IPTA | THE INSTITUTE OF PATENT AND TRADE MARK ATTORNEYS OF AUSTRALIA

FICPI AUSTRALIA

28 September 2012

By E-mail ONLY
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Compulsory Licensing of Patents
Productivity Commission
LB 2 Collins Street East
Melbourne, Victoria 8003

Attention: Delwyn Lanning

Re: Submission by IPTA and FICPI in relation to enquiry by Productivity Commission into compulsory licensing of patents

Dear Sirs,

These submissions are made on behalf of Institute of Patent and Trade Mark Attorneys ("***IPTA***") and FICPI Australia ("***FICPI***").

1. The Institute of Patent and Trade Mark Attorneys ("***IPTA***") represents patent attorneys and trade mark attorneys in Australia. The Australian Federation of Intellectual Property Attorneys known as FICPI Australia ("***FICPI***") is an organisation working for the interests of patent and trade mark professionals world-wide. Importantly for present purposes, members of IPTA and FICPI draft patent specifications for the simplest to the most complex inventions and for the single independent inventor through to the largest of multi-national companies. They are often involved in designing research projects for clients in order to establish the extent to which claims to a new invention can be made. Many are involved in the development of patent strategies, the management of patent portfolios and the commercialisation of patents. This intimate involvement with the client on the one and the patent system on the other places patent attorneys in a unique position to understand how the system influences business decisions.

2. IPTA and FICPI support a strong patent system for Australia in which there are high standards of examination, an efficient and effective application process and granted patents are respected throughout the world for their robustness.

The Rationale for the Patent System

3. As the Issues Paper acknowledges, it is generally accepted that the patent system provides public benefits by stimulating investment in innovation and the commercialisation of the results of innovation. It does this by creating a piece of property comprised of specific exclusive rights with a limited life. This piece of property can be bought and sold, licensed on a wide variety of terms and mortgaged

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among other possible commercial dealings. The attraction of access to this piece of property is that it assists the person or people who have invested time, effort and money in creating the invention or innovation which is the core of the patent to make a return on that investment through the right to exclude others from that invention or innovation. In short, the grant of a patent stops or can be used to stop others from "free riding" on the investment made for a limited period of time.

4. In some cases, as the Commission would be aware, particularly in the pharmaceutical industry, that investment can be significant. In a study conducted in October, 2006 by the Congressional Budget Office of the Congress of the United States, the figure of US$802 million was put (citing a study in 2000 by Joseph DiMasi, Ronald Hansen and Henry Grabowski "The price of innovation: New estimates of drug development costs" Journal of Health Economics, Volume 22 Number 2 (March 2003) pp 151-185") as the estimated average cost of successfully developing a new molecular entity, including research and development spending on failed drug projects. The average direct research and development cost of an incrementally modified drug was said to be no more than one quarter of that cost. It should also be noted that recent estimates have placed the costs associated with developing a new drug to be somewhere in the vicinity of US$1.3 to US$4.5 billion, depending on how the actual costs incurred by pharmaceutical companies are assessed (See Science Based Medicine, “Exploring Issues and Controversies in the Relationship Between Science and Medicine”, Scott Gavura, 14 April 2011 and Forbes.com LLC “The Truly Staggering Cost of Inventing New Drugs”, Matthew Herper, 10 February 2012). In any case, the investment is huge by any standards.

5. The pharmaceutical industry is also characterised by long lead times between conception and commercialisation and a high attrition rate during the process. It is true that the pharmaceutical industry is not necessarily indicative of all industries for which patents may be relevant. However, it has been raised as an issue in the questions asked of the Commission. In any event, the patent system must cater equally for the development of complex and costly technologies as well as the more straightforward in terms of complexity and requirements for commercialisation. Thus, in order to do its job effectively, the patent system must be robust and patentees and investors must be given an adequate opportunity to make a significant return on investment which will encourage further innovation. Furthermore, the price which an inventor pays, in addition to time, money and effort, to make an invention and then pursue a patent in respect of it, is publication of the invention. That knowledge then forms the basis for further research both by the inventor and others who wish to build on the invention or, perhaps, work around it.

6. Furthermore, a point which needs to be borne in mind is that the existence of a patent does not equate to market power of any particular strength. As the Commission would be aware, a market in economic terms "…is the area of close competition between firms, or putting it a little differently, the field of rivalry between them…Within the bounds of a market there is substitution – substitution between one product and another, and between one source of supply and another, in response to changing prices. So a market is the field of actual and potential transactions between buyers and sellers amongst whom there can be strong substitution, at least in the long run, if given a sufficient price incentive….It is the possibilities of such substitution which set the limits upon a firm's ability to "again give less and charge more"…In the language of economics, the question is this: From which products and which activities could we expect a relatively high demand or supply response to price change, i.e., a relatively high cross-elasticity of demand or cross-elasticity of supply?" (Re: Queensland Co-operative Milling Association Limited; re Defiance Holdings Ltd (1976) 25 FLR 169 and approved by the High Court in Queensland Wire Industries Pty Ltd v Broken Hill Pty Co. Ltd (1989) 167 CLR 177).

7. In this market, a patent is likely to be relevant to only one new product or process given that pre-existing products or processes would form part of the prior art base against which the new patent was assessed and which would not be subject matter which could be embraced by the new claims. Neither IPTA nor FICPI are aware of a market situation where there is a single product market in which the single product is covered by a patent. In any event, even if that were to be the case, in the medium term, being the remaining life of such a patent, the disclosure of the product or process and the charging of "monopoly" profits by the participant in the market which has access to the patent, acts as a spur to the development of substitutable products and processes.

