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THE AUSTRALIAN FEDERATION
OF INTELLECTUAL
PROPERTY ATTORNEYS

4 April 2011

By E-mail
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Terry Moore
Director, Office of the Director General
IP Australia
PO Box 200
Woden, ACT 2606

Re: Exposure Draft of Intellectual Property Laws Amendment (Raising the Bar) Bill 2011 and Explanatory Memorandum

Dear Terry,

1. We refer to your email of 21 December 2010 inviting submissions on behalf of the members of the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and the Australian Federation of Intellectual Property Attorneys (FICPI Australia) in respect of the exposure draft of the Intellectual Property Laws amendment (Raising the Bar) Bill 2011 and accompanying explanatory memorandum.

2. As you are aware, IPTA and FICPI Australia have made previous submissions in relation to intellectual property law reform proposals which have been incorporated into the draft Bill, and accordingly the following submissions should be considered supplementary to the submissions previously made on behalf of our respective organisations.

3. Both IPTA and FICPI Australia support the majority of amendments set forth in the draft Bill, and believe that, as a package of amendments, they provide improvements to Australia's systems for protecting and enforcing intellectual property rights. The focus of the submissions below is on the amendments relating to the patent system, as separate submissions have been filed or will be filed in relation to other aspect of the draft Bill. Before commenting on the specific amendments set forth in the draft Bill we would like to make the following general comment in relation to the transitional provisions which have been proposed in relation to the introduction of provisions relating to substantive patentability requirements, disclosure requirements, amendments and allowable claim types. As currently drafted, the

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draft Bill indicates that the new, and substantially more onerous, provisions will apply to all applications for which an examination report has not issued prior to commencement of the amended legislation.

4. Both IPTA and FICPI Australia are deeply concerned that the Government, and its agency for administering Australia's IP rights system, IP Australia, would support such an unfair and inequitable process for the introduction of amendments to Australia's patent laws. Previous submissions from IPTA and FICPI Australia have been made on the assumption that these aspects of our patent laws would only apply to applications and patents based on filings made after the Commencement Date of the amending legislation.

5. While Australian applicants seeking protection for their inventions overseas understand that intellectual property requirements may change as a result of case law developments, courts and the like, they would not expect to be adversely affected by legislative changes introduced subsequent to the filing of their applications. In this regard, any changes to legislation affecting substantive patentability requirements or requirements for specifications in foreign jurisdictions normally only apply to applications filed after commencement of the new legislation. Foreign applicants filing applications in Australia, which represent more than 90% of all patent applicants, would expect, and we submit, have the right to expect, the same consideration when filing their patent applications in Australia.

6. Not only will the new legislation adversely impact foreign applicants filing in Australia, the amendments will also adversely affect Australian applicants who have filed their applications with the expectation that they will be examined according to current laws. Although the transitional provisions relating to the disclosure in provisional applications indicate that the new provisions will only apply to provisional applications filed after commencement of the new legislation, this is of little consolation. This is because the new support requirements being introduced will apply to any complete application claiming priority from that provisional application. This in itself would suggest that there is a strong argument that the new support requirements should only apply to applications with a priority date later than the date of commencement of the legislation.

7. IPTA and FICPI Australia believe that most Australians regard Australia as a fair country and expect to be treated fairly by the Government. We, as Australians, also expect our country to treat foreign nationals in a fair manner. It could also be said that Australia's Constitution is based on fairness, particularly in relation to s 51(xxxi). While we understand that there is a desire to introduce the amendments to our patent law at the earliest opportunity, and that this is considered to be in the public interest, we do not believe that desire goes anywhere near close enough to outweighing the need for Government to treat patent applicants, both local and foreign, in a fair manner. The idea of "moving the goal post after the commencement of play" would be considered to be unfair to most Australians, and is most certainly considered to be unfair by the members of IPTA and FICPI Australia. It is deceptive to elicit disclosure from an inventor based on the current legislative framework and to change that framework before making a decision on grant. In view of the restriction proposed on amendments, patent applicants will

have no opportunity to remedy any deficiencies so as to enable them to obtain the protection that they would have achieved under the current laws.

8. The proposed transitional provisions disregard the "bargain" upon which the whole international patent system is based; patent reward in return for disclosure. They also completely ignore the fact that upon grant, a patent will date from its filing date with the right to enforcement from the date it was laid open to public inspection. Although the transitional provisions will not impact on those applicants already fortunate enough to have been granted their patents, the protection available to applicants who have published details of their invention by relying on the patent system will be diminished, not just from the dates of grant but from the earlier dates upon which their applications were laid open to public inspection.

9. We believe that patent applicants adversely effected by the introduction of the new laws are likely to seek refunds of government fees paid in respect of their patent applications and may seek compensation from the Government in respect of monies outlaid during the patent application process, including attorneys' fees. They may even try to seek compensation from attorneys who have filed applications for their inventions, and who have given advice regarding patentability based on the existing provisions. In the interest of fairness, IPTA and FICPI Australia believe that the transitional provisions should be amended to ensure that any provisions relating to substantive patentability requirements, specification requirements, amendments and claim types should be amended so that the new provisions only apply to applications filed on or after commencement of the amended legislation.

Recommendation 1

Amend the transitional provisions to ensure that any provisions relating to substantive patentability requirements, specification requirements, amendments and claim types should only apply to applications filed on or after commencement of the new legislation.

10. Our comments in relation to the amendments set forth in Schedules 1, 2, 3, 4 and 6, in so far as they relate to the patent system, are set out below:

Preliminary Matters

11. We note the title of the Bill appears incorrectly in the Explanatory Memorandum on page 12.

Schedule 1

Item 1:

12. Our comments in relation to the proposed "preliminary search and opinion" appear below in connection with item 12.

Item 2:

13. We are concerned that the Explanatory Memorandum does not address the concerns raised in our submission of 19 February 2010 which requested clarification in the Bill, or in the Explanatory Memorandum, of the manner in which common general knowledge is to be assessed following removal of the words "in the patent area". Without sufficient guidance in the Explanatory Memorandum it would be open for an Australian Court to interpret the provision to require inventive step to be judged against background of general knowledge common to all, or at least a substantial number of, jurisdictions. The word "common" in "common general knowledge" must, without further qualification, refer to knowledge shared amongst a number of jurisdictions, not a single jurisdiction. In order to demonstrate that general knowledge is truly "common" it may prove necessary for an Examiner, or a party opposing the application or seeking revocation of a patent, to establish that a particular element of general knowledge is shared amongst a number of jurisdictions. This would be an unfortunate consequence of the amendment. However the explanatory memorandum provides no explanation of the manner in which common general knowledge is to be assessed which would remove this possibility. Our concerns could be partially, although not fully, addressed by amending sub-section 7(2) to refer to "common general knowledge in the art", as this would at least imply that the common general knowledge is general knowledge shared by those practicing in the art. This would reduce the scope for an argument to the effect that the commonality must be between different jurisdictions.

