

PRODUCTIVITY COMMISSION DRAFT REPORT
INTELLECTUAL PROPERTY ARRANGEMENTS

SUBMISSION:

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

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Summary of conclusions

- The focus of the Productivity Commission Report should be on building a strong pharmaceutical industry based on innovation to gain maximum leverage from Australia's investment in medical research. The current draft appears more questioning of the system in the absence of any evidence that significant questions exist, and less supportive of innovative industry development.
- The report does not adequately address the three major barriers to innovation and commercialisation in Australia – a) a poor performance in patenting relative to peer economies, b) the lack of funds for patenting in a largely publically funded research enterprise and c) incentivising collaboration between the public and private sectors to address the poor Australian business investment in R&D and IP.
- The risk of continued questioning of Australia's IP system in the face of little evidence must be taken in the context that Australia usually represents only approximately 2% of global markets and can be easily marginalised by transnational corporate decisions.
- The "*Raising the bar*" amendment championed by IP Australia was a significant step forward in increasing rigour in Australia's patent system and to our knowledge there is no evidence of significant negative or neglected issues.
- We recommend a strong focus on developing Australia's research and business culture to embrace patenting, not get too distracted by issues of patent term that largely benefit offshore enterprises, and develop ways of encouraging the creation of an Australian innovator pharmaceutical industry. Recommendations should focus on enhancing Australia's ability to traverse the "valley of death".
- Patent exclusivity should ideally be based on a guaranteed period from market approval for the first therapeutic indication.
- WEHI has no negative experience of patent thickets and no knowledge of evidence that this is an issue in biomedical patents. Clear evidence must be provided before further time is spent on this issue.
- WEHI has no negative experience of patents on research activities and no knowledge of evidence that this is a major issue in Australia. Clear evidence must be provided before further time is spent on this issue.
- The benefit of the research exemption is clarification of the law in Australia and being a jurisdiction where research activities can be carried out. No costs of this exemption have been observed.
- There should be a research exemption for research tools as exemplified by the current situation for CRISPR/CAS9 mouse models
- WEHI has no negative experience of or evidence for "pay for delay" patent strategies and request evidence that this is a significant issue in Australia.
- The questions of ever-greening and follow-on patents appear to be erroneously interlinked in the Report. Most follow-on patents do not come from the originator.
- The proposal for higher patent renewal fees appears to be based on no evidence, will have marginal impact on decisions for major drugs and would seem to be a revenue opportunity rather than an industry development measure.

1. Introduction

The Walter and Eliza Hall Institute of Medical Research (WEHI) welcomes this opportunity to provide input into the draft report of the Productivity Commission on Intellectual Property Arrangements in Australia. The Institute has provided submissions to the many reviews of Intellectual Property over the last 10 or so years and our position remains consistent. Relevant background information with respect to WEHI can be found in Appendix 1.

2. Comments in response to the Productivity Commission Report

We will restrict our comments to pharmaceutical and research tools, and not address other areas of the Draft Report. As an overview comment we are concerned that the Draft appears to come from a view that the Australian Patent System is failing, subject to manipulation and presents no adequate supporting evidence for these propositions. The Report does not appear to be adequately aligned with Australia's quest to be more innovative. It is vital that the Commission concentrate on issues that are real drivers of productivity and pharmaceutical industry creation in Australia. Australia has a very poor track record in patenting, partly due to culture and lack of funds for patents in the public research sector. Australia has a poor track record of engagement between public sector researchers and industry, largely because an innovation pharmaceutical industry has not yet been established – unlike many smaller developed economies. Apart from a few exceptions, Australia has only an embryonic innovation pharmaceutical industry that will not develop in the absence of strong advocacy for a patent system encouraging and protecting innovation in both the public and private sectors.

Due to Australia's weak track record in residential patents and lack of a significant domestic industry, international applications filed in Australia are a critical part of our economy and enhancing access to innovative medicine for the Australian community. The Report should reflect this reality and asymmetry of applicants. Australian patients benefit from early access to patented medicines.

DRAFT RECOMMENDATION 6.1

The Australian Government should amend ss. 7(2) and 7(3) of the Patents Act 1990 (Cth) such that an invention is taken to involve an inventive step if, having regard to the prior art base, it is not obvious to a person skilled in the relevant art.

