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# TRADE PRINCIPLES:

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## GENERIC AND BIOSIMILAR MEDICINES

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INTERNATIONAL GENERIC AND  
BIOSIMILAR MEDICINES ASSOCIATION

# CONTENTS

<b>1.</b>	Executive Summary	<b>1</b>
<b>2.</b>	Introduction	<b>3</b>
<b>3.</b>	Fostering Regulatory Convergence of the Requirements for the Approval of Generic and Biosimilar Medicines, and Recognition of Compliance Inspections	<b>5</b>
	<i>3.1 Generic medicinal products</i> <i>3.2 Biosimilar medicinal products</i> <i>3.3 Mutual recognition of compliance inspections</i>	
<b>4.</b>	Addressing Technical Barriers to Trade in Trade Agreements	<b>13</b>
<b>5.</b>	The Regulation of Intellectual Property Rights in Trade Agreements	<b>14</b>
	<i>5.1 Introduction</i> <i>5.2 Patents</i> <i>5.3 'Best mode' requirement</i> <i>5.4 Patent linkage</i> <i>5.5 Regulatory review ("Bolar") clause</i> <i>5.6 Exclusivity periods</i> <i>5.7 Extension of the duration of the rights conferred by patents</i> <i>5.8 Enforcement of IPRs</i>	
<b>6.</b>	The Inclusion of Provisions to Prevent Misuse/Abuse of IPRs and Anti-Competitive Practices in International Trade Agreements	<b>28</b>
<b>7.</b>	The Inclusion of Appropriate Frameworks on Incentives for Generic and Biosimilar Medicines	<b>30</b>
<b>8.</b>	Conclusions	<b>31</b>



# 1. Executive Summary

The International Generic and Biosimilar Medicines Association (IGBA) is an international network of generic and biosimilar medicines associations that works to promote generic and biosimilar pharmaceutical products and secure patient access to high-quality, safe and effective medicines.

The IGBA strongly supports the rules-based multilateral trading system, which ensures that international trade is conducted on the basis of the rule of law and due process. Therefore, the IGBA opposes current trends that undermine the rules-based multilateral trading system by unilaterally imposing additional tariffs and establishing further restrictive border measures that are harmful to international trade and the global trading environment. Trade policy and domestic trade rules must adhere to internationally agreed rules and jurisprudence.

At the same time, the IGBA strongly supports the negotiation of trade agreements aimed at fostering trade in generic and biosimilar medicines. The competitiveness of the generic and biosimilar industries is threatened by regulatory divergences with respect to country requirements for the approval and marketing of generic and biosimilar medicines, and excessive standards for intellectual property rights (IPR) protection. Specific instances of IPR abuse/misuse, as well as pricing and reimbursement policies are also areas of concern.

The removal of such barriers will reduce costs for the development of generic and biosimilar medicines, and ensure that such products can be traded freely and enter markets without delay.

To this end, the IGBA proposes a set of trade principles that should systematically inform trade negotiation. These principles concern five key priority areas:

- Fostering transparency of legislative and regulatory processes, as well as regulatory convergence of the requirements for the approval of generic and biosimilar medicines, and recognition of compliance inspections through the establishment of frameworks providing for regulatory cooperation and good regulatory practices;
- Defining a certain number of core principles related to technical barriers to trade;
- Ensuring that the regulation of intellectual property rights in trade agreements does not lead to excessive IP standards that delay access to generic and biosimilar products;
- Establishing an appropriate framework of pro-competitive provisions to prevent IPR abuse/misuse; and
- Establishing appropriate frameworks for transparency, as well as for incentivising generic and biosimilar medicines' market access.

The IGBA believes that, where systematically embedded and clearly spelled out in trade agreements, these principles stand to bring substantial improvements to the regulatory environments affecting generic and biosimilar medicines and facilitate trade in such products.

On a larger scale, these principles should also contribute to the overarching public health objectives and to the mitigation of medicines shortages around the world. In this regard, the IGBA notes that trade agreements should systematically make reference to public health, for instance, in the context of sustainable development in light of United Nations Sustainable Development Goal 3.