14. We also believe that the Explanatory Memorandum should provide further guidance to assist the decision maker in weighing up evidence regarding the common general knowledge, particularly where common general knowledge differs between jurisdictions. There are many fields of endeavour in which, contrary to the assertion set out in the Explanatory Memorandum, innovation does not occur globally, but where quite different practices are carried out in different jurisdictions. An example might be the mining industry where mining practices in one country may differ substantially from those in another. In such fields of endeavour there may be very little that is truly "common" and it is unclear how evidence in such circumstances is to be weighed. We believe the Explanatory Memorandum should thoroughly address these concerns and provide additional guidance for relevant decision-makers.

Recommendation 2

- Amend sub-section 7(2) to refer to "common general knowledge in the art";
- Amend Explanatory Memorandum to provide further guidance for decision-makers in weighing evidence in connection with common general knowledge.

Item 3:

15. In our previous submissions we have argued that no amendments are required to sub-section 7(3), and that the assessment of inventive step should be restricted to

documents which would have been "ascertained understood and regarded as relevant". Despite our submissions it is now clear that IP Australia wishes to remove this safeguard against hindsight analysis from the Patents Act 1990.

16. Unfortunately, the Explanatory Memorandum includes a false statement which could mislead the public, and possibly the Courts, should they subsequently rely on the Explanatory Memorandum for assistance in the interpretation of amended sub-section 7(3). The false statement which appears in the Explanatory Memorandum is the following:

"In countries that are our major trading partners, and under the PCT, inventive step is assessed against all information available to the public at the priority date of the application."

17. Attached as **Annex 1A, B and C** are three documents explaining how prior art is treated in considering inventive step under the European Patent Convention. The first article entitled "Novelty and non-obviousness – the relevant prior art" by Mr Mario Franzosi describes four classes of prior art relevant to novelty, and two classes of prior art relevant to non-obviousness. The two classes of prior art referred to by Franzosi which are relevant to non-obviousness are "common general knowledge" and "enhanced knowledge". In explaining what is meant by "enhanced knowledge" Franzosi refers to the *Kraftwerk Union* case which stated that "*if a designer working on the development of (an) apparatus does not possess the technical knowledge to overcome difficulties, he can be expected to consult the relevant prior art for components which perform the same function and are better able to meet the requirements.*"

18. Franzosi explains on pages 84 and 85 of his article why an expert would not search for a class of prior art identified with reference to novelty as "hidden knowledge". Franzosi sums this up well when he states the following:

"What the expert would not seek cannot be taken into consideration. They exist potentially, but not in the real world. It is like hidden treasure buried in a remote shore of an uninhabited island. It cannot be considered as being at the expert's disposal for the purpose of inventiveness."

19. Accordingly, it is very clear that under European Patent law it is not all published prior art that is relevant to an assessment of inventive step. It is only published prior art which would have been realistically consulted by the person skilled in the art which is relevant to the assessment of inventive step.

20. Another distinction with respect to European Patent law in relation to the assessment of obviousness is that under European Patent law the inventive step assessment is confined to the closest piece of prior art. See **Annex 1B** which is an extract from the Guidelines for Examination in the European Patent Office which explains the importance of identifying the closest prior art. As explained in the Guidelines:

"The closest prior art must be assessed from the skilled person's point of view on the day before the filing or priority date valid for the claimed invention."

21. This clearly draws focus away from prior art references which could only be found with knowledge of the invention.

22. Finally, as **Annex 1C** we enclose a copy of a paper presented by Mr Julian Crump, Secretary General of FICPI, explaining the EPO approach to the assessment of inventive step. As explained by Mr Crump, and illustrated with reference to the decision T870/96 (Phillips Electronics NV) the closest prior art against which inventive step is assessed must be the prior art which should realistically have been consulted by the skilled person. This is consistent with the *Kraftwerk Union* case referred to by Franzosi at page 83 of his article.

23. Accordingly, we submit that it is clear that inventive step in Europe is not assessed against all information available to the public at the priority date of the application, but only prior art information considered to be the closest prior art applying a test which includes an assessment of whether the prior art would have been realistically considered or consulted.

24. We also attach **Annex 2A** and **2B** two documents explaining how novelty is assessed in the United States. The first document attached as Annex 2A is an extract from the Manual of Patent Examining Procedure (MPEP) explaining the level of public accessibility required in order to destroy novelty. It is clear from the explanation provided in the MPEP that documents which would be considered novelty destroying in Australia would not be considered novelty destroying in the United States. In this regard, under Australian law it is sufficient for information to be disclosed to a single person who is not under an obligation of confidentiality for that information to be considered to be made available to the public, and therefore relevant to novelty. It is clear from the decisions discussed in the MPEP that a higher level of public accessibility is required in the United States. See, for example, the *IN RE: Cronyn* case. We also attach (as Annex 2B) a copy of the recent *IN RE: Richard S Lister* case in which information filed with the Copyright Office was not considered publicly available until there was adequate Indexing.

25. It is clear that without appropriate safeguards, prior art which would not even be considered relevant to novelty in the United States will, nevertheless, be considered relevant to inventive step under the proposed Australian legislation. Although the Explanatory Memorandum indicates that there is no intention to allow hindsight analysis, this is likely to be the result.

26. We are particularly concerned that, while the Explanatory Memorandum explains that the requirements that prior art be "understood" and "regarded as relevant" are implicit in the pre-existing test for inventive step, no such comments are provided in relation to the requirement for a prior art reference to be one that would have been "ascertained". Rather, the Explanatory Memorandum indicates that the change is to address the outcome of the decision in *Commissioner of Patents v Emperor Sports Pty Ltd [2006] FCACFC 26.* The Explanatory Memorandum does not explain that (i) this was a re-examination case, (ii) a benefit of the doubt standard applied in favour of the patentee, and (iii) the Commissioner of Patents did not submit evidence to the effect that information regarding the prior US patents would have been ascertained. It appears that the main concern in relation to this re-examination decision was that it left open the possibility that one could defeat an obviousness

attack based on a prior art reference by arguing that it was not common in the particular art concerned to conduct prior art searches which would be likely to uncover that prior art reference. We believe that this outcome could be readily addressed by including a suitable explanation in the Explanatory Memorandum, similar to that provided in connection with the words "understood" and "regarded as relevant". For example, the Explanatory Memorandum could explain that in assessing inventive step, and to ensure impermissible hindsight analysis is avoided, it is appropriate to ask whether a particular prior art reference would have been realistically consulted by a person skilled in the art who would be expected to conduct a reasonable search of prior art.

27. As one suggestion, consideration should be given to amending the Explanatory Memorandum along the following lines:

"...The exclusion of this undermines the principle that patents should not be granted for routine modifications of what was available to a skilled person exercising reasonable diligence.

