Alphapharm Submission on the Anti-Counterfeiting Trade Agreement (ACTA)

to

The Secretary
Joint Standing Committee on Treaties
Parliament House
Canberra ACT 2600

Introduction

Alphapharm is a key contributor to the Australian economy.

Alphapharm is Australia's leading supplier of prescription medicines to the Government-subsidised Pharmaceutical Benefits Scheme (PBS). One in five prescriptions for PBS medicines is dispensed with an Alphapharm product. Our specialty is bringing generic medicines to market, which contributes to the sustainability of the PBS by providing affordable access to pharmaceuticals. Alphapharm medicines are made to the highest global quality standards and have the same effect on the body as initial brands.

Alphapharm pioneered generic medicines in Australia in 1982, setting up as a small pharmaceutical manufacturer in Queensland with 12 staff and four products. Today, we have 680 employees nationally, including 500 at our state-of-the-art manufacturing plant at Carole Park, Queensland. This year, the plant will produce 3.5 billion doses of which about 1.7 billion will be exported to some 50 countries around the world.

Alphapharm is part of US-based Mylan. Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies.

Pharmaceuticals are Australia's leading export of manufactured goods. Generating more than $4 billion a year, pharmaceutical exports are more significant to the economy than the exports of cars, wine or information technology. We are pleased to be a major contributor to Australia's balance of trade.

Key recommendations

Recommendation 1: That the Australian Parliament does not ratify the *Anti-Counterfeiting Trade Agreement* (ACTA) in its current form.

Recommendation 2: That the Australian Government instigates an independent and transparent assessment of the final text of ACTA and that it presents the report to the Australian Parliament within 12 months.

Recommendation 3: That the Australian Government issues a public statement to the effect that the word 'counterfeit' in ACTA is not to include generic medicines entered or eligible for entry on the Australian Register of Therapeutic Goods.

Concerns

1. The marketing of generic medicines approved by the Therapeutic Goods Administration (TGA)

In the pharmaceutical context, it must be appreciated that there are other laws that regulate the marketing, distribution and sales of pharmaceutical goods. Under the *Therapeutic Goods Act, 1989* it is a per se offence to do so without the authorisation of the TGA. Therefore, in Australia, as in most countries, whether a specific medicine is 'counterfeit' is not about patent infringement. Rather, it is about whether the 'counterfeit' medicine meets required and published standards of quality, safety and efficacy. In this regard, there is considerable potential for confusion about the use of the word 'counterfeit'. In fact, whether a generic medicine is safe and efficacious is a matter for the TGA not a matter for IP

Australia. Unless the sponsor of the application for the necessary TGA marketing approval shows, through the provision of scientific data, that the generic medicine is safe and efficacious, the application will fail. It is, therefore, the TGA that determines if a specific medicine can be legally marketed in Australia, which has nothing whatsoever to do with whether the medicine infringes a patent or not.

The marketing, distribution and sale of 'counterfeit' medicines, however, are a matter of serious concern to all, not just to pharmaceutical patent owners. Medicines that are made in unsafe conditions, using inferior component products, and which are untested for quality, safety and efficacy are potentially lethal. Clearly, it is not in the interests of Alphapharm to argue against reasonable steps being taken to reduce the trade in 'counterfeit' medicines and it should not be taken, by this submission, that Alphapharm fails to appreciate the seriousness of the situation. To the contrary, Alphapharm supports reasonable attempts to reduce the trade in 'counterfeit' medicines. That said, it is Alphapharm's contention that ACTA does nothing to deal with the marketing, distribution and sale of 'counterfeit' medicines. If anything, it confuses the situation by creating a misleading association between counterfeit medicines and medicines that may infringe a patent.

Alphapharm is very concerned that the word 'counterfeit' may be applied to generic medicines, which may be alleged by the patent owner to infringe an Australian patent. This kind of confusion, were it to occur, would have serious consequences not only for Alphapharm but for the Australian economy. The marketing, distribution and sale of generic medicines are critically important to the affordability and accessibility of medicines under the PBS. Any possibility that the term 'counterfeit' may be understood by the Australian public to be applied to generic medicines that have been approved by the TGA would have regrettable consequences.