The Australian Government should state the following in the associated Explanatory Memorandum:

- *the intent of this change is to better target socially valuable inventions*
- *the test should be applied by asking whether a course of action required to arrive at the invention or solution to the problem would have been obvious for a person skilled in the art to try with a reasonable expectation of success.*

The Australian Government should explore opportunities to further raise the overall threshold for inventive step in collaboration with other countries in international forums.

WEHI welcomed the "Raising the bar" initiatives introduced by IP Australia. Importantly, Australia has clarified its position with respect to the research exemption and has raised its threshold for inventiveness and hence patentability.

The Intellectual Property Laws Amendment (*Raising the Bar*) Act 2012 delivered significant amendments to raise the thresholds for grant of a patent. It raised the threshold for patentability and in particular, the disclosure requirement and criteria for inventiveness. Consequently, WEHI is confident that these new amendments will assist in ensuring appropriate and valid patent grants in Australia and clarity on the scope of the claims. WEHI also believes that the

effectiveness of our patent system and subsequent exploitation of inventions depends on integrity with respect to technological neutrality, noting the unnecessary recent deviation with respect to "gene patents" which has not achieved the goals of equity of access – a quest beyond the patent system.

We believe that the debate about the number of low value patents that are impeding innovation in Australia suffers from lack of objective evidence. We reiterate our position that we have no known example of patents hindering research at WEHI.

It is critical to distinguish between theoretical or academic, and real problems. Therefore, we believe that no changes to the test for inventive step are required and we welcome an evaluation on the effects of the amendments after a fair and reasonable period of operation so that an informed decision can be made. Ongoing questioning of Australia's IP system adds to business uncertainty as to Australia as a consistent IP jurisdiction, particularly if the questions are not based on evidence of tangible issues.

It is stated in the draft report that the Commission sees most merit in providing IP Australia with the discretion to ask for more information in cases where it sees fit so that the onus is on the applicant to articulate why the invention is non-obvious. This is potentially inequitable because IP Australia has access to prior art information through a number of search engines and other patent offices. Examiners, who are trained professionals in their field must object if it is unclear if there is an inventive step and applicants will provide information to articulate why the invention is non-obvious. Hence the Commission's position does not seem to differ from the current process that is functional.

DRAFT RECOMMENDATION 6.2

The Australian Government should incorporate an objects clause into the Patents Act 1990 (Cth) (Patents Act). The objects clause should describe the purposes of the legislation as being to enhance the wellbeing of Australians by providing patent protection to socially valuable innovations that would not have otherwise occurred and by promoting the dissemination of technology. In doing so, the patent system should balance the interests of patent applicants and patent owners, the users of technology — including follow-on innovators and researchers — and Australian society as a whole.

The Australian Government should amend the Patents Act such that, when making a decision in relation to a patent application or an existing patent, the Commissioner of Patents and the Courts must have regard to the objects of the Patents Act.

WEHI agrees that an Objects Clause can assist in the interpretation of the Patents Act and in guiding interpretation by a court, legislators, examiners, patent applicants/owners and the public. A critical aspect is to ensure that such a clause upholds the principles of technology neutrality as it relates to the Australian and global patent systems. We note that recent decisions related to gene patenting appear not to have made any change in equity of access and have undermined the principle of technology neutrality.

It is imperative that an Objects Clause should consider the interests of both patent applicants and owners and the promotion of innovation and dissemination, thereby reflecting the role of the patent system to provide incentives to innovate and to disseminate knowledge. It should also account for the interests of patent applicants, owners, inventors, Australian society and the users of technology. It is critical to keep in mind that patents in themselves disseminate learning, knowledge and catalyse new inventions. Other mechanisms actually influence the critical issues of equity of access and we note as previously that Australia already has Crown Provisions.

DRAFT RECOMMENDATION 6.3

The Australian Government, with input from IP Australia, should explore the costs and benefits of using higher and more pronounced renewal fees later in the life of a standard patent, and making greater use of claim fees to limit the breadth of patent protection and to reduce strategic use of patents.

The Australian Government should seek international cooperation on making greater use of patent fees to help ensure that patent holders are not overcompensated and to limit the costs of patent protection on the community.

Australia seriously underperforms with respect to patenting but patents are central to any licensing activity in pharmaceuticals. Australia's performance in publication of science results is not matched by a commensurate focus on the most critical step to translation – patenting and subsequent licensing.

