JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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Dear Terry Moore
Intellectual Property Australia
Australia

Re: JIPA Comments on the "Draft Report of Pharmaceutical Patents Review on March 31, 2013"

Dear Terry Moore:

The Japan Intellectual Property Association is a non-governmental organization that was established in Japan in 1938, which represents users of intellectual property systems, with about 900 major Japanese companies as members. When appropriate opportunities arise, we offer our opinions on the intellectual property systems of other countries and make recommendations for more effective implementation of the systems. (http://www.jipa.or.jp/english/index.html)

Having learned that the "Draft Report of Pharmaceutical Patents Review on March 31, 2013", on your website, we review your questions carefully and would like to submit our comments as follows. Your consideration on our comments would be greatly appreciated.

JIPA again thanks the Intellectual Property Office for this opportunity to provide these comments and welcomes any questions on them.

Sincerely, yours,

Hirofumi Ueda

(Hirofumi Ueda)
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Draft Recommendation 3.1

The Government should expeditiously seek a situation where Australia has strong yet parsimonious IP rights – that is, rights that are strongly enforced and that provide the incentive necessary to underpin an appropriate level of investment in innovation but that are not defined so broadly as to impose costs on innovation or other activity without commensurate benefits.

For instance such strong yet parsimonious IP rights could provide a desired level of incentive to invest in pharmaceutical innovation without preventing our industry from servicing offshore generic markets, as current law does. Australia should take a leadership role in seeking consensus with jurisdictions with similar interests to identify and pursue a range of changes in international patent law and practice along these lines.

Our comments:

We highly appreciate that the Government is seeking a consensus with other jurisdictions with respect to patent laws for world-wide patients awaiting innovative pharmaceutical products with an aim to contribute to the development of the pharmaceutical industry around the world.

Draft Recommendation 3.2

The Government should ensure that future trade negotiations and renegotiations are based on a sound and strategic economic understanding of the costs and benefits to Australia and the world and of the impacts of current and proposed IP provisions, both for Australia and other parties to the negotiations. The Government should strongly resist changes – such as retrospective extensions of patent rights – which are likely to reduce world economic welfare and lead other countries in opposing such measures.

Our comments:

We find it difficult to understand the Government's opposition to the pro-patent policies, including the changes to the patent term extension system.

The number of compounds synthesized and costs incurred by patentees at the discovery research stage to find out candidate compounds for pharmaceutical products which are eligible for preclinical trials have doubled compared with ten years ago. Moreover, an average development period of 9.2 years and near to 72.7 billion yen are required for placing one new drug on the market after a candidate compound for a pharmaceutical product has been discovered and approved for manufacture as a pharmaceutical product. Furthermore, the patentees are assuming a huge investment risk, where only three out of ten pharmaceutical products which have overcome the abovementioned difficulties and have been placed on the market are capable of revovering the R&D investments made therein (Tufts Center for the Study of Drug Development, NCE Database, 1999). On the other hand, generic manufacturers are deemed as pharmaceutical makers with less investment risk both in terms of time and money, i.e. investment for two or three years which is an extremely shorter period of time

compared to that required for the above-mentioned patentees and in an amount of a few tens of millions yen, which is much less than the amount incurred by patentees.
Developed countries, including Japan, the United States, and Europe, provide the patent term extension system by taking into consideration the above-mentioned circumstances and the balance between the interests of the patentee and the public. Such system does not appear to be disrupting the balance between costs and benefits or hindering the economic development of countries around the world.
We have no doubt that many Australian patients are benefiting from new drugs created by patentees at a huge R&D cost. The Government should consider the fact that if the patentees' incentives to create new drugs are impaired, not only Australian patients would be deprived of the opportunity to receive the benefit of new drugs, but also generic manufacturers would lose their business opportunities.

