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R Review of Singapore-US FTA Implementation Package
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We have reviewed the draft bills concerning patents, trademarks, copyrights and miscellaneous intellectual property amendments bills. We have not received or reviewed any legislation concerning marketing approval and data exclusivity (i.e., the obligations of Article 16.8 of the Agreement). For simplicity, we have prepared a table of the relevant obligations and where, either in existing or new provisions of the Singapore law, the obligations are satisfied.

In general, the amendments attempt to track closely the provisions of the obligations set forth in the FTA. There are a number of problems, however, that should be addressed:

- (i) Several of the changes that enhance the effectiveness of protection of patent rights are made entirely prospective (i.e., they apply only to patents issuing from applications filed on or after date of enactment). The obligations of the FTA require Singapore to extend the enhanced protection standards to any patent in force on the date of enactment, or issuing from an application pending on that date.
- (ii) The generally good “national exhaustion” provisions for pharmaceuticals added by the law appear to be substantially eroded by a new “personal importation” right. The scope of the personal importation right needs to be clarified in the legislation.
- (iii) The amendments to limit compulsory licensing situations to remedy “anticompetitive” behavior is largely undone by the redefinition of this concept to include “insufficient working” of an invention as an “anticompetitive” act. This definitional provision should be deleted.
- (iv) The newly defined grounds for revocation of a patent, while limited to the types of grounds permitted by the FTA, adopt excessively punitive and unrealistic standards corresponding to “inequitable conduct” criteria in the U.S. (i.e., misrepresentations of the patent applicant to the patent office).

Finally, there are a few questions that we could not answer based on this review of the legislation. Answers to the questions reflected below would enable us to determine whether the provisions are compliant with the terms of the FTA.

We note that on the trademark issue (Article 16.2(6)) we have not be able to find any changes associated with this enhanced protection standard. Changes to reflect this standards may not be necessary, and thus may not be implemented in the trademark law proper.

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16.7(1) (patent eligibility)	Sec. 13	Complies with terms of Article 16.7(1) (i.e., only subject matter within scope of Article 27.2 and 27.3(a) excluded).
16.7(2)(national exhaustion)	Sec. 66.2(g), (i) and 66.2A	<p>A new provision (§66.2A) limits the international exhaustion effect of section 66.2(g) to products other than patented pharmaceutical products. It provides that the right of a third party to import products does not apply if the product (a) was not sold originally within the territory of Singapore by or with the consent of the patent owner, and (b) the importation of the product would result in a breach of contract between the patent owner and any person licensed by the patent owner to distribute the product outside of Singapore. Actual or constructive notice from the patent owner is a requirement for the right of the patent to use this authority, and may be given by providing the accused party with written notice.</p> <p>The structure of §66.2A appears to effectively give control to the patent owner to prevent exhaustion of patent rights in Singapore due to actions involving its distributor(s) outside of Singapore. However, new section 66.2(i) seems to take away much of what has been established by §66.2A. Section 66.2(i) provides that the acts of import, use or disposal, or offer for disposal, of a patented pharmaceutical product is not an act of infringement if (i) the product is “required for the eventual use of any specific patient in Singapore, (ii) the relevant authority has granted approval for use of the product by that patient, and (iii) the product was produced with the consent or authorization of the patent owner. As written, §66.2(i) appears to carve out an exception for “personal” importation of products (i.e., one covering the acts of an individual who personally imports the product). However, the language in clause (i) seems to also immunize third parties who import for such persons, which could erode significantly the effectiveness of §66.2A.</p>
16.7(3) (limited exceptions to patent rights)	Sec. 66.2, 71	No changes regarding Article 16.7(3) were required by the FTA. Limited exceptions to patent rights are found in Sections 66.2(a) to (f)(e.g., private non-commercial use experimental use, etc) and 71 (prior user rights) of

		the Singapore law.
16.7(4) (revocation grounds)	Sec. 79, 80	Section 79 (concerning revocation for non-timely disclosure of foreign prosecution results) is revoked. Section 80, which concerns grounds for revoking patents, has been amended to more specifically define circumstances justifying revocation. Section 80(f) expands the grounds for revoking patents to include not only fraud or “any misrepresentation” but also “non-disclosure or inaccurate disclosure of prescribed material information, whether or not the person under a duty to provide the information knew or ought reasonably have known of the information.” Sections 80(f)(ii) and (iii) set an extremely punitive and demanding standard that far exceeds U.S. law on inequitable conduct (the parallel concept). These provisions should be modulated to render them fair.
16.7(5) (“Bolar” exception)	Sec. 66.2(h)	A new section (h) has been added to 66.2 (provisions that are defined to not be infringement and may be raised as defenses to infringement action). The section tracks the language of Art. 16.7(5) by establishing a right of a third party to make, use or sell, or to export, the subject matter of a patent, provided the acts are done for purposes related to meeting the requirements for regulatory approval.
16.7(6)(a) (compulsory licensing for only anticompetitive grounds)	Sec.55	Section 55 is amended to limit compulsory licensing grounds to those where necessary to remedy and antitrust violation. The amendments eliminate the minimum time period of existing law as to when such licenses may be issued. While this is arguably consistent with the Paris Convention, which imposes the time limit only in respect of “non-working” compulsory licenses, the amendments to §55 further provide that non-supply of the Singapore market constitutes an anticompetitive practice. The redefinition of “anticompetitive” in this manner is a significant problem.
16.7(6)(b)(public non-commercial use by government)	Sec. 56, 57	Amendments to these provisions limit (relative to current law) the authority of the Singapore government to use a patented invention to circumstances of “public non-commercial use” and “. The amendments retain the structure of permitting such use without compensation or authorization. In addition, the amendments do not appear to implement the obligations of Art. 16.7(b)(iii) (no compelled transfer of “know how” or undisclosed information). The basis for this may be that no authority

		exists in Singapore law to override trade secret rights. A confirmation to this extent is necessary to confirm compliance with this provision.
16.7(7) (patent term extension for Patent Office delays) and 16.7(8) (patent term extension where “reliance” examination occurs)	Sec. 36A	New §36A implements a system of patent term extensions for (i) administrative delays as required by 16.7(7) [§36A(a)], (ii) where the patent is granted on the basis of a foreign patent and the foreign patent has been extended (§36A(b)) and (iii) regulatory approval time pursuant to 16.8(4)(a) [§36A(c)]. The implementation addresses, in a fair amount of detail, the periods of eligibility and ineligibility for extensions, and appears to be a good-faith implementation of the obligation for patent term extension. Certain of the “disqualifying” events may need to be reevaluated once experience is gained under the regime.
Art. 16.1(6)(a)	Transitional provisions	<p>The transitional provisions (section 29(1)) provide that the patent term adjustment provisions of Sec. 36A apply only to patents issuing on applications filed on or after the date of effect of the law. Article 16.1(6)(a), provides, however, that the enhanced protections of the FTA are to be applied to any subject matter (i.e., any patent or application) existing as of the date of the Agreement. The law must extend the patent term extension provisions to qualifying patents in effect on the date of application of the agreement, or issuing from applications pending on that date.</p> <p>Similarly, the revocation of section 79 is made applicable only to patents that are filed after the date of enactment of the Act. The “enhanced” protection made possible by the revocation of §79 should be extended to any patent in force on the date of enactment, and to any patent issuing from an application pending on that date.</p> <p>The additional protection against importation of patented pharmaceuticals is not specifically addressed by the transitional clauses. It is thus unclear whether the amendments that enhance importation rights apply to all patents that are in force on or after the date of enactment. This should be explicitly clarified consistent with the above principles.</p>