In other words, an alleged act of intellectual property infringement within Australian territorial boundaries may be neither an *act of piracy* nor an *act of counterfeit*.

2. ACTA is too broad in scope

ACTA's scope extends beyond dealing with the international and domestic trade in pirated copyright goods (for example, DVDs, CDs and other media technologies containing copyrighted material reproduced without the licence or authority of the copyright owner) and counterfeit trademark goods (for example, apparel and fashion and other accessories produced, distributed and sold without the licence or authority of the trade mark owner).

The term 'intellectual property' in ACTA includes patents and other forms of intellectual property *beyond copyright and trade marks* (see ACTA Art. 5(h)).

ACTA is more than a treaty "aimed at reducing the international trade" in ***pirated copyright goods*** and ***counterfeit trademark goods*** (see definitions in ACTA Art. 5(d) and 5(k)). ACTA purports to cover *all* kinds of "infringing IP" (see National Interest Analysis (NIA), para 5). Its broad scope, as explained in 1 above, is problematic to the pharmaceutical industry, specifically the generic medicines sector of that industry of which Alphapharm is the largest member.

The principle problems are in regard to ***patents***.[1] Patents, unlike copyright and trade marks, are very complex.

First, patents are scientific and technical documents that provide an exclusive right to the patent owner over an 'invention' that is a 'patentable invention' within s.18 *Patents Act (1990)*. In the case of pharmaceuticals they are scientifically complex.

Next, the grant of a patent by IP Australia is not prima facie evidence of patent validity. Indeed, to the contrary and by virtue of s. 20(1) *Patents Act* (1990): "Nothing done under this Act ... guarantees ... that a patent is valid, in Australia or anywhere else."

Finally, ***patent validity*** is determined only when an Australian court, hearing all of the relevant scientific and technical evidence, both for and against patent validity and taking the legal arguments presented by highly skilled patent lawyers into account, makes a determination on that issue. And even then it is usual, especially when patents concern pharmaceuticals, for the determination to be resolved by the High Court of Australia.

[1] It is noted that footnote 2 at Section 2 (Civil Enforcement) in ACTA provides that: "A Party *may* exclude patents and the protection of confidential information from the scope of this Section" but the extent, scope and effectiveness of this *optional* exclusion is disputed by legal experts. Specifically, throughout the Section there is reference in the substantive provisions applying to "*any* intellectual property right" or "an intellectual property right" (Emphasis added). The term "intellectual property" expressly includes patents. Furthermore, many of the substantive provisions distinguish between "copyright or related rights infringement and trademark counterfeiting" by the term "at least", implying that the provisions may apply in regard to other forms of intellectual property right infringement. The words "at least" are problematic in that they qualify the requirement by setting a floor. This means that at a minimum, criminal provisions shall apply to some kinds of serious copyright and trademark infringements, but it is permissible for parties to go beyond this requirement. Indeed, some legal experts argue that, when read as a whole, ACTA invites precisely this result.

A recent example of this issue is provided by a case study of the pharmaceutical, clopidogrel. In this instance, the relevant patent, which was granted over a reformulated pharmaceutical compound that was itself previously patented, was invalidated but only after considerable expense was incurred by Apotex, a generic pharmaceutical company. The cost of the illegal and invalid patent to the Australian economy (via the Pharmaceutical Benefits Scheme (PBS)) was somewhere between $476 million and $631 million.

Related but separate to patent validity is ***patent infringement***. It is the Australian courts that determine whether there has been an act of patent infringement. This is also a very complex issue to resolve. Unlike copyright or trademark infringement, patent infringement involves, especially with pharmaceutical patents, an analysis of the patent claims that are alleged by the patent owner to be infringed. There is more required than a visual or aural comparison, as is normal with copyright or trademark infringement. Rather, it requires the in-depth involvement of technical and scientific experts, sometimes of world class standards, who must explain to the judge what they understand - based on their common general knowledge and the words in the subject patent - the patent claims to mean. Indeed, one of the most important aspects of patent litigation is in determining the scope of the patent claims and what they mean. The idea that customs agents at the border[2] or even the Australian Federal Police (AFP) or state police forces are able to make these kinds of expert determinations when it comes to patent infringement is simply impossible unless the federal and state governments are prepared to invest tens of millions of dollars in additional recruitment and training.[3]

