



Productivity Commission
GPO Box 1428
CANBERRA ACT 2601

Regarding Submission to Productivity Commission: Draft report on Australia's Intellectual Property Arrangements

Complementary Medicines Australia (CMA) welcomes the opportunity to provide a submission to the Productivity Commission in relation to the Draft Report on Australia's Intellectual Property Arrangements (Draft Report), and in particular with regard to retention of a second-tier patent system.

CMA is the peak industry body for the complementary medicines industry, representing members across the supply chain, including manufacturers, raw material suppliers, wholesalers, distributors and retailers. Regulated in Australia as medicines under the *Therapeutic Goods Act 1989*, complementary medicines are not limited to but include vitamins, mineral and nutritional supplements, and herbal and traditional medicines.

Unlike in some other jurisdictions, the Australian regulation of complementary medicines as *medicines* facilitates their integration within mainstream medicine, both locally and around the world. This reputation has led to a rapidly growing demand for Australian complementary medicines in the Asian countries, and is coupled with growing middle classes and ageing populations that embrace complementary medicines. Recent Austrade data shows Australian complementary medicines exports to Asia have more than doubled in the last year, driven by the industry's reputation for products that meet the highest standards of quality and safety.

Our industry has significant potential to expand exports and needs to be in a position to capitalise on these market opportunities. CMA would like to acknowledge the Government's focus on deepening Australia's economic ties with countries within our region, and strongly supports a focus of Australia's FTA negotiations on helping to position Australia as competitively as possible on issues such as intellectual property (IP) protection.

To leverage the accumulated knowledge, capabilities and a strong international branding for excellence, Australian complementary medicine businesses need the ability to invest in research and development. However, there is a major barrier to the level of investment that businesses direct towards research and development, and that is a limited ability to protect innovation.

Complementary medicines are rarely able to achieve a standard patent because they cannot meet the requirements of novelty and secrecy, given their history of use is often in the public domain. There is also currently little incentive to invest in research and development due to a lack of data protection and/or market exclusivity. The pharmaceutical industry relies on patents more than most. Increasingly, the complementary medicines industry is being asked to provide a similar level of evidence and investment in research and development to support the use of its products. However, once brought to market, there is little in the way of IP protection and products can be readily copied by competitors. CMA agrees that data protection arrangements, separate to patent protections, are required in order to protect the investment in the application data to demonstrate that medicines meet the standards of quality and safety and efficiency.

DRAFT RECOMMENDATION 7.1

The Australian Government should abolish the innovation patent system

As noted in the Draft Paper, the role of IP rights in encouraging innovation also varies by sector and technology. CMA supports the continuation of an innovation patent system for our industry where the innovative step threshold is lower than an inventive step threshold and is for limited claims – a system designed to assist Australian businesses with IP rights for minor improvements or adaptations to existing products. The IPS should be retained and consideration of other administration issues be dealt with by further refinement of the current system.

Whilst our industry members may have not utilised the innovation patent system as well as they might to date, it has been used. For example, Blackmores filed a innovation patent for a folic acid product (reference 2006100071 – Nutritional Supplement) for the claim “a *pregnancy and/or breastfeeding nutritional supplement consisting essentially of folic acid and/or folate and iodine and/or iodide and optionally one or more pharmaceutically acceptable carriers in a miniature oral dosage form*”.

This revision of IP arrangements is occurring at the same time as a number of other reviews. One such review is the Expert Panel Review of Medicines and Medical Devices Regulation, led by Professor Lloyds Sansom AO. On 31 July 2015, the Expert Panel’s [Report on the Regulatory Frameworks for Complementary Medicines and Advertising of Therapeutic Goods](#) was provided to Government. Industry was supportive of a number of the recommendations, and in particular those that aim to encourage businesses to invest in bringing new products to the market and in conducting a greater number of clinical trials to substantiate varying levels of therapeutic indications and health claims. One of the recommendations made by the panel was that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation (Recommendation 50). Retention of a second-tier patent system is one such mechanism that will support our industry to compete at a global level.

Australia has world class academic and research bodies, and holds the potential to be an international leader in complementary medicines research and translation into both commercial and health policy outcomes. Our country is extremely fortunate to be home to two world leading

research institutions for complementary medicines: the National Institute of Complementary Medicines and The Australian Research Centre in Complementary and Integrative Medicine, both five star accredited research centres. CMA notes that the Draft Paper highlights that governments provide a broad suite of policy measures such as tax concessions, grants, and in some cases, the direct provision of research and development, often in combination with IP rights. This multi-pronged approach is vital if Australia is going to improve on measures of international competitiveness. Research validates and supports innovation and informs good government policy, and there is a need for dedicated government funding for complementary medicines research.¹ CMA has urged the National Health and Medical Research Council (NHMRC) to increase its funding from less than 2% of its annual budget, into research to support the evidence base for complementary medicines.²

There are currently 73 TGA licensed sites manufacturing complementary medicines in Australia, and the industry provides substantial employment in the form of approximately 6000 direct highly skilled jobs. The Australian complementary medicines industry holds great potential to grow and to contribute further to our exports and the strength of high-skill local manufacturing, employment opportunities and development of a range of technical and vocational skills. Our manufacturing sector does still face a number of challenges, including increasing global competitiveness and the need to consistently produce innovative and value-added products in order to compete internationally. Intellectual property protections are essential to encourage businesses to invest in research and development. Along with greater support for complementary medicines researchers, this supports the translation of the evidence to commercialisation and further contribution to our economy.

Thank you for the opportunity to submit our feedback; we would be pleased to discuss any points of this submission further as required.

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Complementary Medicines Australia

3 June 2016

¹ Complementary Medicines in the Australian Health System: Expert Committee on Complementary Medicines in the Health System Report to the Parliamentary Secretary to the Minister for Health and Ageing; September 2003

² National Institute of Complementary Medicine, (2013), Research Priorities for complementary medicine in Australia.
http://www.nicm.edu.au/_data/assets/pdf_file/0009/537840/Research_Priorities_for_CM.pdf