8. Furthermore, it is also important to bear in mind the return on investment which is needed to make this spur to investment a reality is generally made over a period of years less than the remaining life of a relevant patent. This is because the period from conception to commercialisation can take up a substantial proportion of the life of a patent. That period over which a return on investment must be made can also be heavily influenced by the ease by which competing products or processes can be introduced or perhaps already exist in the market.

9. Finally, it is also important to understand that, in many cases, the cost of research which leads to invention is very often much less than the cost of commercialisation. Obviously, the more regulated the industry, the more costly commercialisation will be. Thus, the role of the patent system is not only to protect inventors from persons free riding on their invention but also to prevent third parties from free riding on the investment made by those who are taking on the role of commercialisers. The grant of a compulsory licence also comes after the investment decision has been made. Thus, the expenditure which has been made to develop, say a new drug, could be rendered in part irrevocable by the grant of a compulsory licence. For this reason, country which is known as a country which countenances the issuing of compulsory licences, especially on a less rigorous basis, would be assessed as having weak patent legislation. This could have ramifications for future investment in the country.

10. The point of this is that in order to fulfil the role of encouraging and protecting investment in research and development of new products and processes, the piece of property which is created when a patent is granted must be as robust and certain as possible. Any diminution of the strength of the exclusive rights which comprise a patent adversely affects the decision which researchers and, perhaps more importantly, investors will make when assessing whether to engage in research or invest in either research or development of new products or processes. As will be commented on below, compulsory licensing provisions introduce uncertainty into the ability of a patentee to control use or non use of a patent.

11. In a paper delivered to the British Institute of International and Comparative Law, the Deputy Assistant Attorney General of the Anti-Trust Division of the US Department of Justice, Makan Delrahim made the following comments:

> "When uncertainty increases, innovation often decreases, which is exactly the opposite of what should be the long term goal of competition law….There are important policy reasons to cause us to be cautious when considering a compulsory licensing remedy. The most important of these is the concern that an improperly designed compulsory licence can stifle innovation.
>
> Some of the risks being taken by today's innovators are massive; with rewards systems that may be very fragile and that could potentially be destroyed by over-aggressive anti-trust remedies…We don't want to kill the goose that lays the golden egg."

Balancing the interests

12. The long term interest of the wider public is to have an efficient patent system which continually produces advancements in knowledge and new products and processes for the benefit of the economy as part of a competitive process. The legislature has effectively set the long term as 20 years being the period over which the exclusive rights given by a patent persist.

13. IPTA and FICPI would be concerned if as a result of this inquiry any recommendation was made which was designed to make compulsory licences "easier" to obtain for the sake of the short term interest in having a new product or process available earlier than might otherwise be the case, since this will necessarily result in a reduction in the incentive to make an investment in the first place.

14. The compulsory licence regime is, in a sense, a balancing act between the long term interests of the public, inventors and investors and the short term interests of the public. Any dealing with the short term interests of the public should not detract from the overall long term goal of the system which is to encourage investment in research and development. In assessing the compulsory licensing provisions, IPTA and FICPI submit that the assessment must take place in the wider context of what the system delivers in the long term.

15. It is against this background that IPTA and FICPI provide the following responses to and comments on the matters raised in the Issues Paper. In order to assist the Commission in its consideration of the matters raised, this response will be to the specific questions asked on the pages indicated in the Issues Paper.

Page 5: Incentives to Licence

16. In very general terms, the incentives to licence a patented invention include:

    1. To create an income stream or an additional income stream;
    2. To spread the risk associated with commercialisation;
    3. To avoid development and other costs associated with commercialisation;
    4. To resolve or stave off a dispute; and
    5. To enable technology transfer and third party product development.

17. The extent to which these incentives play a role in any particular case will depend upon the business and market context in which they play out. There is no general rule that any of these incentives are industry specific nor, for that matter, dependent upon firm size. However, it is probably true to say that the incentive to licence is much greater in the case of academic and research institutions and small firms where development costs are high, development expertise might be lacking and the capacity to penetrate a market is lacking. Also in very general terms, in industries where development costs are high (such as the pharmaceutical industry), the incentive to share the risks associated with the development of new drugs has led to a variety of cross-licensing arrangements, strategic alliances and co-marketing agreements. However, any licensing decision will be the product of the total environment within which the decision is made.

18. Licensing must be analysed in the context of a business strategy. It is not a solution or panacea for all situations. While licensing can provide a patentee with cheap entry into a market, this is generally at the cost of a loss of some control over its operations. Similarly, licensing can provide a rights owner with an additional income stream but perhaps at the risk of developing a new competitor in relation to the rights licensed. The business considerations behind the decision to give or take a licence

will play a large part in determining the terms and conditions of the licensing arrangement.

19. Licensing has been called a "value extraction mechanism" for intellectual assets. See: "*The LESI Guide to Licensing Best Practices – Strategic Issues and Contemporary Realities*" *LES International, John Wiley & Sons, page 11*. Other value extraction mechanisms include strategic alliances, joint ventures and commercialisation by the rights owner. Whilst these value extraction mechanisms are not mutually exclusive to any situation, each offers particular advantages to particular situations.

