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 600650

REFERENCE: Written Question – Senator Heffernan

QUESTION No.: BI-2

On or about 23 August 1990 IP Australia granted to Kirin-Amgen, Inc Australian Patent Number 600650 for an invention entitled *Polypeptides of erythropoietin*. 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 amended claim 1 reads as follows: "A purified and isolated polypeptide having the primary structural confirmation and possessing a biological property as herein defined of naturally-occurring erythropoietin and characterized by being the product of prokaryotic or eukaryotic expression of an exogenous DNA sequence". In the opinion of IP Australia:

  (i) Does the scope of the patent monopoly as defined by that claim extend to erythropoietin that is identical or materially identical to erythropoietin found naturally in the human body?

  (ii) If not, apart from the isolation, purification and the production of erythropoietin as defined in claim 1, is there any difference between that erythropoietin and the erythropoietin found naturally in the human body?

(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) On or about 19 October 1995 Mr David Herald, as a Deputy Commissioner of Patents, handed down a decision as part of the Opposition to the grant of the said patent.

(i) Did Mr Herald at any time during or subsequent to that decision have any communication, written or oral, with anyone directly or indirectly employed, associated or connected with the patentee? If so, what was the purpose of each communication?

(ii) Did Mr Herald at any time during or subsequent to that decision have any cause to communicate, in writing or otherwise, with anyone directly or indirectly employed, associated or connected with the patentee? If so, what was the purpose of each communication?

(iii) Is Mr Herald still alive? If so, has IP Australia or anyone associated with IP Australia communicated with Mr Herald since 19 March 2009? If so, what was the purpose of each communication?

(iv) In his decision Mr Herald held, in respect to the invention defined in claims 14, 17, 18 and 55 (which, he said, claimed "a 'purified and isolated' sequence limited to that specified in Tables V or VI, or limited to being 'essentially' the sequence encoding erythropoietin.") that these were "an artificially created state of affairs". What did he mean by that?

(v) In his decision Mr Herald held, in respect to the invention defined in claims 33 and 34 (which, he said, claimed "a DNA sequence coding for …" erythropoietin) that these were "directed to molecules which have been deliberately changed from the naturally occurring form". In what way were the molecules deliberately changed? What evidence did he rely on to come to that conclusion?

(vi) At the time of this his decision, was Mr Herald aware, or made aware, of the decision of Federal Magistrate Saris of the United States District Court For The District of Massachusetts (handed down on 11 December 1989 in Civil Action No 87-2617-Y) in which she held: "the overwhelming evidence, including Amgen's own admissions, establishes that uEPO (i.e., natural erythropoietin) and rEPO (i.e., recombinant erythropoietin) are the same product. The EPO gene used to produce rEPO is the same EPO gene as the human body uses to produce uEPO. The amino acid sequences of human uEPO and rEPO are identical. There are no known differences between the secondary structure of rEPO produced in a CHO cell and EPO produced in a human kidney."?

(vii) How does IP Australia reconcile the findings of Mr Herald in his decision discussed in (iv) and (v) above and the finding of Federal Magistrate Saris in (vi)?

(j) In respect of IP Australia's decision to extend the original term of patent protection of the said patent beyond 20 years was any economic analysis undertaken by IP Australia? If so, who undertook that analysis and what was their conclusion? Was the economic analysis reduced to writing? If so, does it still exist? If not, on what basis did IP Australia make the decision to extend the term of patent protection? What was the rationale?

ANSWER

(a) Patent Examiners do not record the time taken to examine any particular patent application.

(b) The cost is not able to be calculated in respect to any particular patent application.

(c)*	(i)	Filing to Acceptance	-	$1,730
	(ii)	Acceptance to Sealing	-	$9,380
	(iii)	Sealing to Expiry	-	$8,085
		*(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 two reports in which issues of clarity, novelty, plurality of invention, fair basis and the specification not defining the invention were raised. All these issues were overcome by way of amendments and persuasive arguments, and a senior examiner accepted the application on 14 June, 1990.

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) No.

(ii) Erythropoietin produced by recombinant or artificial means is not considered to be identical to erythropoietin found naturally in the human body. The physical properties of recombinant erythropoietin might differ in molecular weight, glycosylation status, activity, solubility and stability depending on the expression system employed to produce the recombinant erythropoietin and the manner in which the recombinant protein is purified.

(f) Patent AU 600650 was not examined under the *Patents Act, 1990*.

Patent AU 600650 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) At the date of acceptance (14 June 1990) the official policy was that purified and isolated polypeptides produced by recombinant means for which a new, practical and industrially applicable use had been identified, constituted a manner of new manufacture and represented an invention. IP Australia considered that recombinant polypeptides are molecules necessarily produced through the technical intervention of man.

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 and 35.50 are reproduced in Attachment B. 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.

Also, the *Patents Act, 1990* at section 70(2)(b) provides for the extension of term of a patent for a pharmaceutical substance produced through the use of recombinant DNA technology, indicating that recombinant proteins are patentable subject matter.

(h) There is no record on the file that the Commissioner was advised of, or served with court documents in relation to, any revocation actions.

