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**INNOVATIVE APPROACH AIMED AT ACHIEVING A SEPARATE IPR
SYSTEM FOR PHARMACEUTICALS IN BOTH DEVELOPED AND
DEVELOPING COUNTRIES FOR THE PURPOSE OF ACHIEVING MDG 6 & 8**

If MDG 8 & 6 are to be achieved then a separate and unique international IP system pertaining to pharmaceuticals needs to be developed to provide pharmaceutical companies in developed and developing countries the capabilities and resources to produce drugs for the sole purpose of exporting them to developing regions of the world, where diseases such as HIV, Aids and malaria are rampant. In the developing regions, a humanitarian crisis looms due to the lack of availability and affordability of drugs for people infected with such diseases. So, if MDG 6 is to be achieved, an international pharmaceutical oversight organization must be created or alternatively, existing agreements and agencies operating under the Mutual Recognition of Pharmaceutical Good Manufacturing Practice (MRPGMP) should be broadened to include the less developed countries of the world in order to combat diseases such as HIV, Aids and Malaria in developing countries. Furthermore, the enlargement of the cooperation between the developed and developing countries in particular to pharmaceutical products would inherently eliminate the immoral and possibly illegal practices conducted by the pharmaceutical companies, who have exported expired and worthless drugs to developing countries, especially in times of war and crisis. (The Development Dilemma, Robert L Ostergard, Jr., LFB Scholarly Publishing LLC, NY 2003)

My proposal is a flexible and separate International IP system for the pharmaceutical industry. The IP system I propose would apply only when the production of the particular drugs are for the purposes of exporting them to the developing countries that are in dire need of the drugs to treat the infected populations who do not have the resources to buy the drugs for themselves. I suggest a separate pharmaceutical patent system where it would resemble the one in the US but the difference would be that registration and renewal periods regarding drugs that treat the major diseases rampant in the developing world would be significantly less. 37 CFR

2.181 states that trademarks issued or renewed prior to November 16, 1989 remain in force for 20 years and may be further renewed for periods of 10 years. I recommend in the international IP system, we develop laws that would be enforceable in the court of international trade, where patents and trademarks issued to pharmaceutical companies, who produce drugs that combat diseases listed in MDG 6 should be in force for a period of 10 years upon issuance and allow only a one time, 5 year renewal period. However, it is important to distinguish a caveat to this rule, where the patent system would only apply to companies that want to produce drugs for the sole reason of meeting MDG 6 goals and exporting drugs to developing countries who can not produce the pharmaceuticals in their national drug industry to treat their infected populations with the diseases listed in MDG 6.

I recommend that the US and EU take the lead in assisting the developing countries by allowing them to become members of the MRPGMP, which is a joint agreement between the FDA in the US and its counterpart in the European Community. MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE, the provisions therein apply to pharmaceutical inspections carried out in the United States and Member States of the European Community before products are marketed as well as during their marketing. 21 CFR 26.3.

The MRPGMP also allows equivalence assessment by each nation's agencies with cooperation to achieve similar necessary regulatory authorities for post- and pre-approval inspections of drugs. Information exchanges (including inspection reports), joint training, and joint inspectors for the purpose of assessing regulatory systems and the authorities capabilities. 21 CFR 26.6. Currently obligations contained in MRPGMP do not have force and effect with regard to other countries who are not a party to the mutual recognition agreements. 21 CFR

26.78. Therefore, I recommend that those countries that have pharmaceutical production capability be allowed to join the MRPGMP and the developed countries should assist them in developing the necessary infrastructure to monitor and report to an international commission made up under MRPGMP who would be able to refer violators of the agreement to the Court of International Trade. MRPGMP could work with each individual country's Customs and prevent the exportation and importation of drugs which violate the standards set forth in the agreement and the proposed International IP laws for pharmaceuticals being exported to developing countries.

The regulatory agency that would enforce and police the patent system could later be morphed into an "International Drug Agency" (IDA). In our group policy proposal we proposed that an IDA be created under the auspices of the UN which would create standards similar to that of the FDA on an international scale. We also proposed that funding for IDA would initially be provided by the UN to enable the creation of the organization. If we start an international oversight agency for pharmaceuticals through MRPGMP, we could avoid a lot of obstacles such as initial funding technical expertise which would be provided by the FDA and its European counterparts. Thereafter, we proposed that the IDA be in charge of managing distribution contracts of the drugs that are going to be shipped to the least developed countries which don't have manufacturing capacity. Additionally, companies other than the patent holder would bid for the license to manufacture and distribute to that market. A percentage of the profits would go back to the IDA and if royalties are established from selling the drugs then it would be shared with the IDA and the patent holder.

A major obstacle in implementing an International IP system will rely on the willingness of developed countries such as the US and EU member states to cooperate with developing

countries and their willingness to allocate resources in assisting the development of regulatory agencies such as the FDA in developing countries. But through lobbying and delegating WIPO as a major promoter, then the IP system I proposed could be a viable tool in meeting MDG 6 in the near future. Those pharmaceutical companies who would be interested in exporting their drugs to developing countries for both economic gains and/or philanthropic reasons should be able to reap the benefits of a separate International IP system for pharmaceuticals and would be regulated by the same standards set in developed countries such as the US.