This, of course, raises a very important issue: the spectre of the ***criminalisation of patent infringement***.[4] Never before has this subject been raised in this context. And if the criminalisation of patent infringement should ever become a reality in Australia, it will have a most certain chilling effect on technological advancement in this country. One can only imagine how reputable Australian companies and their employees, such as generic medicines companies, will react to being raided by the AFP on the allegations of a foreign patent owner.[5]

Another complicating factor when it comes to determining patent validity is ***patent jurisdiction***. A patent is territorial in nature, meaning it is a statutory instrument that has no effect beyond territorial borders. And while this is also true for all other forms of intellectual property, it is particularly problematic for patents because the scientific and technical elements make determining validity and infringement across international borders more uncertain. There are many examples of this problem in the European context where the same patent, word-for-word and granted by the European Patent Office in Munich, is held valid in one European country and invalid in another or infringed in one and not infringed in another.

Beyond these issues are the ***transnational border issues that concern the shipment of pharmaceuticals*** destined for countries that have no patents over those goods. Indeed, as has already happened recently, pharmaceutical goods made in India and destined for Brazil were seized by Dutch customs officials while the goods were in transit in European waters. This led to both India and Brazil filing a complaint against the European Union with the World Trade Organization (WTO).

Unfortunately, ACTA draws a legal analogy between "infringing IP" in all its forms and "pirated copyright goods" and "counterfeit trade mark goods".

3. ACTA implementation will require significant changes to existing Australian law

ACTA imposes obligations on Australia that will require the implementation of new laws and policies designed to give effect to its provisions.

Alphapharm has a number of concerns about the ***National Interest Analysis*** (NIA) specifically the statement at para 7: "No new legislative measures are required to implement obligations under ACTA in Australia."

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[2] It is noted that footnote 6 at Art. 13 (Border Measures) in ACTA expressly excludes patents and the protection of confidential information but the extent and scope of this exclusion is disputed by legal experts. Specifically, Art. 13 refers to the "effective border enforcement of *intellectual property rights*". It is not confined in the substantive language of the article to copyright and trademark infringements. (Emphasis added).

[3] Art. 28 in ACTA mandates that parties "encourage the development of specialized expertise within its competent authorities responsible for the enforcement of *intellectual property rights*." (Emphasis added).

[4] Art. 23(1) ACTA refers expressly to parties providing for "criminal procedures and penalties to be applied *at least* in cases of willful trademark counterfeiting or copyright or related rights piracy on a commercial scale." The words "at least" are problematic in that they qualify the requirement by setting a floor. This means that at a minimum, criminal provisions shall apply to some kinds of serious copyright and trademark infringements, but it is permissible for parties to go beyond this requirement. Indeed, some legal experts argue that, when read as a whole, ACTA invites precisely this result.

[5] Over 90% of Australian patents are foreign owned according to IP Australia's statistics.

Alphapharm disagrees. An analysis undertaken at its request by Dr Luigi Palombi from the Regulatory Institutions Network at the Australian National University advises that significant changes will need to be made to Australia's patent laws if ACTA is ratified and is complied with. Alphapharm also sought the independent advice of eminent senior counsel, the Hon. Mr Robert Ellicott Q.C., a former Commonwealth Solicitor-General, Attorney-General and Judge of the Federal Court of Australia. Attached to this submission are Dr. Palombi's analysis and Mr. Ellicott Q.C.'s written opinion.

4. How does ACTA impact on the Australian national interest?

The Productivity Commission's Report into *Bilateral and Regional Trade Agreements* is germane. In the report, the Commission recommended against Australia's participation in bilateral and regional international agreements unless they "afford significant net economic benefits". This has been ignored with regard to ACTA since no such economic analysis has been conducted so far. Indeed, it is also noteworthy that in its comprehensive review of these kinds of agreements the Productivity Commission recommended, among other things, that "before entering negotiations ... [the Australian government] should undertake a transparent analysis of the potential impacts of the options for advancing trade policy objectives ..." Moreover, it recommended that the Australian Government "should commission and publish an independent and transparent assessment of the final text of the agreement, ***at the conclusions of the negotiations, but before an agreement is signed.***" (See Bilateral and Regional Trade Agreements, Productivity Commission Research Report, November 2010, 312, emphasis added).

