

Via email: [sean.applegate@ipaaustralia.gov.au](mailto:sean.applegate@ipaaustralia.gov.au)

Mr Sean Applegate  
Domestic Policy  
IP Australia  
P O Box 200  
Woden ACT 2606

Dear Mr Applegate,

**Consultation Paper concerning the TRIPS Protocol for implementation of compulsory licences to produce patented pharmaceutical products for export to least-developed and developing countries in case of public health crisis**

I have pleasure in enclosing a submission which has been prepared by the Intellectual Property Committee of the Business Law Section of the Law Council of Australia (IPC) in response to IP Australia's consultation paper issued in April 2010.

The submission has been endorsed by the Business Law Section. Owing to time constraints, the submission has not been reviewed by the Directors of the Law Council of Australia.

If you have any questions regarding this submission, please contact either the Committee Chair, Maurice Gonsalves, on 02-9296 2166 or Ian Pascarl on 03-9254 2567.

Yours sincerely,

  
Margery Nicoll  
**Deputy Secretary-General**

23 June 2010

Enc.

*Law Council of Australia, Business Law Section,  
Intellectual Property Committee,*

*Submissions in Response*

to

**IP Australia Consultation Paper concerning the TRIPS Protocol for  
implementation of compulsory licences to produce patented  
pharmaceutical products for export to least-developed and developing  
countries in cases of public health crisis.**

**Introduction**

The Intellectual Property Committee of the Business Law Section of the Law Council of Australia (**IPC**) welcomes the opportunity to comment on the IP Australia Consultation Paper entitled "Implementing the TRIPS Protocol" dated April 2010 ("**the consultation paper**").

*Proposal 1*

The patent legislation is to provide that the Commissioner of Patents has the power to issue compulsory licence(s), including the power to amend issued licences(s), under the TRIPS Protocol system.

The IPC considers that the power to issue, amend and deal with all other issues relating to compulsory licence(s) under the TRIPS Protocol ("**the protocol**") should be vested in the Federal Court of Australia ("**the Court**"). The IPC's reasons are as follows:-

- (a) Chapter 12 of the *Patents Act 1990* ("**the Act**") vests in the Court the power to order compulsory licence(s) under the Act. Section 133 of the Act requires that essentially the same criteria stipulated by the protocol be met before making an order requiring the patentee to grant a compulsory licence to work the patented invention. Although there have been very few compulsory licence applications made and granted in Australia, IPC believes the Court is clearly best equipped to consider and determine whether the requisite criteria have been satisfied under the protocol. The Court makes similar judicial determinations in other areas of substantive law, such as under the *Trade Practices Act 1974* (Cth), and consequently can also bring to the task the experience gained in relation to these other areas of substantive law.
- (b) Chapter 12 of the Act requires the Court to direct the imposition of certain conditions, and empowers the Court to impose any other conditions it considers appropriate. The protocol mandates that any compulsory licence(s) must contain certain conditions and again IPC considers that the Court is best equipped to ensure these conditions are clearly expressed in the order so that policing and enforcement can be properly and effectively undertaken.

- (c) Section 133 of the Act empowers the Court, in the absence of agreement between the parties, to determine just and reasonable compensation to be paid to the patentee. Clearly, having considered the issues relevant to the grant of a compulsory licence, and the conditions to be imposed, the Court is as well informed as it could be to determine just and reasonable compensation. Moreover, Federal Court judges are experienced in making compensation and damages assessments and can apply that experience in determining S133 applications.

The consultation paper recommends the Court should determine adequate remuneration if the parties cannot agree. However, if the consultation paper proposals were fully accepted, the Court would be required to do so without the advantage of having considered the issues relevant to the determination of the grant of a licence and the imposition of terms. That task would, under the consultation paper proposal, be undertaken by the Commissioner of Patents ("**the Commissioner**"). The IPC considers in order for the Court to properly determine remuneration it would be greatly advantaged by having previously determined whether or not a compulsory licence(s) should be ordered, and if so, the terms and conditions to be imposed.

- (d) Section 133 of the Act empowers the Court to revoke a compulsory licence(s) if the parties agree, or the circumstances that justified the granting of the compulsory licence(s) have ceased to exist and are unlikely to recur.

Chapter 12 of the Act does not expressly provide a sanction for failure to comply with conditions set by the Court under Section 133(3), although Section 133(6) probably empowers the Court to revoke a compulsory licence(s) under such circumstances. However, should proposal 6.2 of the consultation paper be enacted expressly providing for revocation of a compulsory licence(s) should a term of the licence(s) be breached, IPC again submits the Court is best equipped to consider the issue of breach, and make a determination with the force of a Court Order.

