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30 April 2013

Terry Moore
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Dear Terry,

Pharmaceutical Patents Review – FICPI Response to Draft Report

This submission in response to the Pharmaceutical Patents Review Draft Report is made on behalf of FICPI Australia and follows on from the earlier submission by FICPI Australia in response to the Background and Suggested Issues Paper.

Although we do not intend to comment on all of the Draft Recommendations included within the Draft Report we consider that a number of the recommendations warrant specific comment, which we provide below.

Draft Recommendation 4.1

The draft recommendation that government should actively seek the agreement of the owner of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export appears misguided and unworkable. It is difficult to imagine why any pharmaceutical company would voluntarily relinquished the rights it has been granted under the *Patents Act 1990* to prevent third parties from exporting infringing products from Australia. As the Panel would well understand, the pharmaceutical industry is a global industry, wherein products are developed for a global market. It is, however, not possible even for the most well resourced pharmaceutical company to seek patent protection in all jurisdictions. The normal strategy therefore is to seek patent protection not only in the most significant markets but also in those jurisdictions where there

are manufacturing capabilities. By following this approach pharmaceutical companies can restrict the movement of infringing product into smaller markets where there may be no patent protection and there is no, or limited, manufacturing capability. Therefore, it is not the case to say that the ability of Australian patent holders to restrict export of infringing product from Australia does not offer some significant value to the patent holder. It therefore seems unlikely that Australian patent holders would be prepared to voluntarily surrender an aspect of their patent rights without some form of compensation.

Another concern with this recommendation is that in the unlikely event that some patent holders agree to voluntarily surrender their rights to enforce Australian patents in respect of competitor activities relating to export of infringing product, while some patent holders do not choose to surrender this right, there would be a significant uncertainty introduced into the patent system regarding freedom to operate in respect of activities relating to export of pharmaceutical products.

Draft Recommendation 5.1

The Panel has suggested that the current model of using the patent system to subsidise pharmaceutical R&D indirectly should be replaced with a direct subsidy. The Panel recommends that the government reduce extensions of term for pharmaceutical patents and use part of the associated savings to fund R&D directly, with some of this funding being targeted to socially beneficial research, for which the Panel suggest patents provide inadequate incentive to conduct.

With respect, we consider that Draft Recommendations 5.1 is unworkable and would not achieve the desired outcome.

As noted above, the pharmaceutical research and development process is an international endeavor. The global industry itself conducts fundamental research and provides funding for external agencies such as universities, research institutes and smaller pharmaceutical development companies to conduct early stage research. Promising developments are then supported through the development pipeline and candidate drugs are progressed through the enormously expensive clinical trial process in order to meet the requirements for product registration. It is only with the promise of significant revenue generation resulting from exploitation of pharmaceutical developments in a range of jurisdictions that it is commercially viable for innovative pharmaceutical companies to take on the high level of risk required to bring a new product to market.

Pharmaceutical extensions of term across a range of important jurisdictions are a significant element of the commercial framework that provides encouragement for innovative pharmaceutical companies to expend capital on research and development and to embark upon the significant risks that are associated with this process. A proportion of resulting revenue is then available to be reinvested into research and development activities to support development of the next generation of innovative medicines.

It is hard to imagine how allocation of a "part" of the savings accrued by the Australian government in limiting pharmaceutical extensions of term could in any way incentivise global pharmaceutical companies to expend hundreds of millions of dollars in research and development activities. It is also unclear what "part" of such savings would be allocated to

increase pharmaceutical research and development funding and how such funding would be allocated. While the pharmaceutical industry would of course be supportive of measures to increase pharmaceutical research and development funding in Australia, it is, with respect, naïve at best to suggest that the Australian government, or any government for that matter, would be anywhere near as efficient in the development and commercialisation of new innovations as the pharmaceutical industry itself would be.

