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Jeff Carl
Secretariat
Advisory Council on Intellectual Property
PO Box 200
WODEN ACT 2606

By email to: mail.acip@ipaaustralia.gov.au

Dear Sir,

Re: Review of the Innovation Patent System

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care products (non-prescription medicines) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. Further information about ASMI and ASMI members is available on our website (www.asmi.com.au).

In response to the Advisory Council of Intellectual Property (ACIP) public call for comments, ASMI provides the following submission in relation to the "Issues Paper", the "Options Paper" and the "Verve Economics Report on the economic value of the innovation patent".

ASMI would be interested in participating in "round-table" or "one-on-one discussions" with ACIP and other stakeholders on this topic. Please contact the undersigned.

Summary

ASMI's response to the Options Paper 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 look like a useful adjunct to data protection and confidentiality arrangements for non-prescription medicines.
- We suggest that no further reforms be undertaken until the most recent reforms introduced in the Raising the Bar Act have had a chance to bed down.
- The most appropriate option is Option A "No change".
- Like ACIP we are puzzled by the (apparent) lack of interest in innovation patents by individuals and SMEs, ASMI suggests that ACIP, IP Australia and other stakeholders (such as ASMI) look at ways of increasing awareness and uptake of innovation patents for non-prescription medicines.

ASMI and the Australian Market

The Australian Self Medication Industry (ASMI) is the peak industry body representing manufacturers of consumer healthcare products in Australia. Our members research, develop and produce the range of health and wellbeing products that include over-the-counter medicines and complementary medicines.

ASMI's mission is to advance public health through responsible self care.

Self care encompasses all the things individuals, families and communities can do to improve or restore health, prevent disease and manage illness, in partnership with a healthcare professional.

ASMI estimates that the consumer healthcare industry turnover in Australia is around \$4 billion, with 5% p.a. growth^{1,2}

ASMI members make up 85% of this market in which the main retail channels are pharmacy (60%), supermarkets (20%) and health food stores (18%).

The highest value product categories per annum^{1,2} are:

- Vitamins and minerals (\$670M)
- Pain relief (\$569M)
- Therapeutic skin care (\$466M)
- Cough & cold (\$409M)

Recent data^{1,2} suggests that the consumer healthcare products industry in Australia comprises:

- 250,000 products in pharmacies and grocery retailers.
- 17,500 people employed across Australia.
- Exports estimated at \$600 million p.a.
- More than 20 local manufacturing facilities.

Typical R&D in the consumer healthcare products sector includes:

- New indications and/or dosage regimes for products or ingredients.
- New formulations of (previously patented) active ingredients.
- Alternate delivery platforms for active ingredients (e.g. slow release formulations, liquids, coating technologies, encapsulation technologies etc).
- New combinations of well-established ingredients.
- New processing technologies.
- Packaging and labelling innovations.

Due to the imperatives imposed by the nature of the market, innovations are typically incremental and need to be progressed rapidly to market. Innovation is critical to the continued success and growth of the sector.

ASMI is committed to finding ways of encouraging investment into consumer healthcare products as a means of maintaining and expanding this important and valuable sector.

¹ Nielsen Scan Data Year End 2011 Pharmacy & Grocery Combined. Extrapolated for Health Food Channel.

² AC Neilson 2012.

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 by the TGA.

Getting an over-the-counter or complementary medicine 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, additionally these sponsors could take advantage of the innovation patent system. Another option (which is not currently available in Australia) would be to take advantage of some sort of data protection arrangement (ASMI's position on data protection reforms is discussed in the following section).

However, sponsor's attempts to keep product information out of the public arena could be negatively impacted by two significant reform programs recently undertaken by the TGA:

1. The Transparency Review of the TGA³ was conducted to examine concerns about the amount of information made available by the TGA. In relation to the different product types, the final report⁴ indicated that:

"... what is commercial-in-confidence will vary with the type of therapeutic good. Not all therapeutic goods have the benefit of patent protection. Sponsors of products without such protection may seek to protect their intellectual property, by keeping information about the product out of the public arena. Publication of the full application to the TGA may therefore devalue the sponsor's asset". [emphasis added]

2. A review of the TGA's approach to disclosure of Commercially Confidential Information (CCI) has recently been conducted⁵. In ASMI's view the TGA needs to strike the right balance between stakeholder access and maintaining a viable medicines industry as the poorly considered release of CCI has the potential to devalue sponsors' assets. Importantly, once information is released it cannot be retrieved and so the damage cannot be remedied.

