



August 6, 2008

**Atty. Adrian Cristobal**  
Director General  
Intellectual Property Office  
351 Sen. Gil Puyat Ave.  
Makati City

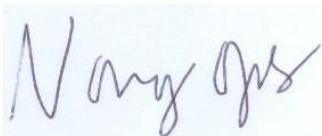
Dear Atty. Cristobal,

May I submit our proposed implementing rules and regulations (IRR) to Amendments to IPC, Chapter 2 of RA 9502. As you have requested during the IPO public consultation last July 29, 2008, specific language of the IRR is hereby provided, as well as the rationale and arguments for proposing the said language.

Hoping that you will invite us again for another public consultation of IPO on this subject. Any questions regarding our proposals, you can reach me at 0915-8204616 (mobile), 6662969 (office), or [nonoy@minimalgovernment.net](mailto:nonoy@minimalgovernment.net) (email).

Thank you very much.

Sincerely,



Bienvenido Oplas, Jr,  
President  
Minimal Government Thinkers, Inc.



# *An IPR System Conducive to Innovators*

*(Proposed Implementing Rules and Regulations  
to Amendments to IPC, Chapter 2 of RA 9502)*

**Bienvenido Oplas, Jr. \***  
August 6, 2008

## ***Introduction***

Newly-enacted law Republic Act (RA) 9502, or the “Universally accessible cheaper medicines act of 2008” contains a number of sweeping provisions that are confiscatory in nature. Such provisions can encourage corrupt and extortionary behaviour on the part of some high government regulators, as well as encourage other pharmaceutical companies not to engage in medical innovation anymore because of such threats of intellectual property confiscation.

Since those provisions are already in the new law, the above-stated dangers should be tempered as much as possible. That is, make their implementing rules and regulations (IRR) reflect full transparency in order to discourage abuse by people with bad intentions. In addition, the intellectual property rights (IPR) system of the country should be conducive to innovators, not discourage them. Newer and more effective medicines must continue coming in to help mankind and the Filipinos in particular, deal with evolving diseases in our evolving lifestyle, evolving communities and evolving climate. More innovator companies from industrialized and emerging markets should come in so that there will be a healthy competition among themselves. A competition between a few innovators and plenty of copycat-ers is not real competition.

Our think tank advocates 4 core principles: small government, small taxes, free market and individual responsibility. Related principles are our strong belief in private property rights, including IPR, and rule of law. So, although we share with the public

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the noble aspiration to have “affordable and quality medicines” be made more available, we do not support, however, moves by the government to weaken, if not disrespect, patents and IPRs to attain this goal. After all, it is the State itself which issued and granted those patents after the patent owners went through certain strict regulations and bureaucracies and paid certain taxes and fees.

The following are proposed language for the Implementing Rules and Regulations (IRR) of Chapter 2 (“Amendments to Republic Act 8293, Otherwise known as the Intellectual Property Code of the Philippines”) of RA 9502, and the rationale why such proposals were made. The proposals and comments are limited to 3 issues only: Patent infringement and parallel importation, Government use of an invention, and issuance of Compulsory Licensing. Because in our view, when these 3 measures are arbitrarily and casually applied and issued, that constitutes patent busting and stealing of IPR, with reference to “national emergencies” as mere excuses.

## ***I. Patent Infringement and Parallel Importation***

(Section 7 of RA 9502)

**Section \_\_\_\_.** Persons or firms cannot engage in parallel importation of locally-patented medicines into the country unless they have valid license to operate as a parallel importer and hold relevant drug registrations issued by BFAD. Their company name, address, contact details, registration numbers with certain government agencies like SEC and BIR should be made available online, both in their company website and in BFAD website.

Licensing and registration requirements required by BFAD for products marketed in the Philippines, including the standards set by the ASEAN Harmonization rules, should apply to products to be parallel imported into the country.