## 2. Introduction

International trade agreements regulate the way in which markets are opened to competition from imported goods. In this context, generic and biosimilar medicines are, like all goods, affected by the obligations and concessions negotiated and reflected in trade agreements. The multilateral trading rules are set forth by member countries within the framework of the World Trade Organization (WTO). In addition, rules affecting pharmaceutical products are increasingly being set by preferential (bilateral or plurilateral) free trade agreements (FTAs).

FTA negotiations may represent an opportunity for the generic and biosimilar industries to foster trade in generic and biosimilar medicines, reducing costs faced by businesses through the reduction and removal of barriers caused by regulatory divergences. FTAs should also promote a balanced approach to IPR protection based on the standards set by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) and the Doha Declaration on the TRIPs Agreement and Public Health, while increasing market access for generic and biosimilar medicines.

In this context, the IGBA intends to proactively engage in trade negotiations and contribute with a set of trade principles that should systematically inform trade negotiations with the objective of fostering trade in generic and biosimilar products and increasing patient access to high-quality, affordable medicines. IGBA's principles concern five key priority areas:

- Fostering transparency of legislative and regulatory processes, as well as regulatory convergence of the requirements for the approval of generic and biosimilar medicines, and recognition of compliance inspections;
- Defining a certain number of core principles related to technical barriers to trade;
- The regulation of IPRs in trade agreements;
- The development of pro-competitive proposals to prevent IPR abuse/misuse; and
- The establishment of frameworks for transparency and for incentivising generic and biosimilar medicines' market access.

Regulatory divergences in the procedures and requirements for the authorisation of generic and biosimilar products increase the development costs of generic and biosimilar medicines. Duplication of inspections is also a significant concern for manufacturing plants. The IGBA is seeking to foster the process of regulatory convergence through the establishment of frameworks for regulatory cooperation in generic and biosimilar medicines within trade agreements.

Requirements on regulatory cooperation in selected sectors, including pharmaceuticals, have increasingly appeared in recently concluded FTAs. The IGBA believes that the establishment of appropriate frameworks for regulatory cooperation and Good Regulatory Practices (GRP) in generic and biosimilar medicines in trade agreements will support the creation of collaborative approaches among regulators, reinforce the existing regulatory exchanges and foster a process of regulatory convergence that would reduce costs for businesses and consumers, together with facilitating trade in generic and biosimilar products.

The regulation of IPRs is an area of concern for the IGBA. Multilateral intellectual property (IP) standards have been established by the TRIPs Agreement. These standards strike a balance between the objective of encouraging investment in new medicines and innovative products and other important societal values, including the need to ensure that IPRs do not inhibit trade and innovation.

However, the increasing push for the inclusion of more extensive IP protection (i.e., so-called ‘TRIPs-plus’ provisions) in trade agreements stands to alter this balance to the detriment of generic and biosimilar products. The IGBA supports the maintenance of a balanced approach with respect to the regulation of IPRs in trade agreements, based on the standards established by the TRIPs Agreement.

The IGBA calls for the inclusion in trade agreements of strong competitive safeguards that would address specific instances of IPR abuse/misuse. This priority is premised on the recognition of the role that competition policy plays in providing for “check and balances” to IPRs, and the effect that certain instances of IPR abuse/misuse conducts have on the entry of generic and biosimilar products in the market.

The IGBA underlines that the increasingly detailed TBT Chapters in trade agreements, often including sector-specific rules, must take into account the interests of the concerned industries.

Another key priority is ensuring that trade agreements provide for transparency regarding relevant legislative and regulatory processes, and a framework for incentivising the entry of generic and biosimilar products into domestic markets.

The IGBA’s recommendations for each of these priority areas are described in more detail in the following sections. The IGBA looks forward to engaging more closely with negotiators, and remains available to provide more detailed information on its positions and on how it considers that they could be best reflected in trade agreements.

