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**Submissions to ACIP's interim report
"Post-grant patent enforcement strategies"**

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Submissions to ACIP's interim report "Post-Grant Patent Enforcement Strategies"

Prepared by the Generics Medicines Industry Association ("GMIA")

The GMIA has prepared this submission in response to ACIP's call for submissions to its interim report on "*Post-grant patent enforcement strategies*". ACIP seeks submissions on the eleven proposals set out in the interim paper, and any other suggestion relevant to ACIP's terms of reference for this enquiry.

The GMIA comments on the consultation paper as follows.

1. *IP dispute resolution centre*

Proposal 1

That IP Australia establish an IP dispute resolution centre along the lines of WIPO's Arbitration and Mediation Center, which in the first instance focuses on patent disputes. Funding for the centre should be on a 'user pays' basis.

GMIA does not oppose the establishment of a new IP dispute resolution centre that focuses on resolving patent disputes. GMIA believes that the proposal has many advantages but does include aspects which are unnecessary. Further, it is not clear what is meant by "*user pays*" as the proposal does not detail any case analysis to support its primary contention that it will be more cost effective than current court action or current mediation and arbitration services.

The stated principal advantage of the proposed IP dispute resolution centre over current mediation and arbitration services is the bringing together of experts with a range of technical expertise to help resolve dispute that require a detailed understanding of technical matters (such as in patent disputes).

Although GMIA supports initiatives for achieving quick and effective resolution of disputes in a cost effective manner, GMIA also believes that the key objectives of the proposed IP dispute resolution centre can likely be achieved using the framework of existing mediation and arbitration services by ensuring that suitable experts can be retained to assist with such disputes.

This proposal also does not seem to acknowledge the changing face of current litigation fast track type rules which have been adopted by courts such as the Federal Court over the past 2 years. It would be useful to test the proposal against that current experience.

2. *Validity and infringement opinion service*

Proposal 2

That IP Australia establish a validity and infringement opinion service (taking into account the needs of SMEs), along similar lines to that provided by the UKIPO, and incorporated with the IP dispute resolution centre.

GMIA supports this proposal in part for the following reasons.

A new validity opinion service

GMIA understands that this proposal would be for a service directed to granted patents. IP Australia already considers issues of validity during the examination process (based on prior art identified in searches conducted by IP Australia, or information submitted by any party under sections 27 or 28 of the *Patents Act*).

On that assumption, it may be beneficial to a patentee or third party to at least test the waters on validity. That would seem to be more valuable to smaller potential patent disputes and avoid the current restrictions on prior use in re-examination. GMIA doubts if there would be any significant use of such a service by the pharmaceutical industry because of the likely complexity of the evidence (especially for obviousness grounds) which is characteristic of pharmaceutical patent disputes.

Insufficient expertise to provide infringement opinion

GMIA acknowledges that IP Australia (like the UKIPO) has a team of experienced patent examiners who have significant technical expertise and knowledge of a specific area of law relating to patent prosecution and patent office procedures. However, IP Australia currently does not have access to sufficient legal expertise, without which GMIA believes there can be no credible basis for providing any reliable infringement opinion.

The assessment of infringement issues can rarely be done in a "*quick and simple*" manner (as ACIP suggests) since the assessment of infringement often require a detailed consideration and verification of key facts, as well as having an understanding and ability to apply relevant legal principles from a broader context (such as on privilege and evidence). GMIA believes that it is unrealistic to expect IP Australia to be able to reliably provide "*quick and simple*" patent infringement opinion based on exchanges of several written statements of fact.

In any event, GMIA doubts if there would be any significant use of such a service by the pharmaceutical industry because of the likely complexity of the infringement issues which is characteristic of method of use and manufacturing process pharmaceutical patents. In relation to patents for actives, the question of infringement by sale of a generic containing that active is rarely a debatable issue.

Cost

ACIP's report mentions that the UKIPO has received over 80 opinion requests over a three year period, and that the WIPO Arbitration and Mediation Centre has received (from 1994 to mid-2009) over 110 requests for arbitration on a wide variety of matters (only some of which relates to patent infringement). These are very small numbers given the period of time. GMIA does not think that the likely user base for the services proposed under this proposal (even on a user-pays basis) would justify such an investment by the Australian Government.

3. *Assessment and mediation services*

Proposal 3

That IP Australia establish:

- a) establish a register of experts that could be drawn upon for non-binding expert assessment and for mediation; and*
- b) provide support for expert assessment and mediation services;*

these functions to be coordinated within the IP dispute resolution centre.

GMIA supports the proposal to establish a register of experts who can be asked to provide a non-binding expert assessment and for mediation. It is common for parties to agree on an expert to provide an opinion (e.g. in court proceedings) on technical matters. By having an up-to-date (and preferably categorised and searchable) register of experts, it will be easier for parties to search for suitable experts to assist with resolving a dispute. Such experts could assist as members of a hearing panel, as under Proposal 4.

However, GMIA does not see the need for IP Australia to provide support for expert assessment and mediation services, since such services are already available. There does not seem to be any significant need for IP Australia to provide similar services in a technology specific context. GMIA considers that the proposed register of experts will be sufficient to enable any party to a dispute to search for and retain a suitable independent expert to assist with resolving the dispute.

