I support the recommendations and the general thrust of this Review. It represents a major contribution towards applying intellectual property policy which better fits our strategic and national interest objectives. Australia is a price taker for all forms of intellectual property, particularly patents and our comparative advantage does not necessarily fall into the same policy framework as those countries holding the bulk of global IP assets. The strategic underpinnings of our IP policy should reflect these objective conditions.

The Review also advocates interim measures to attempt to reverse the situation that has seen Australia forgo the opportunity of a multi million dollar investment in high technology production of generics for export. This situation should never have been allowed to occur. To block such an industry and new jobs because of an interpretation that was untested in court and likely not advocated at the highest level with the US goes entirely against Australia's national interest. Priority should be given to redress this situation at the highest level.

In particular, I fully support the recommendations that aim to ensure that all negotiations on IP strategy and policy development be recalibrated and subject to an effective governance process that reflects Australia's national interest, innovation opportunities, consumer concerns and health priorities.

My comments are based on my experience as a policy officer and former Australian Ambassador with the Department of Foreign Affairs and Trade. More specifically, I was responsible for developing and negotiating IP policy when I held the following positions: Director of WTO TRIPS Section and also as one of the Lead Negotiators (digital economy) during the first half of the Aust/US FTA negotiations. Since leaving DFAT I have actively contributed to dialogue on the governance of IP.

During the period that I worked on IP issues in DFAT I became very conscious of the lack of knowledge about the significance and consequences of IP in policy dialogue. Policy coherence across the public service on IP issues was very weak a situation which continues to be problematic, as has been highlighted in this Review.

Effective operation of the inter-departmental process (IDC) is essential for good governance outcomes and for developing the whole of government strategic approach to policy. When the IDC process is not fully reflecting the broad whole of govt interest, policy outcomes can become skewed or biased towards particular interests, ineffectual or in the case of the export industry damaging to national interest. It becomes particularly problematic when that policy position is used to define Australia's multilateral or bilateral negotiating position, including exposure to taking on new legal and financial obligations.

The two key Ares in the bureaucracy with direct responsible for IP governance - IP Australia and Attorney General's - are rarely challenged, partly because of the esoteric nature of the issue and their advocacy and reference to IP law and strong defence of the interpretations often influenced or developed through significant interaction with the key
countries holding the bulk of IP global asset, US, EU and Japan. Also since the Aust/US FTA came into force, Australian negotiators have tended to become active advocates of the TRIPS Plus provisions. Acting as a stalking horse for these TRIPS Plus provisions, which are controversial and generally not supported by our neighbours or many other countries does not make strategic sense.

DFAT plays a significant role but also operates in an environment where positions are traded against other perceived economic gains. Therefore without active and strong cost benefit analysis guiding policy and feeding into briefing parameters for negotiations, Australia’s economic and options for innovation are not adequately assessed against national interest.

Only very recently has limited consumer interest been registered in IP policy and this was specifically related to the Senate Inquiry into Gene Patents and the recent response to Australia signing the Anti-counterfeiting Trade Agreement (ACTA). The TPP has also been identified by a some specific consumer groups and there is a process of dialogue with government officials but no access to draft text. Consumer interests were almost non-existent in the Aust/US FTA but all the IP stakeholders were included and active in articulating their preferences for positions that extended IP rights and added a considerable ongoing financial burden to Australian consumers and business.

The governance reviews that have taken place on IP have been to a large degree limited by lack of evidence of harm but also rely primarily on input provided by the various IP industry stakeholders, including universities which tend to have similar IP interests given the obligation in grants to produce IP.

It should be noted that the outstanding recommendations made by ACIP on Patents recommends altering the definitions related to ‘invention’. ACIP recommend the same language - artificially created state of endeavour … - as that used by the judge in the recent case which endorsed Myriad Genetics BRCA breast cancer patent - as the definition for awarding patent subject matter status to isolated gene sequences. This is an prime example of the need to bring a much broader set of expertise into governance bodies to ensure that that mistakes do not occur or low standards for invention institutionalised via such governance bodies.

The bureaucracy has generally not been adequately tasked by government or parliament and until recently has generally avoided discussion on IP issues (ie delay in addressing ALRC report). Nor do the key bureaucracies appear to have been capable of internally generating and strategically coordinating evidence based data to assess whether IP governance is promoting innovation. It is the basic principal underpinning awarding monopoly in the first instance and one quoted continually in defence of all IP policy positions and briefings by these Departments but apart from rhetoric the substance is generally weak or missing. See Senate report on Gene Sequences and JSCT Report on ACTA ratification.

Even when problems have been raised by departments (ie Health in relation to gene patents) the evidence provided by the State health sectors has been weak and often contradictory. This situation should have been followed up to ensure that Australia’s international obligation were being adhered to. A similar situation was illustrated in a report prepared by the UK national health system. It revealed significant infringement of IP attached to Diagnostic testing and screening and warned of the legal and budgetary consequences of taking the ‘head in the sand’ approach to IP obligations.
Any reference to evidence based policy can only be analysed adequately if serious attempts are made to collect key data, monitor, scrutinise and assess opportunity costs. The Review recommends that this oversight and coordinating role be taken up by Treasury and involve Finance. Adopting these recommendations will be essential to ensure there is a stronger capacity to analyse and develop strategic policy that serves Australia’s national interest and it should be fully supported.

I congratulate the authors of this timely and essential review of pharmaceutical patents. The subject area is complex and little understood. The analysis, evidence given and insight into the workings of the patent system will also be welcomed at the international level by health professionals and consumer advocacy groups. It should also serve as a learning tool to other countries seeking to manage their health budgets and to allot scarce public resources to this politically sensitive issue.

Please register my support for the recommendations put forward in the Review.

Please note, I am making this submission in my personal capacity and is not confidential.

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