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28 September 2015

David Simmons
Contact Officer
IP Australia

Email: consultation@ipaustrialia.gov.au

Re: Consultation Paper: ACIP's Recommendation on the Innovation Patent System

Dear Sir,

We write in response to the above IP Australia Consultation Paper.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants.

ASMI appreciates this opportunity to provide comment on the Consultation Paper.

Overview

ASMI makes the following recommendations:

- There should be no change to the current innovation patent system.
- Appropriate data protection and market exclusivity options should be made available to incentivise research into non-prescription medicines (i.e. over-the-counter medicines and complementary medicines).

Regulation of Therapeutic Goods in Australia

Therapeutic goods are regulated in Australia by the Therapeutic Goods Administration (the TGA). Prescription medicines, over-the-counter medicines and complementary medicines are all subject to *different* levels of oversight and protection by the TGA.

Current innovation patent system

A copy of ASMI's submission of 4 October 2013 to the ACIP review of the Innovation patent system has been included as Attachment 1.

ASMI's position in relation to reforms to the innovation patent system remain unchanged and can be summarised as follows:

- Non-prescription medicines (both over-the-counter and complementary) do not benefit from the same level of intellectual property protection as do prescription medicines.
- Innovation patents provide an additional avenue to protect investment in relation to more minor innovation and can stimulate research in relation to non-prescription medicines.
- No further reforms should be undertaken until the most recent reforms introduced in the Raising the Bar Act have had a chance to bed down.
- There should be collaboration between all the stakeholders to increase awareness and uptake of innovation patents for non-prescription medicines.

Other Options

As well as retaining the current innovation patent system, other options should be considered.

Where there has been substantial investment, there should be appropriate data protection or market exclusivity to incentivise research into over-the-counter and complementary medicines.

A period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment and costs associated with approvals of new substances, new products and new claims. This would act as an incentive to research new therapeutic claims and products.

Getting an over-the-counter or complementary medicine (or ingredient) onto the market in Australia requires a significant initial capital investment, and investment in research. Currently, the lack of investment protection available deters investment in research to support product innovation.

Unlike innovator prescription products, non-prescription medicines generally lack standard patent protection. This affects both over-the-counter and complementary medicines. This lack of intellectual property protection means that sponsors of these products need to find other ways to protect their investment. Typically, this has meant keeping the information out of the public arena. Another option (which is not currently available in Australia) would be to take advantage of some sort of data protection.

Currently there is no provision for data protection in relation to non-prescription medicines and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage. Data protection is a means by which a sponsor's data (new R&D) is protected for a period of time from competitors, and this includes from a subsequent sponsor seeking similar approval for an equivalent therapeutic good. In this context, "data" refers to the information that a sponsor provides in relation to a therapeutic good when seeking some form of approval for that good under the *Therapeutic Goods Act*.

Other jurisdictions, particularly the European Union and the United States, have data protection regimes that are quite favourable to sponsors and make Australia's look rather restrictive by comparison.

Through some form of data protection, albeit brief, sponsors will be encouraged to invest in innovation if they have the opportunity to gain a return on their investment before competing products enter the market. Industry believes that appropriate data protection provisions in the Therapeutic Goods legislation will create an environment conducive to investment in R&D for this important range of medicines.

In ASMI's view there are four broad options for protecting a sponsor's investment in research into non-prescription medicines:

- Keeping the information out of the public arena (which is getting harder to do),
- Data protection (which is not currently available for non-prescription medicines),
- Patent protection (which non-prescription medicines generally lack), and
- Innovation patent protection

ASMI notes that both the industry and the community desire increased access to evidence based complementary medicines and that greater investment in scientific research and development will expand the range of well-evidenced non-prescription medicines available for self-care.

Additionally, the TGA is tightening regulations in relation to complementary medicines resulting in the need for increased scientific data to support products. Sponsors of complementary medicines will be less likely to invest in generating important scientific and clinical data to support the safety and efficacy of these products if there is no protection of that investment.

ASMI therefore believes that a period of marketplace exclusivity, commensurate with the degree of innovation and investment, is required to recoup investment costs and, importantly, act as an incentive to research new therapeutic claims and products.

