



**THE AUSTRALIAN FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS
FICPI AUSTRALIA**

30 June, 2009

Les McCaffery
Assistant Director, Domestic Policy
IP Australia
PO Box 200
WODEN ACT 2606

***By E-mail
(confirmation by mail)***

PRESIDENT:
PETER HUNTSMAN
1 Nicholson Street
Melbourne 3000
Australia
Telephone
(03) 9254 2777
International
+613 9254 2777
Facsimile
(03) 9254 2770
International Facsimile
+613 9254 2770
E-Mail
phuntsman@davies.com.au

Dear Mr McCaffery,

Exemptions to Patent Infringement – Consultation Paper March 2009

Thank you for your e-mail of 6 May, 2009 allowing us until 30 June, 2009 to respond to this Consultation Paper. The following comments are made on behalf of the members of FICPI Australia.

FICPI Australia is an organisation drawing its members from experienced registered patent attorneys and registered trademarks attorneys in Australia that are proprietors or partners in patent and trade mark attorney firms conducting business in Australia. FICPI Australia does not directly represent intellectual property owners or other users of the IP systems, but its members work directly and closely with such persons and the following comments are based on our members' experience in representing these users of the patent system.

FICPI Australia is a national association of the Fédération Internationale Des Conseils En Propriété Industrielle (FICPI), a non-political organisation of intellectual property attorneys in private practice in some 86 countries.

We have previously had extensive discussions with ACIP in their review from 2004 to 2006 on "Patents and Experimental Use", and strongly supported Recommendation 1 in their Public Consultation Paper of September 2006. A copy of our letter of 29 September, 2006 to Mr Anthony Murfett responding to the Public Consultation Paper is attached for convenience.

You will see from this that we also supported a clarification of the phrase "seeking an improvement to the invention" in the ACIP Recommendation 1 so that it clearly encompasses "determining new properties of, or new uses of, an invention".

You may appreciate from the above that we are disappointed with the proposals in IP Australia's Consultation Paper, since they neither follow ACIP's Recommendation 1 nor include the clarification of "seeking an improvement to

SECRETARY:
GREG CHAMBERS
23rd Floor
367 Collins Street
Melbourne 3000
Australia
Telephone
(03) 9614 1944
International
+613 9614 1944
Facsimile
(03) 9614 1867
International Facsimile
+613 9614 1867
E-Mail
greg.chambers@pof.com.au

TREASURER:
STEPHEN KROUZECKY
Level 21
201 Elizabeth Street
Sydney NSW 2000
Australia
Telephone
(02) 8267 7300
International
+612 8267 7300
Facsimile
(02) 9264 5154
International Facsimile
+612 9264 5154
E-Mail
stephenk@hmcip.com.au

the invention", and no explanation is given as to why a recommendation that was the result of extensive public consultation over two years has not been followed.

In support of our view that IP Australia should adopt ACIP's Recommendation 1 with the above clarification we note that the recently released New Zealand Patents Bill has already done so.

Turning now to IP Australia's proposed changes, we are pleased to note IP Australia's focus on meeting the interests of Australians (sic) stakeholders (paragraph 8), but in practice we believe that the proposal for the exemption to be in respect of "any act on a patented invention which is solely for the purpose of" the listed activities does not achieve this.

While this wording may have been "drafted in such a manner that it can be readily understood by the relevant stakeholders, for example researchers", we do not believe that it provides a workable exemption. As explained clearly to IP Australia in the Patent Consultation Group meeting on 6 May, 2009, it is very rare that any research or experiment is conducted **solely** for the purpose of any of the listed activities.

If this wording is adopted in the proposed legislation, we believe it is likely to result in numerous infringement actions alleging that the research or experiment complained of was not conducted solely for the purpose of one or more of the listed activities.

ACIP's recommendation avoided this difficulty by qualifying that the *experimental act must not unreasonably conflict with the normal exploitation of a patent*, and we believe this approach does achieve an acceptable balance of clarity and fairness as between the rights of researchers and those of the patentee.

We are also concerned that IP Australia's proposal is directed to *acts done on a patented invention* rather than *acts relating to the subject matter of the invention* as recommended by ACIP, and that IP Australia's list of permitted acts appears to be exclusive rather than inclusive as proposed by ACIP, with that inclusive list then being qualified as *acts done for experimental purposes*.

We assume that IP Australia's proposal does not refer to *acts done for experimental purposes* because it broadly encompasses *activities performed for achieving regulatory approval*. We are strongly of the view that it is not appropriate to include regulatory approval activities in an "experimental use" exemption, since the activities are quite distinct, and we note that ACIP did not attempt to do so.

The Patents Act 1990 already contains in S119A an exemption for regulatory approval activities for pharmaceutical patents, but this is balanced at least in part by parallel extension of term provisions for pharmaceutical substances. In other words, if third parties need time to achieve regulatory approval for competing pharmaceutical substances, it is likely that so too did the patentee for its original product so that the patentee effectively lost some of the patent term before its pharmaceutical substance could be brought to market. This effective loss of term can be made up at least in part by the extension of term provisions for patents relating to pharmaceutical substances.

IP Australia's proposed regulatory approval exemptions is not restricted to pharmaceutical patents and we are of the view that such a broadening of the regulatory approval exemption is not acceptable without parallel extension of term provisions, if these broad provisions are necessary at all. We note the ACIP Report recommended in Recommendation 5, prior to the introduction of S119A, that a review be considered to determine the impact on Australian

industry of the absence of an infringement exemption for regulatory approval activities. As far as we are aware, no such detailed review has been conducted. We believe such a review should be conducted to determine whether any broadening of the regulatory approval exemptions is necessary. The review should encompass the question of whether patent term extensions should be made available for all areas of technology for which regulatory approval is needed.

In the meantime, we urge IP Australia to adopt Recommendation 1 from ACIP's Public Consultation Paper of September 2006, especially if the inclusive list of acts done for experimental purposes is included in the Regulations, rather than the Patents Act, and if "determining the scope of the invention" is clarified along the lines suggested above. We believe such an amendment would give Australian researchers far greater protection for experimental use than that given by IP Australia's proposal, with much greater clarity for both researchers and patentees than is currently available.

We will be pleased to discuss or expand upon these comments if desired. We particularly request a further opportunity to comment should IP Australia contemplate proceeding with its proposed approach notwithstanding the concerns that have been raised.

Yours sincerely

A handwritten signature in black ink, appearing to read 'P. Huntsman', with a long horizontal flourish extending to the right.

PETER HUNTSMAN
President
FICPI AUSTRALIA