
Yvonne Ong


Chew Phye Keat

Malaysia and the TPPA: What's next?

Yvonne Ong and Chew Phye Keat, Raja, Darryl & Loh, investigate the impact of Malaysia joining the TPPA, concentrating on six of the most significant changes to Malaysian patent law.

On 28 January 2016, amidst protest from a large sector of its citizens, the Lower House of the Parliament of Malaysia (by a vote of 127 to 84), passed a motion to approve Malaysia's participation in the Trans-Pacific Partnership Agreement (TPPA). Effectively, this resolution gives a *carte blanche* to the government to implement the TPPA provisions, although specific domestic laws need to be further passed for alignment with its relevant provisions. The TPPA, arguably one of the world's biggest trade deals, was subsequently signed off by all 12 member countries in Auckland on 4 February 2016 and the TPPA is now in its two year ratification phase to come into effect.

Chapter 18 of the TPPA deals with Intellectual Property and this article will be focusing on Section F of Chapter 18 on patents and related rights and its far reaching impact on Malaysia's current patent and related laws. There are at least 6 points worthy of note:

(1) Disclosure of patent applications and examination results.

Full details of patent applications are to be published after 18 months from filing date or priority date, whichever is earlier. Currently, only limited information is made available on inspection request. There will also be provisions for allowing earlier publication of a patent application. In addition to that the Intellectual Property Corporation of Malaysia (MyIPO) will now be under an obligation to make available certain information such as search and examination results, communications from the patent applicant and relevant literature submitted by the applicant and third parties.

(2) Patent Term Adjustment for Patent Office delays.

This is a further major change, requiring the MyIPO to extend the patent term, should there be delay in the examination process. Due care should be taken when making amendments to the Patents Act to only compute such delay from the actual filing date in Malaysia, as opposed to the deemed filing date.

(3) Patent Term Adjustment for pharmaceutical patents for unreasonable curtailment.

Similarly, the patent term for a pharmaceutical patent is to be extended when an untoward delay is caused by the Drug Control Authority (DCA) of the Ministry of Health, in the granting of marketing approval for a pharmaceutical product. Whilst a pharmaceutical product owner should of course not be prejudiced by such delay, it must be balanced against and exclude any such delay that is attributable to an act or omission of the applicant itself in the marketing approval process.

(4) Data exclusivity in respect of clinical data submitted by a pharmaceutical manufacturer.

Currently, data exclusivity is not automatically provided in Malaysia – an application must be made and conditions (as set out in the Data Exclusivity Directions issued by the Director of Pharmaceutical Services effective 1 March 2011) must be met. The TPPA, on the other hand, requires automatic and unconditional *Protection of Undisclosed Test or Other Data* submitted by a pharmaceutical manufacturer concerning the safety and efficacy of a

Résumés

Yvonne Ong, Partner, Raja, Darryl & Loh intellectual property practice, Kuala Lumpur

Yvonne joined the firm following graduation from Monash University (with double degrees in Law and Commerce) and being called to the Malaysian Bar in 2002.

She is a registered trademark, industrial designs and patent agent and deals with all types of IP issues from prosecution and enforcement to brand strategizing and developing IP policies and even undertaking litigation where necessary.

Chew Phye Keat, Raja, Darryl & Loh intellectual property practice, Kuala Lumpur

Phye Keat was called to the Malaysian Bar in 1987 and has been practising intellectual property law for over 25 years in the firm. A registered patent agent, trademark agent and industrial designs agent, he is currently President of the ASEAN Intellectual Property Association (ASEAN IPA) and is the Acting President of the Malaysian Intellectual Property Association (MIPA). He heads the IP department of the firm with a focus on the commercialization aspects of intellectual property.

He also heads the Competition Law team in the firm and regularly gives seminars on this area of law and its relationship with intellectual property law.

pharmaceutical product in its marketing approval application. In order to meet this obligation - and to ensure that this requirement is in line with our current practice - Malaysia has negotiated for an exception to this requirement (see Annex 18-C of Chapter 18- which is in fact an access window), wherein this Malaysian Exception provides that the 5 year data exclusivity period imposed will only be applicable on condition that the manufacturer commences the process of marketing approval in Malaysia within 18 months from the date that the product is first granted marketing approval in any other country.

It appears that this Malaysian Exception may have been driven by the need to strike a balance between public health concerns (i.e. to ensure that Malaysians have access to new drugs as well as generic drugs) and the interest of pharmaceutical patent owners. Whether or not such an exception would indeed encourage the pharmaceutical manufacturers to introduce new pharmaceuticals into Malaysia earlier is yet to be proven.

(5) Patent linkage for pharmaceutical patents.

The TPPA imposes an obligation on the DCA to have a system to provide notification to patent holders that another person is seeking marketing approval of a pharmaceutical product that is still under patent protection and to allow the patent holder to take the necessary action. It will be interesting to see how this obligation will fit with our current laws which have expressly provided that a patent holder's rights shall not extend to acts done by third parties for the purposes of obtaining marketing approval from the relevant authority (this is known as the Regulatory Exception and is also provided for in the TPPA).

(6) Extended protection for biologics.

The TPPA enhances the data exclusivity protection for the type of pharmaceutical product known as biologics (which is broadly defined as medicines that are made using certain types of cells to produce the right kind of protein). The TPPA provides that for biologics data exclusivity of 8 years from the date of marketing approval is to be accorded or at least 5 years in combination with other protective measures. Again, the Malaysian Exception applies to this particular Article in the TPPA whereby the exclusivity period imposed will only be applicable on condition that the manufacturer commences the process of marketing approval in Malaysia within 18 months from the date that the product is first granted marketing approval in any other country.

It can be seen that the above TPPA provisions have significant impact on Malaysian patent and related laws. They, in fact, generally benefit patent owners more than the users and arguably therefore in a developing economy like Malaysia's, there could be an adverse effect. The Malaysian Exception discussed above does try to provide some kind of counterbalance to this at least in the pharmaceutical field. The justification being proposed by the Malaysian government is that there is "more good than bad" in the TPPA for Malaysia. The jury is still out on that score.