(i) (i) Yes. The patent application was subject of pre-grant opposition proceedings and as the Delegate hearing and deciding the opposition matter, Mr Herald was necessarily required to communicate with legal representatives acting on behalf of the patentee and opponents during and after the opposition hearing. Correspondence on file relates to actions and matters raised by the legal representatives acting on behalf of the patentee and opponents during the ongoing prosecution of the patent application.

(i) (ii) Yes. The legal representatives associated with the patentee of AU 600605 also act on behalf of many other patentees. As Deputy Commissioner of Patents, Opposition, Hearings and Legislation Section, Mr Herald would necessarily have had cause to communicate with the legal representatives associated with the patentee of AU 600605 in the course of his normal duties in respect of many patent applications other than AU 600605. It is not possible to establish the purpose of each communication.

(i) (iii) Mr Herald is still alive and was employed with IP Australia on a contract basis from 8 May 2006 to 5 June 2009 in the Trademark and Designs Group. Accordingly, many people within IP Australia have had contact with Mr Herald since 19 March 2009.

In particular, the Deputy Director General Mrs Fatima Beattie recalls a discussion on a date sometime soon after 19 March 2009. This was a per chance encounter during Mr Herald's visit with Mr Portelli, General Manager of Patent and Plant Breeder's Rights. The purpose of the discussion was a simple greeting and inquiry about his current activities. Mrs Beattie had a second communication with Mr Herald on 29 May 2009. She was returning his telephone call of 21 May 2009. The purpose of this communication was an inquiry by Mr Herald as to whether IP Australia was intending to make a formal response to Dr Palombi's assertions of 'incompetence or corruption' at the Senate Community Affairs Committee's Inquiry into Gene Patents hearing in Canberra on 19 March 2009.

Mr Portelli, General Manager of Patent and Plant Breeder's Rights recalls having an informal discussion with Mr Herald sometime soon after 19 March 2009 when they discussed personal matters.

Senior Examiner, Lexie Press recalls discussions with Mr Herald on three occasions since 19 March 2009. The exact dates are not known. On each occasion the purpose of the communication was to respond to questions Mr Herald asked regarding the references made to him at the Senate Inquiry into Gene Patents hearing on 19 March 2009 and in written submissions to the inquiry. On the two latter occasions Lexie Press recalls that Mr Herald also discussed his recollections of the pre-grant opposition proceedings for patent AU 600650.

(iv) Purified and isolated nucleic acid represents a different physical state to

chromosomal nucleic acid as it occurs in the body. The different physical state is the result of technical intervention.

(v) The polypeptides defined in the claims are synthetic molecules manufactured by assembling excised fragments of isolated nucleic acid encoding human erythropoietin and incorporating preference codons into the synthetic molecule for expression of recombinant erythropoietin in bacterial cells. Analogs of erythropoietin were manufactured by substitution of amino acids.

The specification at Example 11 provides laboratory protocols for making examples of the claimed synthetic molecules.

(vi) Yes, at page 2 of his decision Mr Herald refers to Federal Magistrate Saris's judgement as providing an account of the scientific activities of different organisations engaged in cloning the erythropoietin gene. The judgement was also referred to in evidence submitted by the Board of Regents of the University of Washington, being one of the parties opposed to the grant of patent AU 600650.

(vii) Views and judgements relating to actions in other jurisdictions are not generally determinative of Australian law. In reaching a decision, a hearing officer decides the case on the basis of evidence submitted to IP Australia and the law applying in Australia. A decision in a different jurisdiction, based on different evidence, may be considered by a hearing officer, but is not binding.

With respect to (iv) Mr Herald's findings regarding claims 14, 17, 18 and 55 relate to whether the claimed isolated and purified nucleic acid sequences constitute an invention or a discovery. In contrast Magistrate Saris's statement (the subject of this question) was not in respect of whether isolated and purified nucleic acid sequences constitute an invention or a discovery. Her statement was in respect of claims and counterclaims for infringement by the parties in the dispute.

However, Magistrate Saris did note that:

> "The invention claimed in '008 patent is *not* as plaintiff argues the DNA sequence encoding human EPO since that is a nonpatentable phenomenon "free to all men and reserved exclusively to none." *Diamond v. Chakrabarty*, 447 U.S. 303. 309 [206 USPQ 193, 197] (1980). Neither is it the approach called "the invention" by defendants in DX 827. Rather, the invention as claimed in claim 2 of the patent is the "purified and isolated" DNA sequence encoding erythropoietin."

With respect to (v) Mr Herald's findings on the subject matter of claims 33 and 34 relates to analogs of naturally occurring erythropoietin. Analogs do not have the same amino acid sequence as naturally occurring erythropoietin. Magistrate Saris's statement does not address analogs of naturally occurring erythropoietin.

(j) No economic analysis was undertaken by IP Australia. Sections 70 to 79A of the *Patents Act, 1990* sets out the statutory basis for extension of term of pharmaceutical patents. The application for the extension of term was granted because the statutory provisions were satisfied. No other considerations can lawfully be taken into account when granting an extension of term.

Attachment A to BI-2

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.