Secondly, this restriction is out of alignment with the patent systems of our major trading partners. In other jurisdictions, publicly available information is generally considered as prior art for inventive step if a person interested and ordinarily skilled in the subject matter would locate the information when exercising reasonable diligence. If a document could be readily ascertained by a skilled searcher, for example, on the internet, it should be information considered as prior art for inventive step. It is recognised, however, that some previously published documents may be particularly obscure. In such cases, it is considered better that this be a factor included in the broader question of whether the invention would have been obvious to the skilled addressee.

Thirdly, the requirements..."

28. Without such an explanation, there is a strong likelihood that the level of inventive step required to meet Australian patentability requirements will considerably exceed the levels required in Europe and the United States, not to mention those of other major trading partners.

Recommendation 3

Amend the Explanatory Memorandum to explain that the assessment of inventive step based on one or more prior art references requires a consideration of the likelihood that the particular prior art reference or references would have been consulted at the priority date.

Item 4:

29. See comments above in relation to item 3.

Item 5:

30. No comment.

Item 6:

31. We have substantial concerns in relation to the proposal to introduce a two-pronged utility test. We do not believe that such a test is required, and we believe that the requirements for subject matter and utility are adequately dealt with by the current manner of manufacture requirement and the proposed disclosure/sufficiency requirement. Although the words "specific, substantial and credible" have now been considered in a couple of United States court decisions, we do not believe that the terms are sufficiently clear to warrant inclusion in the Australian patent legislation. In fact, no patent law anywhere in the world (so far as we are aware) includes an express requirement to disclose a specific, substantial and credible utility. As explained in our previous submissions, this language was derived from the US Patent and Trade Mark Office Guidelines for examining the utility of inventions comprising DNA sequences.

32. While the guidelines may be useful in the United States for examining particular biotech related inventions, it is far from certain how the proposed provision would be applied in connection with the more predictable arts where a specific use for an invention does not need to be explicitly described. Although the Explanatory Memorandum suggests that the "specific, substantial and credible" use need not be explicit "if a skilled person could appreciate the use, with their background knowledge in the art and without undue burden", this is little comfort given the clear words of the requirement. In particular, it is not clear how the provision would be interpreted in relation to inventions relating, for example, to a motor vehicle tyre, or a surfboard, the use of which might generally not be specifically disclosed in the complete specification, as the use would be self-evident. There is a danger that such a specification would fail to satisfy the express requirements proposed in new s 7A.

33. A further difficulty is that it would not be possible to remedy a s 7A deficiency after filing, due to the proposed amendment provisions which will not allow for an applicant to add new matter.

34. It is also unclear why a second usefulness test is required, given that the current test for usefulness requires claimed inventions to meet the promise of the invention as explained in the specification. Examination of our current utility requirements under a balance of probabilities standard will also require an assessment of whether an invention has a credible utility. In fact, proposed s 7A is more akin to a specification disclosure requirement, and if pursued, would be better placed within s 40. It is not a requirement for an invention to be useful; it is simply a requirement for a specific substantial and credible use to be disclosed in the specification.

35. Also, if IP Australia proposes to continue with this proposal, the provision should be amended to clarify that disclosure in the specification is not required in circumstances where the use would be apparent to a person skilled in the art. In addition, we consider that proposed s 7A(2) is ambiguous as the term "useful" is not

otherwise defined in the Act. It is not clear that s 7A(2) would have the result of drawing in all of the relevant common law.

Recommendation 4

Delete proposed s 7A from the draft Patents Bill.

Item 7:

36. It is unclear why the disclosure requirements for a provisional specification need to be amended. In this regard, a provisional application is not subjected to an examination to ensure that it meets s 40 requirements. The only function of a provisional specification is to provide a priority date for later complete applications, Australian or foreign. Regardless of the requirements set out in s 40(1) the overriding requirement for a provisional application is to support a claim in a complete application. This is currently achieved by considering whether a claim in a complete application is fairly based on matter disclosed in the provisional specification. Under the proposed new provisions, this will be assessed by considering whether the claims of the complete application are supported by the provisional application. Under the new provisions, the claims will only be supported by a disclosure in a provisional specification if the invention is disclosed in the provisional specification in the manner which is clear enough and complete enough for an invention to be performed by a person skilled in the relevant art. Accordingly, there is no need to make any amendments to s 40(1). We comment further on the proposed new support requirements later in relation to item 9.

Item 8:

37. We note, with some relief, that the proposal set out in IP Australia's November 2009 Consultation Paper entitled "Towards a Stronger and More Efficient IP Rights System" to amend s 40(2)(a) of the Patents Act to require the applicant to describe the invention fully in a manner which enables the invention to be performed across the whole scope of the claim has not been adopted. Instead it is now proposed to amend s 40(2)(a) to require the applicant to "disclose the invention, in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the relevant art". This is largely based on the corresponding UK and EPC sufficiency requirement.

38. We are, however, still concerned that the Explanatory Memorandum indicates that this modified wording is still intended to require enablement "across the full scope of the claim".

39. As set out in our submission of 19 February 2010 responsive to the November 2009 Consultation Paper, an absolute requirement for enablement across the full scope of a claim presents two key difficulties, as further discussed below.

40. First, the requirement to provide enablement across the full scope of a claim provides the unintended result of requiring enablement of all possible later inventive

improvements of the claimed invention that fall within the scope of the relevant claim. Clearly such improvements could not have been envisaged when the original invention was conceived. It would of course be impossible to satisfy this test to enable all possible future inventive improvements falling within the scope of a claim. As a result, any such later improvement would invalidate any claim for the original invention. Any later inventive improvements of an invention defined in a relevant claim could thus not infringe such a claim.

41. Secondly, contrary to the assertion set out in the Explanatory Memorandum, there is not an absolute requirement for enablement across the full scope of the claim in the provisions of the UK legislation, the European Patent Convention and the Patent Co-operation Treaty. This was also addressed in our submission of 19 February 2010. An assessment of the position in the UK is set out in Appendix 1 to our submission of 19 February 2010 (originally submitted responsive to the "Getting the Balance Right" Paper of March 2009). In the *Biogen* case referred to in the Explanatory Memorandum, the sufficiency test purportedly set out in that decision was merely *obiter*. In that case, the claims were found to lack an inventive step for failing to meet the express requirement of s 5 of the Patents Act 1977 to provide support for the claims "across the full extent of the monopoly claimed".

42. The sufficiency test purportedly set out in *Biogen* was defined by equating it with the requirement of support for any Paris Convention priority claim. Further, in *Biogen* it was acknowledged that there is a tension between the desire for all things within a claim to be enabled and the fact that inventive improvements can be made within the scope of claims of existing patents (e.g., the Wright Brothers and Balloon Analogy discussed in *Biogen).* This tension is reflected in the absurd result discussed above.

