Senate Standing Committee on Economics
ANSWERS TO QUESTIONS ON NOTICE
Innovation, Industry, Science and Research Portfolio
Budget Estimates Hearing 2009-10
1 June 2009

AGENCY/DEPARTMENT: IP AUSTRALIA

TOPIC: Australian Patent Number 624105

REFERENCE: Written Question – Senator Heffernan

QUESTION No.: BI-1

On or about 28 September 1992 IP Australia granted to Chiron Corporation Australian Patent Number 624105 for an invention entitled *NANBV diagnostics and vaccines*. In respect of this patent:

(a) For how long did the patent examiner or examiners examine the patent application?

(b) What was the cost of that patent examination to IP Australia?

(c) How much did IP Australia receive in fees between the time of the filing of the patent application and:

  (i) the date of the acceptance of the grant of the patent?

  (ii) the date of the sealing of the patent?

  (iii) the date of the expiration of the patent?

(d) Did the patent examiner or examiners refer the patent application, or any aspect of it, to a superior within IP Australia or to anyone else either inside or outside of IP Australia for advice? If so, please give, as detailed as possible, an account of the advice sought and the advice received. From whom was the advice sought and received? Was the advice in writing?

(e) Looking at the patent claims as granted (i.e. as they were prior to being amended in 1997) claim 1 reads as follows: "A purified HCV (hepatitis C virus) polynucleotide". In the opinion of IP Australia:

  (i) Does the scope of the patent monopoly as defined by that claim extend to the genetic material of the hepatitis C virus derived from any source including a human body?

  (ii) If not, apart from the purification of the virus's genetic material, is there any difference between that material and the genetic material of an HCV as it occurs in nature?

(f) At any stage during the patent examination process did the patent examiner consider whether, what was claimed as, the invention in claim 1 was patentable subject matter within section 18(1)(a) *Patents Act, 1990*?

(g) As at the date of the acceptance for grant of the patent what was the official policy with respect to claim 1 and claims like it? Was that policy in writing? What steps were taken by IP Australia in arriving at

that policy?

(h) Was IP Australia served with a copy of the court documents in revocation proceedings relating to that patent? If so, when and, in respect of each occasion (if more than one), did IP Australia intervene or participate in those proceedings? If not, why not?

(i) In 1997 IP Australia approved the patentees request to amend the claims. Why did IP Australia approve the patentee's request?

(j) Did IP Australia become aware (and if so when) of the decision of the Technical Board of Appeal of the European Patent Office to revoke the patents claims granted in European Patent Number 0,318,216 (which was the corresponding European patent)?

(k) Did IP Australia reconsider or review the grant of Australian Patent Number 624105 prior to its expiry in November 2008? If so, explain the steps involved in review process, the decision arrived at and, its rationale. If not, why not?

ANSWER

(a) As advised at the hearing, patent examiners do not record the time taken to examine any particular patent application.

(b) As advised at the hearing, the cost is not able to be calculated in respect to any particular patent application.

(c)*	(i)	Filing to Acceptance	-	$2,637
	(ii)	Acceptance to Sealing	-	$250
	(iii)	Sealing to Expiry	-	$7,665
		*(GST not applicable)		

(d) There is no record on the file indicating whether the examiners did or did not seek advice from a superior within IP Australia. The application was comprehensively examined through three reports in which issues of novelty, manner of manufacture, plurality of invention, the specification not defining the invention and formalities were raised. All these issues were overcome by way of amendment or through substantial and persuasive argument. A senior examiner accepted the application on 24 March 1992.

It is not IP Australia's practice to seek advice from external sources during examination of a patent application. There is no record on the file of any such advice being sought in relation to this application.

(e) (i) Yes, the scope of accepted claim 1 is directed to a purified HCV polynucleotide isolated from any source including the human body.

(e) (ii) Not Applicable.

(f) Patent AU 624105 was not examined under the *Patents Act, 1990*.

Patent AU 624105 was examined under the *Patents Act, 1952*. Section

35(1)(a) of the *Patents Act, 1952* required an examiner to consider whether an application was in respect of a manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies.

