AusBiotech's response to the ACCC *Draft Guidelines on the repeal of subsection 51(3) of the CCA*

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Context

AusBiotech is pleased to provide comments on the Draft Guidelines on the repeal of subsection 51(3) of the *Competition and Consumer Act 2010 (Cth)* (**CCA**), developed by the Australian Competition and Consumer Commission (**ACCC**).

AusBiotech is Australia's life sciences organisation, working on behalf of members for more than 30 years to provide representation and services to promote the global growth of the Australian life sciences industry. AusBiotech is a well-connected network of over 3,000 members in the life sciences, including therapeutics, medical technology (devices and diagnostics), digital health, food technology and agricultural sectors.

We have representation in each Australian state, and our members are diverse in size, approach and structure, ranging from SME's to national and international businesses.

This response has been led by AusBiotech's Intellectual Property Expert Panel, which provides expert advice on intellectual property issues in relation to medical devices and diagnostics, pharmaceuticals and therapeutics.

Summary

IP is integral to the life sciences industry. Indeed, unlike in some other industries, patents provide clear incentives for innovation in the pharmaceuticals, biotechnology, medical instruments and speciality chemicals sectors.[1] In the circumstances, it is likely that the repeal of subsection 51(3) of the CCA (also known as the IP Exemption) will have a more significant impact on our members than firms in other industries.

We have not attempted to provide a detailed response to each of the issues identified in the Draft Guidelines in this submission, instead focusing on those of most relevance to our members.

Key recommendations

1. **Contracts, arrangements, understandings and concerted practices:** AusBiotech considers the concept of 'collateral purpose' as a useful criterion for determining when licence conditions should be regarded as inherently lawful and pro-competitive.

2. **Exclusive dealing:** AusBiotech suggests that the example used to demonstrate exclusive dealing in the Draft Guidance is too simplistic and that there needs to be more specific details on what types of licensing arrangements involving exclusivity are likely to be considered to harm competition.

3. **Authorisations and notifications:** The ACCC should be conscious of the unique nature of the life sciences sector when considering whether there is a 'net public benefit' to a proposed arrangement in this sector.

4. **Class exemptions:** AusBiotech suggests that the ACCC consider implementing class exemptions in Australia that are similar to the existing EU exemptions, including vertical agreements, R&D and technology transfer agreements.

[1] Hall, B and Harhoff D 2012, *Recent Research on the Economics of Patents*, NBER Working Paper No 17773, National Bureau of Economic Research, Cambridge, referred to in Harper Review, Part 3, p 103.

5. **Cartel conduct:** AusBiotech requests more specific guidance on what types of vertical licensing arrangements are likely to harm competition.

When applying the Draft Guidelines, the ACCC should be conscious of the unique nature of the life sciences sector and, in particular, the need to create an environment in which the life sciences sector in Australia can legitimately exploit IP and compete in an increasingly competitive global market.

General Principles

The Draft Guidelines set out three general principles that the ACCC say will guide its approach to compliance and enforcement activities related to IP rights and the anti-competitive conduct prohibitions in Part IV of the CCA.[2]

1. IP rights do not necessarily confer substantial market power, and even where ownership of an IP right is determinant of a firm's market power, this will not of itself contravene the CCA;

2. The licensing or assignment of IP rights usually encourages competition, by enabling IP to be exploited to a greater extent than would occur if those rights were not licensed or assigned; and

3. However, in some cases, licensing or assignment agreements will have the purpose, effect or likely effect of substantially lessening competition in contravention of sections 45, 46 or 47 of the CCA.

AusBiotech agrees that assignment and licensing of IP rights should generally be viewed as pro-competitive. The ACCC should recognise that an IP owner has the right not to licence their IP rights at all, thus entirely preventing anyone else from exploiting such rights in Australia. Thus, any licence (even if highly restrictive) is by definition pro-competitive. AusBiotech suggests that, similar to the US, the same analysis should be applied to conduct involving IP as to conduct involving other forms of property, taking into account the specific characteristics of the relevant IP right.[3]

When assessing whether conduct 'substantially lessens competition', the Draft Guidelines state that the ACCC will focus on the impact of the conduct on the competitive process.[4] The Draft Guidelines go on to refer to the fact that the ACCC may apply a 'with or without test' (or *Stirling Harbour* test).[5] This compares the likely state of competition 'with' the relevant conduct, to the likely state of competition 'without' the conduct, to isolate the effect on competition. This type of test is commonly used when examining proposed conduct.