At the same time, the TGA's complementary medicines reforms⁶ will inevitably lead to an increase in regulatory burden and an increased need to generate scientific data to support product claims.

So, on the one hand it is getting harder to protect a research investment and on the other more research will be required.

³ <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

⁴ Review to improve the transparency of the Therapeutic Goods Administration, Final Report, June 2011 at: <http://www.tga.gov.au/newsroom/review-tga-transparency-1101.htm>

⁵ <http://www.tga.gov.au/newsroom/consult-disclosure-cci-130627.htm>

⁶ <http://www.tga.gov.au/newsroom/consult-cm-evidence-listed-medicines-120423.htm>

Innovation patents therefore look like a useful adjunct to data protection and confidentiality for over-the-counter and complementary medicines. In ASMI's view, now is not the time to be removing or restricting the innovation patent system.

Regardless of the reforms adopted, ASMI suggests that a slightly different approach is required for over-the-counter medicines and complementary medicines since they are not afforded the same intellectual property protections as prescription medicines.

Data protection

As discussed in the previous section, in ASMI's view there are three broad options for protecting a sponsor's investment in research into consumer healthcare products:

- 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), and
- Patent protection (both standard patent and innovation patent)

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.

ASMI 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 this context "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. Here, "data" refers to the information that a sponsor provides in relation to a therapeutic good when seeking some form of approval for that good from the TGA. 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.
- 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 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.

It is important to note that the solutions proposed are intended to address issues of regulatory failure in relation to non-prescription and complementary medicines only and are not designed to impact on prescription medicines generally, and the PBS in particular. ASMI supports measures to prevent any unintended consequences resulting from the introduction of these reforms.

As well, ASMI supports the principles of a free market and healthy competition. The proposed measures are not designed to restrict competition but to encourage investment in innovation through the ability of sponsors to recoup their investment in innovative products before competitor products enter the market.

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

ASMI's views on the Options Paper

As far as non-prescription medicines are concerned, innovation patents appear to be a useful adjunct to the standard patent system.

Furthermore, innovation patents appear to be a useful adjunct to the current method of keeping information out of the public arena (which is becoming increasingly difficult) and the possible methods of data protection (which are not currently available).

In ASMI's view, the changes introduced in the Raising the Bar Act should be allowed to bed down before further reform takes place. In particular, ASMI notes that specific changes were made to address some of the strategic uses to which the innovation patent system was being put. In ASMI's view it would be

reasonable to see how the recent changes interact and to allow sufficient time for the reforms to have their full effect before making any more changes to the system. As the authors of the Options Paper note (at page 39):

“There have been significant changes to the innovation patent system due to the final implementation of the Raising the Bar Act.”[emphasis added]

ASMI notes the suggestion that chemical and pharmaceutical compositions should be excluded subject matter and we do not support such an exclusion.

For the reasons outlined above, in ASMI’s view, the most appropriate option is Option A – No change.

ASMI is concerned that an apparently useful tool such as the innovation patent system is underused for non-prescription medicines. In particular we note that the following statement from the Options Paper (at page 37):

“Even allowing for the Verve report, there is a lack of credible information available on how SMEs are using the system—abolishing the system might remove IP protection that is really useful to SMEs.”

In ASMI’s view there is work to be done in communicating the advantages of the innovation patent system to those individuals and SMEs that could benefit from its use. As the authors of the Options Paper note (at page 42):

“... it is clear from the written submissions and roundtable discussions that a significant number of individuals and SMEs are generally ill-informed of the advantages and disadvantages of using the innovation patent system.”

“It is arguable whether this information is being accessed/understood by Australian individuals/SMEs. Perhaps other communication channels may be needed to get the information disseminated to this audience or use group.”

ASMI therefore encourages ACIP and the Australian Government to invest in raising awareness of the Innovation Patent system. With this in mind, ASMI intends to take steps to educate its Members about the value of the system and we express our willingness to work with ACIP and other stakeholders to bring about this increased awareness.

Summary

For the reasons outlined above, in ASMI’s view, the most appropriate option is Option A – No change.

We remain committed to working with ACIP and other stakeholders in bringing about meaningful reform in this area.

Yours faithfully,

Steven Scarff
Regulatory and Scientific Affairs Director