(g) Australia has a long history of granting patents over products isolated from nature for which a practical and industrially applicable use is identified. At the date of acceptance (24 March, 1992) the official policy was that purified or isolated biological material (including micro-organisms), or a product or chemical isolated from nature for which a new, practical and industrially applicable use had been identified, constituted a manner of new manufacture and therefore an invention. The policy was based on established principles of what constitutes a manner of new manufacture. These principles were confirmed by the Australian High Court in *National Research Development Corporation's Application*, (1961) 78 RPC 134 at 142 and, with respect to living organisms, by the Patent Office decision in *Rank Hovis McDougall Ltd.*, (1976) AOJP 3915.

The policy was documented in the *Australian Patent Examiner's Manual* (issued in July 1984 and applicable to the *Patents Act, 1952*). The relevant section is titled Manner of New Manufacture (Section 35(1)(a)). Relevant paragraphs; 35.47, 35.50 and 35.76, are reproduced in Attachment A. This superseded version of the Manual is no longer publicly available. However the current version of the Manual is available from IP Australia's website.

(h) Yes, IP Australia was served with a copy of the court documents in revocation proceedings relating to the patent AU 624105.

IP Australia was served on 9 March 1994 with a copy of an application to the Federal Court of Australia by Murex Diagnostics Australia Pty Limited seeking an order to revoke Australian patent AU 624105.

IP Australia was also served on 23 January 1998 with a copy of an application to the Federal Court of Australia by F. Hoffmann-La Roche seeking an order to revoke Australian patent AU 624105.

With respect to the 1994 Federal Court action the Commissioner of Patents appeared at the directions hearing on 16 September 1994, having been put on notice on 13 September 1994 by the applicant's legal representative that issues concerning the procedures adopted by the Commissioner in relation to section 105 amendments would be raised. At the hearing the applicant's counsel advised that the applicant no longer intended to raise those issues.

The role that the Commissioner may take in proceedings is very limited as a matter of law. It was the opinion of Gibbs, Stephen, Mason, Aickin, and Wilson *JJ* in *R v. Australian Broadcasting Tribunal; Ex parte Hardiman* (1980) 144 CLR at 35-36 that:

> If a tribunal becomes a protagonist in this Court there is a risk that by doing so it endangers the impartiality which it is expected to maintain

> in subsequent proceedings which take place if and when relief is granted. The presentation of a case in this Court by a tribunal should be regarded as exceptional and, where it occurs should, in general be limited to submissions going to the powers and procedures of the tribunal.

Accordingly, the Commissioner only intervenes in a matter before the Federal Court if matters concerning the powers of, or the procedures and practices adopted by the Commissioner are raised.

(i) The amendments to the patent were considered to meet the statutory requirements regarding allowable amendments as set out in section 102 of the *Patents Act, 1990*.

(j) There is no record on the case file indicating that IP Australia was aware of the February 2001 decision of the Technical Board of Appeal of the European Patent Office.

(k) There is no record on the case file indicating that the Australian Patent AU 624105 was reviewed or reconsidered prior to its expiry in November 2008.

It is not the practice of IP Australia to routinely and actively monitor legal actions and opposition proceedings in other jurisdictions. However, IP Australia takes note of key decisions of foreign courts and tribunals and commentary to inform itself of developments in foreign patent laws. IP Australia may initiate re-examination of an Australian patent on grounds of lack of novelty or of an inventive step where there are clear and unequivocal reasons to do so. This may arise in a number of circumstances including from the consideration of an equivalent patent or patent application in a foreign jurisdiction.

Attachment A to BI-1

EXTRACT FROM PATENT EXAMINER'S MANUAL – applicable to *Patents Act, 1952*

MANNER OF NEW MANUFACTURE (Section 35(1)(a))

Definition - "Manufacture"

35.47 No general rule can be laid down as to what constitutes a "manner of manufacture", but some relevant decisions will be discussed under separate headings in the following paragraphs. It is to be noted that the term "manner of manufacture" does not appear in the Act except in section 59(1)(f). The High Court has pointed out that:

> "The truth is that any attempt to state the ambit of s.6 of the Statute of Monopolies by precisely defining 'manufacture' is bound to fail. The purpose of s.6, it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already, in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept."
> *(National Research Development Corporation's Application,* 78 RPC 134 at page 142).

