Note on Exclusion of the Philippines and the OCR for India Under Special 301 Review by the USTR

1. The World Intellectual Property Organization (WIPO) administers 27 treaties as per its website (www.wipo.int/treaties/en) as of June 2014. These are listed in Annex-1. A summary of these treaties is given below:

WIPO Administered Treaties

Types of Treaties	Total
General (WIPO & UPOV Convention)	2
IP Protection	15
Global Protection System	6
Classification	4
Total	**27**

An analysis of the signatories to these treaties is revealing in many ways:

a. The countries that are signatory to the maximum treaties (24 out of 27) are not the developed economies, pushing for the higher standards of protection and enforcement of IPRs. They are Bosnia, Republic of Moldova and Serbia.

b. They are followed by Montenegro (23), Croatia (22) and France (22).

c. The USA is signatory to only 15 treaties.

d. As many as 136 out of 195 countries are signatory to less than 10 treaties. They include Brazil, Canada, Ecuador, Ghana, India, Indonesia, Iran, Iraq, Jordan, Kenya, Lesotho, Libya, Malaysia, Malta, New Zealand, Nigeria, Pakistan, Paraguay, Philippines, Qatar, Saudi Arabia, South Africa, Sri Lanka, Thailand, Uganda, UAE, Venezuela, Viet Nam. Some of them are high income countries.

Both, India and the Philippines are signatories to nine major treaties as may be seen from the following table:

WIPO Administered Treaties: the Philippines, India & the USA

No	Types of Treaties	Philippines	India	USA
1	WIPO Convention	1980	1975	1970
2	Berne Convention	1950	1928	1988
3	Brussels Convention	x	x	1984
4	Nairobi Treaty	x	1983	x
5	Paris Convention	1965	1998	1887
6	Patent Law Treaty	x	x	2013
7	Phonograms Convention	x	1974	1973
8	Rome Convention	1984	x	x
9	Singapore Treaty	x	x	2008
10	Trademark Law Treaty	x	x	2000
11	Washington Treaty	x	1990	x
12	WIPO Copyright Treaty	2002	x	1999
13	WIPO Performances and Phonograms Treaty	2002	x	1999
14	Budapest Treaty	1981	2001	1979
15	Madrid Protocol	2012	2013	2003
16	Patent Cooperation Treaty	2001	1998	1975
17	Nice Agreement	x	x	1972
18	Strasbourg Agreement	x	x	1973
	Total	**9**	**9**	**15**

Source: (www.wipo.int/treaties/en)

Many of these treaties are common to all three. In some others, there is difference in the timing of accession.

2. The 2014 PhRMA Submission (http://www..phrma.org/sites/default/files/pdf/2014-special-301-submission.pdg) to the USTR on Special 301 for Intellectual Property Protections in the Philippines and India are reproduced in Annex-2. As may be seen therefrom, there is hardly any difference in the nature of its complaints against India vis-a-vis the Philippines. The complaints which are common to both are:

   a. Narrow Standards of Patentability:
      Sec3(d) for India and Cheaper Medicines Act for the Philippines
   b. Lack of Regulatory Data Protection
   c. Patent Enforcement & Drug Regulatory Approval

   The difference is the use of compulsory license by India. This is understandable because the local industry of the Philippines does not have capability to develop and produce generic version of a patented drug. Hence, even if the Philippines wanted to make use of this flexibility, it is incapable of using it. Instead, it has used *parallel importation* for access to affordable medicines.

   Yet, the PhRMA classified the Philippines under Watch List and India under Priority Foreign Country (PFC) along with Turkey. It defies logic that PhRMA has found Turkey inhospitable, inspite of it being signatory to as many as 17 WIPO Administered Treaties – two more than the US itself. Apparently, it is miffed by delays in new drug approvals (product registrations), price control and reimbursement policies. The rest of the concerns relating to intellectual property protections are similar to those for India and the Philippines.

3. The USTR appears to have ignored some of the demands of the PhRMA raising a doubt about its infamous clout on the USTR. It has:

   a. Removed the Philippines altogether from the Watch List/Special Watch List;

   b. Retained Turkey under Watch List;

   c. Ordered Out-of-Cycle Review to elevate Kuwait to the Priority Watch List; and

   d. Ordered Out-of-Cycle Review to downgrade India to Priority Foreign Country.