Rationale: To weed out undesirable traders and importers who will just bring in fake, counterfeit, and unsafe medicines for a big and quick profit at the expense of poor patients. Traders should be made as transparent as possible to the public. The same for the quality of the medicines that they bring in from abroad.

**Section \_\_.** All applications for the granting of a parallel import drug registration to be filed with the BFAD and shall contain information and documents such as: name of the local product as known in the Philippines and in the country of source; qualitative and quantitative composition in terms of active pharmaceutical ingredients (API), by dosage unit or in percentage; therapeutic indications and normal dosage; contra-indications and main side effects; storage considerations, if any.

Rationale: To ensure that the products being applied for parallel importation are identical to or have no significant therapeutic differences from their locally registered counterpart.

**Section \_\_.** Parallel importers should present original testing certificates; if there is none, their imported drugs must be tested and granted testing certificates by BFAD-accredited testing institutes for bio-equivalence with the locally-patented medicines. Only those medicines that pass the quality standards will be allowed circulation and distribution/sale.

Parallel importers should also ensure that there is a clear audit trail from the manufacturer, authorized wholesaler or distributor in the source country, the shipper, local storage until distribution. In the event of a recall of a batch of the parallel imported product in the source country, the supplier should promptly inform the parallel importer so that the latter can also recall the distributed drugs or take other appropriate actions.

They should be required by BFAD to implement post-approval monitoring and pharmaco-vigilance procedures. They should be held accountable should patients develop bad allergies or non-response to treatment, other negative consequences after taking the drugs they brought in.

Rationale: To ensure the entry only of safe and effective drugs parallel imported into the country, discourage the entry of fake and counterfeit medicines. Putting clear and direct accountability on the quality of the imported products will compel parallel importers to bring in only good quality and reliable medicines and help discourage the proliferation of counterfeit and ineffective drugs.

**Section \_\_.** No repackaging of parallel imported medicinal products be allowed. The drugs must be stored in the warehouses of the parallel importers and should be printed or stuck with additional labels on the outer medicine packages before being put into circulation.

Parallel imported medicines should contain labels for the following: brand name/generic name; the parallel importer's name, address, telephone numbers, website, serial number of parallel import license; date of grant of license.

BFAD shall ensure that all parallel imported drugs should conform to international standards for the content, purity and quality of pharmaceutical products as established in the International Pharmacopoeia or be certified under the World Health Organization (WHO) certification scheme on the quality of pharmaceutical products.

Rationale: Again, make sure that only quality medicines will get into the country. Repackaging normally invites certain risks like

## ***II. Use of Invention by Government***

(Section 8 of RA 9502)

**Section \_\_\_\_.** “National security, nutrition, health” shall mean at least fifteen percent (15%) of the entire population has been actually affected by a particular disease outbreak, with potential to further affect more people. When the affected population does not reach this percentage, Government use of an invention cannot be declared.

Rationale: Declaration of “public interest”, “national security” and related concepts should be properly defined and quantified to prevent arbitrary declaration and hence, abuse by any government agency.

**Section \_\_\_\_.** “Anti-competitive” exploitation of an invention shall mean introducing a new medicine that is so effective, at least thrice (3x) more effective than the second- or next-known effective medicine (can cure an average patient in one-third period of time compared to effectiveness by the second-known medicine) by another branded or generics company, and is priced at least ten times (10x) the price of the second- or next-known effective medicine.

Rationale: “Anti-competitive” behaviour is often broadly defined and can be subject to arbitrary definition by certain government agencies just to justify Government use and take-over the patent of an innovative and effective yet high-priced medicine. In addition, “anti-competitive” behaviour can range from “predatory pricing” (selling at a very low price to eradicate certain competitors), “price gouging” (selling at a very high price due to certain emergency situations), and “price collusion” (all major players have similar price for the same product).

**Section \_\_\_\_.** In the case of drugs and medicines, “national emergency” shall mean at least fifteen percent (15%) of the entire population has been actually affected by a particular disease outbreak.