In ASMI's view, there are two methods of implementing data protection, as follows:

- Data exclusivity. Which means a defined period during which subsequent sponsors of equivalent therapeutic goods may not, during the period of data exclusivity, benefit from data provided by the first sponsor. This data exclusivity may take different forms, all ultimately having the same effect, i.e. a prohibition on relevant regulatory bodies from granting approval to subsequent sponsors of equivalent therapeutic goods if the application in question is dependent upon referral to data provided or generated by the first sponsor. This is the form of data exclusivity currently in the Therapeutic Goods Act in so far as concerns new active ingredients (new chemical entities, as opposed to well-established entities). Section 25A of the *Therapeutic Goods Act* provides for a five-year period of data exclusivity, but only in respect of information about new active ingredients (i.e. active ingredients not contained in any already approved therapeutic good) which are not publicly available. This form of data exclusivity prevents the TGA from using data provided by the first sponsor in considering an application put forward by a subsequent sponsor. Emphasis is placed on not relying, as opposed to not disclosing, since generally most of the regulatory bodies under the Act already treat information supplied to them by sponsors as commercial-in-confidence. However, this provision does not apply to new complementary medicine ingredients. Put simply, data exclusivity prevents Person B from using Person A's data package (as submitted to the TGA) to register the same medicine. Unlike a patent, data exclusivity: generally does not require lengthy, complex litigation to enforce; does not prevent Person B, or anyone else, from doing any research; and does not prevent person B from lodging their own data package, if they have one, to register and bring to market a competitor medicine.
- Market exclusivity. Which means a defined, enforced period during which a sponsor that is successful in obtaining some form of approval for a therapeutic good is granted an exclusive market status that prevents subsequent sponsors from obtaining similar approval for equivalent goods during the period of market exclusivity, even if new data is provided. This is analogous to patent protection, which grants the patent holder a monopoly in relation to their innovation for the life of the patent, preventing others from making use of that innovation, even if it is arrived at independently. Currently there is no provision for market exclusivity and where competitors benefit from the data generated by the innovator, the latter is placed at a significant commercial disadvantage

There are regulatory impediments to innovation in the non-prescription and complementary medicines industry in Australia and measures need to be implemented to address this market failure and to create an environment more conducive to investment in the generation of regulatory data to support innovative products.

In ASMI's view, *data* exclusivity would be appropriate for:

- New indications, claims and/or dosage regimes for products or ingredients.
- New Listable ingredients.
- New formulations.
- New combinations.

Whereas *market* exclusivity would be appropriate for:

- Rescheduling.

The above forms of data protection will encourage investment in innovation, because they will give sponsors an opportunity to gain a return on their investment before competing products enter the market.

In ASMI's view, data protection and confidentiality can both be used collectively to incentivise and protect research into innovative consumer healthcare products.

Expansion of the existing data protection provisions in the above ways would not require any budgetary outlay by the Commonwealth but would, in fact, be revenue positive for its encouragement of additional investment and employment.

Non-prescription medicines (both over-the-counter and complementary) do not benefit from the same level of intellectual property protection as do prescription medicines and so, measures designed to encourage investment in innovation need to be tailored to suit these differences between the different types of therapeutic goods.

For a full discussion, refer to ASMI's submission to the Senate Inquiry into Australia's Innovation System of July 2014, which has been included as Attachment 2.

Summary

ASMI's position in response to the Consultation Paper can be summarised as follows:

- There should be no change to the current innovation patent system.
- Appropriate data protection and market exclusivity options should be made available to incentivise research into non-prescription medicines (i.e. over-the-counter medicines and complementary medicines).

We remain committed to working with IP Australia and other stakeholders to bring about meaningful reform in this area.

Please contact me should you require any further clarification relating to this submission.

Yours sincerely,

Steven Scarff
Scientific and Regulatory Affairs Director

List of Attachments

- 1 ASMI submission to the ACIP Review of the Innovation Patent System (Oct 2013)
- 2 ASMI submission to the Senate Inquiry into Australia's Innovation System(July 2014)