### 3. Fostering Regulatory Convergence of the Requirements for the Approval of Generic and Biosimilar Medicines, and Recognition of Compliance Inspections

Trade agreements provide the unique opportunity to foster regulatory convergence and regulatory cooperation. In order to ensure their continued enhancement and for purposes of turning the agreements into ‘living’ agreements, trade agreements should provide for structured and influential committees and/or working groups, competent to advance the agreement and capable to address and streamline non-tariff measures (NTMs) and to remove non-tariff barriers (NTBs). In this context, the general principles of transparency and fairness are supported by the IGBA. Such principles should extend to all regulatory steps relevant for pharmaceuticals. Similarly, the IGBA supports the introduction of general provisions or dedicated chapters on Good Regulatory Practices, in particular as the rules on transparency and participation of non-governmental entities could enhance public participation.

#### 3.1 Generic medicinal products

The approval of any pharmaceutical product to be placed on the market requires an evaluation of the quality, safety and efficacy of the product, conducted by the relevant regulatory authorities. For new medicines, this evaluation is in large part determined through pre-clinical and clinical research and trials. For generic medicines, quality, safety and efficacy is assessed on the basis of evidence of therapeutic equivalence and interchangeability with originator products through bioequivalence or other appropriate scientific studies. Clinical trials are not repeated in order to avoid unethical duplication.

The development of a generic medicine is a process that involves a number of steps, which normally include:

- Securing the active pharmaceutical ingredient (API);
- Developing the formulation of the product;<sup>1</sup>
- Testing and manufacturing the generic medicine;
- Undertaking bioequivalence studies (and, when required, other clinical studies); and
- Filing an application for marketing authorisation.

Domestic regulatory authorities around the world have established their own processes and procedures for the assessment and granting of marketing authorisation to generic medicines. Convergence of the different national systems, in conjunction with convergence of technical requirements, can remove many of the transactional and human resource costs associated with preparing submissions that reflect different regulatory submission requirements in each country.

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<sup>1</sup> This step, in turn, includes a number of stages, such as, *inter alia*: the reverse engineering of the reference product to determine the composition of its active and non-active pharmaceutical ingredients; collecting and reviewing data and analysing the product monograph of the reference product; and the development of various formulations of the active and non-active ingredients and laboratory testing.

In this context, the IGBA strongly supports the conclusion of trade agreements that would create the conditions for simplifying divergences between national and regional frameworks and stimulating recognition of assessments of generic medicinal products with the final objective of achieving '*single development programmes*', in particular for complex generics. The recognition of reference products from other jurisdictions would greatly contribute to the development of the generic medicines sector. In this context, the IGBA strongly condemns practices in some jurisdictions undertaken by originator drug companies that have prevented or impeded access to reference products.

Trade agreements should provide for the establishment of regulatory frameworks that will allow countries to converge the requirements for the assessment of generic medicines in order to reduce the development costs and enable the industry concerned to increase patient access to high-quality generic medicines.

A more harmonised approach could be sought, for example, with regard to the studies required to support generic applications, the criteria that have to be met for an application to be successful, and the possibility of sourcing the same reference product in the markets involved for purposes of trials and studies mutually accepted by the parties. The guidelines issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) should serve as a basis for domestic legislation, at least in all territories that are Parties to the ICH, and domestic requirements going beyond those agreed by the ICH should be removed where not scientifically justified.<sup>2</sup> Trade agreements should also deliver ways to achieve mutualisation of efforts with respect to the filing and review of the active substances used and recognition of assessment, in order to facilitate and shorten the review process and accelerate regulatory approval.

The IGBA recognises that convergence of technical requirements may be advanced through the setting-up, in trade agreements, of frameworks establishing a process of regulatory cooperation and convergence, as well as through the agreement on good regulatory practices. While premised on the acceptance of the existing institutional differences, this approach aims to gradually establish the necessary degree of '*comfort*' among authorities and different systems over time. In addition, it can accommodate standardisation, harmonisation, mutual recognition and/or equivalence, as they come to fruition and with an asymmetrical approach that allows the specificities of sectors or sub-sectors to be factored-in.

To this end, there are a number of core principles and key objectives that the IGBA considers important to be systematically embedded in trade agreements. Principles include increased transparency requirements and participation in decision-making processes with respect to the authorisation, marketing, listing and reimbursement, and the objectives must provide for the reduction of unnecessary barriers to trade that result from avoidable divergences of regulatory requirements, partly also through a commitment to participate in the process on international standardisation.

