Submission to the Office of the United States Trade Representative

IGPA Recommendations for 2015 Special 301 Review

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INTERNATIONAL GENERIC PHARMACEUTICAL ALLIANCE

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THE INTERNATIONAL GENERIC PHARMCEUTICAL ALLIANCE

In an era when increasing demands are being made on the world's healthcare services, generic and biosimilar medicines provide a major benefit to society by ensuring patient access to quality, safe and effective medicines while reducing the cost of pharmaceutical care.

Founded in 1997, the International Generic Pharmaceutical Alliance (IGPA) is a group of generic and biosimilar medicines associations that are committed to promoting generic and biosimilar medicines, and exchanging information worldwide.

Through its constituent member associations, the IGPA maintains constant dialogue with international organizations, including the International Conference on Harmonization (ICH), World Trade Organization (WTO), World Intellectual Property Organization (WIPO) and World Health Organization (WHO).

The following national and regional associations comprise the current IGPA Management Committee:

- Canadian Generic Pharmaceutical Association (CGPA-Canada)
- European Generic medicines Association (EGA-Europe)
- Generic Pharmaceutical Association (GPhA-USA)
- Jordanian Association of Pharmaceutical Manufacturers (JAPM-Jordan)
- Japan Generic Medicines Association (JGA-Japan)
- National Association of Pharmaceutical Manufacturers (NAPM-South Africa)

Questions and comments regarding this submission can be sent to the attention of the IGPA Trade Committee Chair at info@igpagenerics.com

EXECUTIVE SUMMARY

The availability of generic and biosimilar medicines helps to facilitates global access to affordable medicines. In the United States alone, generic medicines are used to fill 86% of all prescriptions, providing extraordinary savings and access to American patients. The companies that manufacture and market these products are also major contributors to the U.S. and other national economies through their R&D and manufacturing activities, and the highly skilled workforce these companies employ.

Section 182 of the Trade Act of 1974 requires the United States Trade Representative to identify countries that "...deny fair and equitable market access to U.S. persons who rely on intellectual property protection." The U.S. generic and biosimilar industry depends on patented products to provide the pipeline for the high quality and affordable medicines it exports when patents expire. In addition, many producers of generic and biosimilar drugs themselves hold patents and, thus, rely directly on protection of intellectual property rights.

Unfortunately, the adoption of generic medicines in some countries can be unnecessarily curtailed due to their domestic legislation, regulations, policies and practices.

In our inaugural contribution to the Office of the United States Trade Representative (USTR), the International Generic Pharmaceutical Alliance (IGPA) has identified market access barriers in 13 countries that pose harmful and unnecessary barriers to U.S. and global generic pharmaceutical and biosimilar medicines companies seeking to export to the identified countries. The issues identified range from domestic pricing policies to domestic regulatory requirements to blatant bias in favour of products manufactured in a domestic market over those manufactured in the United States and other countries. The International Generic Pharmaceutical Alliance requests that USTR add all of these countries to the Special 301 Watch List until such time as the identified market access barriers are addressed.

In addition, this submission highlights concerns with respect to the operation of intellectual property enforcement mechanisms in one country due to duplicative legal

processes that are inefficient and create unnecessary financial risk exposure to generic and biosimilar medicines companies seeking to bring products to that market.

It must be noted that this submission in no way provides an exhaustive list of all barriers, impediments and intellectual property enforcement issues faced by the generic pharmaceutical and biosimilar medicines industry. These are numerous. IGPA is seeking USTR's assistance in addressing the issues identified, and hopes to include additional issues of concern to the industry requiring action in future submissions.

SECTION I: MARKET ACCESS BARRIERS & IMPEDIMENTS

AUSTRALIA

There are Good Manufacturing Practice (GMP) considerations for supply and registration in Australia. The Therapeutic Goods Administration (TGA) reserves the right to undertake an audit of an overseas manufacturing site, irrespective of any other evidence supplied. For example, this may happen where TGA has other regulatory information, has concerns regarding compliance, or is auditing an adjacent facility. An audit may take place prior to granting an initial GMP Clearance for supply of the relevant product in Australia or at any time following the issue of a GMP Clearance.

Australia's GMP requirements may result in delays and could even result in the removal of a product from a U.S. company's submission plan, because the cost of the audit impacts the business case to such a degree that it becomes negative.