43. The requirement for sufficiency and support under UK law have been intermingled and confused as a result of the fact that lack of support is not a ground of revocation under s 72 of the UK Patents Act 1977 (or under Article 84 of the European Patent Convention). Without lack of support being available as a ground to control speculative claim scope, sufficiency has been used to achieve the same goal. With fair basis (or support under the proposed amendments) being available as a ground of revocation in Australia, there is no such need in Australia. As pointed out in Appendix 1 to our previous submission, in the *Lundbeck* case also referred to in the Explanatory Memorandum, it was clarified by Lord Mance, at paragraph 51, that "what the description discloses must .... enable a skilled person to make the patented product across its full width or extent. <u>This does not mean that it must also enable a skilled person to make it by all possible methods.</u>"

44. The position in Europe also provides some flexibility, as again set out in our 19 February 2010 submission. The EPO Examination Guidelines set out at paragraph 4.9, that the sufficiency requirements of Article 83 of the EPC require "*a detailed description of at least one way of carrying out the invention must be given*", and that "*a single example may suffice, but where the claims cover a broad field, the application should not usually be regarded as satisfying the requirements of Article 83 unless the description gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims. However, regard must be had to the facts of the particular case*". Similarly, as set

out in our previous response, there is no strict requirement for enablement across the full scope of a claim in the provisions of the Patent Co-operation Treaty, as appears to be asserted in the Explanatory Memorandum.

45. We are particularly concerned that undue attention has been focused undue attention on the *Biogen v Medeva* case referred to in the Explanatory Memorandum. This decision has been the subject of significant criticism. In 2009 David Brennan of The Melbourne Law School published a particularly good paper explaining the problems caused by the *Biogen* decision, and explaining why Biogen is not good law, and why the House of Lords in *Generics (UK) Limited v H Lundbeck* went to great lengths to distinguish that decision. A copy of David Brennan's paper is ***attached*** as **Annex 3**.

46. It is clear that UK law on sufficiency will seek to move away from the *Biogen* case, for the reasons explained by David Brennan, and accordingly we believe all reference to "enablement across the full scope of the claim" should be removed from the Explanatory Memorandum. It will be preferable to simply indicate that the intention is for the Australian sufficiency requirement to be interpreted in a similar manner to the corresponding UK requirement, but taking into account that the provision is not intended to duplicate any fair basis or support requirement.

Recommendation 5

Amend Explanatory Memorandum to remove any reference to enablement across the full scope of the claim, but include indication that the provision is intended to operate in a similar manner to the corresponding UK provision.

Item 9:

47. This item replaces the present requirement in s 40(3) that the invention defined in any claim must be "fairly based on the matter described" with a requirement that the invention be "supported by matter disclosed". On its face, this would not seem to make any change to the present law, although of course patentees and litigants challenging the validity of patents will have to go to great expense in proceedings over the next several years to establish whether this is in fact the case.

48. There has been extensive development of the law of fair basis before the Australian courts over the years and, since the *Lockwood* High Court decision, the test has been relatively clear. The present fair basis test clearly satisfies the two concepts set out in the Explanatory Memorandum, being that there must be a basis in the description for each claim and that the scope of the claims must not be broader than is justified by the extent of the description, drawings and contribution to the art.

49. In short, therefore, there would not seem to be any particular difficulty with the current law which the proposed change would address. The proposed change would merely serve to create significant uncertainty and additional cost to litigants.

50. Whilst we do not have any problem *per se* with the concept of "support", we do have significant problems with the assertion set out in the Explanatory Memorandum that

the concept of support requires a degree of enablement. Enablement is already separately and sufficiently dealt with in the sufficiency requirements of s 40(2)(a). As set out in our previous submission of 19 February 2010, a requirement for enablement within any support test would only be appropriate where there is no such separate and specific sufficiency test available. In the US, there is no specific sufficiency test, instead there is a broader written description requirement which covers the concepts of both support and sufficiency (see 35 USC 112). The unclear distinction between support and sufficiency has only evolved in UK and European law as a result of the fact that lack of support is not available as a ground of revocation either under Article 84 of the EPC or under s 72 of the UK Patents Act 1977. This unclear overlap has become very confusing under European and UK practice, and it would not be appropriate to replicate such confusion in Australian practice. The High Court in *Lockwood* stressed the importance of maintaining a clear distinction between each of the various patentability grounds so that there is not a blurring of one ground into another. We consider that this is one of the strengths of the current Australian patent system.

51. Replicating the requirement for sufficiency within the support requirement would also significantly add to costs for patent litigants, with any person challenging the validity of a patent on the basis of lack of enablement/sufficiency most likely pursuing two separate grounds of revocation, being lack of sufficiency under s 40(2)(a) and lack of support under s 40(3). This will add unnecessary cost, complexity and uncertainty.

52. Accordingly, we believe the Explanatory Memorandum should be amended to make it clear that enablement is a concept to be considered under s 40(2)(a) only, and that there is no specific requirement for enablement in the concept of support under s 40(3).

53. The second aim of the support test could be better explained by requiring the claims to be framed within the limits of sound prediction based on the disclosure, as per Graham J in *Olin Matheson v Biorex 1970 RPC 157.*

54. However, this represents an unnecessary duplication of the requirement for an invention to be useful. Under the proposed amendments Examiners are required to examine patent applications for utility, applying a balance of probabilities test. Accordingly, it will be necessary for an Examiner to be satisfied that an invention is useful before accepting an application. A similar test is to be applied in opposition decisions, and in re-examinations. Since an Examiner will not be able to test whether or not a particular invention works as promised, the Examiner will need to rely on the disclosure in the specification and information at hand regarding the common general knowledge in the art to make this assessment. The "sound prediction" test expounded by Graham J represents a very effective way for Examiners to assess utility. In fact, this is how utility is assessed under Canadian patent law, and accordingly we do not see any reason why this approach could not be used by Australian Examiners in assessing utility. If this test was adopted then there would seem to be no need to replace the current fair basis requirement with a support requirement. The second aim of the support test would not be required and the result will be that overlap between utility and fair basis will also be avoided.

Recommendation 6a

Retain current fair basis requirements throughout the Patents Act 1990.

55. Alternatively, if this recommendation is not accepted:

Recommendation 6b

Amend the Explanatory Memorandum to ensure that enablement considerations are restricted to s 40(2)(a), and are not part of the support test under s 40(3).

Item 10:

56. We believe introduction of this provision will limit the usefulness of a provisional application to a vehicle for extending the commencement of the 20 year patent term by one year. In the past, it has been possible to generally describe one's invention in a provisional application and set a priority date and then spend the next 12 months further developing the invention so that a full description can be provided when the application is completed or a PCT application is filed. Australian applicants will now be required to provide an extremely detailed description of their invention at the time they file their provisional application to ensure that any subsequent claim to the invention in a complete application is entitled to the claimed priority date. This applies to most standard patents and innovation patents. This is an unfortunate consequence of the proposal to introduce a support requirement for both internal fair basis and external fair basis, that is for the assessment of priority entitlement. As previously submitted, we believe fair basis should be retained, particularly in relation to the assessment of priority claims. In this regard, the so called "Mond Nickel" rules are well known and established and provide a particularly useful tool for the assessment of priority claims based on provisional applications or foreign priority applications.