20. If a patentee intends to commercialise an innovation itself, it not only needs the appropriate rights but also needs the necessary financial resources, any necessary complementary assets, the relevant core competencies and either an existing market position with appropriate distribution channels or the opportunity to secure those. There will be an incentive to deal with third parties if any of these elements is missing. Ultimately, the type of arrangement which is appropriate will be the one which fits in best with the patentee's overall business strategy.

Page 5: Refusals to Licence

21. The reasons why a patentee might refuse to licence an invention would include such reasons as a desire not to create a competitor (although field of use licensing might deal with this concern), the availability internally of the resources needed to fully complete the development and commercialisation process itself, the time and effort required to negotiate and administer a licence agreement and a consideration of the capabilities and resources of interested potential licensees.

Page 5: The OECD Survey

22. Neither IPTA nor FICPI is aware of any similar study which might have been undertaken in Australia. However, IPTA and FICPI do not take issue with any of the conclusions reached in the survey and believes that the conclusion that "licensing markets are less developed than they could be" would equally apply in Australia. As is noted in the following section, the difficulty in finding a licensee is a major obstacle facing would be licensors.

Page 6: The process of licensing

23. The vast majority of patent licence agreements entered into in Australia would be voluntarily negotiated. Furthermore, IPTA and FICPI believe that most patent licences would also deal with the transfer of unpatented technology such as "know how".

24. As a general comment, there would be far more patentees who are unsuccessful in seeking a licensee in Australia than there would be patentees entering into licensing arrangements. One of the major obstacles for patentees is to find a licensee who is both willing and capable of bringing an invention to market. This is not a problem with the patent system but rather due to the fact that not every patentable idea will be commercially valuable. This may be due to the point in time during which the patent is in force, whether the switching costs associated with the use of the patented invention sufficiently outweigh the status quo to warrant commercialisation, whether the development costs will be able to be recouped with sufficient profit to compensate for the risk and whether the marketplace actually wants a new "mouse trap".

25. Whilst licence agreements tend to follow a similar format, the actual content of a licence agreement varies widely between one situation and another. These differences are dictated by the different commercial considerations which surround the giving or taking of the licence. However, one would expect to find clauses in a licence agreement dealing with most of the following matters:

- (a) parties;
- (b) grant:
  - (i) nature (exclusive, sole or non-exclusive);
  - (ii) field of use;
  - (iii) sub-licensing rights;
  - (iv) territory;
- (c) technical assistance;
- (d) improvements;
- (e) confidentiality;
- (f) warranties & indemnities;
- (g) quality control;
- (h) performance criteria;
- (i) management, defence and enforcement of ip rights;
- (j) consideration:
  - (i) lump sum fees;
  - (ii) royalties – minimum/running;
- (k) reporting, auditing & inspection;
- (l) term & termination;
- (m) consequences of termination;
- (n) boiler plate.

Page 6: Problems?

26. There is no "system of patent licensing" in Australia as such. Patent licensing takes place in the general commercial environment and is subject to the usual business considerations which are part and parcel of investment decisions on a daily basis. To the extent that there are problems in patentees finding licensees for their patented inventions, this is not a problem which is peculiar to Australia. Over the years, various "marketplaces" have developed to assist in the licensing of patented inventions, for example, yet2.com, General Patent Corporation and the Ocean Tomo auctions. Whilst the listing of patented inventions which might be available for licensing might assist a patentee in finding a licensee, the success of any such solution depends upon potential licensees reviewing the list for inventions to licence. Thus, unless potential licensees are in the habit of actively seeking out new technologies, the current "problem" is likely to remain.

27. The compulsory licensing provisions are not relevant to the problem which patentees encounter in trying to find a willing and capable licensee. Nor would any reform of the compulsory licensing provisions affect this problem because the problem as stated is for a willing patentee to find a willing and capable licensee. The compulsory licensing system deals with an unwilling patentee and a willing licensee and the circumstances in which the patentee ought be forced to licence.

Page 9: Exemptions

28. The regulatory and research exemptions which now exist in Sections 119B and 119C of the Patents Act 1990 are important new additions to the range of activities which do not amount to infringement of a patent. From the point of view of both IPTA and FICPI, the addition of Section 119B is an important addition because it goes some way to making the regulatory use exemptions in technology and industry neutral.

29. Section 119A was introduced into the Act in 2006 and provides for an exemption for exploitation of a patented invention solely for the approval of pharmaceuticals for inclusion in the Australian Register of Therapeutic Goods. Section 119B now extends that protection to non-pharmaceuticals where an approval is required from the Commonwealth, State or Territory or another country or region to exploit a patented product, method or process.

30. Section 119C was introduced to clarify the situation regarding experimental use of patented inventions. The section makes it clear that such use is not infringement and must satisfy the concerns of researchers and others who had voiced concerns over whether patents were inhibiting the conduct of research in Australia.

31. IPTA and FICPI cannot see that there would be any need to invoke the compulsory licensing provisions where the exemptions now apply.

Page 13: Crown Use

32. The Crown use provisions were extensively reviewed by the Advisory Council on Intellectual Property in its report dated November, 2005. IPTA and FICPI endorse the conclusions reached by ACIP and only makes the additional comment below on the impact of the Australia-United States Free Trade Agreement. They were also the subject of comment from the Australian Law Reform Commission in its report on gene patenting (ALRC Report 99).

33. The Crown use provisions have potentially greater application than the compulsory licence provisions because they require merely that use be for the purposes of the Crown and do not require any assessment of the reasonable requirements of the public or a breach of the competition provisions of the *Competition and Consumer Act*. However, as a matter of policy, IPTA and FICPI would caution the Crown against use of the Crown use provisions except in cases of extreme urgency in order to preserve the integrity of the patent system so far as patentees and investors are concerned.