With regard to standards, the default standards accepted by TGA are the United States Pharmacopeia (USP), the European Pharmacopoeia (Ph.Eur.), and/or British Pharmacopeia (BP) monographs. Where in-house monographs or adaptions of monographs are used, evidence is required to show at least equivalence to the pharmacopeial standards.

With respect to bioequivalence studies, the TGA requires data against the innovator product in Australia. Therefore, if bioequivalence studies have been carried out with the innovator products sourced from the US, EU, or another country, additional laboratory analytical work is required to confirm that the overseas product is chemically equivalent to the Australian product. If chemical equivalence cannot be demonstrated it may be required to conduct bioequivalence studies specific for Australia.

USTR should encourage the Government of Australia to eliminate duplicative requirements with respect to bioequivalence and GMP, which create barriers and impediments for U.S. generic pharmaceutical companies seeking to bring products to the Australian market.

BRAZIL

There are numerous duplicative regulatory requirements in Brazil that create additional costs and delays for U.S. generic pharmaceutical companies seeking to export their American-made products to Brazil.

Brazil will only accept imports of finished products. Companies are not permitted to conduct any manufacturing step locally, including the packaging of final dosage forms. The imported products must be registered at the country of origin. Foreign companies must also carry all quality control tests in Brazil. There is also a requirement to present the bioequivalence tests and the equivalence tests at labs located in Brazil, which causes three more months of delay since the samples must be imported. Zone IV stability tests are required. The Brazilian sanitary agency also conducts international inspections at the finished production site and at the API producer site for the same products. The prices at which generic medicines can be sold in Brazil are regulated by the government based on a very subjective analysis. The process of analysis and registration by the Brazilian National Health Surveillance Agency (ANVISA) is delayed (sometimes with more than two years) and does not respect any legal deadlines. The analysis of the marketing authorization depends on the understanding of the responsible technical person and there is no equalization of understandings. There is political and sanitary tendency to protect national companies. There is a requirement of preapproval of pharmaceutical products importation not only by the Federal Revenue Service, but also by ANVISA.

There is a misalignment between the United States and Brazil with respect to the regulatory approval pathways for follow-on biologics. Brazil has implemented a third approval pathway in addition to the innovator and biosimilar (via comparability) pathways. This so-called “individual development” pathway enables approval for a “biosimilar”/”copy biological” with only a non-inferiority Phase III trial. There is no requirement for physico-chemical and biological comparability with a reference product.
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Such an approach will be counterproductive for both the Brazilian and global development of the industry over the medium term. The anticipated business model for

follow-on biological medicines is that manufacturing sites will supply global markets for specific medicines because these products are high value/low volume. It will be uneconomic to produce biological medicines in each and every market.

Serialization and tracing mandates vary from country-to-country, presenting a difficult challenge for manufacturers to outfit product and packaging lines that serve more than one international market to achieve compliance with many different mandated specifications.

To explain how large a challenge unit tracing systems and processes represent to large generic drug manufacturers, it is helpful to discuss the two main mandates separately. The first mandate is serialization and, in some cases, this is compounded by mandated aggregation of units-to-cases-to-pallets. The second is the tracing system itself.

Unit serialization is the enabling technology of most tracing systems whether their goal is to encompass movement of a certain unit through each step in the supply chain or whether safety is the goal and the process is only concerned with authentication of the unit to manufacturer's records before dispense to a patient. The drug industry has settled on two-dimensional (2D) barcode as its medium of choice for carrying serialization information. The reason for this choice is a combination of relatively low cost, reliability of information and standardization of format, thanks to international organizations like GS-1 Global. And the new 2D serialized barcode is placed on the product label and sometimes accompanied with the same serialization information in human readable format as well as the barcode matrix.

To equip an existing packaging line for unit serialization (without aggregation) costs an average of $250,000 per line plus annual operating costs. To provide some clarity around this number, many generic manufacturers have hundreds of lines globally.

Serialization using a custom Brazil numbering syntax is required, so companies must build unique systems in order to supply the Brazilian market. Aggregation is mandated in the specification, introducing higher cost, increased possibility of data errors and unproven safety value. Brazil's model uses tracing on a "change of

possession" rather than a "change of ownership" basis, mandating that every entity that handles the product be identified and report their activity. This includes transportation companies, third party logistics providers, returns processors, and others who never actually own the product. And finally, all of these companies must post to a tracing database created and owned by each manufacturer of product sold in Brazil. Posting requirements include even companies with which the given manufacturer does not have a standing business relationship.