Rationale: “National emergency” should be properly defined and quantified to prevent arbitrary declaration and hence, abuse by any government agency.

**Section \_\_\_\_.** “Demand for patented drugs not being met to an adequate extent” shall mean demand by up to twenty percent (20%) of the affected people.

Rationale: Supposing there will be one (or two or more) million people affected by a particular disease outbreak, and all of them will demand a particular patented medicine because it will cure them within one week or less, while other drugs will cure them within 2 to 20 weeks, then the demand for that effective but patented drugs will definitely not be met. Putting a cap to “public demand” will reign in any abuse of government confiscation of a patent by the innovator pharmaceutical company.

**Section \_\_\_\_.** Duration of Government use should be no more than six (6) months. After which, the patent should be respected. And Government use shall be authorized only for the supply of the domestic market in the Philippines,

Rationale: If Government use will be open-ended and have no time table, then disrespect of the patent can be indefinite. If this is the case, issuance of patents will be useless and a farce. In addition, damage to patent holder should be limited to Philippine soil and not be further expanded to other markets abroad.

**Section \_\_\_\_**. “Adequate remuneration” to patent holder shall mean no less than eighty percent (80%) of the projected revenues if government did not come in and allowed the patent holder to reap the benefits of producing an innovative and highly effective medicine.

Rationale: Adequate remuneration should be properly defined and quantified, otherwise it will be subject to abuse; say the DOH can pay the right holder only 10 to 20 percent of projected revenues, and the third person or firm authorized by the DOH, a crony of certain high government officials, will corner the big profit even if that third party did not spend a single centavo in very costly pharmaceutical R&D.

### ***III. Grounds for Compulsory Licensing (CL)***

#### **1. Sections 10 of RA 9502**

**Section \_\_\_\_.** “National emergency” “public interest”, “national security, nutrition, health” as ground for issuance of Compulsory Licensing shall mean at least fifteen percent (15%) of the entire population has been actually affected by a particular disease outbreak, with a potential to expand and affect more people.

**Rationale:** Such concepts should be properly defined and quantified to prevent arbitrary declaration of CL and hence, subject to abuse by any government agency for certain vested interests or pure envy.

**Section \_\_\_\_.** “Anti-competitive” exploitation of an invention shall mean introducing a new medicine that is so effective, at least thrice (3x) more effective than the second- or next-known effective medicine (can cure an average patient in one-third period of time compared to effectiveness by the second-known medicine) by another branded or generics company, and is priced at least ten times (10x) the price of the second- or next-known effective medicine.

**Rationale:** “Anti-competitive” behaviour is often broadly defined and can be subject to arbitrary definition by certain government agencies just to justify Government use and take-over the patent of an innovative and effective yet high-priced medicine.

**Section \_\_\_\_.** “Demand for patented drugs not being met to an adequate extent” shall mean demand by up to twenty percent (20%) of the affected people, and not by all affected people.

**Rationale:** Supposing there will be two (or more) million people affected by a particular disease outbreak, and all of them will demand a particular patented medicine because it will cure them within one week or less, while other drugs will cure them within 2 to 20 weeks, then the demand for that effective but patented drugs will definitely not be met.

**Section \_\_\_\_.** Before issuing any compulsory license, the patent holder shall be notified of the grounds for which the same is being issued and shall be given an opportunity to respond and request review of the potential findings within ninety (90) days maximum from receipt of the notification.

**Rationale:** The patent holder should be informed why its innovative medicine where it spent hundreds of millions of dollars and up to 12 years to develop, will be taken over by the State, and it will be deprived of recovering such huge cost and risks with the issuance of CL.

