CPTech Analysis of the Settlement Order
Republic of the Philippines - Civil Case No. 06-172

In March 2006 Pfizer sued the Philippine International Trading Corporation (hereinafter referred to as PITC), the Bureau of Food & Drugs (BFAD) and two BFAD regulators for importing samples of a Pfizer drug, amlodipine besylate, submitting the samples to BFAD and obtaining Parallel Drug Importation Registrations (PIDRs) on 5mg and 10mg formulations, so that the product can promptly enter the market when the Pfizer patent expires in 2007. Pfizer's apparent purpose was to prevent the early registration of a patented product[1] and delay parallel trade. As evidenced by the BFAD's grant of PDIRs in this case, parallel importation is legal in the Philippines, as it is in many other countries.

The Philippine's Regional Trial Court dealing with the case issued a Settlement Order last August 17, 2006. CPTech's interpretation of the Court Settlement Order is that: 1) PITC is ordered to adopt a Board resolution confirming its prior commitment to not import amlodipine besylate for distribution and sale until expiration of the subject patent; 2) BFAD agrees to expressly condition all future registrations of patented drugs to become effective only after the expiration of applicable patent term(s), a practice commonly known as linkage[2]; and 3) BFAD will amend PITC's PIDRs to become effective after Pfizer's patent expires in 2007. In consideration of these actions, Pfizer's counsel will secure approval for this settlement of the case between the parties.

What is not expressly resolved by the Order is the issue of whether PITC and BFAD infringed Pfizer's Philippine patent (Philippine Letters Patent No. 24348) by the past act of importing samples of Pfizer's drug from another country solely for the purposes of analysis in support of securing the PIDRs. In its Complaint, Pfizer asserted that such acts comprised infringement (despite the experimental use exemption under Article 72.3 of the Philippines Intellectual Property Code). Implicitly, the Order suggests that the Parties agree that such acts are not infringement, as the Order expressly permits PITC to begin importing after expiration of Pfizer's controlling patent, and permits BFAD to issue registrations in the future on patented medicines subject to their agreement to link the effective date of any such registration to patent terms.

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[1] The so- called "early working" of a patent or "Bolar" provision. To overturn a controversial judicial decision (Roche Products, Inc. v Bolar Pharmaceutical Co., 733. F.2d 858 (Fed.Cir.1984)), in 1984 the United States changed the patent law to allow for the early working of a patent when preparing a drug registration. U.S. 35 USC 271(e)(1): "It shall not be an act of infringement to make, use, offer to sell or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products." Some countries have implemented similar statutory changes in their laws (Australia, Canada, Argentina, Israel), and recently the European Union required its member states to implement similar provisions through the experimental use exemption.

[2] Patent-Registration Linkage ("linkage") is the practice of linking drug marketing approval to the patent status of the originator's product and delaying the grant of marketing approval to any third party until expiration of the patent term unless by consent of the patent owner. Under this kind of regulation, national regulatory authorities have the obligation to prevent the registration and marketing of second applicants when a patent covers the product.

This Order thus embodies a compromise, which is typical of any settlement of litigation. The compromise reflects the imbalance of what each party has to lose if the case is pursued to judgment (and appeal). If Pfizer loses, they would be in the same place they are now (less litigation fees): BFAD would be free to continue to issue parallel importation licenses prior to expiration of patents, and PITC will begin parallel importation in 2007. If Pfizer wins, however, then PITC would be compelled to give up its already-issued importation licenses on amlodipine besylate and re-apply for those licenses only after the patent expires, and BFAD would be prohibited from accepting applications for these licenses prior to the expiration of the relevant patents in the future.

Despite this imbalance, the Settlement Order is not a fair compromise. The BFAD's agreement to adopt linkage applicable to all of its registrations of generic drugs or parallel importation of drugs is a substantial change of policy that reaches far beyond the current litigation and has serious import for drug competition in the Philippines.

RECOMMENDATIONS

CPTech believes that the compromise presented in the Order is an inadequate and harmful basis for final settlement of the Pfizer lawsuit. As such, CPTech suggests that the final settlement agreement embody the following specific changes:

I. PITC Board Resolution

Under Paragraph 1 of the Court Orders, the PITC is ordered to issue a Board resolution assuring that they will not import Pfizer's drug until after the patent expires.

If such a resolution is issued, CPTech recommends consideration of the following language:

"The Board of Directors of the Philippines International Trading Corporation (PITC), in compliance with the settlement agreement of the Civil Case No. 06-172 and consistent with prior letters September 26, 2005 and February 7, 2006, declares that the PITC will not make an importation for sale of the subject matter of this lawsuit until after the expiration of the plaintiff's patent. This declaration is without prejudice to the ability of the PITC to import and submit commercial samples in support of a BFAD application for any other products, to the degree that such activity is permitted under Section 72.3 of Republic Act No. 8293 or subsequent revisions of the Act.