However, there is no reference to the 'but for' test (the *Dandy Power* test), which is of often used when examining conduct that has already occurred. In the *Dandy Power* case Smithers J stated (at [43,887]):

> *To apply the concept of substantially lessening competition in a market, it is necessary to assess the nature and extent of the market, the probable nature and extent of competition which would exist therein but for the conduct in question, the way the market operates and the nature and extend of the contemplated lessening. To my mind one must look at the*

[2] Draft Guidelines at [2.1]-[2.13].
[3] United States Antitrust Guidelines for the Licensing of Intellectual Property, 12 January 2017, at [2.0].
[4] Draft Guidelines at [2.8].
[5] Draft Guidelines at [2.13].

relevant significant portion of the market, ask oneself how and to what extend there would have been competition therein but for the conduct, assess what is left and determine whether what has been lost in relation to what would have been, is seen to be a substantial lessening of competition.

We suggest that the *Dandy Power* test could also be used by the ACCC when assessing whether conduct has the purpose, effect or likely effect of substantially lessening competition, and therefore should be referred to in the Draft Guidelines.

The Draft Guidelines indicate that, when assessing market definition, the ACCC will identify the product market[6], geographic market[7], and the functional dimensions of the market[8]. The latter is said to be particularly relevant where some firms in the market are vertically integrated.[9]

Vertical integration is commonplace in the life sciences sector, particularly in the pharmaceutical industry which is dominated globally by horizontally and vertically integrated multinational entities.[10]

When considering the conduct of vertically integrated companies, the ACCC should take into account the fact that vertical integration is often used as a way to reduce costs and increase efficiencies (as a result of greater process control and increased supply chain co-ordination), which will result in increased competitiveness. When defining the relevant market, the complexities of the Australian life sciences sector – which is strongly influenced by trends in the global market – also need to be recognised.

Response to application of competition law to IP

Cartel conduct

The prohibitions against cartel conduct now apply to all conditions of a licence or assignment, including any that relate to the subject matter of an IP right.[11] In particular, the ACCC refers to territorial restraints[12], pricing restrictions[13] and output restrictions[14] as examples of provisions in contracts between competitors that are likely to be prohibited cartel conduct.[15]

We note that, in conjunction with the repeal of s51(3), the Harper Report also recommended the widening of the vertical supply exception to the cartel prohibitions, so that the exception would apply to restrictions contained in IP licences. The Harper Committee considered that IP licensing restrictions should be assessed under the standard competition test, and not be prohibited *per se*. However, this recommendation has not (yet) been implemented.[16]

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[6] That is, goods/services supplied or acquired by the relevant firm and their close substitutes.
[7] That is, geographic region in which a firm supplies or acquires goods/services and close geographic substitutes.
[8] That is, different levels in the supply chain such as the production, wholesale, or retail levels.
[9] Draft Guidelines at [2.12].
[10] Department of Industry Tourism and Resources, *Pharmaceuticals Industry Profile*, <www.industry. gov.au> at 16 June 2004.
[11] Draft Guidelines at [3.7].
[12] 'Territorial restraints' are conditions that restrict the territories in which firms can supply goods, including as part of a cross-licensing arrangement.
[13] 'Pricing restrictions' are conditions that restrict or influence the price that a licensee or assignee can charge.
[14] 'Output restrictions' are conditions that restrict the output of a party.
[15] Draft Guidelines at [3.8].
[16] O'Bryan J (a member of the Harper Committee) recently suggested that the current exception, which is focussed on conduct that falls within s 47 of the CCA, is not adequate because s 47 does not define all forms of vertical dealings, and

This means that vertically integrated entities, who both exploit IP themselves and licence others to do so, must be aware of the potential application of cartel laws to such licences. Accordingly, it would be useful if the ACCC could include more specific guidance on what types of vertical licensing arrangements are likely to harm competition. For example, see United States Antitrust Guidelines for the Licensing of Intellectual Property, 12 January 2017 at [4.1.1].