4. *Patent tribunal*

Proposal 4

That IP Australia establish, within the IP dispute resolution centre, a non-binding determinative ADR process in the form of a Patent Tribunal along the following lines:

- a) each Tribunal hearing panel comprise up to 3 people, integrating legal and technical expertise;*
- b) Tribunal hearing panel members to be drawn from the register of experts established under Proposal 3;*
- c) patent attorneys to have a right to appear;*
- d) the Tribunal to have more streamlined procedures and simplified evidentiary requirements;*
- e) the Tribunal to take a pro-active and inquisitorial role;*
- f) mechanisms be introduced to encourage parties to comply with the Tribunal's determinations, and to discourage parties from using the courts instead of the Tribunal where it would be appropriate to do so; and*
- g) that the effectiveness of the Patent Tribunal be monitored from its date of establishment.*

GMIA believes that the Tribunal is unlikely to be an attractive avenue to users mainly because the proposed Tribunal can only make a non-binding determination and adds an additional level of complexity. The Tribunal will not be able to give the parties any degree of certainty as to the outcome of a dispute. The parties will incur the additional costs which are likely to be significant as it will include the cost of hiring a venue, retaining suitably qualified technical and legal experts on the hearing panel, the need to pay for legal representatives or patent attorneys to prepare for the case including submissions and dealing with issues leading up to the hearing (such as the selection of panel members).

GMIA also does not support the introduction of mechanisms to encourage parties to accept the determination of a Patent Tribunal and specifically requiring courts to consider "*additional damages*" in later proceedings. GMIA believes that such measures are likely to be a significant disincentive to using a Patent Tribunal in the first place.

Specifically, GMIA endorses the quoted comments of CSIRO, Law Council of Australia and Ipernica appearing at page 39 of the paper.

5. *Patent enforcement information resource*

Proposal 5

That IP Australia establish a resource which provides information about patent enforcement.

GMIA supports this proposal.

Proposal 6

That

- a) the Patents Act 1990 (Cth), and the rules of courts exercising jurisdiction under the Patents Act, be amended to ensure that the Commissioner of Patents is provided with information about the existence and the outcome of all court actions in respect of a patent; and*
- b) IP Australia provide public access to the information so provided to the Commissioner of Patents, either through or in association with its online searchable database of patent information.*

GMIA supports this proposal. It is very important that IP Australia's online searchable database accurately reflect the status of any court action or orders from the courts so the public can be certain about all matters affecting a particular patent. For example, commercial parties regularly have a need to know if there are any court proceedings relating to a patent to assess deals with the patentee or with a competitor. Equally, it would be a convenient means by which the public can ascertain if the patent has had its validity certified by a court having regard to cost penalties specified under section 19 of the Patents Act.

6. Patent enforcement in other countries

Proposal 7

That IP Australia continue to encourage and assist countries in the region to improve their patent enforcement systems.

GMIA supports this proposal. Clear and effective enforcement systems benefit both the patentee and an alleged infringer or party seeking to invalidate a patent. Commercially any move towards certainty and consistency in regional patent enforcement is welcomed.

Proposal 8

That IP Australia expand its advocacy program to other countries in the region in which Australian companies do business.

GMIA supports this proposal.

7. Alternative and additional strategies - other courts

Proposal 9

That the jurisdiction of the lower tier of the Federal Court be expressly stated to include patent matters.

GMIA does not support this proposal, and is concerned whether the Federal Magistrates of the Federal Magistrate's Court would have the necessary experience and expertise in handling a complex patent (or other technology related) disputes.

GMIA also repeats its earlier comment that this proposal also does not seem to acknowledge the changing face of current litigation fast track type rules which have been adopted by the judges of the Federal Court over the past 2 years to manage such complex litigation in a timely and cost effective way.

8. Alternative and additional strategies - customs

Proposal 10

That legislation be introduced to empower Australian Customs officials to seize goods at the border where the rights holder has forewarned them of a shipment of infringement product.

GMIA does not support this proposal.

The members of the GMIA import active ingredients into Australia to make finished medicinal drugs, as well as importing finished drugs. These products have a definite and relatively short shelf life and any provisions which allow seizure (in addition to the normal court processes) are likely to adversely impact on the marketability of those products. In particular, the

pharmaceutical industry originator players are sophisticated users of legal systems and may see such provisions as an additional means to delay entry of such drugs into Australia. That would also deny the Australian public access to those low cost generic drugs. The current court system permits patentees in the pharmaceutical industry to seek interlocutory injunctions and this is more appropriate than customs provisions. Likewise, given that ARTG registrations are published and therefore provide a potential trigger for a patentee, patentees are given fair warning of what is planned in the pharmaceutical industry.

Whilst the GMIA acknowledges that similar provisions exist elsewhere, it appears that Australia has not experienced the significant issue of imported counterfeit patented drugs which has been prevalent in the Northern Hemisphere. Accordingly, there appears to be no existing problem in Australia which mandates the inclusion of such provisions.

Further, the GMIA is concerned how Customs officials will identify or assess whether particular goods constitute an infringement of a patent. This will require the ability to interpret a patent claim, which requires both technical and legal expertise and does not seem to be within the typical skill set of a Custom official. In contrast, infringement of registered trade marks will be evident from the goods themselves (e.g. by the labels that appear on a product) which makes it easier for Customs officials to identify or assess.

9. Alternative and additional strategies - opposition of patent grant

Proposal 11

That IP Australia continue to monitor and review opposition processes both locally and abroad to identify whether there is any convincing reason to change from the pre-grant opposition process.

GMIA supports this proposal, and considers that it would be desirable to retain the existing system of pre-grant oppositions.