Item 11:

57. The draft Bill proposes the introduction of a new system allowing the Commissioner to conduct a preliminary search and opinion in relation to applications for which such a preliminary search and examination are not otherwise available. Although not stated in the Explanatory Memorandum, we assume that the conduct of such searches and opinions is considered to be a public service exercise, with the cost being borne by the Crown. If IP Australia proposes to charge the applicant for the search and opinion, then it is unclear how the new system will work, and what the consequences would be if an applicant did not want the search and opinion, or at least did not want to pay for it. Such applicants already have the opportunity to request an early search and opinion, and so it would be expected that all applicants requiring an early search and opinion will have requested one. Accordingly, it is unclear what the new preliminary search and opinion provision is intended to achieve.

58. Further, it seems to us that the new provisions are primarily directed to Australian inventors, and small to medium Australian enterprises who only wish to file their applications in Australia. Such applicants would be the ones most adversely affected by any additional search costs. It is also apparent to us that preliminary search and examination is generally not available for most non-PCT convention applications given examination delays in the major patent offices, including those in the US, Europe, Japan and Canada. Are the provisions intended to allow the Commissioner to conduct searches and opinions on cases originating from overseas, for which a search or opinion is not otherwise available, and if so, will IP Australia also absorb the cost of carrying out such searches and opinions?

Item 12:

59. We agree that an examiner should be in a position to raise a utility issue during examination, although, as mentioned above, we are concerned that the requirement for utility is to be expanded by the introduction of sub-section 7A. It is also not clear how examination for utility will be carried out, and whether there will now be overlap between the utility requirement, the manner of manufacture requirement, the support requirement and the sufficiency requirement. It is not clear to what extent the applicant will be required to satisfy the Examiner that an invention is useful.

Item 13:

60. As explained in previous submissions, it is not clear how an Examiner could maintain an objection based on prior use. However, we do believe that placing information regarding possible prior use on the official file would be in the interest of third parties.

Items 14 and 15:

61. No comment.

Items 16 and 17:

62. There are typographical errors in the Explanatory Memorandum on page 29, the first reference to item 17a should refer to item 16, and the first reference to item 18 should refer to item 17.

Items 18 to 28:

63. No comment.

Item 29:

64. In implementing this provision it will be important to ensure that amendments relating to the incorporation of missing elements or parts (as they are referred to in the Patent Law Treaty and PCT) will be effective. It will also need to take into account missing elements and parts introduced under Regulation 3.5A.

Item 30:

65. No comment.

Item 31:

66. Beyond the restriction on added matter, it is not clear what types of amendments should not be permitted. We would like to be consulted before any exclusions are introduced in relation to the types of amendments that may be filed.

Item 32:

67. No comment.

Item 33:

68. It is important to ensure that s 114 does not apply to amendments filed to correct a clerical error or an obvious mistake. While this is reasonably clear from the wording of s 102(3) and proposed new s 114, we believe it would be helpful if the Explanatory Memorandum could clarify this.

Items 34 and 35:

69. No comment.

Items 36 and 37:

70. See comments above in relation to item 11.

Item 38:

71. No comment.

Item 39:

72. As mentioned previously in this submission, we consider the transitional provisions to be extremely unfair to patent applicants. We strongly urge the Government to amend the transitional provisions set out in items 1(a), (b), (c), (e), (f), and g must be removed so that the new patentability and specification requirements only apply to applications filed on or after the date of commencement of the new provisions.

Schedule 2:

Item 1: (s 119B)

73. We believe that insufficient research has been conducted in relation to the impact of regulatory processes on companies seeking to exploit patented inventions, after patent expiration, in fields other than the pharmaceutical field. There has also been insufficient consideration of the impact of regulatory delays on patentees in non-pharmaceutical industries seeking to put their products on the market and whether

patent term extensions should be provided in any non-pharmaceutical fields, for example medical devices. Accordingly, we strongly believe that it is premature to introduce such a broad infringement exemption in relation to or for obtaining regulatory approval for non-pharmaceutical inventions.

74. We are particularly concerned in relation to the introduction of this extremely broad regulatory exemption. Due to the way the regulatory exemption is worded, it would seem possible to use any patented invention without a license if the invention is being used for an act solely related to obtaining regulatory approval in Australia or overseas. This exemption is far broader than merely allowing a person to obtain regulatory approval for a non-pharmaceutical product, method or process without infringing a patent on that product, method or process. We consider this to be unfair on persons holding patents covering methods and products used in the course of carrying out activities required for regulatory approval, and is most likely in contravention of the TRIPS agreement. For this reason, we believe s 119B needs to be amended to restrict the provision to patents covering the product, method or process which is to be the subject of the regulatory approval, or otherwise limited to the use of patents reasonably necessary for the performance of the regulatory work.

75. To illustrate the problems which could be caused by the proposed exemption consider a patent covering a method or apparatus for testing the efficacy of plant growth regulators within a controlled environment, such as a hot house. The only reasonable use of such a method or apparatus would be in a research context by agrochemical companies in testing the efficacy of plant growth regulators. All such work conducted in Australia by agrochemical companies could be said to be solely directed to obtaining approval required by a law of the Commonwealth or other State or territory to exploit a product, method or process, or purposes connected with obtaining similar approval under a law of another country or region. Under the proposed exemption, an agrochemical company could manufacture its own equipment or conduct the patented testing process without a license from the patentee, and they will be able to use the apparatus and method in connection with all of the plant growth regulators tested and trialled within their research facility.

76. This result undermines the objective described in relation to proposed for an experimental research exemption set out in s 119C (discussed below) where it states that *"it is not intended to exempt the use of patented "research tools" from infringement"*. Unfortunately the regulatory exemption does just that.

77. We believe that the problem mentioned above in connection with proposed s 119B also applies to current s 119A. Unfortunately this provision was introduced without consultation with the patent profession, and it is likely to have the unintended consequence of rendering substantially unenforceable all research tool patents in the biomedical research field. Consider, for example, the patent which was the subject of the decision of the Court of Appeals of the Federal Circuit in United States in *Proveris Scientific Corp. v. Innovasystems, Inc. (5 August 2008)*. In that case the patent related to the system and apparatus for characterising aerosol sprays used in drug delivery devices, such as nasal sprays, pumps and inhalers. In the United States the pharmaceutical regulatory exemption is set out in s 271(e)(1), and is often referred to as the "safe harbour" provision. This provision has recently been interpreted very broadly in the decision of the Supreme Court in *Merck KGaA v*

Integra Lifesciences I, Ltd. In order to avoid a finding that the use of the patented system and apparatus was exempt under the safe harbour provision, the Court was required to read s 271(e)(1) restrictively, such that it only related to patents covering products and methods that were, themselves, subject to regulatory approval. Unfortunately, proposed s 119A does not appear to be capable of such a narrow reading. In fact, it appears to be drafted with the intention that it apply to patents covering methods and products not subject to regulatory approval. We believe that this provision should also be amended so that it is restricted to patents covering products and methods which are subject to regulatory approval, or limited to the use of patents reasonably necessary for the performance of the regulatory work.