Contracts, arrangements, understandings and concerted practices

Section 45 of the CCA prohibits a corporation from making or giving effect to a contract, arrangement or understanding, or engaging in a concerted practice, for the purpose, or with the effect or likely effect, of substantially lessening competition.

The ACCC gives time restrictions[17], grant-back provisions[18], and no challenge provisions[19] as examples of clauses that involve a licensor seeking to 'gain advantages collateral to'[20] the relevant IP rights and are therefore prohibited under this provision.[21]

We consider the concept of 'collateral purpose' as a useful criterion for determining when licence conditions should be regarded as inherently lawful and pro-competitive, as opposed to when they should be subject to a competition test. The High Court decision in *Transfield v Arlo* (1980) 1444 CLR 83 suggests that this concept is relevant to competition law. Thus, the ACCC should recognise that it cannot be anti-competitive for an IP owner to allow, even under highly restrictive licence conditions, what the IP owner could otherwise lawfully prohibit entirely, provided that there is no collateral purpose. The concept of collateral purpose is useful as a screening criterion; if a condition imposed on a licensee is within the scope of the monopoly afforded by the licensed IP right (i.e. it is restricting a thing that the IP right exists to restrict, and that the owner could completely determine or prohibit), then including that condition in a licence does not lessen competition at all (let alone substantially). Conditions going beyond these conditions can be regarded as 'collateral' – they restrict or require something not within the scope of the monopoly afforded by the licensed right.

In relation to time restriction clauses, AusBiotech accepts that a prohibition on these types of clauses is generally in-line with Australian patent law. In particular, section 145(1) of the *Patents Act 1990* (Cth) provides that a licence to exploit a patented invention may be terminated at any time after the patent (or all the patents) by which the invention was protected at the time the contract was made have ceased to be in force. Therefore, if an Australian patent has expired, then any related IP licence agreement for that patent can be terminated by a party to the contract.[22] However, it should be recognised by the ACCC that the situation is more complicated if there are foreign patents and/or other IP rights that are also included in the licence, and a party seeks to terminate the licence under s 145(1) because the relevant Australian patent (or patents) has expired.

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generally does not apply to restrictions contained in IP licences: see O'Bryan J, *The repeal of s 51(3) of the Competition and Consumer Act 2010 (Cth)*, LEZANZ Breakfast Meeting, 10 April 2019.

[17] 'Time restrictions' are conditions which seek to restrain a licensee's behaviour beyond the time scope of the IP rights given to the licensor.

[18] 'Grant-back provisions' are conditions which require a licensee to assign or grant an exclusive licence back to the original licensor for any improvements generated through the licensee's exploitation of the IP rights.

[19] 'No challenge provisions' are conditions that prohibit a licensee from challenging the validity of IP rights that underlie a licence.

[20] *Transfield v Arlo* (1980) 1444 CLR 83 at 103.

[21] Draft Guidelines at [3.15].

[22] See *Regency Media Pty Ltd v MPEG LA, LLC* (2014) FCAFC 183.

Further, the Supreme Court of Victoria held in *ARB Corporation v Robert & Ors*[23] that royalties were payable beyond the life of the patent. In this case, the respondents had entered into a sale agreement in which the rights to a differential locking system, which was the subject of pending patent applications in various jurisdictions, were sold to ARB. The sale agreement referred to pending patents (which later proceeded to grant), but did not specify an end date for the payment of royalties. After the patents had expired, ARB asked the Court to consider the preliminary question of whether royalties were still payable. Justice Vickery held that the relevant clauses of the sale agreement were consistent with a construction that the parties intention was that the royalty payments continue after any patents granted on the applications expired. This view was reached having regard to the fact that the sale agreement recognised that no patents may in fact be granted, and that the obligation to pay royalties was not contingent on the grant of any patents. Thus, when considering a time restriction clause, we suggest that the ACCC should carefully consider the terms of the relevant agreement as a whole, the relevant IP rights, and the intentions of the parties.