While the Australian Government has not accepted all of the Productivity Commission's recommendations, specifically the latter two mentioned above, it is concerning that in this instance the Australian Parliament has been presented with a treaty by the minister which may have serious and far reaching effects, without the minister having received the benefit of "an independent and transparent assessment of the final text". Clearly, on the basis of Dr. Palombi's analysis and Mr. Ellicott Q.C.'s advice, there is cause to question the internal Department of Foreign Affairs and Trade (DFAT) advice received by the minister on the potential and unforeseen consequences of the Australian Parliament's ratification of ACTA.

One of the Productivity Commission's stated recommendations agreed to by the Australian Government is that it do the following:

> ... prepare a trade policy strategy which identifies impediments to trade and investment and available opportunities for liberalisation, and includes a priority list of trading partners. This trade policy strategy should be reviewed by Cabinet on an annual basis, and be prepared before the pursuit of any further BRTAs. A public version of the Cabinet determined strategy should be released.

However, ACTA does not appear to live up to the spirit of the philosophy contained within this recommendation. Indeed, the approach implied in ACTA arguably does not serve the best interests of the Australian economy nor the Australian people. In this regard, Alphapharm refers to the *Review of the National Innovation System* conducted under the chair of the eminent economist, Dr. Terry Cutler. One of the recommendations of Dr. Cutler's review was:

> ... IP policy is economic policy. It should make the same transition as competition policy did in the 1980s and 90s to being managed as such" (see VenturousAustralia Report, Recommendation 7.3, 86).

In other words, according to the VenturousAustralia Report, IP policy must be coordinated by a centralised economic ministry, namely, Treasury. In support of this recommendation the Report stated:

> Before the economic reforms of the last two decades what we now know as competition policy – which was then known as 'trade practices' policy fell within the portfolio of the Attorney General's Department. Given its economic significance it is now located within the Treasury portfolio. Today copyright policy is handled within the Attorney General's Department whilst patents are handled within the Innovation portfolio. Nevertheless the consideration of policy with regard to both is dominated by IP practitioners and by the beneficiaries of the IP system. We need the expertise of lawyers in this as in many other areas of policy *but it is imperative that IP policy make the transition that competition policy made over a decade ago now, from a specialist policy area dominated by lawyers, to an important front of micro-economic reform*." (Emphasis added).

5. The process of ACTA negotiations

The second aspect of the NIA that is unsatisfactory is in regard to its description of the "ACTA negotiation process" (see NIA, Attachment on Consultation, para 38.) The NIA refers to "extensive public consultations", yet nowhere does the NIA

make it plain that the process of negotiation, initiated by the U.S. Government in October 2007, was held under conditions of strict secrecy. Other than DFAT making it known that Australia was participating in ACTA, the actual ACTA text remained known only to the participating country officials involved. That is, until pressure from civil society groups, academics and other interested parties, including a vote of the European Parliament (663 to 13) on a resolution critical of the secrecy and calling for the public release of the ACTA draft text, proved too much for the participating parties.

The official public release of the draft ACTA text on April 21, 2010, is certainly acknowledged at para 41 of the NIA, but unless intimately involved in the negotiation or 'consultation' process, a reader of this document would be none the wiser as to the extent of the controversy surrounding the ACTA negotiation process.

While the public release of the official ACTA text provided stakeholders with the details for all practical purposes, the draft ACTA text in treaty language made it impossible for Australian stakeholders to make any practical difference to its contents.

In conclusion

The issues raised in this submission clearly show why it is not in Australia's interests for ACTA to be ratified in its current form by the Australian Parliament. On the contrary, we request the government to instigate an independent and transparent assessment of the final text of ACTA and to present the report to the parliament within 12 months. At a minimum and most importantly, we urge the government - in the strongest possible terms - to issue a public statement to the effect that the word "counterfeit" in ACTA is not to include generic medicines entered or eligible for entry on the Australian Register of Therapeutic Goods.