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<sup>2</sup> The ICH is a relevant organization for purposes of fostering regulatory convergence and harmonisation of technical requirements. The ICH issued a number of guidelines relating to quality, safety, efficacy and cross-cutting issues relating to the manufacture of pharmaceutical products.



These principles and objectives must be included and properly spelled out in all relevant sections of trade agreements (*i.e.*, both at the '*horizontal*' level, in the Chapter on Technical Barriers to Trade and/or in a dedicated Chapter on Regulatory Co-operation, as well as in any Pharmaceutical-specific Chapter or Annex that may be systematically included in trade agreements). A commitment to protect confidential information transmitted within the framework of regulatory cooperation activities must be included.

In addition, it is also important that closer cooperation and convergence in the area of generic medicines be systematically informed by a shared commitment to high regulatory standards with respect to the safety and efficacy of generic medicines, and by the recognition of the positive role played by collaborative approaches in facilitating the development and use of new tools, standards and approaches for purposes of developing products more efficiently and evaluating more effectively product safety, efficacy and quality.

### **SUMMARY OF KEY RECOMMENDATIONS – GENERIC MEDICINES**

- ✓ Ensure that trade agreements include appropriate provisions to strengthen cooperation in the field of technical regulations and standards;
- ✓ Ensure that trade agreements include a dedicated Pharmaceutical-specific Chapter or Annex and provisions enhancing the development of, and access to, high quality generic medicines;
- ✓ The Pharmaceutical-specific Chapter or Annex must refer to a system of international standardisation (*e.g.*, the ICH, the World Health Organization (WHO)) and contain an obligation for Parties to conform to such standards;
- ✓ Ensure that trade agreements (both at the horizontal section and/or the Pharmaceutical-specific Chapter or Annex) contain transparency and consultation requirements enabling affected stakeholders to be promptly informed about new regulations and to present their views to the regulators/legislators;
- ✓ Enhanced transparency requirements need to be included to enable stakeholders' participation in decision-making processes for purposes of streamlining unnecessary divergences of regulatory requirements affecting the authorisation of generic medicines;
- ✓ Ensure that the Pharmaceutical-specific Chapter or Annex contain appropriate provisions establishing the basic framework of regulatory cooperation and regulatory exchange among authorities for purposes of future convergence of national technical requirements with respect to generic medicines;
- ✓ Include a commitment for the protection of confidential business information with respect to data and information exchanged within regulatory cooperation activities;

- ✓ Provide for balanced rules on good regulatory practices in a dedicated chapter or annex; and
- ✓ Ensure the access of generic medicines manufacturers to reference product samples.

The IGBA looks forward to continuing to engage with negotiators and stakeholders, and remains available to provide more detailed information on its positions and on how it considers that treaty language could best reflect the specific objectives of the generic medicines industry to support access to medicines.

### 3.2 *Biosimilar medicinal products*

Biological products (also referred to as “*biopharmaceutical products*”, “*biologicals*” or “*biologics*”) represent one of the fastest-growing pharmaceutical industry sectors.<sup>3</sup> Examples of biologics include vaccines, blood and blood components, therapeutic proteins and tissues.

With the expiry of patents on biologics, pharmaceutical companies have started to develop and produce their own versions of previously approved, existing biological medicines (*i.e.*, the reference medicines). Biosimilar medicines are biological medicines that are developed to yield the same clinical results as their reference biologic drugs.

Biologics are large, complex molecules compared to most traditional, chemically synthesised medicines. The efficacy and safety of a biosimilar cannot be assessed by relying on the *in vitro* test data and chemical structure of the originator product (as it is the case for generics); rather, biosimilars require more costly clinical trials.<sup>4</sup> The development of a biosimilar requires the creation of a molecule that is highly similar to the reference biologic. In relevant part, this process requires an extensive comparability exercise based on a robust head-to-head comparison between the biosimilar and the reference medicinal product at the levels of quality, safety and efficacy. In this context, the IGBA strongly condemns the recent instances whereby originator drug companies have prevented or impeded access to reference products.