Australia's relative IP performance

Metric	Australia	US	Sweden	Source
Scientific articles per million	791	725	1,143	1
Triadic patents per million	19	53	81	1
Resident patent applications per \$bn GDP	3.7	17.8	8.2	2
US patent applications per \$100m R&D	1.5	6.6		3
% of triadic patents	0.64		1.64	4
% of highly cited articles	4.0		2.5	5

1. OECD (2010) Science, technology and industry outlook
2. WIPO (2010) World intellectual property indicators
3. Commonwealth of Australia (2011) National survey of research commercialisation
4. OECD (2010) Main science and technology indicators
5. OECD (2010) Measuring innovation: a new perspective

A key explanation for Australia's relative poor performance in patenting is that funds are not available to support patenting activities for potential inventions from the public sector. Most public research organisations therefore will capture invention disclosures but be often forced to abandon provisional patent applications if they are not partnered before the PCT application. It is relatively rare that a public research organisation in Australia will continue with National Phase prosecution of a patent if it is not partnered.

Increasing patent fees towards the end of the life of an exploited patent is closely linked to the marginal returns for the patent holder. Most patent holders in the later life of an exploited product are successful transnational companies. Within reasonable limits an increase in patent fees is not material to corporate behaviour and the proposal is akin to the rationale for "speed cameras" to raise revenue. Therefore, we do not understand what issue the PC is trying to solve through this recommendation. Most patent holders understand the need to pay for patent prosecution since this is largely funded by the tax payer. However, it should not be seen as a revenue business that in itself generates conflicts of interest with respect to the almost inevitable offering of expedited processing for addition fees.

Raising patent fees will only increase Australia's poor performance and hamper innovation. The Productivity Commission agrees that patent troll activity is not prevalent in Australia and if necessary, compulsory licensing and crown use provisions are available. Efforts should be redirected into strengthening Australia's weak IP culture, making it more competitive and ready to deliver translational outcomes and benefits to the public.

DRAFT RECOMMENDATION 9.1

The Australian Government should reform extensions of patent term for pharmaceuticals such that they are calculated based only on the time taken for regulatory approval by the Therapeutic Goods Administration over and above one year.

DRAFT RECOMMENDATION 9.2

Regardless of the method of calculating their duration (draft recommendation 9.1), extensions of term in Australia should only be granted through a tailored system which explicitly allows for manufacture for export in the extension period.

In the therapeutics arena it is essential to develop clear policies that ensure investment in and success of both the originator and generics segments. Nowhere is this more important than for the interlinked processes of patent exclusivity and expiry, and regulatory authorisation for approved indications.

Therefore, any review of patents and in particular, pharmaceutical patents in Australia must be undertaken with respect to four critical contexts:

- The reality of high risks and costs associated with innovative pharmaceutical development must be matched by certainty of a significant period of marketing exclusivity based on regulatory approval.
- Australia seriously underperforms with respect to patenting and our performance in publication of science results is not matched by a commensurate focus on the most critical step to translation – patenting, subsequent licensing and business investment.
- A patent and regulatory regime attractive to originators enhances Australia's opportunity for early access to world leading treatments whether they originate in Australia or elsewhere.
- Once a reasonable and relevant period of exclusivity has expired there should be efficient entry of generics players into the market with access to all originator data and no unwarranted "ever-greening" tactics by originators.

The pharmaceutical industry has become a major employer in Australia resulting in a significant contribution to GDP through manufactured export sales. However, our relative strength in generics and as a manufacturing base is not matched by a national ability to transform investments in biomedical research into innovative new therapies – in both the public and private sectors. WEHI fully respects the need to balance the interests of the innovator and generics sectors. However, our focus must be on creating a patent and regulatory regime that is attractive for investment in innovation and translation rather than being solely a potentially transient manufacturing base for generics (noting the mobility of generics companies between Puerto Rico, Ireland, India, Vietnam and beyond). Such a regime will be critical to attracting the capital required to translate Australia's investment in biomedical research into clinical outcomes and to ensure that Australia's communities have early access to leading therapies.

WEHI has established many collaborations with originator companies in recent years as they try to develop new therapies based on strong science and clinical evidence. In the same period we have had no significant interactions with the generics industry to add further value to existing medicines that are no longer protected by patent. Our practical experience is that generally the current generics industry, while being critical to health economics and access, has little interest in adding further value to the understanding and use of the drugs that they promote.

In our view the Productivity Commission should explicitly address Australia's two most important challenges - the risk and cost of pharmaceutical development, and our relatively poor performance in IP and business investment in development.