Brazil's system is a well-intentioned one, with a stated goal of improving patient safety in the country. However the model is a very difficult one for companies to achieve. The reliance on manufacturers to establish data connections with every party who would ever have a drug product in their possession, while still maintaining integrity of that data creates enormous costs and business risks for manufacturers.

CANADA

A regulatory linkage exists between chemical drug submissions and the requirement to establishment license in Canada, which has a negative impact on both brand and generic pharmaceutical companies seeking approval for chemical prescription drugs in Canada. Work on a chemical drug submission does not proceed within the Therapeutic Products Directorate at Health Canada until the associated manufacturing site has been approved as GMP compliant by the department's Health Product and Food Branch Inspectorate. This creates unnecessary market access delays, particularly given the ongoing severe review performance issues within the HPFB Inspectorate.

These regulatory review activities should not be conducted sequentially. Canada should follow the lead of the United States and other jurisdictions by allowing the activities to be conducted in parallel. There is no legal basis on which this regulatory linkage exists. Further, it is a specific discriminatory policy against chemical drugs as no such regulatory linkage exists for biologic drugs and veterinary drugs.

CHINA

Different Technical Requirements for Imported Products and Domestic Products

Under Chinese drug registration regulations, In the context of the draft of Drug Registration Regulation (changes on the Generics submission), the issue is that the local generic company can submit the application at any time before the patent expiry date, but the imported generic medicine has to provide the Certificate of Pharmaceutical Product in the clinical trial application. This creates the potential that the review and approval of imported generic medicines drop behind those of local manufacturers.

Lengthy Approval Timeline for All Types of Applications

These are mainly caused by prolonged technical evaluation in CDE (Center of Drug Evaluation). Significant deviations in approval timelines create a lack of predictability with respect to product launch dates. The registration timeline for generic medicines is typically more than 7 years – much longer than in the United States and far beyond international norms.

Prolonged Review and Approval Timeline for Clinical Trials

The statutory and actual timeline for clinical trials in China are relatively longer than in most other countries. While the statutory timeline in China is 145 working days, actual clinical trial approvals typically take between one to one-and-a-half years. This has had the effect of lengthening the average period for new drug research and development, and has seriously affected new drug accessibility.

MAGHREB (ALGERIA, MOROCCO, TUNISIA)

Pharmaceutical exports to Maghreb (Algeria, Morocco, Tunisia) are mainly hindered by a preference for locally manufactured products. There are specific lists of products that are banned from importation as these products are produced locally. The

registration of products in Maghreb requires that the product is both registered and marketed in the United States or other country of origin. This blocks exports of products that are licensed or that are not currently registered and marketed in the United States but are manufactured in the United States.

RUSSIA

Exclusive Product Sourcing

Only one product can be marketed per dossier. As a consequence, licensors can only out-license their products to one marketing company in Russia.

As a result, economies of scale cannot be achieved and cost of goods increase, resulting in higher prices and limited opportunities for licensors. In certain cases this regulation is not supporting the creation of a competitive environment.

GMP Audit of Local Authorities

The draft amendment to the federal law N61-FZ (expected to come in force on July 1, 2015) includes an obligatory requirement for GMP certificate submission issued by the Russian drug regulatory authority during registration of new products beginning in January 2016, and for variations and renewals beginning in January 2017. Timelines for GMP inspections could delay market entry of products from sites that have not yet been inspected by the Russian authorities.

Registration

The registration of any generic medicine in Russia can only be done if the bioequivalence study has been performed in Russia. This leads to repetition of bioequivalence studies. Clinical studies have to be repeated for Russia before launching new medicines.

Imports

The import of finished products and active pharmaceutical ingredients (APIs) into Russia attracts a high and variable amount of customs clearance charges.

In addition, local producers may have a monopoly on the production of certain APIs or finished products. They can undercut the price of sourcing from a foreign supplier by a significant margin, making the option of sourcing from within the foreign supplier's internal network very unattractive.

Prices

Prices for essential drugs on a list maintained by Russia's Ministry of Health can be adjusted each year to inflation. This right is denied to foreign manufacturers. For essential drugs to be imported, the Russian price registration system has the minimum price threshold requirement (out of 20 reference countries). This limits U.S. and other generic pharmaceutical companies to register a reasonable retail price.