- (e) The reasons advanced by the consultation paper for proposing the Commissioner should determine whether or not a compulsory licence(s) should be issued, and on what terms, are that it would be "faster, cheaper, and a simpler application process". However, IPC submits that:-

- it is far more important to ensure that the tribunal best equipped to determine the issue actually determines the issue and that tribunal is in IPC's submission the Court.
- that the Court has the procedural machinery to enable it to consider and determine cases quickly and efficiently. Many examples can be given of urgent cases being brought to the attention of a registrar of the Court, and the docket or another judge allocated to hear the matter immediately, a decision made, and if necessary an Appeal Court expeditiously assembled to deal with any appeal.
- IPC considers that the cost of any such application is likely to be similar whether heard by the Court or the Commissioner. The parties are likely to be represented whether the application is made to the Court or the Commissioner.

The material upon which the parties will rely will be the same and therefore the cost of preparation of the material will be the same. The length of the hearing is likely to be similar and, if so, the cost similar.

- (f) The consultation paper recommends that appeals from decisions of the Commissioner be made to the Administrative Appeals Tribunal. The Court appeal process has the advantage of judges experienced in appellate matters determining any appeal from a single judge and, as stated above, in cases of urgency, the Court has demonstrated it can assemble an Appeal Court very quickly to hear and determine an appeal.

### **Proposals 2 – 10 both inclusive**

IPC's comments in response to proposal 1 of the consultation paper obviously to a large extent, determines its responses to proposals 2 – 10. For completeness, IPC will now respond specifically to proposals 2 – 10 and apologises in advance for a degree of repetition.

#### *Proposal 2*

The patent legislation is to define the products covered by the system as per the Protocol definition. That is, any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems afflicting many developing and least-developed countries. This includes active ingredients necessary for its manufacture and diagnostic kits need for its use. Specific products are not to be listed in the Australian legislation.

IPC agrees with this proposal.

#### *Proposal 3*

The patent legislation is to provide that eligibility to import pharmaceuticals under the system will not be limited to World Trade Organisation (WTO) membership. Least-developed countries are automatically an eligible importing country. Countries that are not a least-developed country must make the required notification of their intention to use the system. Other legal entities are also eligible, provided that the authorisation of the eligible importing country is demonstrated.

Additional obligations may need to be placed on non-WTO members through the terms of the compulsory licence to ensure sufficient anti-diversionary measures are enacted.

IPC agrees with this proposal.

### *Proposal 4.1*

The patent legislation is to provide that a compulsory licence may only be granted under the system if the proposed licensee has made efforts to obtain authorisation from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the case of a national emergency, or other circumstances of extreme urgency or in cases of public non-commercial use. The patent owner shall be notified as soon as practicable in a national emergency, or other circumstances of extreme urgency. In the case of public non-commercial use, the patent owner shall be informed promptly.

IP Australia proposes that the applicant who seeks the licence should provide documentary evidence to the Commissioner establishing that other circumstances of extreme urgency exists in the eligible importing country or that a national emergency exists. IP Australia will consider this documentary evidence in determining whether the requirement for prior negotiation efforts with the patent owner can be waived.

Firstly, IPC considers the Court, not the Commissioner, should determine these issues.

Secondly, in relation to the waiver of the requirement for prior efforts to have been made to agree reasonable commercial terms and conditions within a reasonable period, IPC considers the Court could determine without difficulty if a national emergency or other circumstances of extreme urgency exist. Presumably, any tribunal considering the waiver issue will be presented with evidence of the conditions in the importing country that are asserted amount to a national emergency or extreme urgency, the tribunal will then weigh up the evidence and decide if those conditions for waiver are satisfied based on common general knowledge and precedent. As to precedent, IPC considers the Court best equipped to consider and apply decisions made under other Australian legislation defining states of emergency and extreme urgency.

Thirdly the term "public non-commercial use" appears in TRIPS Article 31, but is not defined in TRIPS. A number of commentators have commented upon this term in Article 31 of TRIPS and have suggested that it is likely to refer to some type of legitimate government or non-government organisation function within the importing country. However, it appears from point 12 of the consultation paper, last sentence, that the term "public non-commercial use" is intended by this proposal to be the conditions stipulated in Section 135(1) of the Act. Proceeding on that assumption, IPC again considers the Court should continue to be the tribunal to consider and determine whether such a condition is satisfied.