In making this recommendation the Panel appears to be suggesting that the pharmaceutical industry would be incentivised by supporting the funding of basic pharmaceutical research in Australia. Given the global nature of the pharmaceutical industry and the enormous capital requirements for clinical development, it cannot be seen how direct government subsidies in Australia would assist the development process. It is the need for conducting extensive clinical trials, and compensating for the resulting time delays in bringing pharmaceutical products to market that justify the extension of term of pharmaceutical patents. It is therefore the development end of the R&D spectrum that would require government support, rather than the research end, in order to incentivise the pharmaceutical industry to continue to invest the large capital amounts required to fund high risk development of innovative medicines.

The Panel appears to be suggesting in making this Draft Recommendation that Australia should in effect adopt an approach of free riding upon the investment in pharmaceutical research and development provided in other jurisdictions through the pharmaceutical extensions of term available in those other jurisdictions. If all countries took this approach we run the risk that the innovative pharmaceutical industry becomes unviable. Further, if Australia takes the approach of free riding upon the support provided in other jurisdictions, what incentive is there for innovative pharmaceutical companies to seek approval for marketing in Australia of new medicines, given that Australia represents such as small market? Also in view of the unsupportive framework recommended it is likely that the innovative pharmaceutical industry would withdraw its support for the high level medical research conducted in this country – and this is an area in which Australia has a competitive advantage and that requires strong government policy support.

In summary, FICPI Australia considers that the pharmaceutical industry itself is far better placed than Government to efficiently develop innovative medicines that will serve to provide the best prospect of successful commercialisation of innovation in the pharmaceutical field, and that will lead to the best prospect of access to new medicines in Australia.

Draft Recommendation 5.2

The Panel has recommended that the government should change the current extension of term provisions such that patents receiving extensions of term in Australia will not expire later than the equivalent patents in major trading partners. This proposal would tie extensions of term in Australia to the regulatory approval processes in other jurisdictions.

FICPI Australia has concerns that adopting recommendations along these lines may in fact lead to unintended adverse consequences. As we understand it, it is presently not uncommon for an application for regulatory approval in Australia to be filed some time later than an application for regulatory approval of the same product in jurisdictions such as Europe and the United States. There is good reason for this approach both from the perspective of the pharmaceutical companies and the Therapeutic Goods Administration itself. It is

conventionally the case that the dossier of information in support for a new application for regulatory approval is submitted to the European or the United States regulatory authority in the first instance. Working closely with the sponsored company the regulator will identify any potential shortcomings within the data package so that further data can be submitted, or indeed further clinical studies can be conducted and documented, as appropriate. Once the sponsor company has received notification in one of these major jurisdictions that the application for regulatory approval is in condition for acceptance it may be only then that the applications for approval in smaller jurisdictions such as Australia are filed. This approach has the effect of streamlining the Australian regulatory process and avoiding duplication of effort.

The result of in effect forcing sponsors of applications for regulatory approval in Australia to submit their dossier to the TGA at the same time as filing submissions in other jurisdictions may well be to increased the workload of the TGA and is very likely to lead to an increase the cost and resources required to secure regulatory approval within the pharmaceutical companies themselves. The effect of this recommendation could well be to not only reduce the efficiency of the pharmaceutical development process but to ultimately increased the costs of pharmaceuticals to the Australian market. It is also quite foreseeable that the timeframe for the approval of drugs within Australia could in fact be increased if this recommendation is adopted.

Draft Recommendation 6.1

There does not appear to be any logical reason as to why second and subsequent medical uses should fall outside the pharmaceutical extension of term. Pharmaceutical products that fall within the category of second or subsequent pharmaceutical uses, or indeed products that embody pharmaceutical substances that currently fall outside the definition of pharmaceutical substances *per se*, equally require significant capital investment and risk to bring a product to market. FICPI Australia considers that there is no logical reason why the pharmaceutical extension provisions should not be extended to cover these categories of products.

Draft Recommendation 6.2

FICPI Australia agrees with the recommendation to delete Section 76A of the Patents Act.