With respect to grant-back provisions (otherwise known as improvement clauses), these types of clauses are a normal part of the structure of many technology licences and can have pro-competitive effects, especially if they are non-exclusive.[24] Our understanding of the Draft Guidelines Example 5 is that only grant-back provisions which grant an exclusive licence back to the licensee will be anti-competitive. In this regard, it may be useful to consider these types of provisions as able to be divided into two types: severable (improvements that do not fall within the scope of the licensor's IP rights) and non-severable (any improvement which if used or practiced without licence from the licensor would infringe the licensor's IP rights). With respect to non-severable improvements, we submit that exclusive ownership or control of these improvements by the licensor should be permitted, given that the licensee only enjoys the right to exploit these improvements by virtue of the licensor's grant of the licence in the first place.

Exclusive dealing

Section 47 of the CCA prohibits a corporation from engaging in exclusive dealing which has the purpose, effect or likely effect, of substantially lessening competition. Broadly, exclusive dealing includes third line forcing and other types of conditional licences which seek to restrict a party's ability to supply or acquire goods for a third party.[25]

The life sciences sector is very dependent on patents, and exclusive licensing is common. The existence of a patent may give rise to a single product market. Example 8 in the Draft Guidelines appears to suggest that exclusive licensing which involves a single product market will be anti-competitive because of a desire by the licensee to have the exclusive right that has been granted by statute to the licensor. This is despite the fact that the licensor has the right to grant an exclusive licence. In our submission, this example is too simplistic and cannot be correct. We suggest that this example should be either deleted or amended, and that there needs to be more specific details in the Draft Guidelines in relation to what types of licensing arrangements involving exclusivity are likely to be considered to harm competition. For example, see US Antitrust Guidelines at [4.1.2].

Authorisation, notification and class exemptions

Authorisations and notifications

Where businesses are concerned that proposed conduct would or might contravene the anti-competitive conduct prohibitions of the CCA, they can seek authorisation from the ACCC, or lodge a notification.

[23] [2014] VSC 495.
[24] United States Antitrust Guidelines for the Licensing of Intellectual Property, 12 January 2017 at [5.6].
[25] Draft Guidelines at [3.20].

Broadly, the ACCC will grant authorisation where the proposed conduct is likely to result in a net public benefit, that is where the likely public benefit resulting from the conduct outweighs the likely public detriment. Similarly, the ACCC will only object to a notification if there is no net public benefit.[26]

In assessing net public benefit, to the extent that there is a consideration beyond price and efficiency benefits, AusBiotech submits that the unique nature of the life sciences industry should be considered.

The types of products being produced by the industry generally have a public health benefit. Without IP protection these products can be readily copied, and the substantial costs accrued in developing life science inventions (especially relative to other industries) cannot be recovered. It is the cornerstone on which most life sciences companies are created, and the fundamental means through which revenue is generated.

Developing IP can be expensive and time-consuming for any firm, but must be done if it wishes to see its developments successfully commercialised. The challenge for the sector is that IP is also highly portable. Decisions on where to locate the management, manufacture, registration and sale of life sciences-based products is therefore highly dependent on the business and public policy environment, inclusive of IP arrangements.

Thus, the ACCC should be conscious of the nature of the life sciences market and, in particular, the need to create an environment in which the life sciences sector in Australia can compete in an increasingly competitive global market when considering whether there is a net public benefit.

Class exemptions

The ACCC also has the power to issue a class exemption, which can be limited to parties in a particular industry. Class exemptions provide a 'safe harbour', allowing businesses to engage in conduct of the specific kind without risk of contravening the CCA. It is not possible for a firm to apply for a class exemption, but it can suggest options to the ACCC.[27]

The ACCC's class exemption powers are relatively new. Comparable provisions exist in the EU, for instance there are block exemption regulations in the EU for vertical agreements, R&D and technology transfer agreements. AusBiotech suggests that the ACCC consider implementing class exemptions in Australia that are similar to the existing EU exemptions.

In particular, as noted above, since the Harper Review recommended the widening of the vertical supply exception to the cartel prohibition, and this has not been implemented, a class exemption for vertical arrangements should be considered as a priority.

In the life sciences industry, we also think that it is possible that overseas-based multinational licensees may seek to take advantage of the uncertainties that have resulted from the repeal of the IP Exemption to resist licence clauses favouring early stage Australian-based innovative companies. An R&D class exemption would be useful in this context.

[26] Draft Guidelines at [6.4] and [6.9].
[27] Draft Guidelines at [6.11]-[6.12].