Regulatory frameworks for the approval of biosimilars have now been established in a number of countries. Regulatory authorities apply stringent criteria in their evaluation of the studies comparing the quality, safety and efficacy of the two medicines. Analytical data proving high similarity is the most important part of biosimilar development and approval. Following the adoption of national guidelines on biosimilars development, regulators around the world determine on a case-by-case basis the scope and extent of human clinical trials to support a demonstration of biosimilarity after they review the analytical and pre-clinical data. Robust analytical data and high similarity of the product are expected to reduce clinical trial requirements.<sup>5</sup>

<sup>3</sup> WTO, WIPO, WHO, “*Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade*”, 2012, p. 52.

<sup>4</sup> *Ibid.*

<sup>5</sup> In the EU, according to the *Guideline on Similar Biologic Medical Products*, adopted on 23 October 2014, “[t]he extent and nature of the non-clinical *in vivo* studies and clinical studies to be performed depend on the level of evidence obtained in the previous step(s) including the robustness of the physicochemical, biological and non-clinical *in vitro* data”.

In some jurisdictions, regulatory frameworks are evolving to allow the use of reference products authorised in third countries with similar scientific and regulatory standards in certain studies for purposes of the comparability exercise. The IGBA supports these developments, which should also increasingly waive the requirement for bridging data in certain instances. The recognition of reference products from other jurisdictions would greatly contribute to the development of the biosimilar medicines sector.

In this context, the IGBA supports the conclusion of trade agreements that would facilitate or lead to the establishment of frameworks allowing for greater convergence of requirements for the approval of biosimilars, in order to reduce the development costs and enable the industry concerned to increase patient access to high-quality biopharmaceuticals.

On the basis of the regulatory experience and objectives of the parties involved, trade agreements could require the establishment of regulatory frameworks allowing for a global development programme for biosimilar medicinal products and convergence of data requirements for their approval.

The institutionalisation and increase of '*cluster*'<sup>6</sup> interactions between regulators, and the establishment of, and engagement in, regulatory discussions would strengthen the framework for the regular exchange of information and collaborative meetings between regulators, thereby increasing the opportunity of moving towards convergence in this area.<sup>7</sup>

Moreover, trade agreements should also seek to increase cooperation of regulatory authorities in relevant international *fora* for purposes of the harmonisation of the scientific principles of biosimilarity.

The IGBA considers that increased cooperation and convergence in the area of biosimilar medicines assessment should be advanced through the establishment, in trade agreements, of frameworks to manage the process of regulatory convergence and increasing market access through the harmonisation of requirements towards existing international standards.

Cooperation in the area of biosimilar medicines should be made an explicit objective of any agreement, which must also include enhanced transparency requirements with respect to regulations affecting the authorisation, marketing, listing and reimbursement of biosimilar medicines, and a commitment to abide by international standards and participate in the international standardisation process. According to the level of cooperation already achieved and/or sought by trading partners with respect to biosimilars, the process of regulatory cooperation could entail, *inter alia*, provisions enhancing cooperation and fostering technical discussions with respect to the requirements for the authorisation of biosimilar medicines. The confidentiality of the information exchanged would need to be protected by appropriate provisions.

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<sup>6</sup> '*Clusters*' are topics of mutual interest for regulatory agencies, which they have identified as benefiting from the regular exchange of information and collaborative meetings. These cluster interactions provide a framework for the regular exchange of information and collaborative meetings between regulators involved.

<sup>7</sup> In relation to ongoing collaborative interactions see, e.g., *Press release: FDA, European Commission and EMA reinforce collaboration to advance medicine development and evaluation*, 14 July 2015, available at: <https://www.ema.europa.eu/en/news/fda-european-commission-ema-reinforce-collaboration-advance-medicine-development-evaluation>

Again, closer cooperation and convergence in the area of biosimilar medicines should be systematically informed by a shared commitment to high regulatory standards with respect to the safety and efficacy of biosimilar medicines and by the recognition of the positive role played by collaborative approaches in facilitating the development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality.