34. The effect of the *Australia–United States Free Trade Agreement (AUSFTA)([2005] ATS 1)* on Ch 17 of the *Patents Act 1990* has yet to be considered. Article 17.9(7) of that Agreement limits Crown use to situations of anticompetitive practices and "non-commercial use, or of national emergency, or other circumstances of extreme urgency" and then only on certain conditions. The provisions of Art 17 have not been carried into effect in the *US Free Trade Agreement Implementation Act 2004* (Cth) and there is no counterpart in Ch 17 to the provisions of s 136 of the *Patents Act 1990* which applies in respect of compulsory licences. It is an open question as to what effect AUSFTA has in relation to Ch 17, if any. This is a matter which IPTA and FICPI believe should be clarified. IPTA and FICPI would support the limitation of the Crown use provisions in the general manner averted to by ACIP and consistently with AUSFTA. Having said this, IPTA and FICPI are not aware of any conduct which it would regard as an abuse of the provisions which might adversely impact on the integrity of the patent system.

35. Neither IPTA nor FICPI is qualified to comment on the question relating to an acquisition of property under section 51 (xxxi) of the Constitution.

Page 15: Efficiency of the Australian Provisions

36. IPTA and FICPI believe that the compulsory licensing provisions do not assist in achieving economic efficiency and agrees with the Commission that the liberal use of the provisions would act as a disincentive to investment in research and development.

37. IPTA and FICPI believe that to preserve the integrity of the patent system so as to maximise its effect in incentivising investment in research and development, these circumstances should be rare. As part of the exclusive rights given by a patent must be the right to refuse to licence except on terms acceptable to it. Certainly a patentee would always have a business reason for refusing to licence if one assumes that all businesses have an overall objective of maximising long term profitability. As the compulsory licensing system acts a potential disincentive to investment, its role should be limited to matters of highly important public policy.

38. As the Intellectual Property and Competition Review Committee ("***the ERGAS Committee"***) commented in its report, the provisions of chapter 12 (prior to the 2006 amendments which added the "competition" ground for the grant of a licence), were very much directed to the promotion of domestic industry rather than securing the best use of resources and achieving high levels of productivity. In the opinion of both IPTA and FICPI, this flows from section 133 which concentrates attention on domestic industries reminiscent of the protection measures of the past which lead to a lack of international competitiveness on the part of Australian industry. If the compulsory licenses are made easier to obtain, then Australian companies will not be forced to innovate themselves but may come to rely on following the innovators by compulsorily acquiring rights to their technology. Furthermore, the Committee commented that the provisions did "…not seem to allow for the legitimate interests of the rights owner to be adequately protected" (page 162).

39. Section 133(5) of the Act focuses the determination of a royalty on what is "…just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of…the *Competition and Consumer Act 2010*…". IPTA and FICPI believe that the concept of "economic value" is both unclear and directs attention to the value of the licence to the licensee rather than the cost of the licence to the patentee. Furthermore, IPTA and FICPI would also argue that the legitimate interest of the patentee includes recovery of the investment made in research and development of both successful and unsuccessful projects. If it is not the case that research and development expenditure is regarded as a legitimate cost to be recovered and the compulsory licensing provisions become the means by which potential licensees negotiate with a patent owner for a lower rate than is being offered for a licence, there will be significantly reduced incentive to invest in research and development where the costs are substantial.

40. This problem with the calculation of "reasonable" royalties in the context of compulsory licence applications is dealt with in an article by Tom Arnold and Floyd Nation ("Case against Compulsory Licenses" by Tom Arnold and Floyd Nation", les Nouvelles December, 1976, page 191). In that article, the authors argue that a reasonable royalty to compensate a patent owner for access to its patent which is insufficient to support research and development activities acts as a disincentive to invention. The authors also comment that a reasonable royalty set in the context of a judicial process is rarely high enough to promote further investment and that a royalty which does compensate fully becomes so high that it would make the licence not worth obtaining in a commercial context.

41. As noted above, both IPTA and FICPI are concerned that the compulsory licence provisions sacrifice the long term public interest in generating new technology and improving economic welfare for the short term interest in having products or processes available in a shorter time frame. Such a trade off only makes sense if the circumstances in which it occurs are emergencies and the like. Thus, IPTA and FICPI would favour a change so that the Court is given clearer direction as to the matters to be taken into account; particularly, the legitimate interests of the patent owner and that existing tests in Section 133 should be revised to limit the grounds to be consistent with AUSFTA and the recommendations of the ERGAS Committee.

42. The financial cost and time involved in applying to the Federal Court for a compulsory license would vary from case to case and, to some extent, depend upon which ground was used to justify the order. For instance, if the situation was that an order was sought on the basis that the patentee had contravened Part IV of the *Competition and Consumer Act 2010* and that contravention had been established through the Court processes, an application would be straightforward and not involve the presentation of detailed and complex evidence which might otherwise be required. Thus, the scenario would be that a patentee has been held to have breached Part IV "in connection with the patent" as a result of which a third party could seek an order for a compulsory licence. It is noteworthy that the grounds specified in Section 133(2)(b) of the Act do not expressly require the consideration of any public interest criteria. This is in stark contrast to the ground set out in Section 133(2)(a). However, in *Fastening Supplies Pty Ltd v Olin Mathieson Chemical Corp* (1969) 119CLR572, the High Court held that even if the Court makes an affirmative finding that the grounds for the grant of a compulsory licence have been made out, the Court has a discretion whether or not to make the order. Thus, notwithstanding the lack of any public interest criteria in the ground set out in Section 133(2)(b), the Court might use such criteria in the exercise of its discretion as to whether or not an order should be granted.