Recommendation 7a

Delete s 119B from the exposure draft.

78. Or if Recommendation 7a is not accepted:

Recommendation 7b

(i) Amend s 119B so that it is restricted to patents covering the product or method for which regulatory approval is being sought, or

(ii) Amend s 119B to restrict its operation to the use of patents reasonably necessary for the performance of the regulatory work.

Item 1: (s 119C)

79. Although we are of the view that the experimental research exemption proposed by ACIP better serves the needs of the Australian research community than the infringement exemption proposed in the draft Bill, we do believe that infringement exemption will be well received by the Australian research community. We believe that sub-section 2(c) may be better worded "determining an improvement or modification of the invention" for consistency with the other sub-sections. We also believe that item (2)(e) should be worded "determining whether the patent for the invention is infringed" or "determining whether the patent for the invention has or would be infringed". This latter amendment is necessary to ensure that a person is able to assess, prior to infringement, whether a proposed activity is likely to represent infringement of the patent.

80. We also have some concerns in relation to the Explanatory Memorandum. The Explanatory Memorandum on page 44, second paragraph, refers to the state of awareness of a researcher in relation to the existence of a patent. This is irrelevant to the assessment of whether or not a researcher falls inside or outside the experimental use exemption. For this reason, and to avoid causing confusion among researchers as to whether awareness of a patent is relevant to infringement, the paragraph should be amended to remove reference to the state of awareness of the researcher. We also believe that the herbicide example could cause confusion for

researchers. If the experiment relates to the use of the herbicide with the wetting agent, rather than just use of the herbicide, then the researcher should be exempt from infringing both the herbicide patent and the wetting agent patent. In this regard, it is well known in the herbicide field that particular wetting agents work differently with different herbicides. A better example might be an example taken from the *Proveris Scientific Corp. v. Innovasystems, Inc.* case mentioned above. In that case, if the experiment is directed to improving the apparatus or aerosol testing system, the activity should be exempt. If the apparatus or method is being used to test an aerosol formulation of a patented drug, then the activity should not be exempt.

Schedule 3: (Patent related amendments)

Items 1 and 2:

81. No comment.

Item 3:

82. We are concerned that this provision removes the possibility to file a divisional innovation patent from a parent application which is subject to opposition. In this regard, it is possible during the course of an opposition that an applicant could be convinced that their invention does not possess an inventive step and would have been better pursued in an innovation patent application. In such circumstances we believe it will be unfair not to allow the applicant to abandon their opposed application in favour of a divisional innovation patent application. Alternatively, provisions could be introduced to clearly allow such an applicant to convert their opposed application to an application for an innovation patent. We also have some concerns in relation to the proposed wording of s 79B. In this regard, we do not believe it is appropriate to refer to the parent application as "the first application", as the parent application could itself be a divisional application. In this regard we prefer the wording of current s 79B where the parent application is identified as the "first-mentioned application".

Recommendation 8

Amend s 79B to allow an applicant to file a divisional innovation patent application during the course of an opposition.

Items 4 and 5:

83. No comment.

Item 6:

84. No comment, but see comments below in relation to item 10.

Items 7 to 9:

85. No comment.

Item 10:

86. We are particularly concerned in relation to the amendments proposed under this item.

87. While we do not object to the Court being given the authority to consider amendments to patent applications, as per s 105(1A), we do not support the proposal to remove the ability of the Commissioner to consider amendments when an appeal has been made to the Federal Court following an opposition. We are also particularly concerned that under the transitional provisions the Patent Office will not be able to progress amendments of opposed applications filed before commencement which had not previously been dealt with. This will cause difficulties and extra expense for both applicants and opponents as amendments following an opposition will, in many cases, need to be dealt with in a Court, rather than before the Patent Office.

88. In our view, and as argued in our previous submissions, a patent applicant should be given an opportunity to amend his patent application following an adverse opposition decision without having to progress the amendment before the Court. In this regard, in many cases appeal proceedings will be discontinued if a suitable amendment is filed with the Patent Office which is allowable and removes any ground of lawful objection. In many cases appeals are filed because of the current uncertainty associated with the process for progressing amendments before the Patent Office following an opposition decision.

89. We believe that a better procedure would be for any opposition decision adverse to the applicant to be issued in the form of an interim decision which is not subject to appeal. The applicant could be given an opportunity to propose suitable amendments which seek to address the deficiencies noted in the interim decision, giving the opponent an opportunity to comment. The Patent Office can then issue a final decision which will either be adverse to the applicant, or will be a decision to progress the application to grant. This decision could then be the subject of an appeal.

90. We believe that our proposed procedure for dealing with amendments resulting from an opposition decision will reduce the need for both applicants and opponents to get involved in expensive Court proceedings.

Recommendation 9

Remove proposed s 112A from the exposure draft and introduce new provisions, as described above, allowing amendments following an opposition to be progressed before the Patent Office.

91. We also disagree with the proposal set forth in Sub-section 141(1). In this regard it is inappropriate to require an applicant to obtain the consent of the Commissioner before withdrawing an opposed application. Where a divisional application has been filed the applicant and opponent will be forced to continue with the opposition as the applicant will be unwilling to consent to withdraw the divisional application even if they would be prepared to withdraw the parent application. This will result in increased costs for both the applicant and the opponent, and it is likely that the applicant will simply allow the application to lapse through a non-payment of renewal fees rather than withdraw the application.

92. We believe it is particularly unfair to both applicants and opponents to force them to continue with oppositions in the above circumstances.

Recommendation 10

Remove Sub-section 141(1) from the exposure draft.

Items 12 to 14:

93. No comment.

Item 210a:

94. No comment.

Item 16:

95. No comment.

Schedule 4:

Items 1 to 21:

96. No comment.

Item 22:

97. See submission filed jointly with AIPPI, APAA and IPC of LCA on 16 March 2011.

Items 23 to 36:

98. No comment.

Items 54 and 55:

99. See submission filed with AIPPI, APAA and IPC of LCA on 16 March 2011.

Schedule 5:

100. Comments have been provided or will be provided separately in response to item 11 items listed in the Schedule.

Schedule 6:

Items 22 to 27:

101. No comment.

Item 28:

102. For consistency with items (a), (b) and (c), we believe item (e) should be worded as follows:

> "(e) Any other use of the invention by, or on behalf of, or with the authority of, the patentee or nominated person, or his or her predecessor in title to the invention, for any purpose, if a complete application is made for the invention within the prescribed period".