   Its Report on India is full of inaccuracies, e.g. attributes requirement of local manufacture to IPAB, whereas the IPAB had overruled it. The growing challenges to patents/copyrights/trademarks applications are seen as ineffective protection and enforcement. These challenges, which are legitimate component of any IPR regime, are perceived as weak "innovation climate". India's disagreement on some IP issues with the USA is reduced to "difficulties in attaining constructive engagement" and "challenging environment". In short, the USTR Report is a flawed assessment of India's IPR regime.

   Not only its assessment is flawed, the Report has completely ignored several steps taken by India to bring transparency and accountability in the IP administration; to improve efficiency and speed through recruitment and training; and modernization of IP Offices. These include:

   Efficiency Improvement

   - Comprehensive e-filing facility for Patents and Trade Marks.
   - Digitisation of all IP records - both old and current.
   - Electronic processing of Patents and Trademarks Applications.
   - Access to online global Patent and Non-Patent database and Trademark database.

Transparency and Dissemination

- Real time status of IP applications with entire file wrappers and e-registers (P/TM).
- Weekly publication of online journals.
- Public search facility (P/TM).
- Instant e-mail communication to applicants.
- QR coded office communication for authentication.
- Dynamic utilities for patents - First examination reports, disposal, working of patents information, lapsed/ceased patents.
- Dynamic utilities for trademarks - Examinations, show cause hearing, publications, registrations and other disposals, notices and international applications designating India.

Quality Assurance

- Manuals of Office Practice and Procedures for Patents, Designs and GI.
- Specialized technology groups for examination of patent applications.
- Examination Guidelines for Traditional Knowledge and Biotechnology.
- Training of newly recruited examiners and refresher training for others.
- Exposure to international best practices.
- Quality Management Teams at all locations.

International Search and Preliminary Examining Authority (ISA/IPEA)

- Operationalised from 15 October 2013.
- Indian Patent Office is one of 17 countries designated as ISA/IPEA.
- Nationals/residents of India can avail search and examination facilities for international patent applications under PCT.

Madrid Protocol

- International registration of trademarks effective 8 July 2013.
- Application can be made in over 90 countries through a single application in one language with one set of fees filed at the Trademarks Registry.
- Time-bound processing and registration of Trademarks.
- 4704 international applications received from WIPO and 107 applications filed from India.
- All applications filed online and processed electronically.

On the other hand, Pfizer's offer to become a British company for its failed $106 Bn bid of Astra Zeneca with a view to save US taxes on $68 Bn parked overseas would make it difficult for Pfizer now to waive the American flag. Moreover, a very diverse group of stakeholders ranging from doctors to trade unionists and insurers to pharmacy-benefit-managers (PBMs) have been up in arms against the PhRMA for abusive pricing. The time has therefore come to challenge their clout. It is in this context that the IPA endorses Prof Arvind Panagariya's suggestion to call the US bluff on the patents and ask to remove India from the Special 301 Review.

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Annex-1

WIPO Administered Treaties

	Types of Treaties
A	**General**
1	WIPO Convention
2	UPOV Convention
B	**IP Protection**
1	Beijing Treaty on Audiovisual Performances
2	Berne Convention
3	Brussels Convention
4	Madrid Agreement (Indications of Source)
5	Marrakesh VIP Treaty
6	Nairobi Treaty
7	Paris Convention
8	Patent Law Treaty
9	Phonograms Convention
10	Rome Convention
11	Singapore Treaty
12	Trademark Law Treaty
13	Washington Treaty
14	WIPO Copyright Treaty
15	WIPO Performances and Phonograms Treaty
C	**Global Protection System**
1	Budapest Treaty
2	Hague Agreement
3	Lisbon Agreement
4	Madrid Agreement
5	Madrid Protocol
6	Patent Cooperation Treaty
D	**Classification**
1	Locarno Agreement
2	Nice Agreement
3	Strasbourg Agreement
4	Vienna Agreement

Annex-2

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (P*h*RMA) SPECIAL 301 SUBMISSION 2014

PRIORITY FOREIGN COUNTRY

INDIA

Intellectual Property Protections

Narrow Standards for Patentability

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) of the Indian Patents Act as amended by the Patents (Amendment) Act 2005 adds an impermissible hurdle to this by adding a fourth substantive criteria of "enhanced efficacy" to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to pharmaceuticals. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are presumed to be the same substance as the original chemical and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy.