43. If an application where made for a compulsory licence under the ground in Section 133(2)(a), the applicant is required to establish three conditions. Of those, the condition that the reasonable requirements of the public have not been satisfied is likely to be the most problematic. Section 135 of the Act sets out the circumstances in which the reasonable requirements of the public will be taken not to have been satisfied. Whilst the requirement in Section 135(1)(c) to the effect that the patented invention is not being worked in Australian on a commercial scale but is capable of being so work is straightforward, the requirements in paragraphs (a) and (b) would require expert evidence as to the state of trade or industry in Australia. The assessment of this requirement is also problematic in circumstances where the reasonable requirements of the public are being met by another product or method patented by the patentee, rather than the product or process the subject of a compulsory licensing application. A patentee should be able to maintain a patent (which gives the patentee an exclusive right to prevent others from exploiting the invention) for the purpose of preventing competitors from commercialising an alternative which might interfere with the patentee's ability to recoup their investment costs and generate a profit based on all research and development it has carried out in that field. For example, if a pharmaceutical company identifies two equivalently active analgesic agents which it patents separately, a decision to put one of those agents through clinical trials to enable commercialisation should not, of itself, leave the patent on the other agent vulnerable to compulsory licensing. The marketing of the one analgesic product should justify the patentee's inaction with respect to the other "by legitimate reasons" as provided for in Article 5A(4) of the Paris Convention. It is also important during the term of a patent that "reasonable requirements of the public" are not open to be interpreted as including a requirement for choice of product or provider, or, in the case of inventions which have extremely high development costs (such as pharmaceuticals and diagnostics), a requirement that the product be

affordable to the average member of the public without Government subsidy. If pharmaceutical patents were open to compulsory licenses on the basis of affordability to the public without subsidy this would significantly undermine the value of pharmaceutical patents in Australia, and would no doubt result in reduced investment in this sector in Australia, and reduced availability of important pharmaceuticals to the Australian public. Introducing evidence in Court in relation to the "reasonable requirements of the public" test would involve significant costs.

44. The likely legal and ancillary costs involved in making or defending an application for a compulsory licence on grounds that do not involve anti-competitive behaviour will vary very substantially, because they will depend largely on the extent to which the patentee is prepared to contest the application. Factors which will impact on the overall cost include: whether the subject matter of the dispute involves simple or complex technology; whether the market is small, well defined, large, complex, new and emerging or mature; the availability of local witnesses; the resources available to one or both of the parties to apply to preparation or defence of the application; and whether junior or senior and junior counsel is engaged. However, we believe a reasonable estimate for a relatively straightforward application would be in the order of $105,000 (junior counsel only) to $150,000 (senior and junior counsel). However the costs for an application for a compulsory licence under a pharmaceutical patent which is vigorously contested by the patent owner could easily reach $1m and probably higher.

45. There is no hard evidence of which IPTA or FICPI is aware of as to whether or not cost plays a significant role in the decision of whether to seek a compulsory licence. However, anecdotally, neither IPTA nor FICPI believe that costs alone would be a significant deterrent. Bearing in mind that the applicant for a compulsory licence must be determined by the Court to be a suitable and capable licensee to exploit the invention (as was found not be the case in the Fastening Supplies case), the only people likely to be applicants for a compulsory licence are those who are technologically and financially capable of exploiting the relevant invention. These people will generally have alternative means of achieving their business aims and these may well not involve the need for access to a particular invention. Furthermore, in evaluating which alternative to follow, these people would recognise that, if successful in obtaining a compulsory licence, they will have to pay reasonable remuneration to the patentee as determined by the Court. That remuneration may well be in excess of what they would be willing to pay in a voluntarily negotiated context. The level of remuneration set by the Court could well make commercialisation of the invention or the product to which the invention is relevant, uneconomic. Furthermore, a compulsory licence cannot be exclusive (Section 133(3)) and therefore, the successful applicant for a compulsory licence may well find itself in due course competing with another licensee which has been voluntarily granted a licence by the patentee; perhaps on more favourable terms. Thus, the outcome of a compulsory licence application is uncertain as far as both the patentee and the applicant are concerned. This uncertainty affects both the strategic planning of the patentee and the conduct of would be applicants. In balancing the respective interests of each of the parties and the community, neither IPTA nor FICPI would favour any amendment to the provisions which weakened the value of a patent as an exclusive right upon which a patentee should be able to rely for planning, investment and communication purposes and easier for an applicant to obtain, except in the limited circumstances of national emergency and the like.

Page 17: Effectiveness of the Australian Provisions

46. A number of the questions asked on this page are responded to in earlier parts of this submission.

47. The provisions for compulsory licensing in the Patents Act prior to the ERGAS amendments flow from Article 5 of the Paris Convention for the Protection of Intellectual Property. It appears that at the time of the negotiation of the Convention, it was "…believed in many countries that, in order to be fully justified, patents should also be *used* for *working the patented invention in the country where the patent is granted*, and not merely as an exclusive way to prevent others from doing so or to control importation. (GHC Bodenhausen "Guide to the Application of the Paris Convention for the Protection of Industrial Property" published by the United International Bureau for the Protection of Intellectual Property 1968 (page 70). It was never a requirement under Australian law that a patent had to be "worked" in order to be valid. IPTA and FICPI believe that the objectives of the current provisions are not clear. The first limb relating to the requirements of the Australian public not being met is difficult to rationalise in the modern world where the preservation of industries, as such, has been superseded by a concern for the wellbeing of the economy as a whole.