Draft Recommendation 4.1
As an interim measure, the Government should actively seek the agreement of the owners of Australian pharmaceutical patents to voluntarily agree not to enforce their patents in respect of manufacturing for export.
Our comments:
As long as the owners of Australian pharmaceutical patents are allowed to enforce their patents in respect to the manufacture for exportation under the Australian Patents Act, they should not be deprived of the freedom to enforce their rights, and the decision on such enforcement should be left to them. Moreover, we believe that above-mentioned Recommendation 4.1 is against the spirit of Article 27 of the Agreement of Trade-Related Aspects of Intellectual Property Rights (TRIPS), which does not allow any discrimination on the basis of the type of invention.

Draft Recommendation 5
Option 5.1
The current model of using the patents system to subsidise pharmaceutical R&D indirectly should be replaced with a direct subsidy. To this end, the Government should reduce extensions of term for pharmaceutical patents and use part of the associated savings to fund R&D directly. Some of this funding should be targeted to socially beneficial research for which patents provide inadequate incentives to conduct. Such areas include new antibiotics which, once developed, must be used as sparingly as possible to prevent the development of antibodies and pharmaceuticals to address rare diseases, paediatric illnesses and endemic health issues in low income countries.

This option could also include an annual review of the savings delivered through any reduction in the length of extensions of term to be used in allocating funding to the replacement R&D subsidies.

Our comments:

It remains unclear as to what extent the subsidy system proposed by the Government would support the R&D costs borne by pharmaceutical companies around the world. Although the Government's proposal to subsidise R&D made in areas receiving less attention than others, such as antibiotics, is preferable, it should not be discussed in conjunction with the issue of extension of patent terms. This is based on the understanding that if no incentives (e.g. extension of patent terms) are given to the development of pharmaceuticals of advanced fields, such as antibody drugs, in Australia, Australian patients would gain less opportunity to receive advanced medical treatment by such pharmaceuticals of advanced fields.

Moreover, we find an obvious contradiction between the patent term extension system which has been originally provided for to cover the detriment incurred by the patentee for not being able to work the invention, and above-mentioned recommendation 5.1, which requires a reduction to such period.

Draft Recommendation 5

Option 5.2

The Government should change the current extension of term provisions such that patents receiving an extension of term in Australia will not expire later than the equivalent patents in major trading partners.

Potential ways of achieving this include:

(a) Providing an extension expiring up to 5 years after the original patent term or upon the expiry of the equivalent patent extension in one of a list of other jurisdictions including the United States and European Union.

This option ensures Australian extended patents would not expire later than equivalent patents elsewhere. If originators are unable to seek regulatory approval in Australia at the same time as elsewhere, this option would reduce the effective patent life.

(b) Changing the method of calculating the length extensions of term to provide an incentive to submit applications for regulatory approval in Australia earlier than is currently the practice. This could be similar to the US method described above.

This option creates an incentive to seek regulatory approval in Australia as soon as possible, reducing delays in access to medicines for Australian health consumers. Under this system, one-to-one compensation is still provided for the time taken to

process applications for regulatory approval.

Our comments:

We support the above-mentioned option to provide an extension of up to 5 years after the original patent term. However, due to the variation in the approval process in each country and the R&D timeline of each development company with respect to the clinical development of new drugs, it is doubtful whether patentees can sufficiently revover the R&D costs necessary for the acquisition of approval in each country in the following cases: (i) where the patent term extension in Australia is made equivalent to that of other countries as mentioned in (a) above; and (ii) where Australia adopts the US method of calculating the length extensions of term as mentioned in (b) above. If patentees are unable to sufficiently recover R&D costs, the patentees' incentives to create new drugs might be impaired, and consequently, Australian health consumers may lose access to medicines.

Draft Recommendation 6.1

The Government should maintain the current approach that allows extensions for drugs and formulations but not for methods of use and manufacture, which will continue to provide an incentive for the development and supply of active pharmaceutical ingredients and new formulations, without adding to the existing cost of medicines in Australia.

Our comments:

As we mentioned in the public comment we provided previously, inventions of new use of active ingredients and new formulation of its product should be covered by the patent term extension system as in Japan. If these inventions are covered by such a system, incentives for development of new pharmaceutical products would be built, and thereby, improved and superior pharmaceutical products would be provided to the patients in need of them.