The US already invests more than 17% of its GDP into healthcare; Australia is approaching 10% of GDP. The pharmaceutical industry is transnational in nature with sales in several major territories, usually North America, Europe and Japan, being required to justify investment in new product discovery and development. In spite of more than a doubling in investment since the 1990s, new drug approvals have fallen by one half to only about 21 drugs per year¹ and the total industry cost has now reached a US\$1.9 billion investment to achieve each approved new drug². This sets the scene for the notorious "valley of death", a wasteland of exceptionally poor global productivity where potentially exciting research discoveries funded largely by taxpayers fall off the precipice on one side of the valley, fail to traverse the development terrain in the valley, and fail to make the onward journey to benefit patients.

Despite major investments of time and money, only 14% of new health related scientific discoveries are applied to day-to-day clinical practice, meaning a wastage of 86%, and translation takes an average of 17 years from discovery³ when the life of a patent is normally 20 years. This sobering reality shows that there is little time to reap the rewards of an exclusive commercial monopoly provided by a granted patent or regulatory exclusivity. In spite of major patent policy reforms over the last few decades, triggered largely by the Waxman-Hatch and Bayh-Dole Acts in the US, there is still inadequate recognition of the realities of the costs, risk and benefits of investing in drug development.

The challenge for an academic organisation or originator company is to define the best time to lodge a patent application. Academia is an important source of drug target and pharmaceutical IP that is of interest to industry provided there is a strong IP position. As a consequence the challenge for academic inventors is to file early in the face of few resources to exemplify the claims. This initial IP position establishes an early priority date and IP position that may attract a commercial partner but much more proof-of-concept science investment is required, while the patent clock is ticking. In our practical experience of several therapeutic areas this proof-of-concept stage from discovery can take from five to fifteen years, a major debit from the IP time account. Originator companies may elect to keep their IP secret until the late clinical or IND stage before filing patent applications. The upside is a delay in starting the patent clock, but the downside is delayed disclosure for public benefit and use of the information.

When developing patent and regulatory policies it is critical to recognise that development times, failure rates, investment levels and peak median sales vary widely according to therapeutic area⁴ as well as large variations within therapeutic areas such as cancer⁵.

By way of example, the Walter and Eliza Hall Institute recently embarked on a major drug discovery and development collaboration where industry experience would show that the initial chance of commercial success was less than 2%, i.e. a 98% chance of failure. As a

¹ Williams RS, Desmond-Hillman S (2011) Making translation work. *Science* 332:1359

² Mestre-Ferrandiz J, Sussex J, Towse A (2012) The R&D cost of a new medicine. London: Office of Health Economics (www.fiercebiotech.com/press-releases/new-ohe-study-pharmaceutical-rd-costs-released)

³ Pozen R, Kline H (2011) Defining success for translational research organisations. *Sci Transl Med* 3(94):1-5

⁴ Bogdan B, Villiger R (2008) Valuation in life sciences: a practical guide. Springer Verlag Berlin ISBN 978-3-540-78247-6

⁵ Arrowsmith J (2011) Phase III and submission failures: 2007 – 2010. *Nature Rev Drug Disc* 10:1

consequence of investment by the commercial partner, intellectual property was created, the project de-risked and after a successful Phase 1 clinical trial the project had a 25% chance of reaching the market, based on previous experience. The Institute and its commercialisation partner still faced a 75% chance of failure based on market experience, after the investment of many millions of dollars. The drug candidate, venetoclax, has recently been approved by the US FDA as a consequence of significant investment in IP beyond the capacity of an Australian research organisation and supported by international partner resources and expertise.

The extensive period of time required for research, development and regulatory approval means that a drug is frequently not brought to market in time for the pharmaceutical company and research organisation to benefit from the twenty year patent term to obtain a return on their investment. Consequently, patent term extensions under s70 of the Patents Act provide extensions of up to 5 years to provide 15 years of effective patent life for pharmaceuticals. The voracity of these 15 years is not certain and it is not clear that there is a simple exclusivity period from regulatory approval without the artificial constructs of an arbitrary five-year extension of the patent life.

Without specifically considering Australia's relatively poor performance in capturing and transforming IP a review of pharmaceutical patents could be a distraction. With a high public investment in research, a relatively low business investment in research, a small industry with few large players and originators and risk avoiding capital resources, it is reasonable to assume that Australia is particularly vulnerable to the "valley of death" but has a significant opportunity to establish attractive patent and regulatory policies.