48. IPTA and FICPI believe that, whether by accident or design, the competition limb of section 135, subject to the point made in paragraph 49(4) of this Submission, catches only appropriate conduct by virtue of section 51(3) of the *Competition and Consumer Act 2010*. IPTA and FICPI agree that the effect of that section is to significantly limit the application of the competition based test in the *Competition and Consumer Act*. IPTA and FICPI also note that this may be the result of the government adopting a corrupted version of the recommendations of the ERGAS Committee in relation to the insertion of the competition limb but not accepting the recommendation that Section 51(3) should be repealed and replaced by a provision which, in intellectual property matters, would have applied a competition test to what would otherwise have been *per se* offences. However, IPTA and FICPI would argue that the only ground for the grant of a compulsory licence should be where there has been the abuse of substantial market power in the terms of section 46 of the *Competition and Consumer Act* through the refusal to licence a patent or there is a national emergency or the like declared by the Australian government. Thus, in light of the fact that the government has not amended section 51(3) as recommended by the ERGAS Committee, IPTA and FICPI propose that the current "competition" ground be replaced by a ground which relies upon a breach by section 46 of the *Competition and Consumer Act.*

Page 18: What does the limited use of the provisions imply?

49. Many of the questions on this page have been answered in what has been said to this point in this Submission. IPTA and FICPI reiterate the comment in paragraph 7 to argue that it is rarely the case that the inability to gain access to a patent results in the reasonable requirements of the public not being met. Furthermore, that a refusal to licence a patent would rarely constitute a use of market power for a prescribed purpose for the purposes of section 46 of the *Competition and Consumer Act.*

50. Notwithstanding that there have been very few applications for a compulsory licence, anecdotally, members of IPTA and FICPI are aware of situations where, in negotiations, companies have used the threat of an application for a compulsory licence as a tactic. Further information can be provided in relation to these circumstances if this would be beneficial to the Commission.

Page 19: Impact of International Agreements on Australia

51. As noted above, AUSFTA provides that Australia is not to permit the use of patented subject matter without the authorisation of the patentee except where that grant is to remedy a practice "determined after judicial or administrative process to be anti-competitive" or in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency. In relation to cases of public non-commercial use, national emergency or extreme urgency, there are additional provisos that any Crown use or compulsory licence must be limited to use by the Government or third persons authorised by the Government, the patentee is be provided with reasonable compensation and is not be required to provide undisclosed information or technical knowhow related to the patented invention which is the subject of the Crown use or a compulsory licence.

52. As noted below, IPTA and FICPI query the need for a competition remedy to be contained in the Patents legislation when the Court would have power to grant such a licence in the exercise of its normal powers. Leaving that issue to one side for the moment, the following comments are made.

53. On the assumption that the ground provided for in Section 133(2)(a) of the Act falls within the concept of "public non-commercial use", there are a number of inconsistencies between AUSFTA and sections 133 and 135. These are:

(1) There is no provision that the applicant for a compulsory licence under section 133(2)(a) is required to be authorised by the government to either apply for a compulsory licence or to be so authorised once the Court has determined that a compulsory licence will be granted.

(2) AUSFTA requires that a patent owner is to be provided with reasonable compensation for public non-commercial use. Section 133(5) of the Act provides that, in default of agreement, the compensation for the grant of the compulsory licence is to be determined by the Court as that which is just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of the Competition and Consumer Act. It appears that Section 133(5)(b) could apply to both the public non-commercial use and competition grounds. Whether it does so or not, Section 133(5)(b) appears to go beyond the requirement in AUSFTA that the patentee is to be provided with reasonable compensation.

(3) AUSFTA mandates that a patentee may not be required to disclose information or know-how relating to a patented invention in respect of which a compulsory licence has been granted. There is no provision to this effect in chapter 12 of the Act.

(4) Finally, AUSFTA permits the grant of a compulsory licence as a remedy to prevent anti-competitive practices. However, the ground provided for under Section 133(2)(b) does not limit an application for a compulsory licence to a person who has suffered loss or damage as a result of an anti-competitive practice. In other words, the ground provided for in section 133(2)(b) is beyond the scope permitted by AUSFTA in that it potentially allows any third party to apply for a compulsory licence where a patentee has contravened or is contravening Part IV of the Competition and Consumer Act in connection with the patent. It is therefore not a "remedy".

54. The relationship between AUSFTA and chapters 12 and 17 of the Act in light of these inconsistencies and the effect of Section 136 create uncertainty which is undesirable. Accordingly, IPTA and FICPI submit that, subject to the qualification in paragraph 48, these uncertainties should be resolved in the manner proposed in paragraph 41.

55. The inconsistencies between Australia's compulsory licensing provisions and Crown use provisions with AUSFTA have been referred to in earlier paragraphs of this Submission.

Page 25: Specific Industry Concerns

56. The terms of reference for the Commission's enquiry identify a number of industries where access to patents has become an issue. One of the most controversial debates was the debate in relation to gene patents in the bio-medical industry. IPTA and FICPI support the decision of the majority of the Senate Legal and Constitutional Affairs Legislation Committee on the gene patents issue. The general issues which were raised in respect of gene patents are also raised in respect of alternative energy and other climate change mitigation technologies, food and certain essential patents. As already stated, IPTA and FICPI believe that the *Patents Act* should be technology neutral and that there should be no industry specific provisions or at least any more industry specific provisions.