Draft Recommendation 6.2

Section 76A of the Patents Act should be deleted. The Pharmaceutical System Coordinating Committee recommended in Draft Recommendation 10.1 should consider whether a mechanism for reporting on the use of public and private research funds in pharmaceutical R&D, similar to that established by the PMPRB and superior to s.76A, can and should be developed.

Our comments:

Australia should keep in step with other countries for reasons such that the amount of R&D costs is highly confidential information for pharmaceutical companies and that the reporting of R&D costs is not required in countries other than Australia upon applying for an extension of a patent term.

Draft Recommendation 6.3

Section 70(3) should be amended to clarify that the ARTG registration on which an extension of term is based is that of the relevant product, the use of which would infringe the claim. The Panel requests feedback from stakeholders on the effects of clarifying the legislation in this manner.

Our comments:

We agree with the amendment of Section 70(3) of the Australian Patents Act because clarifying for what type of pharmaceutical product or the use thereof the patent term extension has been allowed will make it easier for third parties to make a judgment on infringement or non-infringement. Yet, the patentees should not face unpredictable disadvantages due to the strict requirement on the full identity between the use of the relevant invention stated in the description of the patent and the approved use. Unpredictable infringement lawsuits would not only increase the burden on monetary and human resources but would also cause a heavy loss to the patentees, generic manufacturers, and Australia in general.

Draft Recommendation 6.4

Section 117 of the Patents Act 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. Policy should further impose a presumption that "reasonable steps" have been taken where the product has been labeled with indications which do not include any infringing indications

Our comments:

We find it appropriate to label pharmaceutical products with indications to make it easier to make a judgment on patent infringement or non-infringement of pharmaceutical products. Yet, as mentioned above, the patentees should not face unpredictable disadvantages due to the strict requirement on the full identity between the indication stated in the description of the relevant patent and the indication of the relevant label. Unpredictable infringement lawsuits would not only increase the burden on monetary and human resources but would also cause a heavy loss to the patentees, generic manufacturers, and Australia in general.

Draft Recommendation 7.1

The Government should ask the Productivity Commission to review the effectiveness of Raising the Bar Act at the earliest opportunity and not later than three years from the commencement of the Act.

Our comments:

No comment.

Draft Recommendation 7.2

The Government should 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.

Our comments:

We find it meaningful to establish the practice of review by an external patent oversight committee to enhance the accuracy and swiftness of the granting of patents or decisions relating thereto. Yet, patent examinations should be an exclusive prerogative of the patent office, and one should be reminded that unnecessary delay in examinations due to the involvement of an external patent oversight committee would result in a waste of monetary and human resources.

Draft Recommendation 8.1

As the party that 'internalises' the most benefits of a successful challenge to a patent for a product on the PBS, the Government should take a more active role in managing the cost of the PBS where a patent relating to a PBS-listed pharmaceutical is successfully challenged in the courts. This could involve ensuring that the Government recoups more of the cost to the PBS arising from delayed generic entry.

It should also include implementing measures to reduce disincentives for generic manufacturers to challenge patents by providing negotiated incentives for a party who successfully challenges a patent.

Our comments:

No comment.

Draft Recommendation 8.2

A transparency register linking therapeutic goods registered with the TGA with related patents should be introduced.

Our comments:

No comment.

Draft Recommendation 9.1

The Government should actively contribute to the development of an internationally coordinated and harmonised system where data protection is provided in exchange for the publication of clinical trial data.

