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A Mylan Company

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14 March, 2011

Ms. Melissa Hutchings
Executive Officer
Trade Commitments Branch
FTA Commitments & Implementation Section
RG Casey Building
John McEwen Crescent
Barton ACT 0221 Australia

Dear Ms. Hutchings,

We appreciate the opportunity provided by the Federal Government to submit comments on the Trans-Pacific Partnership (TPP) that is currently being negotiated.

Alphapharm is Australia's leading supplier by volume of prescription medicines and of generic medicines. One in five of all Pharmaceutical Benefits Scheme (PBS) prescriptions are dispensed with an Alphapharm product. Most of these products are produced at our state-of-the art manufacturing facility in Queensland by 400 of more than 550 employees nationally. Last year, the plant produced more than 2.5 billion tablets and capsules, of which half were exported to some 50 countries.

Alphapharm is the wholly owned affiliate of Mylan. Mylan is the third largest generic and specialty pharmaceuticals company in the world. Mylan serves customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios, which is regularly bolstered by an innovative and robust product pipeline. With a workforce of more than 16,000, Mylan has attained leading positions in key international markets through its wide array of dosage forms and delivery systems, significant manufacturing capacity, global commercial scale and a committed focus on quality and customer service. The company ranks among the top five generics companies in several international markets – including Australia - and is the largest US-based generics manufacturer in the world.

While Mylan and Alphapharm fully support international trade, we are concerned that recent trade negotiations have had a negative impact on the exports of generic drugs as well as on the generic pharmaceutical industry as a whole. Indeed, during the past ten years, trade agreements have increased the standards of protection of intellectual property rights (IPR), which can have the consequence of delaying the entry of generic

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drugs into the market and therefore undermine consumers' access to more affordable generic drugs that are equally safe and effective.

The Productivity Commission Research Report on Bilateral and Regional Trade Agreements (BRTA) released in November 2010 states: "Reducing domestic barriers to trade and investment leads to benefits to countries by improving resource allocation and efficiency within the economy, through reduced import prices and increased availability of capital, labour and knowledge, which in turn can improve the competitiveness and productivity of domestic businesses." [1] Unfortunately, this is not the case for the pharmaceutical sector where instead of reducing domestic trade barriers, new ones were created or existing ones were increased particularly through the adoption of higher levels of IPR protection that delay competition from domestic and international generic companies. These barriers to entry reduce the supply of drugs and the number of suppliers competing in the market, which results in higher drug prices and fewer exports of generic pharmaceuticals. This has an obvious detrimental impact on consumers, who are faced with higher drug prices. Furthermore, the same report states: "From an economic efficiency viewpoint, finding the appropriate degree of IP protection involves balancing the incentives for creators and the costs for users[2]. Indeed the report also says: "IP protections that are either too strong or too weak can have adverse economic effects." [3]

The report also states: "The Commission is not convinced, however, that the approach adopted by Australia in relation to IP in trade agreements has always been in the best interests of either Australia or (most of) its trading partners." [4] In addition, the report mentions: "To the extent that "emerging international standards" would extend IP rights further, requiring developing countries to adhere to these standards could do them further harm, again principally to the benefit of business interests in the United States and Europe." [5]

Finally, the report concludes the intellectual property section by saying: "The Commission considers that Australia should not generally seek to include IP provisions in further BRTAs and that any IP provisions that are proposed for a particular agreement should only be included after an economic assessment of the impacts, including on consumers, in Australia and partner countries." [6]

Both Alphapharm and Mylan completely agree with the assessment made by the government on this matter. Throughout the past few years we have witnessed the

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[1] Australian Government, Productivity Commission, "Bilateral and Regional Trade Agreements – Productivity Commission Research Report, November 2010.
[2] Idem - Page 257
[3] Idem – Page 258
[4] Idem – Page 263
[5] Idem – Page 263
[6] Idem – Page 264

multiplication of trade agreements with increasing levels of intellectual property protection that were negotiated without having made the necessary analysis of their economic impact on consumers as well as on domestic jobs in the generics pharmaceutical industry.