TAIWAN

Taiwan requests PIC/s GMP approval for a manufacturing site and a site validation/inspection for a manufacturing site before the file can be approved. The site validation and PIC/s GMP approval processes each take approximately 1.5 years, and are separate processes from the file registration process.

THAILAND

The ASEAN countries request 12 months of Zone IV stability data is filed with the drug submission. The approval process then takes an additional 1-2 years after the submission is filed. The total process is 2-3 years from the beginning of the stability testing until the product approval.

Any production site transfer is considered to be a new registration, which means a new application must be submitted along with 12 months of Zone IV stability data from the new site. This means that approval of a new site can take 2-3 years. This differs from most other non-ASEAN markets.

TURKEY

Pharmaceutical pricing in Turkey is based on international reference pricing whereby the price in Turkey will be the lowest price available amongst France, Italy, Portugal, Greece and Spain. The prices set by the international reference pricing regime are then converted in local currency (TL) by using the Government €/TL conversion rate.

In April 2009, the Government fixed the €/TL exchange rate for pharmaceutical pricing purposes only to 1.9595TL/€ and has not adjusted it since. The pricing legislation dictates that if the Central Bank Rate is 15% higher than the fixed rate for 90 days rolling average, the government should revise the rate. The rolling average has been at least 15% higher since 2011, and it is now approximately 50% higher.

UKRAINE

Ukraine has local manufacturer preferences, which unfavorably impact importers of generic medicines from the United States and other countries.

GMP Requirements

During the state registration process, companies are required to submit a huge list of documents to obtain a local confirmation that a medicinal product is produced in accordance to GMP requirements. This is an unnecessary duplicative, time-consuming, and costly process for foreign companies.

Quality Controls at Customs

Long quality controls are conducted at customs on each product. In addition, different distributors selling the same product have to pass the controls on the same products separately.

VIETNAM

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Quality Standards

Our member companies welcome the Government of Vietnam's significant efforts towards administrative reforms of the healthcare system. We believe that particular consideration needs to be given to the general promotion of Good Practices (GxPs), such as Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

In particular, current policies for generic medicine registration and procurement carry significant risk of the widespread use of Vietnamese generic medicines which have not been proven bioequivalent. The level of supervision and enforcement by Vietnamese competent authorities cannot be deemed equivalent to that fostered within PIC/S.

In order to achieve a level playing field for all manufacturers supplying the Vietnamese market, highest priority should be given to a transparent supervision and enforcement system by Vietnamese competent authorities, based on internationally recognized principles and practices.

It is important that the demonstration of bioequivalence be introduced in Vietnam as a fundamental part of the marketing authorization granting process in order to secure access to safe effective medicines of the desired quality.

i. Hospital Tenders & Quality Standards

Hospital/provincial tendering systems disproportionately favor price competition over assurance of quality, safety and efficacy through compliance with internationally recognized standards, particularly bioequivalence of the generic medicine with its reference product. Recent evolutions of the system have attempted at creating different "categories" or "lots" within tenders, to acknowledge differences in regulatory / GMP standards.

While a clear distinction between products based on different levels of assurance of quality, safety and efficacy is welcome, it would be desirable that medicines produced according to internationally recognized standards become broadly available to the local population.

Additionally, the current criteria to allocate volumes among the different "lots" appear unclear and the associated process arbitrary. As a result, hospitals need to reduce the volume of medicines produced according to internationally recognized standards already planned to be purchased, even when hospitals own estimates were based on clinical needs for the different products.

ii. New Drug Registration Circular

Under current Circular 22 (issued in 2009), an applicant cannot submit a dossier for the renewal of a marketing authorization registration earlier than six months before the expiry of the product's existing registration.

According to industry experience over the past several years, renewal times typically exceed 6 months, thus leading to "off-visa" period for a product for several months. During such off-visa period, importation of the product is not permitted. Providing information to doctors about the product is very restricted, particularly because all promotional materials must be withdrawn, no new materials can get an authorization visa from the Ministry of Health, and all materials will have to get a new visa after the renewal. In addition, participation in hospital tenders is not permitted during the off-visa

period because most hospitals will not accept Ministry of Health documents that stipulate the product has been legally registered and is merely under a renewal process. Such a situation restricts the access to essential pharmaceutical products both for health care providers and patients in Vietnam.

USTR should add Vietnam to the Priority Watch List until such time as:

- Renewal dossiers can be submitted at least 12 months before expiry date and marketing authorization of existing products should remain valid until renewal is completed.
- The restriction on product importation, product promotion, and product information is waived, which would allow generic pharmaceutical companies to participate in tenders during renewal application period.