103. Alternatively the language "by, or on behalf of, or with the authority of, the patentee or nominated person, or his or her predecessor in title to the invention" can be deleted from sub-sections 9A, B and C since it is only secret use "by, or on behalf of, or with the authority of, the patentee or nominated person or the patentees or nominated persons, predecessor in title to the invention" that falls within the scope of s 18(1)(d) and 18(1A)(d) and other sub-sections relating to the validity of patents and innovation patents.

104. We further note that there is an error in the Explanatory Memorandum, in that it suggests that the amendment to s 9 is relevant to an assessment of novelty or inventive step. Secret use is a ground of invalidity which is quite separate from novelty and inventive step grounds. This error in the Explanatory Memorandum should be corrected.

Items 29 to 41:

105. No comment.

Item 42:

106. We believe that the requirement for a reference to descriptions or the drawings to be "absolutely necessary" is excessively onerous. In this regard, there will be circumstances where it may be possible to describe an invention without reference to descriptions or drawings, but where the amount of effort and expense required to provide such a description is excessive. For this reason we believe that the word "absolutely" should be replaced with the word "reasonably". It is also important to ensure that this sub-section is worded in a way which would not prevent applicants from defining their inventions with reference to sequence listings, or defining their

inventions with reference to dictionary definitions appearing in the body of the description.

Item 43:

107. While we support the introduction of new sub-section 43(5), we believe that the Explanatory Memorandum is unclear with respect to the prescribed period. The Explanatory Memorandum indicates that the prescribed period is 12 months, whereas it should clarify that the prescribed period is the period more than 12 months prior to the filing date of the Convention application. As currently worded, the Explanatory Memorandum suggests that the earlier application to be disregarded is one made during the 12 months preceding the filing date of the Convention application.

Items 44 to 49:

108. No comment.

Items 50 and 52:

109. We are concerned by the repeal of sub-sections 49(3) and (4) and the introduction of new s 49A. In this regard, we believe that giving the Commissioner the discretion to refuse to accept a request for postponement of acceptance, and leaving it up to the Commissioner to specify a day to which acceptance is postponed should the request be accepted, will create uncertainty for applicants.

110. It would appear that the most appropriate time for an applicant to request postponement of acceptance is at the time of requesting examination. However, at that time the applicant will not be aware of the final acceptance deadline. It is therefore unclear how the Commissioner will deal with requests for postponement of acceptance filed by applicants with their examination requests. It would appear from the wording of proposed s 49A that postponement is not effective until the Commissioner specifies a day to which acceptance is postponed. The uncertainty about whether or not the request will be accepted will cause difficulties for the applicant in progressing the application, and will cause the applicant concern that the application may proceed to acceptance without the applicant being given a reasonable opportunity to ensure that the application is in order prior to acceptance. In this regard, one of the main reasons why applicants request postponement of acceptance is to ensure that they have an opportunity to amend an application, for example by reducing the number of claims or amending the claims to address problems identified in overseas jurisdictions, prior to acceptance. In fact, we believe it may be possible to remove postponement of acceptance provisions altogether if IP Australia would ensure that examination reports are issued on all applications, even those in order for acceptance. This would provide the applicant with an opportunity to propose amendments before an application proceeded to acceptance.

111. If, despite our submissions, IP Australia decides to proceed with this amendment we believe that allowance of the request should be mandatory, but that the Commissioner could retain some discretion to set the period of postponement. In all cases where a request is made, acceptance should be postponed to a date at least six

months from the date of the first examination report. An applicant needs certainty as to whether they will be provided with an opportunity following initial examination to file any pre-acceptance amendments or take any other action that may be required before acceptance. It is much more efficient for desired pre-acceptance amendments to be filed at the same time as filing amendments responsive to an Examiner's report rather than filing preliminary amendments before examination and further amendments responsive to an Examiner's report. This would also significantly increase the workload of Examiners.

Item 51:

112. No comment.

Item 53:

113. We are concerned about the breadth of the power afforded to the Commissioner under the proposed s 50A. Although the Explanatory Memorandum indicates that the procedure is intended to be used to correct administrative errors, there is nothing in the provision which restricts this application to administrative errors. The provisions also do not include any protection for applicants whose applications have had acceptance revoked. In this regard, the provisions should be expanded to ensure that an applicant is always given an opportunity to regain acceptance following a revocation of acceptance. For example, if the 21 month period for acceptance has expired at the time the Commissioner revokes acceptance, and further action is required by the applicant, a period of time of at least six months should be provided to enable the applicant to regain acceptance. Provisions should also be introduced to compensate any opponent who has filed a notice of opposition to an accepted application, the acceptance of which is subsequently revoked, and to refund any acceptance fees paid by the applicant. It will also be important to ensure that a new opposition period is provided when the application is re-accepted, and that a new period is allowed for the filing of divisional applications.

Recommendation 11

Restrict s 50A to correction of administration errors and introduce additional provisions to allow acceptance fees and opposition fees to be refunded, for the acceptance period and opposition periods to be reset and for the deadline for filing divisionals to be reset.

Items 54 to 67:

114. No comment.

Item 68:

115. We refer to our comments above in relation to item 53. It will be important to introduce provisions to ensure that examination can continue following revocation of the certificate.

Items 69 to 71:

116. No comment.

Item 72:

117. We are greatly concerned by the proposal to allow the validity of a claim to be questioned during proceedings for a non-infringement declaration. We believe that it is completely inappropriate for the validity of a claim to be questioned in such proceedings, and believe that a revocation action is the appropriate way to proceed in circumstances where a party wishes to invalidate a claim or a patent. In this regard, we believe it is not in the public interest, or in the interests of the Courts or patentees, to introduce a procedure in which claim validity is assessed, but where the validity finding is only applicable to the party seeking the non-infringement declaration. It is also unfair to the patentee who is put to the trouble of defending the validity of the claims for the sole purpose of preventing a single party from obtaining a non-infringement declaration. While the potential infringer would obtain significant benefit from the issuance of a non-infringement declaration, the patentee would gain no benefit after expending considerable time resources and money in establishing validity of the claims for the purpose of that proceeding.

118. Allowing validity to be questioned in non-infringement declaration proceedings will encourage potential infringers to proceed via this route instead of seeking revocation of the patent. This will mean, if successful, that they will have cleared the way for themselves while leaving the patent in place to act as a deterrent to competitors. This is not to the benefit of the public generally. We also believe that it is an inefficient use of the Courts' time to require consideration of validity of a claim in circumstances where a patent or claim cannot be revoked. If the Court is put to the trouble of considering the validity of the claim then the Court should be able to revoke a claim in circumstances where a claim is found to be invalid. This will not only benefit the party seeking but also benefit any other party who wishes to exploit the subject matter of that claim.

