Medicines Australia

Better health through research & innovation

21 December 2018

Sean Applegate
IP Australia
Discovery House
47 Bowes Street
Phillip ACT 2606

consultation@ipaustralia.gov.au

Dear Mr Applegate,

Medicines Australia welcomes the opportunity to provide input on the public consultation on the draft Intellectual Property (IP) regulations and appreciates the process undertaken.

Medicines Australia is concerned by some of the recommendations being made by IP Australia and reiterates its position that some of the changes are unnecessary and unwarranted.

A strong, effective and stable IP system is critical to fostering pharmaceutical innovation, productivity and competitiveness. Indeed, research has shown that the more robust a country's IP system is, the higher the level of innovation for the pharmaceutical industry[1]. This is important for Australia's future competitiveness as a destination for pharmaceutical investment, which encourages highly skilled Science Technology Engineering and Mathematics (STEM) jobs, fosters economic growth and provides faster access to new medicines for Australian patients.

Whilst Medicines Australia supports Australian standards to be consistent with international best practice, frequent changes to fundamental aspects of the IP system in Australia can lead to business uncertainty and reduce Australia's attractiveness as an investment and innovation destination.

Medicines Australia maintains its view that the Innovation Patent system should be retained and continues to support the recommendations made by the Advisory Council on Intellectual Property in its 2014 final report that proposed changing and strengthening the IP system rather than completely abolishing innovation patents. It should be noted that the Australian Government has identified Innovation Patents as being an industry strength "…as a relatively quick and inexpensive way to obtain IP protection for a new medical device or pharmaceutical substance, method or process."[2]

A compulsory license has never been granted in Australia, and Crown Use has rarely been used. As such, Medicines Australia maintains that these areas are not pressing issues for legislative amendment. Whilst we agree that the patentee has the right "…to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention" as described in paragraph 133(5)(b)(iii), guidance may be required on how the return is calculated to ensure Australia meets its international obligations that the compensation received by the patentee is adequate and reasonable. Compulsory licensing is rarely the best policy option to promote access to medicines and as with Crown Use, should be used only very sparingly as they override and interfere with the private property law rights of the patentee.

Medicines Australia is available for further discussion if required. Any queries should be directed to Andrew Bowskill, Manager, Industry Policy and Research at abowskill@medaus.com.au.

Yours sincerely,

Elizabeth de Somer
CEO, Medicines Australia

References

1. QuintilesIMS, Value of Innovation
2. Commonwealth of Australia. 2018. Clinical trials Industry Capability Report