Additional requirements for patentability beyond that the invention be new, involve an inventive step and capable of industrial application, are inconsistent with the TRIPS Agreement. Article 27 of the TRIPS Agreement provides a non-extendable list of the types of subject matter that can be excluded from patent coverage, and this list does not include "new forms of known substances lacking enhanced efficacy," as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principle also provided by TRIPS Article 27. From a policy perspective, Section 3(d) undermines incentives for innovation by preventing patentability for improvements which do not relate to efficacy, for example an invention relating to the improved safety of a product.

Other examples of the overly narrow standards for patentability in India are the recent patent revocations using "hindsight" analyses made during post-grant oppositions and pre-grant oppositions citing a lack of inventiveness concluding that the patent applications are based on "old science" or failed to demonstrate an inventive step.

Compulsory Licenses on Patented Pharmaceutical Products

The Government has set up a Committee under the Ministry of Health and Family Welfare (MoH Committee), which has been tasked with examining the medicines under patent which are required for various diseases such as HIV/AIDS, cancer, diabetes, Hepatitis C, TB, and MDR TB and which they assert are not affordable on account of the price barriers created by patents. The Government Committee is proceeding under the special provisions of Section 92 and Section 66 of India's Patents Act for grant of CLs, which would make it even more difficult for patent owners to defend their patents. In fact, it is reported that the Government of India is considering whether to issue CLs under Section 92 on approximately 20 patented medicines across a wide range of therapeutic areas. None of the grounds have been justified and the Government has not given any of the patentees a chance to be heard.

On March 9, 2012, India issued the first-ever CL for an anti-cancer patented pharmaceutical product. The research-based pharmaceutical industry is concerned that the findings in the CL decision on the working requirements contravene India's obligations under the TRIPS Agreement (as well as the General Agreement on Tariffs and Trade and the WTO Agreement on Trade-related Investment Measures), which prohibit WTO members from discriminating based on whether products are imported or locally produced. Moreover, India's use of CLs in these circumstances distorts provisions that were intended to be used in limited circumstances into tools of industrial policy. We further believe that resort to CLs is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by our member companies can better ensure that current and future patients have access to innovative medicines. Statements from the Government incorrectly

imply that CLs are widely used by other governments, both developed and developing.[1] These are misunderstandings and do not justify widespread use of compulsory licensing.

At a minimum, India should ensure that the CL provisions comply with TRIPS. India should also clarify that importation satisfies the "working" requirement, pursuant to TRIPS Article 27.1.

Unnecessarily Burdensome Patent Application Requirements

Section 8 of the Patents Act, as interpreted by recent jurisprudence, sets forth overly burdensome requirements that effectively target foreign patent applicants in a discriminatory manner. Section 8(1) requires patent applicants to notify the Controller and "keep the Controller informed in writing" of the "detailed particulars" of patent applications for the "same or substantially the same invention" filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those same foreign patent applications if that information is requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that target foreign patent applicants – those most likely to have patent applications pending in other jurisdictions.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared to other countries with similar (but less onerous) administrative requirements. In India, the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent. This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel. Thus, India's disclosure requirement and remedy are each more burdensome as compared to other jurisdictions, thereby creating a barrier to patentability that has an unfairly greater effect on foreign patent applicants, and, in some instances resulted in India revoking patents on the grounds of non-compliance with this particular provision.[2]

Patent Enforcement and Regulatory Approval

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a medicine four years after the original product was first approved. State regulatory authorities are not required to verify or consider the remaining term of the patent on the original product. Therefore, an infringer can obtain marketing authorization from the government for a generic version of an on-patent drug, forcing the patent holder to seek redress in India's court system. India should close this regulatory loophole in order to provide effective patent protection and enforcement for pharmaceutical patent holders.