Table 1 illustrates Australia's predicament. Australia has less than one half of the OECD level of patents on a population basis. Residential patent applications in Australia are one half those in Sweden and one quarter those in the US. Australia's investment in R&D is nearly 50% below that of the OECD average, a metric exacerbated by Australia's even greater relative underperformance in the level of business R&D as a proportion of GDP. The OECD business investment in R&D is 60% greater than that in Australia. Swedish company investment in R&D is nearly three times that of their counterparts in Australia. Australia's relatively high participation rate in global science publications, reflecting significant public investment in basic research, is matched by a venture capital industry underinvesting at a level around one quarter of the OECD average. Australia published nearly 60% more scientific articles than the OECD on a population basis but has venture capital investment at one quarter of the level in the OECD.

Table 1: Australia's position

Metric	Australia	US	Sweden	Switzerland	Japan	OECD
Triadic patent families per million population ⁶	18	53	80	108	117	43
Residential patent applications per \$bn GDP ⁷	3.7	17.8	8.2	5.5	82.2	n/a
Gross domestic expenditure on R&D (% GDP) ⁸	1.8	2.6	3.7	2.9	3.4	2.8

⁶ OECD (2008) Compendium of patent statistics.
www.oecd.org/sti/innovationinsciencetechnologyandindustry/oecdpatentdatabases.htm

⁷ WIPO (2010) World IP indicators (www.wipo.int/ipstats/en/)

Business expenditure on R&D (%GDP) ⁹	1.0	1.8	2.8	2.1	2.6	1.6
Scientific articles per million population ¹²	780	700	1,100	1,180	420	500
Venture capital investment as % GDP ¹²	0.04	0.20	0.23	0.13	n/a	0.17
Health expenditure as % GDP ¹⁰	9.2	17.2	9.3	11.5	8.2	n/a

With respect to innovation, Australia performs well below the OECD average, and most innovation is incremental with only 7% of SMEs and 12% of large firms introducing new-to-the-market product innovations²⁹. Of approximately 6.7 million patents in force globally in 2008, only 31,000 (0.5%) were of Australian origin, although 108,000 (1.6%) of the global total had Australia as a destination¹. This is a major intellectual property trade imbalance that underpins our relative weakness in being able to traverse the "valley of death" and is contrary to our 4.4% global share of highly cited scientific articles³⁰.

It is important that generic companies do not enter the market prior to the expiration of a patent, or equivalent regulatory period of granted exclusivity. This could result in major losses for the patent owner or licensee when they have invested significant funds in research and development in comparison to a generic competitor.

The current system of determining pharmaceutical patent exclusivity is flawed and does not reflect the realities of drug development. Obtaining and keeping market exclusivity has become an increasingly uncertain task due to inconsistencies in court opinions and jurisdictions. The technologies evolve rapidly while the courts struggle to apply patent law consistently in a constantly shifting landscape with inadequate account of the realities of current drug development¹¹.

Because the patent term for an NCE¹² often extends beyond the exclusivity period provided by the regulatory agencies, patents generally define the duration of market exclusivity for an NCE. Extension provisions allow for up to 14 years of post-approval patent life in the US¹³ and 15 years in Europe¹⁴. Extensions are normally limited to a single patent that is in effect at the time of the first regulatory approval of a drug's active ingredient; new formulations and generic drugs are not eligible. Australia claims an exclusivity period of 15 years for pharmaceuticals. In all major jurisdictions exclusivity for pharmaceuticals falls well short of the standard claimed 20 years exclusive monopoly for a general patent in spite of the high risk, long time span to approval and high investment. We believe that pharmaceutical exclusivity is still disadvantaged globally and in Australia. It is critical to note that the best certainty for patent exclusivity comes from a guaranteed term from market approval.

⁸ OECD (2008) OECD Science, Technology and Industry Outlook www.oecd.org/publishing ISBN 978-92-64-04991-8

⁹ WIPO (2010) World IP indicators. www.wipo.int/ipstats/en/

¹⁰ OECD (2010) Measuring innovation: a new perspective ISBN 978-9264-95947

¹¹ Gersten DM (2005) The quest for market exclusivity in biotechnology: navigating the patent minefield. *J Am Soc Exp Neurotherap* 2:572-578

¹² NCE – New Chemical Entity

¹³ US Legislation 21 CFR 60 and 35 USC 156

¹⁴ European Supplemental Protection Certificate (SPC: EEC No. 1768/92

With little relevance for the reality of current drug development, in the US the Patent Term Extension (PTE) is calculated as half of the duration of clinical trials plus the duration of regulatory review; this may be reduced owing to lack of developmental diligence¹⁵. Curiously, the PTE may not exceed 5 years, and the expiration date of the extended patent may not exceed 14 years beyond the marketing authorisation date. The basis in Europe is calculated differently but similarly does not reflect the realities of drug development.