### *Proposal 4.2*

The patent legislation is to provide that the Commissioner of Patents must be satisfied that the importing country has provided the TRIPS Council with the appropriate notification before issuing a licence under the system. The publication on the WTO website of the importing country's notification to the TRIPS Council is deemed to be sufficient evidence of the importing country fulfilling this obligation. Importing countries that are not WTO Members must provide the same information, but this maybe provided directly to the Commissioner. The Commissioner may require other information to be provided as she sees fit.

IPC agrees with this proposal except that the Court should be substituted for the Commissioner.

*Proposal 5.1*

The patent legislation is to require that licences issued under the system include the minimum conditions mandated under the TRIPS Protocol (see subparagraph 2(b) of the new Annex to the TRIPS Agreement). The amount of product to be manufactured, the duration of the licence and any details of the labelling of the product would be determined by the Commissioner of Patents on a case by case basis. Further, the Commissioner would have a power to:

- determine the amount of pharmaceutical product to be exported based on the public health needs of the eligible importing country;
- determine and specify more detailed product labelling requirements as he or she sees fit; and
- determine what information, in addition to those under subparagraph 2(b), must be published or supplied by the licensee, and how that information must be published or supplied.

IPC agrees with this proposal except that the Court should be substituted for the Commissioner.

*Proposal 5.2*

The patent legislation is to require that, where a licence is granted by Australia under the system, the licensee shall pay adequate remuneration to the patent owner, taking into account the economic value to the importing country of the use that has been authorised (see paragraph 2 of Article 31*bis* of the Protocol). Where parties cannot agree on the remuneration, the remuneration is to be determined by the court.

IPC agrees with this proposal and reiterates that in determining adequate remuneration it is important that the Court have the advantage of having considered and determined the application for the compulsory licence.

*Proposal 5.3*

The patent legislation is to require that the Australian Government must notify the TRIPS Council of the issuing of a licence under the system and the associated details stipulated in the Protocol (see subparagraph 2(c) of the new Annex to the TRIPS Agreement).

IP Australia intends to publish the details of the grant of the licence on its website.

IPC agrees with this proposal except the details of the grant should be, consistent with earlier submissions, published on the Court website.

*Proposal 6.1*

The patent legislation is to provide that the decision of the Commissioner of Patents to issue or refuse to issue a compulsory licence under the Protocol system may be appealed to the Administrative Appeals Tribunal. An issued licence would stand pending the outcome of any court challenge to its validity.

IPC considers the Court should determine whether or not to issue a compulsory licence and that any appeal should then be made to the Full Court of the Court. Otherwise, IPC is content for the licence to stand pending the outcome of the appeal consistent with established law that the judgment below stands, unless stayed, until overturned on appeal.

*Proposal 6.2*

The patent legislation is to provide that compulsory licences granted under the system may be revoked by the Commissioner of Patents if a term of the licence is breached.

IPC considers that revocation of the compulsory licence for breach of a term, or for any other reason, should be determined by the Court. IPC also queries whether the Commissioner would be acting administratively or judicially if proposal 6.2 were implemented. Obviously, if it were properly termed a judicial act, pursuant to Section 71 of The Constitution, such an act can only be exercised by a Chapter III Court.

*Proposal 6.3*

Interlocutory injunctions to prevent a person from engaging in allegedly infringing conduct until the matter is resolved by a court or between the parties will be available in relation to licences granted under the system according to the current criteria for such injunctions. In deciding whether an injunction should be granted, courts should also consider the impact on the importing country's public health situation.

Clearly the Court is empowered to consider and determine applications for injunctive relief.

*Query 1*

Should the exemption from having to list a therapeutic good on the Australian Register of Therapeutic Goods be clarified by way of an amendment to the Therapeutic Goods Regulation or some other procedural or policy document provided by the Therapeutic Goods Administration?

IPC does not wish to comment on this issue.

*Proposal 7*

The patent legislation is to provide that, amongst other requirements, a compulsory licence may only be granted under the Protocol system in cases of public non-commercial use, national emergency, or circumstances of extreme urgency.

IPC agrees with this proposal, subject to public non-commercial use being defined in the terms of the last sentence of point 12 of the consultation paper.

**Conclusion**

IPC trusts that this submission is of assistance and would be happy to clarify or expand upon any aspect of it if required.