Discoveries and Ideas

35.50 Abstract discoveries or mere ideas, such as the recognition of the existence of principles previously unknown, are not per se patentable, because they do not exhibit the requirements of a manner of manufacture. In *Hickton's Patent Syndicate v. Patents and Machine Improvements Co. Ltd.,* 26 RPC 339 at page 348 it was said "No doubt you cannot patent an idea, which you have simply conceived, and have suggested no way of carrying out, but the invention consists in thinking of or conceiving something and suggesting a way of doing it. ….. I think you can have a Patent for an idea, which is new and original and very meritorious, if you suggest a way of carrying it out. If you do not so suggest, you cannot no doubt have a Patent; ..…".

In other words, a patent cannot be obtained for a discovery, but it may be granted for a practical application of the discovery.

No general definition can be given as to what constitutes a discovery as opposed to an invention. The High Court indicated: "The truth is that the distinction between discovery and invention is not precise enough to be other than misleading in this area of discussion. There may indeed be a discovery without invention - either because the discovery is of some piece of abstract information without any suggestion of a

practical application of it to a useful end, or because its application lies outside the realm of ‘manufacture’”.
(National Research Development Corporation's Application, 78 RPC 134 at page 138).

35.51 In *Hickton's Patent Syndicate case* (supra), it was made clear that there must be invention in order that there be patentable subject matter; however once a discovery is made or an idea conceived, (obviously one that involves invention), it is immaterial that no invention is required to put the discovery or idea into practice. It was stated: “…..invention may lie in the idea, and it may lie in the way in which it is carried out, and it may lie in the combination of the two; …..”.

However in *Clayton Furniture Ltd.’s Application,* (1965) AOJP 2303, an application for a lunchbox having a lid incorporating a closed container of aqueous liquid detachably connected to the underside thereof, whereby the container could be separately refrigerated, was refused on the basis of the above quotation. Neither the idea nor the means for carrying it into effect constituted suitable subject matter for Letters Patent.

Living Organisms

35.76 Applications dealing with products containing living organisms (e.g. vaccines or starter cultures for yoghurt production) or processes which use living organisms to produce useful products (e.g. fermentation processes) clearly are capable of satisfying the requirements of patentability. It is the practice to consider the following criteria in relation to such applications:

(i) useful ness,

(ii) newness,

(iii) requiring the intervention of man to produce the product,

(iv) the ability to achieve the same result on repetition of the described method of performance of the invention.

If these criteria are satisfied, then no objection is taken to the fact that the product is, contains or uses, a living organism.

The question of patents directed to living organisms is discussed in the matter of an application by *Rank Hovis McDougall Ltd.,* (1976) AOJP 3915. The following points emerge from the decision (page 3918):

(i) a method of producing new variants or strains is patentable if the method gives reproducible results;

(ii) the variants produced must have improved or altered useful properties and not merely have changed morphological characteristics;

(iii) no objection can be taken to a claim to a new organism on the ground that it is something living;

(iv) naturally occurring organisms per se are not patentable, as they represent a discovery and not an invention.

Current practice rests upon this decision.

With respect to point (iv) above, the position would be different if such an organism were claimed as a pure culture in the presence of some specified ingredients. While it is not a claim to the organism *per se*, it would give almost the same protection as a *per se* claim, and such a claim could be acceptable, but would of course, have to be considered on its merits. This matter is further discussed in this Manual in the appropriate section dealing with Section 40.

The above principles regarding patentability apply to (non-human) higher life forms and to processes to alter the characteristics of such, as well as to micro-organisms. Any application which claims a higher life form animal or a process of altering such should be referred to the Deputy Commissioner.

(Section 35.76 in the *Australian Patent Examiner's Manual, July 1984* was amended in December 1987. The December 1987 version is reproduced above.)