As a result of the adoption of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs), Australia went from granting patents for 16 years to 20 years. Since then, Australia has also approved the granting of patent extensions for delays in the granting of a patent and in the regulatory approval process. In addition, the implementation of the trade agreement with the United States (AUSFTA) entailed the adoption of a linkage mechanism between the registration of therapeutic goods in the Australian Register of Therapeutic Goods (ARTG) and the patent status which has opened the door to enable abuse of patent rights with the intent of delaying the entry of generic drugs into the market. The potential for such abuse is a particular concern in the 2011-2014 "patent cliff" period. Furthermore, the AUSFTA also seriously restricted the use of compulsory licenses, parallel imports and eliminated some of the restrictions on patentable subject matter[7] allowed for in the TRIPs Agreement (article 27).[8] These provisions are part of the flexibilities contemplated by the TRIPs Agreement and reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health of 2001.[9] In addition, article 17.9.11 of the AUSFTA refers to the disclosure of a claimed invention but fails to include the best mode requirement, which is a key element for the development of biosimilar drugs and a key provision currently included in Australia's Patents Act (Section 40(2)(a)). We also have other concerns about the AUSFTA with regard to the exclusivity of data[10] and the weak language related to the bolar-type provision. It is relevant to appreciate that provisions of this kind have been advocated by the mainstream pharmaceutical/biotech lobby to delay the legitimate impact of competition produced by the entry of generic drugs. According to the ANU's Prof Peter Drahos, they provide a "means of creating a regulatory barrier to entry for generic companies that is independent of the patent system."[11] Drahos et al argue that generics competitors have "globally pushed" the adoption of these kinds of provisions through bilateral free trade agreements, going beyond the "benchmark principle" set by the TRIPS Agreement "to protect such data against unfair competition", so as to further restrict the ability of generics producers from fairly and appropriately competing with them.[12]

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[7] See Article 17.9.7 of the AUSFTA.

[8] Drahos, P., Lokuge, B., Faunce, T., Goddard, M. and Henry, D. "Pharmaceuticals, Intellectual Property and Free Trade: The Case of the US-Australia Free Trade Agreement", *Prometheus*, Vol 22, No. 3, September 2004 at p.249-251.

[9] Ibid p.249. See also Scherer, F.M., "The Economic Effects of Compulsory Licensing", *The Monograph Series in Finance and Economics*, New York University, 1977.

[10] See Article 17.10.1 of the AUSFTA.

[11] Op cit, 9.

[12] Although a data exclusivity provision (section 25A) was inserted into the *Therapeutic Goods Act, 1989* in 1998, the bilateral free trade agreements provide a mechanism to introduce further restrictions on the access and use of such data.

As a result of the AUSFTA, Alphapharm and Mylan have been impacted in a number of ways including the requirement to give patent certificates and penalties on directors.

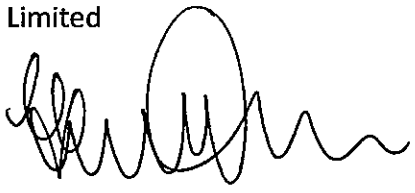
Taking all this into consideration, we are deeply concerned about the impact that the Trans-Pacific Partnership (TPP) could have on the generic pharmaceutical industry in Australia, on consumers and on the Government's budget. In less than 20 years, Australia has extended patent terms, granted patent extensions, adopted a patent linkage mechanism, as well as other provisions that, rather than increasing and promoting trade, result in restricting competition and trade and therefore timely access to affordable drugs. Alphapharm and Mylan are concerned that, even before we can understand the full impact of these agreements, the Government is embarking on new negotiations that may lead to even higher levels of intellectual property protection.

We agree with the Government's report, so we believe that Australia should refrain from negotiating new trade agreements that include intellectual property provisions. The significance of these provisions was even acknowledged by the United States, which - in 2007 - renegotiated three trade agreements that were pending congressional ratification in an effort, among other things, to strike a better balance between fostering innovation and ensuring access to affordable medicines. Indeed, the New Trade Policy eliminated patent extensions for pharmaceuticals, the requirement to adopt patent linkage mechanisms and improved significantly the data provision.

If the TPP were to include an IPR chapter, we believe that it should fully reflect the New Trade Policy and strongly endorse the Doha Declaration on the TRIPs Agreement and Public Health supported by all TPP negotiating parties. Furthermore, other important provisions should also be included such as exceptions to the data provision to export under compulsory licensing, opposition procedures to the granting of data exclusivity periods, declarations of non-infringement, the best mode requirement and measures to prevent patent or litigation abuse, including penalties, consistent with Article 8.2 of TRIPS, among others.

We look forward to working closely with you throughout this process. Please let us know if it would help for us to meet with you.

Yours sincerely,
Alphapharm Pty Limited



Martin Cross
Managing Director