#### **2. Section 11 of RA 9502:**

**Section \_\_\_\_.** Upon issuance of compulsory license, the Director General of the IPO shall notify the Council for TRIPS the names and expected quantities of the pharmaceutical product(s) imported. The Director General of IPO shall present a certification to the TRIPS Council that the Philippines has no manufacturing capacity in the pharmaceutical sector for the product(s) in question, or if such capacity exists, it is not sufficient to produce the local needs. To prevent or minimize the risk of re-exportation, the outside packaging of all drugs and medicines imported under this Section shall bear the note **“Imported by the Republic of the Philippines under special compulsory license. Not for re-export or re-sale outside the Philippines.”**

Rationale: To inform the Council for TRIPS the extent of use or abuse of CL by the Philippine government for imported medicines that are still on patent locally. And to ensure that domestic capacity to produce the local needs is indeed not present, and for issuance of CL not be taken so lightly and arbitrarily. The notice against re-exportation is consistent with the provision of Section 11 of the new law.

**Section \_\_\_\_.** “Adequate remuneration to the patent owner” shall mean at least eighty percent (80%) of projected revenues by the patent owner if government did not come in and issued the compulsory license.

Rationale: Adequate remuneration should be properly defined and quantified, otherwise it will be subject to abuse or arbitrary setting of remuneration that does not reflect the cost of damage of disrespecting patent and IPR of the innovator company.

**Section \_\_\_\_.** Before the Director General of IPO can issue a compulsory license for the manufacture and export of drugs or medicines under patent to any eligible importing country, he/she should present a certification from the Council for TRIPS that the importing member-country has informed said Council that it has also issued its own special compulsory license to import certain pharmaceutical products under patent, and that it has no or limited domestic capacity to manufacture said products. The names and expected quantities of products to be manufactured in the Philippines, the name of local manufacturer and exporter, should be posted in the IPO website.

The outside packaging of the pharmaceutical products manufactured in the Philippines should bear either one of the following notices: (a) **“Exported by the Philippines under special compulsory license for \_\_\_\_\_ (name of importing country). Not for export or sale to any other country.”** Or (b) **“Imported by \_\_\_\_\_ (name of importing country) from the Philippines under special compulsory license. Not for re-export or sale to any other country or re-importation to the Philippines.”**

Rationale: This is another safeguard so that issuance of CL should not be done lightly and arbitrarily; otherwise, a new pharmaceutical cronyism will emerge, favoring a Philippine-based manufacturer and an importing country-based trader, and possibly corrupting the IPO and the CL-issuing agency in the importing country.

Also to safeguard against trade diversion and prevent the Philippines becoming a base for manufacture and exportation of patent-disrespected medicines.

**Section \_\_\_\_.** Adequate remuneration shall be paid to the Philippine patentee, equivalent to at least eighty percent (80%) of the projected revenues if the government did not issue the compulsory license.

Rationale: Clearly define and quantify “adequate remuneration”.

#### ***IV. Concluding Notes***

June this year, two innovator companies have announced scaling back research against AIDS. [Roche](#) of Switzerland said it was withdrawing from HIV research, while [Merck](#) of the US recently cancelled one such treatment project; poor results have also left it with no HIV vaccine under test (Jack, Andrew, FT, 2008).

Another company, Glaxo announced last month that it will shift away from relying on blockbuster prescription drugs and build on its vaccine and consumer health business (BBC report, 2008).

These could be examples of innovator companies who spend billions of dollars in very expensive R&D and clinical trials to produce drugs that are both safe and efficient for millions of patients around the world. And when they succeed in producing such drugs, the IPR system can work against them in favour of some generics companies who never exposed themselves to such risks and huge costs, and some government leaders who confiscate pharmaceutical patents possibly for some personal and vested interests.

For those companies therefore, it would be better to produce new drugs on fat burner, wart and eyebag remover, breast and male organ enlarger, height and muscle enhancer, or new headache and cough tablets, new shampoo and toothpaste, than new drugs against evolving strains of AIDS, malaria and cancer. This is because those consumer products are not covered by “national emergencies” and there are no laws or government orders that justify patent confiscation, drug price control, and other forms of government intervention.

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#### ***References:***

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