Moreover, India does not provide mechanisms for resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products. There is a pending bill in the Indian Parliament that would establish fast-track IP Courts and assist in addressing disputes. To ensure proper patent enforcement, the U.S. Government should urge the Indian Government to implement such mechanisms as part of greater efforts to create an environment that supports innovation.

[1] See https://www.indianembassy.org/prdetail2164/note-on-indiaandrsquo%3Bs-intellectual-property-regime and http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws. These allegations of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA

[2] See, e.g., *Ajantha Pharma Limited v. Allergan*, Intellectual Property Appellate Board (2013).

Lack of Regulatory Data Protection

TRIPS Article 39.3 requires India to provide protection for certain pharmaceutical test and other data, but India has not yet done so. India conditions the approval of pharmaceutical products on the prior approval by a Regulatory Authority in another country rather than requiring submission of the entire dossier for review by its Regulatory Authority. An applicant in India needs only to prove that the drug has been approved and marketed in another country and submit confirmatory test and other data from clinical studies on a very few (in some cases as few as 16) Indian patients.

By linking approval in other countries that require the submission of confidential test and other data to its own drug approval process, India, in effect, uses those countries as its agents. Thus, India relies on test data submitted by originators to another country. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

WATCH LIST

THE PHILIPPINES

Intellectual Property Protections

Cheaper Medicines Act

While meaningful dialogue has taken place since 2010 with President Aquino's Administration and the Intellectual Property Office of the Philippines on the intellectual property provisions and implementing rules and regulations of Republic Act No. 9502: The Universally Accessible Cheaper and Quality Medicine Act of 2008 (Cheaper Medicines Act), there are a number of provisions which degrade intellectual property protections and serve as market access barriers. The Cheaper Medicines Act, for example, amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. As a limitation designed to discriminate against certain technologies, PhRMA's member companies continue to assert the Cheaper Medicines Act is inconsistent with the TRIPS Agreement. Examination of patent applications subject to this provision of the Act has been delayed by the Philippines patent office. PhRMA member companies understand examination of these applications might begin in 2014 (examination guidelines were published in 2012), but effective patent term has been lost as a result of these delays. This illustrates the need for adoption by the Philippines Government of patent term adjustment that compensates for such losses in effective patent term.

Regulatory Data Protection

The Philippines has trade secret protection laws but does not provide mechanisms that prevent "unfair commercial use" of regulatory test data that is generated and used by innovators to meet safety and efficacy requirements for marketing approval. Consistent with TRIPS Article 39.3, PhRMA members urge the Philippines to adopt measures, such as regulatory data protection, that prevent "unfair commercial use" that occurs through direct or indirect reliance on protected regulatory test data.

Effective Patent Enforcement

It is important that the Philippines adopt mechanisms for resolving patent issues prior to the marketing of follow-on products, such as generics. Such a mechanism was in place before a 2005 DOH Administrative Order (A.O. No. 2005-0001) took effect, which has resulted in PhRMA's member companies having to pursue costly and time consuming legal remedies to protect products from patent infringement prior to patent expiration. If sufficient time were allowed to resolve such issues prior to marketing of follow-on products, the Philippines could alleviate legal resource burdens as well as restore the rights of patent holders. PhRMA's member companies recommend the repeal of Administrative Order 2005-0001 and that an agreement be signed by the Intellectual Property Office of the Philippines (IPOPHL) and the Food and Drug Administration of the Philippines (FDA) recognizing that a certificate of product registration for a generic medicine will not be issued by FDA unless the applicant can present a certification from IPOPHL confirming the patent covering a particular product has expired.

Parallel Importation

There is concern that the Philippines is resorting to implementation of Rule 9 of the Implementing Rules and Regulations (IRR) of the Cheaper Medicines Act, enabling the parallel importation of unregistered pharmaceutical products. With the lack of adequate infrastructure and monitoring mechanisms in the Philippines, the safety and quality of parallel imports is at risk or unlikely, and the prevention of imported counterfeit medicines is not possible. PhRMA's member companies hope to work closely with the Government of the Philippines to require the FDA to impose full registration requirements on parallel imports and for the Bureau of Customs to stop the importation of unregistered medicines.