57. The danger in responding to the emotion charged debate in relation to gene patents by amending the compulsory licensing provisions to accommodate access to patents in relation to the use of particular gene sequences for diagnostic and other healthcare reasons runs the risk that, in the long term, investment in research and the commercialisation of research in the healthcare area will be substantially reduced. As noted at various points in this Submission, if investors are not able to recoup their investment in successful and failed projects because a compulsory licence is obtained in respect of a successful innovation, there will be less incentive to invest and less money for investment.

58. Whilst neither IPTA nor FICPI is suggesting that the Australian government or the Australian provisions would lend themselves to the Federal Court arbitrarily issuing compulsory licences, the experience in other countries implementing the DOHA Declaration is salutary.

59. Whilst some countries have taken a responsible stance in respect of compulsory licences, others appear not to have done so. For instance, the DOHA Declaration is designed to allow the grant of compulsory licences for the production of healthcare products for export to developing and least developed countries experiencing an epidemic. However, Thailand, a middle income country, issued a compulsory licence for a heart disease medication; whilst being a chronic disease it is certainly not an epidemic confined to a lesser developed country. Thailand also issued a compulsory licence to an AIDS medication which was at that stage being sold in Thailand at a special rate by the manufacturer, Abbott Laboratories. Abbott Laboratories responded by not introducing new medicines in Thailand and by withdrawing 7 applications for registration for new pharmaceutical products. In addition, the United States placed Thailand on its Priority Watch List.

60. Egypt is another case in point. As noted in paragraph 9 this Submission, countries which issue compulsory licences are regarded as having weak intellectual property protection which reduces the likelihood of investment in research and development. In the case of Egypt, within 2 months of Pfizer entering the Egyptian market with Viagra, the Egyptian government granted authorisation to produce Viagra to all Egyptian companies who applied to produce a generic version. The result was that

Pfizer cancelled plans to construct production facilities in Egypt as well as other investment being lost.

61. India is another country which has issued a compulsory licence for a pharmaceutical product in circumstances which did not take due account of the significant research and development costs associated with the commercialisation of a pharmaceutical product. In that case a compulsory licence was granted to an Indian generic company, Natco Pharma Ltd, to produce a generic version of Bayer's drug, Nevaxar (sorefanib) which is used to extend the lives of patients with advanced liver or kidney cancer. The compulsory licence was granted on the basis that the price at which the drug was offered by Bayer was much more than general members of the public could afford. The generic company, who did not have to expend the money associated with the research and development of the product, was able to produce the product and offer it for a price much lower than the Bayer's price. On this basis the compulsory licence was granted. This decision, which is under appeal, is considered to have set a dangerous precedent in India, and will likely have an adverse effect on the availability of new medicines in India. It also confirms the perceived negative attitude in India to research based pharmaceutical companies, and sends a strong message that India would prefer to "free ride" on the research and expenditure of others than contribute to this effort through subsidising the cost of medicines to the general public. Refer also to our comments above in paragraph 43.

62. It follows from what has already been commented upon in this Submission that IPTA and FICPI would not favour the introduction of any special provisions which were industry specific. Furthermore, IPTA and FICPI do not believe that the issuing of compulsory licences is a solution to the perceived problem but that, in the long term, the impact of those licences will be to substantially reduce the incentive to innovate and to invest in innovation and commercialisation.

Page 26: Clarifying the operation of compulsory licensing

63. The Issues Paper acknowledges, as outlined above in paragraph 3, that the patent system provides public benefits by stimulating investment in innovation and the commercialisation of the results of innovation. This is achieved by granting an exclusive right to a patentee as a means for rewarding and fostering innovation and disclosing to the public the details of the patented invention. Communicating the objectives of the patent system in the *Patents Act* would encourage application of the legislation consistently with the stated objectives and would also clarify the interaction between the patent system and competition policy.

64. IPTA and FICPI support the recommendation by ACIP in its report on Patentable Subject Matter (2010) to include a statement of objectives in the *Patents Act* to outline its purpose and provide general guidance in the application of the legislation. IPTA and FICPI agree that a statement of objectives should be consistent with the objectives of the intellectual property system as stated in the TRIPS Agreement, which recognises the tension between economic and non-economic aspects of the intellectual property system and encourages a balanced approach to application of the legislation. The following objectives statement proposed by ACIP conveys a similar balance of those interests:

> *…to provide an environment that promotes Australia's national interest and enhances the well-being of Australians by balancing the competing interests of patent rights holders, the users of technological knowledge, and Australian society as a whole.*

65. IPTA and FICPI are of the view that ACIP's proposed objectives clause adequately conveys the purpose of the *Patents Act* as a whole, and that no separate objectives clause is necessary for the compulsory licensing provisions of the *Patents Act*.

66. IPTA and FICPI are concerned that the compulsory licensing provisions, particularly in so far as they relate to a patentee's failure to meet the reasonable requirements of the public, have the potential to diminish generation of new technology which is indigenous to Australia. As the Issues Paper notes, Australia is a net importer of technology. Softening of the compulsory licensing provisions has the potential to favour further adoption of foreign technology by invoking those provisions, over investment in domestic innovation and technology development.