Recommendation 12

Remove sub-section (2) from proposed new s 126.

Items 73 and 74:

119. No comment

Item 75:

120. See comments in relation to Schedule 3, item 11.

Items 76 and 77:

121. No comment.

Item 78:

122. While we support the introduction of s 191A we do not believe that the new provision goes far enough. In particular, although an error in the Register in relation to a person's entitlement may flow from an error in inventorship, the new provision does not provide power for the Commissioner to correct an error in the Register in relation to inventorship.

123. Although s 191A allows the correction of various entries in the Register, it is not clear that this provision would allow a correction of inventorship. This is because in most cases the inventors listed in the Register correspond to those listed at the time of grant. Accordingly, even when there is an error in the naming of the inventors, the Register correctly reflects the basis upon which the patent was granted. For this reason it is not clear that a missing inventor, or a wrongly included inventor, would satisfy any of the sub-sections of s 191A(1).

124. Accordingly we believe that s 191A(2) should be amended to require the Commissioner to rectify the Register in circumstances where the Register does not properly record inventorship. Alternatively, an additional sub-section could be introduced dealing with rectification of the Register to correct inventorship.

Recommendation 13

Amend s 191A to introduce a power for the Commissioner to rectify the Register in circumstances where inventors are incorrectly listed.

Item 79:

125. No comment.

Items 80 to 83:

126. As discussed in detail in earlier submissions, we are particularly concerned in relation to the proposal to remove the requirement for Sub-offices. We are particularly concerned that IP Australia may withdraw physical lodgement services while they are still needed for a significant proportion of our members. While it is true in general that more business is being conducted electronically at the present time than previously, we do not believe that the proportion of transactions which can be conducted electronically with IP Australia presently, or is likely to be able to be conducted with IP Australia in the near future, warrants removal of the Sub-office requirement. In this regard we believe that it is likely to be many years before State lodgement facilities will not be required by our members.

127. For many years our members have worked closely with IP Australia to develop e-business channels to allow attorneys and applicants to conduct their business with IP Australia electronically. While this work is continuing, it is apparent that IP Australia's current efforts are in relation to allowing renewal payments to be made

electronically. This will be of little assistance to our members in their dealings with IP Australia. We believe that the requirement for a Sub-office to be maintained in each State should be retained until our members, which represent over 80% of patent applicants in Australia, are satisfied that the requirement can be removed. The removal of sub-offices and associated physical lodgement facilities will also be greatly detrimental to Australian small businesses and individuals who may not have appropriate electronic lodgement facilities or expertise to enable them to conduct their business electronically with IP Australia. We do not see any justification for removing the requirement at this early stage.

Recommendation 14

Retain current sub-section 205(2).

Items 84 and 85:

128. No comment.

Item 86:

129. The rationale outlined in the Explanatory Memorandum for the proposed amendment to s 226 is to ensure that documents are available via the internet and to allow IP Australia to implement an e-dossier system. We agree that if the current provision hinders IP Australia in moving to these systems, then s 226 should be amended accordingly. However, the proposed new s 226 is in broad terms which could have unintended consequences. For example, a patent specification may include a drawing of a new product. In some cases, the product will not have been sold or otherwise exploited and the drawing will constitute a copyright work. The applicant, in such circumstances, will have an opportunity to secure registered design rights at a later time. In its proposed form, s 226 would provide a defence to a person who made a three dimensional reproduction of a product shown in a drawing in a patent specification where the drawing was the subject of copyright and where s 77 of the *Copyright Act* did not apply. Current s 226 explicitly limits the defence to two dimensional reproduction. We recommend that proposed s 226 be amended to explicitly limit the copyright infringement defence so that it does not include three dimensional reproductions.

Recommendation 15

Amend proposed s 226 so that it does not extend to three dimensional reproduction of a copyright work.

Items 88 to 100:

130. No comment.

Item 101:

131. We support this amendment on the condition that IP Australia introduces a system to ensure that applications are published in the form in which they are filed. Although the new provisions introduce a prohibition on adding matter when amending a patent application, there is no prohibition on deleting matter. It would cause considerable uncertainty for applicants if IP Australia publishes applications in a form in which matter present in the specification as originally filed is deleted, particularly since the deleted matter will now be relevant under a whole of contents novelty assessment.

Item 102:

132. No comment.

Items 103 to 131:

133. Comments will be provided in relation to these items separately.

Item 132:

134. There is an error in the Explanatory Memorandum in relation to sub-item (3). In this regard the transitional provisions on page 117 indicate that items 30 and 78 "apply only to patents granted on or after commencement". It is clear from the wording of the provision that items 30 and 78 also apply to patents granted before commencement.

135. As previously mentioned, we are concerned in relation to a number of transitional provisions which will result in new provisions relating to patentability, specification requirements, amendments and allowable claim forms being applied to applications filed prior to commencement of the new provisions. Sub-item (7) is such an item. In this regard we believe that sub-sections (b), (c), (e), (f) and (g) should be removed. An applicant who has filed a patent application which includes claims relying on the drawings should not be adversely affected by amendments to the patent legislation. This will not only adversely affect applicants who were wishing to pursue omnibus claims, but will also adversely affect applicants who have relied substantially on drawings or the description to define their inventions. Such applicants may have considerable difficulty in remedying their claims without adding matter to their applications.

136. We also believe it is inappropriate to apply a different whole of contents novelty standard to applications which have already been filed, particularly since, under current practices, IP Australia has not always published applications in the form in which they have been filed. In this regard it will be inappropriate to implement a whole of contents novelty provision in which deleted subject matter currently not relevant to novelty, becomes relevant to novelty.

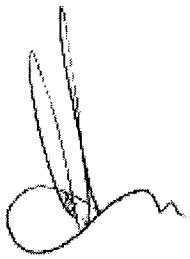
Recommendation 16

Delete sub-items 7(e), (c), (e), (f) and (g).

137. Although the submissions above do not specifically indicate support for particular amendments proposed in the draft Bill, we do believe that the package of amendments set out in the draft Bill will substantially improve the legislative system underpinning patents granted by IP Australia. In this regard, in most circumstances the indication "no comment" indicates our support for the proposed amendment. However, we do believe that our recommendations should be adopted, particularly those highlighted in boxes above, before the draft Bill is presented to Parliament. Of all the amendments proposed, we consider that the proposed transitional provisions relating to patentability and specification requirements, amendments and allowable claim types are the ones most likely to cause harm for patent applicants and also to Australia's reputation internationally.

138. We appreciate the opportunity to comment on the draft Bill and we are very happy to take part in any further discussions in relation to the draft Bill and our recommendations.

Yours sincerely



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