Our comments:

We endorse this recommendation because the data protection period is an extremely important element for patentees to recover the huge R&D investments made, as is the case with the patent term. Moreover, we find that the data protection period should be at least eight years, which is allowed in Japan, and that the ten-year period allowed in Europe is most reasonable for the recovery of R&D investments made. Regarding orphan drugs and paediatric indication, an additional data exclusivity period is

necessitated for keeping an incentive for clinical development

Draft Recommendation 10.1

The Government should establish a non-statutory Pharmaceutical System Coordinating Committee (PSCC) that reports to Parliament on an annual basis on the success and effectiveness of the patent, marketing approval and PBS systems, particularly where these interface. The PSCC should ensure there is sufficient engagement and coordination between the relevant agencies and take account of costs to government, efficiency of registration and approval processes and respond to issues raised by industry. The PSCC should comprise senior officials from at least DIICCSRTE, IP Australia, DoHA (Pharmaceutical Benefits Division and TGA), DFAT, Finance and Treasury (as chair).

Our comments:

No comment.

Draft Recommendation 10.2

When drafting the objects clause to be inserted in the Patents Act, as agreed to in the Government's response to the Senate Community Affairs Committee's Gene Patents report, the Government should take into account that the purpose of the legislation is to:

- further Australia's national interest and enhance the well-being of Australians, including by providing reasonable access to healthcare; and
- provide strong, targeted IP protection - but only up to the point at which the costs (to consumers and the impediment of 'follow on innovation') are no greater than the benefits of incentivising innovation that would otherwise not occur.

Our comments:

No comment.

Draft findings

Draft finding 3.1

In their negotiation of international agreement, Australian Governments have lacked strategic intent, been too passive in their IP negotiations, and given insufficient attention to domestic IP interests.

For example, preventing MFE appears to have deprived the Australian economy of billions of dollars of export revenue from Australian based generic manufactures. Yet allowing this to occur would have generated negligible costs for Australian patentees.

The Government does not appear to have a positive agenda regarding the IP chapters of the TPP Agreement which comprehends national and regional economic interests.

The Government has rightly agreed to only include IP provisions in bilateral and regional trade agreements where economic analysis has demonstrated net benefits, however this policy has not always been followed.

Our comments:

No comment.

Draft finding 4.1

Governments appear to have shown little strategic interest in the issue of MFE, despite a number of opportunities to do so and the significant potential advantages MFE could provide for Australia. If MFE had been rendered unambiguously consistent with our international obligations, it is likely that Australia's annual pharmaceutical exports would have been several hundreds of millions of dollars higher than they are.

Our comments:

No comment.

Draft finding 9.1

The Panel considered whether data protection should be increased for biologics. The Panel is unconvinced that an extension of data protection would be beneficial. The Panel found no evidence to suggest that patents for biologics will be more difficult to obtain than patents for small molecule drugs, or that effective patent life would be substantially reduced by the complexity of biologics.

Additionally, given that the generic manufacturer of a biosimilar cannot rely solely on the clinical data of the reference product to obtain regulatory approval, there is reduced advantage to be gained from granting an additional term of data protection.

The Panel is of the view that given the substantial market opportunity that will arise in the near future for biosimilars, and the corresponding potential for cost savings to the PBS and consumers, competition in this area should be encouraged. At present the Panel does not have sufficient evidence to support an increase in data protection beyond the current five year period for biologics.

Our comments:

We consider that not less than eight years of data protection as provided in Japan, and preferably ten years of such protection as provided in Europe, should at least be given to bilogics that require clinical trials and a huge amount of equipment investment, regardless of whether they are brand drugs or generics. It is desirable for the approval standards of various countries to be harmonized in the future.

Draft finding 10.1

The patent system is of obvious significance to the pharmaceutical industry, trade negotiations and health policy. However, the government agencies with policy and program responsibility in these areas are not engaging sufficiently with each other and are not taking highly relevant issues into account. Each agency needs to be actively engaging from its own perspective – end users, innovation, industry and international implications – in order to optimise policy settings for the pharmaceutical system in what is a complex regulatory and service delivery environment. The areas of government responsible for regulating pricing of pharmaceuticals particularly have the need for and the resources to obtain a well-informed appreciation of the pharmaceutical patent system and its impact on a range of health issues. However, the only area in which they appear to have a strong view is in relation to gene patents.

Our comments:

No comment.