Australia must not continue this illogical attempt to confuse issues of patent exclusivity with regulatory approval times. The current global process is entirely flawed since it is based on the traditional patent and regulatory approval processes while the time lines for drug development are defined by pre-clinical and clinical development times. Quite simply, under the current policies "a delayed IND filing is likely to reduce the period of market exclusivity"¹⁶. Therefore, market exclusivity should only begin upon regulatory approval for a defined indication and it is this point that should define the start of marketing exclusivity, irrespective of prior development and approval times. Such a policy would provide simplicity and clarity and set the basis for a clear understanding of the entry time for generics.

We understand that Australia aims to provide a 15-year effective life for pharmaceuticals which must mean a period of 15 years exclusivity from the date of regulatory approval for each indication. There are two immediate issues – a) does this effective life actually occur and b) why 15 years rather than 17 or 20 years? In spite of the high risk and expense it would appear that even if achieved this effective life puts pharmaceuticals at a disadvantage when compared with other technologies where a 20-year life is assumed.

The interface between patent term and regulatory exclusivity is unnecessarily cluttered and unclear in most jurisdictions. There are many unnecessary transactions that add little value and provide potential uncertainty. Exclusivities can be tailored to the reasonable needs of both the originator and generic player. In our opinion the originator's term should be not less than 20 years from the filing date and should provide for 17 years exclusivity from regulatory approval.

Therefore we recommend a strong focus on developing Australia's research and business culture to embrace patenting, not get too distracted by issues of patent term that largely benefit offshore enterprises, and develop ways of encouraging the creation of an Australian innovator pharmaceutical industry.

Evergreening and follow-on patents:

The report makes reference to the need for a more stringent standard and application of the inventive step test to stop evergreening. As previously stated, the Intellectual Property Laws Amendment (Raising the Bar) Act 2012 delivered significant amendments to raise the thresholds for grant of a patent.

A generic is free to enter the market based on the compound alone. If the innovator then has an improvement in formulation or delivery, it is exactly that, an improvement that is novel, inventive and adds value to the drug. Such improvements are themselves the result of significant investment in R&D, clinical validation and regulatory approval and should benefit from the exclusivity period offered by a granted patent. We find no argument whatsoever why a generic company should have "free access" to such advances where there is a clear inventive and patented step.

¹⁵ Dunn MK (2011) Timing of patent filing and market exclusivity. *Nature Rev Drug Disc* 10:487-488

¹⁶ Dunn MK (2011) Timing of patent filing and market exclusivity. *Nature Rev Drug Disc* 10:487-488

The reality is that most pharmaceutical and biotechnology companies simply do not have the resources or time to explore all formulation and delivery opportunities at the time of development of the original innovator drug. As a consequence the industry has the well established practice of developing follow on products once returns from the initial drug approval can then be directed to improvements such as oral dose forms, controlled release, manufacturing processes and molecular life extension, for example through pegylation.

Follow on patenting is a natural consequence of original patenting and provided the innovations fulfil our established criteria for valid patent claims such activities should be encouraged. It is clear that an originator is in a strong position to establish follow-on patents due to their expertise. Therefore, it would be quite extraordinary to have an IP policy that only allows "one shot on goal"! Provided follow-on patents fulfil our improved criteria for patentability they should be strongly encouraged.

Research institutes exist to discover and invent, and further advance scientific understanding. Such organisations are only successful if they advance beyond existing publications and patents. The patent system exists to protect the inventor's commercial interests and to promote research, development and innovation. WEHI is not aware of any patent thickets in the pharmaceutical area and the recent amendments to increase the thresholds for the grant of an Australian patent will assist in minimising the grant of broad claims or patents that do not meet the patentability requirements.

As for all patent applications, follow-on or ever-greening applications must not be based on broad claims and should conform with the more rigorous criteria for inventiveness established under the *Raising the Bar Act*.

DRAFT RECOMMENDATION 9.3

There should be no extension of the period of data protection, including that applicable to biologics.

Further, in the context of international negotiations, the Australian Government should work with other nations towards a system of eventual publication of clinical trial data in exchange for statutory data protection.