Draft Recommendation 6.4

The Panel has recommended that Section 117 of the *Patents Act 1990* should be amended to provide that the supply of a pharmaceutical product subject to a patent which is used for a non-patented indication will not amount to infringement, where reasonable steps have been taken to ensure that the product will only be used in a non-infringing manner. With respect, this recommendation fails to take into account the significant problem of off-label prescription of pharmaceutical products. While off-label prescription of pharmaceuticals is possible it is inappropriate to contemplate amendments to section 117 as recommended.

Draft Recommendation 7.1

The Panel has suggested that the government should ask the productivity commission to review the effectiveness of the Raising the Bar Act at the earliest opportunity, and not later than 3 years from the commencement of that Act. FICPI Australia is of the view that the

conduct of any form of review of the effectiveness of the Raising the Bar Act within 3 years will be a wasted effort.

The Panel may well be aware that due to the manner in which the Raising the Bar Act was implemented there was an enormous rush of applicants filing requests for examination, and indeed filing new divisional and national phase entry applications (along with requests for examination) to ensure that the pre-Raising the Bar patentability and specification requirements apply to those applications. The result of this is that there will not be any significant number of applications examined under the Raising the Bar provisions for several years. Further, it is unlikely that clarification of legal issues arising out of the Raising the Bar amendments by the Courts will take place within the next few years.

While it does makes sense to consider the effectiveness of the Raising the Bar Act at some stage, we consider that it will not be possible to effectively do so for some considerable period. It may well be that an understanding of the effectiveness of the Raising the Bar legislation cannot be obtained for some five years or more.

Draft Recommendation 7.2

The recommendation to establish an external patent oversight committee that is tasked with reviewing grants and decisions issued by IP Australia and auditing the processes involved in making such decisions would appear to introduce an unnecessary bureaucratic layer.

Draft Recommendation 8.1

FICPI Australia strongly disagrees with the recommendation that Government should take a more active role in managing the costs of PBS where a patent relating to a PBS-pharmaceutical is successfully challenged in the Courts by providing negotiated incentives for a party who successfully challenges such a patent.

FICPI Australia is of the view that it does not sit well at all for the Australian Government to on the one hand be the patent granting authority (through IP Australia) and to then on the other hand be financially supporting parties wishing to revoke patents it has granted. As the Panel will be well aware, there are already in existence compulsory licensing and Crown use provisions that enable patented technologies to be exploited by the Crown or by third parties under prescribed circumstances. Further, there is already provision for the Government (through the guise of the Commissioner of Patents) to re-examine accepted patent applications or granted patents, for example if information comes to light that places doubt upon the validity of the accepted or granted claims. In our opinion this is a preferable approach for the Government to take in cases where there are concerns as to the validity of patent claims.

Furthermore, it does not appear appropriate to suggest the adoption of a system that provides incentives for generic pharmaceutical manufacturers to challenge patents, where no such provisions would apply in the case of other industries. There are several other instances where it would be to the Government's benefit to invalidate patent claims of suppliers of products or services to the Commonwealth, such as suppliers of equipment to the Defence department or suppliers of telecommunications equipments for the National Broadband Network.

Draft Recommendation 8.2

FICPI Australia is not in principal opposed to the recommendation of providing a transparency register linking the therapeutic goods registered with the TGA with related patents. However, it is noted that while the introduction of such a register would be to the benefit of the generics industry there does not appear to be any benefit associated with the current recommendation for the originator pharmaceutical sector. FICPI Australia suggests that the adoption of a transparency register should also include a requirement that, at the very least, generic companies must notify the patentee of a relevant patent that they intend to seek regulatory approval in respect of a related product in Australia. This notification should be provided a period of time in advance of filing of the TGA application in order to ensure that the patentee has adequate time available to it to consider its position.

Should you have any questions in relation to these submissions please contact Greg Chambers, President of FICPI Australia and Australian delegate on the FICPI International Executive Committee. Greg can be contacted at:

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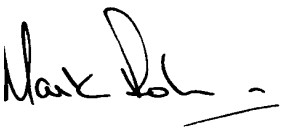
Yours faithfully



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