of the patent is a new use for an old chemical compound, it is enough that the invention is reduced to a definite and practical shape "by the formulation of a written or oral description". This cannot be correct. The concept might be beautifully described but at the same time be quite wrong and misleading to people who consult it. In such a case, the public would be spending its monopoly rights for misinformation, and in the process litter the patent registry with useless patents that might impede others in their search for a real solution to the same problem. Nor, in my view, is it enough for a patent owner to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold. Utility is an essential part of the definition of an invention (*Patent Act*, §2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove invalidity, without the patent owner's ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent.

* * *

Glaxo/Wellcome says the invention was complete when the draft patent application was circulated internally on February 6, 1985. Its argument here, as in the United States, was that the written description identified the drug and its new use sufficiently to give the invention "definite and practical shape". It taught persons skilled in the art how the invention could be practised. This, however, misses the point. The question on February 6, 1985 was not whether or how the invention could be practised. The question was whether AZT did the job against HIV that was claimed; in other words, whether on February 6, 1985, there was any invention at all...

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Glaxo/Wellcome contends that because AZT turned out to have both treatment and (limited) prophylactic properties, its prediction must necessarily have been sound, and the patent upheld on that basis. This argument presupposes that the critical date to establish utility is the state of knowledge when the patent is attacked, even though the attack may come years after its issuance, rather than as of the date the patent application is filed.... In my view, with respect, Glaxo/Wellcome's proposition is consistent neither with the *Act* (which does not postpone the requirement of utility to the vagaries of when such proof might actually be demanded) nor with patent policy (which does not encourage the stockpiling of useless or misleading patent disclosures). Were the law to be otherwise, major pharmaceutical corporations could (subject to cost considerations) patent whole stables of chemical compounds for all sorts of desirable but unrealized purposes in a shot-gun approach hoping that, as in a lottery, a certain percentage of

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compounds will serendipitously turn out to be useful for the purposes claimed. Such a patent system would reward deep pockets and the ingenuity of patent agents rather than the ingenuity of true inventors.

The Court held that if a patent sought to be supported on the basis of sound prediction is subsequently challenged, the challenge will succeed if the prediction at the date of application was not sound, or, irrespective of the soundness of the prediction, there is evidence of lack of utility in respect of some of the subject-matter covered by the claims.

The Court said that the doctrine of sound prediction has three components. First, there must be a factual basis for the prediction. Second, the inventor must have at the date of the patent application a sound line of reasoning from which the disclosed utility can be inferred from the facts. Third, there must be proper disclosure in the specification. Whether the prediction is sound is a question of fact. In applying the doctrine of sound prediction, one presupposes that further testing or other developmental work remains to be done. Sound prediction does not include a lucky guess or mere speculation. The claims must be fairly based on the sound prediction; they must not be covetous.

On the question whether the NIH scientists should have been named as co-inventors, the Court said this:

Section 34(1) [of the *Patent Act*] requires that at least at the time the patent application is filed, the specification "correctly and fully describe the invention ... to enable any person skilled in the art or science to which it pertains ... to ... use it". It is therefore not enough to have a good idea ... the ingenious idea must be "reduced to a definite and practical shape". Of course, in the steps leading from conception to patentability, the inventor(s) may utilize the services of others, who may be highly skilled, but those others will not be co-inventors unless they participated in the conception as opposed to its verification. As Jenkins J. notes in *May & Baker Ltd. v. Ciba Ltd.* (1948), 65 R.P.C. 255 (Ch. D.), at p. 281, the requisite "useful qualities" of an invention, "must be the inventor's own discovery as opposed to mere verification by him of previous predictions".

The Court noted that despite the contribution of the NIH scientists, they were not co-inventors of the invention of the patent in suit. Moreover, the Court noted that a patent is void pursuant to the *Patent Act* only if it contains a "material" misstatement that is "wilfully made for the purpose of misleading". Here, there was no evidence of the latter.

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**Sound prediction
has three components:**

- 1. factual basis for prediction;**
- 2. sound line of reasoning from which utility can be inferred from the facts; and**
- 3. proper disclosure in the specification.**

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