SECTION II: INTELLECTUAL PROPERTY ENFORCEMENT

The generic pharmaceutical and biosimilar medicines industry supports the adoption of reasonable and well-functioning intellectual property enforcement mechanisms.

Excessive levels of protection and poorly functioning intellectual property systems can have the effect of negatively curtailing, delaying or imposing an outright block on pharmaceutical competition within a given country. This in turn creates a significant barrier or impediment to trade for U.S. and global generic pharmaceutical and biosimilar medicines companies.

USTR has given a particular focus to Canada in recent 301 Reports, and this inaugural IGPA submission focuses exclusively on this country . IGPA expects to provide information about additional intellectual property enforcement issues in future submissions.

CANADA

Patent Linkage

Canada's pharmaceutical patent linkage regime provides summary or administrative judgements and does not provide for finality to legal proceedings, allowing generic pharmaceutical companies to routinely be sued for patent infringement following success under the patent linkage litigation proceedings.

As a result, generic pharmaceutical companies face enormous and potentially catastrophic risk when launching generic medicines on the Canadian market. The potential financial risk exposure for a generic pharmaceutical company is the full lost brand profits, which can be many multiples of any potential generic profits that can be earned given the enormous price differentials between brand and generic drugs in Canada.

Such a system that affords a brand-name pharmaceutical company two sequential tracks of litigation to protect the same patent or group of patent(s) exists nowhere else in the world. It creates a significant market access barrier for U.S. generic pharmaceutical companies seeking to sell products in Canada.

The Government of Canada has publicly committed to ending this "dual litigation" scenario – while also ensuring the system provides equal rights of appeal – when it implements the Comprehensive Economic and Trade Agreement (CETA) it has reached with the European Union. However, implementation may not occur for many years.

Given the ongoing harm experienced by U.S. generic pharmaceutical companies USTR should encourage the Government of Canada to move forward with ending "dual litigation" created by its patent linkage system without delay.

Other aspects of Canada's patent linkage system that legally discriminate against generic pharmaceutical companies:

i. Insufficient Incentives to Encourage Patent Challenges Under Patent Linkage System

USTR has advocated globally for the inclusion of strong incentives under patent linkage systems – particularly where automatic injunctions are present – to encourage generic pharmaceutical companies to challenge weak and frivolous patents and bring competition to the market at the earliest, legally appropriate opportunity.

Canada's patent linkage system provides insufficient incentives for generic pharmaceutical companies to challenge weak and frivolous patents. The United States provides a strong incentive to challenge patents under its Hatch-Waxman system by providing a 180 day market exclusivity period to the first generic company to successfully litigate under the US Hatch-Waxman system.

No national market exclusivity period is available in Canada. In contrast, the only Canadian incentive is weak and takes the form of a financial award to successful generic pharmaceutical litigants (who is the injured legal party) to compensate for damages suffered.

These damage awards have been severely curtailed through narrow interpretation of Canada's patent linkage laws by the Courts and, as a result, compensate a generic pharmaceutical company with only a small fraction of the actual damages it has suffered.

Generic pharmaceutical companies are also discriminated against in relation to all other parties in Canada who are subjected to court injunctions in Canada, as common law damages permit far more expansive damages to be awarded than the patent linkage system.

USTR should encourage the Government of Canada to increase the flexibility of the Court to compensate generic pharmaceutical companies for the full damages suffered.

ii. Inability to Amend "Notice of Allegation"

Given the summary nature of the patent linkage system, all legal arguments have to be included in the “Notice of Allegation” a generic pharmaceutical company must file to address any patents on the Canadian Patent Register that are associated with the brand reference product upon filing a generic drug submission.

If new evidence emerges in Canada or another jurisdiction, a generic pharmaceutical company seeking to bring a product to the market is currently left with two unsavory options: abandon the process and start over (which delays potential market entry) or continue with the existing legal case without the use of the new evidence.

Generic and brand companies alike should have the opportunity to present new evidence at trial, as afforded to patentees and challengers in all other industrial sectors in Canada, and under the U.S. patent linkage system.

To avoid such legal discrimination in the future Canada should adopt a simplified notice, akin to the Form IV notification in the United States, and allow evidence to be presented – and amended – in Court where it belongs.