67. Furthermore, s. 136 of the Patents Act directs the Federal Court not to make orders under the compulsory licensing provisions which are inconsistent with Australia's international obligations. Any guidelines proposed for setting out the criteria for invoking the compulsory licensing provisions, particularly as they relate to the reasonable requirements of the public, should be consistent with Australia's international obligations. As outlined in paragraph 41 above, IPTA and FICPI would support development of guidelines that are consistent with AUSFTA and the recommendations of the ERGAS Committee.

68. The terms of any technology licence vary widely, depending on the nature of the technology being licensed, the size and capability of the licensee to exploit the technology as well as extraneous factors such as the prevailing economic climate. Whilst guidance indicative of the criteria used by the Federal Court to determine the terms of a compulsory licence may be useful to parties in negotiations, IPTA and FICPI caution against overly prescriptive guidelines, instead favouring a flexible approach that is generic to all technologies and potential licensees.

Page 27: Consolidating and harmonising non-voluntary access provisions

69. While the non-voluntary access provisions of the *Patents Act* are all aimed at balancing the monopoly right granted under the Act with public interest factors, they are each aimed at meeting the needs of distinct groups. The compulsory licensing provisions provide commercial entities with a remedy against patentee behaviour which is deemed anti-competitive or failing to meet the reasonable requirements of the public. Those provisions do not exclude further voluntary licences being granted by the patentee.

70. Similarly, the Crown use provisions permit exploitation by the Commonwealth or a State of patented technology, but not to the exclusion of other licensees. However, exploitation by the Crown is permitted only if the patented invention is necessary for the proper provision of services by the Crown; it is not a right granted for commercial exploitation. Despite the Crown use provisions being in the public interest, to ensure proper provision of services, they contain no requirement to show that the reasonable requirements of the public are not being met.

71. In contrast, compulsory acquisition under s. 171 terminates the patentee's control over the patented invention and transfers all rights in respect of the patent and the invention to the Commonwealth (but not to a State or Territory). There is no stipulation of conditions or circumstances in which the Commonwealth may acquire an invention, except that the Commonwealth must pay compensation as agreed with the patentee or determined by a prescribed Court.

72. IPTA and FICPI do not consider consolidation of the non-voluntary access provisions necessary or likely to be helpful in providing clarification of those provisions, nor would consolidation be likely to assist in meeting the objectives of those provisions, in the broader context of the objectives statement referred to in paragraph 64.

Page 28: Alternative dispute resolution and awareness

73. Very few applications have been made for the grant of a compulsory licence. Duplicating the powers of the Federal Court to arbitrate on such matters is likely to have a significant administrative cost for establishment and then maintenance of the necessary tribunal or dispute resolution forum. As pointed out in the Issues Paper, establishing such a forum may also lead to vexatious claims and forum shopping, as well as the possibility of such claims proceeding to the Federal Court on appeal. Neither IPTA nor FICPI supports the establishment of an alternative dispute resolution body, in the absence of evidence that demonstrates a genuine need for such a forum and its economic viability.

74. Awareness of compulsory licensing among small businesses and the healthcare sector is not considered by IPTA or FICPI to be a significant problem. However, both IPTA and FICPI would support a balanced approach to raising awareness of the compulsory licensing provisions as they apply to small businesses and the healthcare sector (as well as other industries) as both patentees and potential licensees.

Page 29: Non-voluntary licensing by a collecting society

75. A key feature of the patent system is the value of the exclusive right granted to the patentee in recognition of the investment made in the patented invention. A collecting society may have a place in administering the rights of copyright owners where the rights are limited to reproduction of a copyright work. However such societies have no place in administering granted rights such as patents, where the value of each granted right and the potential for exploitation under the *Patents Act* must be individually determined according to a unique combination of factors intrinsic and extrinsic to the patented technology.

76. A collecting agency having the power to compel patent licenses to be granted for a specific purpose would diminish the value of patents granted under the *Patents Act*, and would compromise the balance between the economic and non-economic aspects of the patents system that are set out in the proposed objectives statement referred to above in paragraph 64. Neither IPTA nor FICPI supports the establishment of a collecting agency for the purpose of administering non-voluntary licenses.

Additional matter – Error in s133(3B)

77. As an additional matter we point out that there is an error in the wording of s133(3B). This provision is clearly intended to cover the situation where a patentee cannot work the invention because of another patent owned by another party, which is the situation referred to in Article 31 of TRIPS. However, the way the provision is currently worded only relates to the situation where the patented invention to be worked is already the subject of a compulsory licence application. This flows from the reference to “the patented invention” in the first line of s1333(3B). The reference to the granting of a “cross licence” in s133(3B)(b) seems inappropriate since the provision does not provide the patentee of the “patented invention” a licence under the “other” patent. The provision could be extended to cover the circumstances set out in Article 31 by substituting the introductory part of s133(3B) with words such as: “If the patented invention cannot be worked by the applicant, or if the applicant has

an invention which is the subject of a patent which cannot be worked by the applicant, without infringing another patent:…". Consequential amendments would also need to be made to subsections (a), (b) and (c) to make reference to the invention patented by the applicant. In circumstances where the applicant is not the patentee of either patent, the provisions should be amended to at least provide the patentee of the patented invention with a licence under the "other" patent. Otherwise the result is that the applicant and the other patentee have rights to work the patented invention, but not the patentee of the patented invention, who still requires a licence under the other patent.

IPTA and FICPI appreciate the opportunity to comment on the Issues Paper and we are very happy to take part in any further discussions in relation to the review of the compulsory licensing provisions and our recommendations.

Yours sincerely

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