### ***SUMMARY OF KEY RECOMMENDATIONS – BIOSIMILAR MEDICINES***

- ✓ Ensure that trade agreements include appropriate provisions to strengthen cooperation in the field of technical regulations and standards;
- ✓ Ensure that trade agreements include a dedicated and balanced Pharmaceutical-specific Chapter or Annex and provisions enhancing the development of, and access to, high-quality biosimilar medicines;
- ✓ The Pharmaceutical-specific Chapter or Annex must refer to a system of international standardisation and contain an obligation for Parties to conform to such standards;
- ✓ Ensure that the Pharmaceutical-specific Chapter or Annex contain appropriate provisions establishing the basic framework of regulatory cooperation and regulatory exchange among authorities for purposes of future convergence of national technical requirements with respect to biosimilar medicines;
- ✓ Ensure that trade agreements (both in the horizontal sections and/or the Pharmaceutical-specific Chapter or Annex) contain transparency requirements enabling affected stakeholders to be promptly informed about new regulations and to present their views to the regulators/legislators;
- ✓ Include provisions enhancing further cooperation with respect to the technical requirements for the authorisation of biosimilar medicines;
- ✓ Include, as the case may be, a commitment for the protection of confidential business information with respect to data and information exchanged within regulatory cooperation activities; and
- ✓ Provide for balanced rules on good regulatory practices in a dedicated chapter or annex.

The IGBA looks forward to continued engagement with negotiators and stakeholders for purposes of facilitating the trade of high-quality biosimilar medicines, and would welcome the opportunity to provide more detailed information on its positions and on how it considers that treaty language could best reflect the specific objectives of the biosimilar medicines industry and access to medicines.

### 3.3 *Mutual recognition of compliance inspections*

Good manufacturing practices (GMP) are the practices required in order to conform to guidelines recommended by agencies that control the authorisation and licensing for the manufacture and sale of pharmaceutical products. These guidelines provide the minimum requirements that a pharmaceutical product manufacturer must meet in order to assure that the products are of high quality and do not pose any undue risk to the public.

Many countries require that pharmaceutical manufacturers follow GMP procedures, and have created their own GMP guidelines, which are reflected in their legislation. The ICH issued the *Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients*, which applies to the regulatory Parties to the ICH, as well as to other countries that have adopted ICH guidelines for the manufacturing and testing of active raw materials. In addition, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international schemes applied among countries and pharmaceutical inspection authorities active in the development and promotion of harmonised GMP standards and guidance documents.

Supervisory authorities conduct inspections of manufacturing authorisation holders to ensure that they are in compliance with the principles and guidelines of GMPs. This applies to imported products, too, with the supervisory authorities responsible for verifying that the manufacturer conforms to standards of GMPs equivalent to those in force domestically, unless there is a Mutual Recognition Agreement (MRA) covering GMP inspections.

A number of collaborative initiatives among some regulators, with respect to inspections of API and '*finished*' pharmaceutical products, are already taking place. Some countries and territories have negotiated and concluded Mutual Recognition Agreements (MRAs) in relation to conformity assessment, including the EU and the US. Some countries and territories are also discussing the issue of good clinical practice (GCP) inspections. Additionally, ASEAN Member States have agreed on a Mutual Recognition Agreement for Bioequivalence Study Reports of Generic Medicinal Products.

Duplication of inspections is a significant concern for manufacturers. Multiple inspections have led to diverging inspection outcomes and, ultimately, to high costs for the companies and to occasional shortages of medicines. In addition, the removal or reduction of redundant inspections would contribute to bringing a level playing field to all pharmaceutical supply chain operators by ensuring that more manufacturing sites are visited in countries and regions.

The IGBA calls for trade agreements to build on, and further develop, collaborative approaches in the field of GMPs and to provide for mechanisms aimed at the avoidance of duplication of inspections and at the negotiation and conclusion of MRAs on GMP inspections on both API and finished products. Again, such a mechanism would need to include specific provisions for the protection of confidential information.