DRAFT RECOMMENDATION 9.4

The Australian Government should introduce a transparent reporting and monitoring system to detect any pay-for-delay settlement between originator and generic pharmaceutical companies. This system should be administered by the Australian Competition and Consumer Commission.

The monitoring should operate for a period of five years. Following this period, the Australian Government should institute a review of the regulation of pay-for-delay agreements (and other potentially anticompetitive arrangements specific to the pharmaceutical sector).

Data exclusivity is a time-bound form of IP protection that seeks to allow companies to recoup the cost of investment in producing data required by the regulatory authority. The effect of data exclusivity is to prevent the entry of generic competitors, independent of the patent status of the product in question. It is intended that generic players need to establish "bioequivalence" as an independent and rigorous data set.

Data exclusivity is attractive to originator companies because, unlike a patent, data exclusivity is automatic, rather like copyright. There is more limited scope than exists in patent law for legal challenges. For those reasons pharmaceutical companies are strong proponents of data exclusivity regimes and data exclusivity provides an additional opportunity for originator companies to recoup their investments where marketing approval is given late in the patent life, so that the protection afforded extends beyond patent expiry¹⁷.

Once marketing exclusivity has expired it makes economic sense to allow full access to supporting data on the drug, formulation and use to encourage cost effective transition to a generic market. At present we understand that data exclusivity currently refers only to the drug itself and not to uses or formulations of that drug. Australia must ensure that it is both fair and competitive by making data fully available for exploitation after the exclusivity period, including the drug, formulations and methods of use.

WEHI agrees that there should be a review of patents related to recent originator expiries to confirm that generics companies are not being unfairly excluded and that any follow-on patents granted to originators are appropriate. WEHI also agrees that "pay for delay" arrangements are essentially anticompetitive and should be monitored from well before formal patent expiry. However, we note that there is no evidence that this is a major issue in Australia.

INFORMATION REQUEST 6.2

The Commission is seeking information from participants on the costs and benefits of an exemption from infringement for experimental activities that use a patented invention. Are there any examples in Australia where the efforts of researchers have been hindered by the lack of such an exemption?

The Walter and Eliza Hall Institute of Medical Research (WEHI) strongly believes in the principles of exemption for the purposes of research and experimentation whilst fully recognising the rights of a patent holder. In the last 15 years WEHI has not had any experience of research being hindered by patents. In this time we have entered into more than 5,000 Material Transfer Agreements to protect the rights of owners of materials. In our opinion there are no costs to having a research exemption and the benefit is legal clarity.

The implied research exemption guided Australian and other research organisation's behaviours prior to April 2012 and therefore, the new provisions have formalised and clarified the exemption provisions and have not led us to do new research which we would not have previously attempted. Experimental and research use is an essential part of an effective patent and innovation system, and underpins a competitive economy. Research use of intellectual property does not infringe or erode value of the invention claimed, and in fact enhances the possibility of new inventions and value creation for the patent holder. The repurposing of current drugs is a very good example of how the research exemption creates value. For example, WEHI discovered that birinapant, a cancer drug developed and patented by TetraLogic Pharmaceuticals in the US could be used to clear viral infections such as hepatitis B and HIV. A provisional patent was filed then a successful license agreement was reached whereby TetraLogic could exploit the new finding.

WEHI believes that the research exemption should extend to research tools. The vast majority of patented and unpatented research tools are purchased and there is a general understanding in the research community that research tools and reagents that are published should be shared for the greater good. Research institutes in particular, generally transfer materials and research tools via material transfer agreements (MTA). These agreements specify that the material is to be used for research purposes and for a particular use. The agreements also set out the rights of a party if there is inventive development. Providers of research tools benefit from such

¹⁷ Clift C (2007) Data protection and data exclusivity in pharmaceuticals and agrochemicals. in IP Management in Health and Agriculture Innovation: A handbook of best practices (eds Krattiger A et al) MIHR, Oxford (www.ipHandbook.org)

publications since these form an important part of the marketing mix, advertisement and validation

A "home-cooking" market segment has existed for many decades and has not undermined the commercial success of companies supplying the research tools market. WEHI has direct experience of the discovery, development and commercialisation of patented research tools. Human Leukaemia Inhibitory Factor (LIF) discovered at WEHI in the 1990s is now widely used as a critical laboratory research reagent for controlling the differentiation of mouse stem cells. LIF is exclusively manufactured and marketed world-wide by Millipore and WEHI receives a royalty on sales. The pGEX vector expression system was also invented at WEHI and is also marketed world-wide by Millipore for research use. Both LIF and pGEX are the subject of issued patents, and to the best of our knowledge, an assumed research exemption has not had a significant impact on commercial returns. For the rare highly valued methods such as PCR, the majority of commercial value lies in diagnostic testing where licenses are given and royalties paid. The research market value is much smaller and the value to the patent holder is usually captured through value adding kits and premium pricing.