II. Modification BFAD registration procedure: Patent linkage

Paragraph 2 of the Court Order requires BFAD to modify its registration procedure from now on by incorporating the controversial patent-registration linkage practice. There is no requirement under the TRIPS Agreement for WTO Member States to recognize this practice and until recently, linkage was only included in the United States and the Canadian pharmaceutical legislation.

The use of linkage is subject to several critiques. The most important are that it creates many problems if the national patent office grants low quality patents, a problem in many countries, including the United States. The system of linkage changes the status quo and shifts the enforcement burden, so the patent owner gets an automatic barrier to competition, without having to persuade a judge that the patent is both valid and relevant. That is, with linkage, a generic manufacturer or importer bears the obligation to challenge any patent in order to get a license effective prior to patent expiration; patent law typically requires patentees to actively enforce their patents against infringers, but linkage uses extra-patent regulatory authority to inhibit infringement (selling or importing). Further, linkage places an administrative burden on the drug regulatory authority to determine the validity and relevance of any patents asserted by the brand owner, which may be beyond the specific competencies of these agencies. -

CPTech does not recommend the incorporation of linkage into national regulatory practices. It is the Philippines Government, not the judicial branch that should make the decision of incorporating such a practice into national law after considering all its policy implications.

If the Philippine government is to adopt the form of linkage that is presented in the proposed settlement order, it would have the worst linkage regime in the world. Consider, for example, how the order would differ from the US system of linkage.

1. The US system of linkage does not apply to biologics or antibiotics. The Philippines order would apply to all medicines.

2. The US system does not extend to the life of a patent. It gives the patent only a maximum 30 month stay of a generic registration in cases where there is a dispute about patent validity.

3. The US system can only be used once for a product. The Philippines order could be used for many different patents.

4. The US system includes a system of appeals and mechanisms to avoid applications in cases where patents are weak or not relevant to the products.

None of these safeguards would be included in the proposed settlement. We also note that in the US, linkage was introduced as part of a larger compromise that included introduction of early working of patents for drug registration (the “bolar” provision).

If some type of linkage is considered necessary we strongly urge the negotiators to limit the effect of linkage by considering the following options:

a) Apply linkage in the case at bar only, and amend PITC’s BFADs to only become effective upon the expiration of Pfizer’s patent. We believe this adequately addresses the concerns of the parties in the instant case.

b) In lieu of adopting the linkage terms as proposed in the Order, BFAD should agree only to promulgate formal regulations for the implementation of linkage, enabling them to duly consider

the difficult policy questions involved and to develop a system that adequately addresses concerns such as those raised above.

If a linkage regulation is agreed there are several actions that can be taken to reduce its negative effects, like for example reduce the linkage regulation to a "Mandatory Notification System", where the patent holders have the burden to list the relevant patents, and also introduce a mechanism of appeal to challenge the validity/applicability of the patent, like the U.S. stay period.

For a description of the U.S. linkage system and CPTech concrete policy proposals on a pro-public health linkage system, see: CPTech Discussion Paper No. 2. Patent-Registration Linkage (April 3, 2006). Available online at:
http://www.cptech.org/publications/CPTechDPNo2Linkage.pdf

III. Legality of the early working of a patented product

The final settlement should not be used by Pfizer or other parties to claim that early working of a patent for registration purposes constitutes infringement under the Philippines Intellectual Property Code. The Philippine government might suggest the judge to add language in the final settlement agreement which states:

"The parties disagree on whether the submission of commercial samples in support of PITC's BFAD applications that necessitated actual use and importation of patented products without authorization, and that making or using patented products exclusively for the purpose of experiments that relate to the subject matter constitutes an act of infringement under Section 72.3 of Republic Act No. 8293."

IV. Patent Law amendment: incorporating public health flexibilities

The Philippine government should amend the Intellectual Property Code to address, in a fully democratic way, these issues. CPTech is following the excellent initiative to amend the Philippine Patent Law by taking advantage of public health flexibilities that other countries already have. We are following with great interest the work of the Senate Committees on Trade & Commerce and Health & Demography, chaired by Sen. Roxas and Sen. Cayetano, respectively and by Congressman Junie Cua, Chairman of the House of Represenatives Committee on Trade and Commerce.

The settlement agreement should not be used to undermine the right of the Government to change its law and the policy adopted in this settlement. We recommend adding the following language to any final settlement agreement:

"Nothing in this Settlement Agreement prejudices or constrains the right of the Government of the Philippines to enact any laws and to make any and all changes and amendments to the Intellectual Property Code, the Food, Drug and Cosmetic Act, and any applicable Executive Orders, as it sees fit, in its absolute discretion, including changes to implement its obligations under Paragraph 4 of the Doha Declaration on TRIPS and Public Health that states the TRIPS

'Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all'."

MORE INFORMATION

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