Patent Utility

IGPA is aware of submissions that have been made in recent years by other parties citing alleged deficiencies with respect to the laws governing the usefulness of patents in Canada, sometimes referred to as “patent utility” or “the utility of the patent”. We submit that such claims are inaccurate and provide an incomplete portrait of Canadian law in this area. It is also important to recognize that pharmaceutical patents are in fact upheld in most cases where utility is a central issue.

Canada provides patent protection for inventions if they meet the statutory criteria of being new, inventive and useful. This is a requirement of Canada’s international treaty obligations, and is the same criteria applied in other countries – including the United States.

Guarding against speculative patents is an internationally accepted and fundamental feature of patent law. To remove such safeguards would be harmful to innovation through the increase issuance and legally upheld retention of speculative patents.

The standard of proof for utility in Canadian law is also not overly onerous. An inventor must show a "*prima facie* reasonable inference of utility". This standard is met as long as the patent is soundly based on science and is not speculative in nature. This is also not a new standard as it has been in place in Canada for more than 70 years. The actual utility of an invention is defined by the inventor in the patent.

IGPA would also urge USTR to approach with caution and skepticism any claims or statistics presented by other parties that suggest litigation outcomes on particular drugs in Canada and the US are different due to a deficiency in Canadian patent utility law for several reasons:

- First, the patents at issue in Canada may be different than the patents filed in the United States.
- Second, the legal arguments presented in Canada – as well as the evidence presented – may be different than the arguments and evidence presented in the United States.
- Third, and perhaps most importantly, the structure of patent linkage proceedings in Canada (which are summary proceedings) is different than the structure of patent linkage proceedings in the United States.
    - The decisions rendered under Canada's patent linkage regime determine whether market authorization can be granted whereas the final status of the patent is determined under the U.S. patent linkage system.
    - Further, there are no live witnesses and no discovery under Canada's patent linkage system. Both are permitted under the U.S. patent linkage system.

The inclusion of Canada on previous Special 301 Watch List for reasons of deficiencies in its patent utility laws is unjustified given the country's laws in this area are consistent with both its international obligations and U.S. law. As such, we respectfully request that USTR remove this item from the Special 301 Report in 2015.

Patented Medicine Prices Review Board (PMPRB)

The PMPRB is an arms-length federal agency that was created in 1987 to guard against excessive monopoly drug prices when patent rights to the brand-name pharmaceutical industry were being expanded in Canada. The PMPRB now claims it has jurisdiction over any medicine that is associated with a patent, including generic drugs, even though such patents do not confer a market monopoly and generic drug competition in Canada is fierce. The generic pharmaceutical industry has not accepted this jurisdiction, and this is the subject of ongoing matters before the courts.

Price regulation of generic medicines in Canada is a sub-national (provincial) jurisdiction. As such, the PMPRB is creating excessive red tape – and conflicting requirements – on generic companies. The PMPRB places an additional layer of pricing controls on specific generic drug company products, limiting a company's ability to adjust to changing market developments for that product, including the ability to adapt to changes in price set by the provinces. It also creates an enormous burden for some generic pharmaceuticals companies as domestic prices, international prices and R&D spending need to be reported.

The asserted jurisdiction serves no public policy purpose. As a result of activity by this rogue arms-length agency, the Government of Canada is advertently penalizing generic pharmaceutical companies for being innovative, investing in R&D and entering into licensing arrangements. USTR should ask Canada to clarify the mandate of the PMPRB to confirm that its jurisdiction does not extend to generic medicines.

CONCLUSION

The International Generic Pharmaceutical Alliance wishes to thank the Office of the United States Trade Representative for providing this opportunity to submit the recommendations of the generic pharmaceutical and biosimilar medicines industry for the USTR 2015 Special 301 Report.

There are numerous barriers, impediments and intellectual property enforcement issues faced by the generic pharmaceutical and biosimilar medicines industry worldwide. This inaugural Special 301 submission of the International Generic Pharmaceutical Alliance provides information on only a small subset of these issues in a small number of priority countries. It is IGPA's hope and expectation that additional issues of concern to the industry will be included in future Special 301 submissions.

IGPA requests USTR's support in working with the generic pharmaceutical and biosimilar medicines industry to address the market access barriers and impediments, and intellectual enforcement issues identified in this submission.

IGPA remains available to provide any additional expert assistance required with respect to the market access and intellectual property enforcement issues included in this submission, and can be reached at info@igpagenerics.com.