Non-inclusion of research tools and reagents from the exemption provisions has created uncertainty and we question its effect on value creation for research platform technology such as CRISPR/CAS9, where one of the inventing organisations, the Broad Institute, promotes academic access for non-commercial purposes even though the technology has several patent applications.

Appendix: Overview of the Walter and Eliza Hall Institute

The Walter and Eliza Hall Institute of Medical Research (WEHI) has a strong track record of research, capture and management of intellectual property (IP), and translation of research into medical outcomes. We have extensive experience of the Australian and international patent systems.

WEHI is Australia's largest and oldest medical research institute. Founded in 1915 we currently invest approximately \$110 m per year in medical research. Most of these funds are provided by public funding agencies such as NHMRC and NIH, with an important revenue flow also coming from licensing activities. Our research efforts are underpinned by more than 800 full-time equivalent employees and post-graduate students. Approximately 86 laboratories focus on major medical challenges associated with cancer, immunity, autoimmunity and infectious diseases such as malaria, hepatitis, tuberculosis and HIV. We have extensive research collaborations with the public sector, and with private sector partners such as Genentech, Abbvie, Servier, Merck, and CSL and Bionomics in Australia.

As a research institute, our core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. As a consequence we place great emphasis on publications, and have the highest citation impact of any research organization in Australia. We are committed to translation of our discoveries, both clinically and commercially. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most of our funds. Our critical issue is effective translation of knowledge into community outcomes, whether in Australia or globally.

A strong, transparent and consistent IP regime is critical to our success. The cytokines G-CSF and GM-CSF were discovered at WEHI and the Ludwig Institute of Cancer Research in Melbourne during the early days of exploiting gene technology. Both human proteins, developed and marketed by Amgen and Immunex/Berlex respectively, have been used to treat more than 20 million people world wide as they battle the consequences of chemotherapy for treatment of cancer. Without patent protection these valuable therapeutics would never have come to market.

Recently, WEHI discovered a repurposed application for TetraLogic Pharmaceutical's compound birinapant. A patent application for use of the anti-cancer compound in the treatment of hepatitis and other infectious diseases has resulted in a Phase 1 clinical trial in an area not previously considered by TetraLogic's management and investors. Venetoclax, the subject of a highly effective collaboration between WEHI, Genentech (Roche) and Abbvie, has been achieved through extensive IP protection across many jurisdictions and US FDA approval for chronic lymphocytic leukaemia was granted in just under seven years from initial compound discovery. More than 2,000 patients suffering from relapsed or refractory chronic lymphocytic leukaemia have already been treated with a 79% rate of remission. A strong patent regime will be critical for this drug becoming available to patients.

WEHI was a founder of Cancer Therapeutics CRC (CTx), a translationally driven CRC whose success is totally dependent on strong IP positions. Early high throughput chemical screening and medicinal chemistry at WEHI resulted in the project being developed and commercialised by CTx. A deal with Merck worth potentially US\$700 million was recently announced for compounds targeting PRMT5 for the treatment of cancer. A broad ranging and comprehensive patent strategy was essential to this success.

Being a not-for-profit research institute, WEHI's core business is the conduct and dissemination of world-class medical research, with the goal of improving human health. We are committed to translation of our discoveries, both clinically and commercially. While WEHI benefits from commercialisation of its IP, this comes as a consequence of our primary focus on uncompromising world-class medical research and accountability to tax payers who provide most

of our funds and the majority of our commercial returns are re-invested in biomedical research. Our critical challenge is effective translation of knowledge into community health outcomes, whether in Australia or globally. In general WEHI seeks ongoing collaborations and engagement with commercial partners since our intellectual property is rarely "market ready" and requires further "reduction to practise".

WEHI is unusual in the Australia IP landscape in that patent prosecution is driven by in-house patent counsel. Historically, a provisional application has been lodged every 4 – 6 weeks. Due to shortage of funds it is rare that WEHI funds national phase transitions and usually partners/licenses the IP before such a transition.