#### ***SUMMARY OF KEY RECOMMENDATIONS – RECOGNITION OF COMPLIANCE INSPECTIONS***

- ✓ Ensure that trade agreements include appropriate provisions to strengthen cooperation in the field of conformity assessment procedures;
- ✓ Ensure that trade agreements contain a dedicated Pharmaceutical-specific Chapter or Annex promoting the elimination of duplicative and unnecessarily burdensome conformity assessment procedures;
- ✓ Include a commitment for Parties to consider the request to recognise the results of conformity assessment procedures conducted in the other Party's territory, including the commitment to negotiate a mutual recognition agreement with respect to GMP inspections; and
- ✓ Include a commitment for the protection of confidential business information with respect to inspection reports.

The IGBA looks forward to continuing its engagement with negotiators and stakeholders, and is prepared to provide more detailed information on its positions and on how it considers that its objectives with respect to recognition of compliance inspections could be best achieved.

## 4. Addressing Technical Barriers to Trade in Trade Agreements

The chapters on Technical Barriers to Trade (hereinafter, TBT) figure among the core chapters of free trade agreements. As countries lower or remove tariffs, addressing tariffs in trade agreements becomes less important, while addressing non-tariff measures (NTMs), which can often constitute non-tariff barriers (NTBs), increases in importance. TBT provisions in trade agreements, along with the WTO TBT Agreement, aim to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. In recent years, certain trade agreements also include sector-specific chapters on TBT-related issues, such as sector-specific annexes for pharmaceuticals (often in combination with medical devices), which also provide TBT-related rules.

Clearly, TBT chapters will remain important parts of existing and future trade agreements. Considering the increasing importance of non-tariff measures, such as those based on technical regulations, this should be reflected in increasingly ambitious TBT chapters. At the same time, adequate sector-specific commitments, *inter alia* for pharmaceuticals, should complement the horizontal rules. These provisions should be regularly reviewed and updated so as to keep pace with scientific and regulatory developments.

### ***SUMMARY OF KEY RECOMMENDATIONS – TECHNICAL BARRIERS TO TRADE***

- ✓ Trade agreements should continue to reflect the importance of addressing technical barriers to trade through detailed TBT chapters;
- ✓ Where necessary, sector-specific annexes or chapters should be negotiated, including for pharmaceuticals; and
- ✓ These rules should be regularly reviewed and updated so as to keep pace with scientific and regulatory developments and be reflective of the needs and interests of the generic and biosimilar medicines sector.

## 5. The Regulation of Intellectual Property Rights in Trade Agreements

### 5.1 Introduction

When developing intellectual property (IP) policies and laws, national decision-makers and legislators must take into account the international IP legal framework, which provides the standards and general principles that must inform national IP systems. The relevant international framework is defined by the Paris Convention for the Protection of Industrial Property (Paris Convention), administered by the World Intellectual Property Organization (WIPO), and by the TRIPs Agreement, which incorporates the substantive provisions of the Paris Convention. In addition, standards concerning IPR protection are increasingly being set as a result of the negotiation and conclusion of FTAs.

The TRIPs Agreement is the first international agreement to introduce extensive intellectual property rules into the realm of multilateral trade regulation. It has considerable implications for the application of IPRs to pharmaceutical products, particularly through the implementation of international standards on patents, which the TRIPs Agreement required WTO Members to make available for inventions in all areas of technology, including pharmaceutical products<sup>8</sup>, and the requirement to protect clinical trial data submitted to obtain marketing approval against unfair commercial use<sup>9</sup>, *inter alia*. The TRIPs Agreement also introduced multilateral standards for the protection and enforcement of IPRs.

The rationale of patent protection is to stimulate investment in innovation and to offer a mechanism that ensures that the knowledge contained in the patent application is accessible to society. The protection of test and other data is a distinct form of IPR, which concerns the information (*i.e.*, test data) that is required for regulatory approval of the pharmaceutical product. The terms of test data protection are defined by pharmaceutical legislation; at the same time, test data protection is part of intellectual property frameworks in that it represents a form of protection against unfair competition.

The standards set by the TRIPs Agreement leave considerable scope for implementation, and WTO Members remain free to determine the appropriate method of implementing the provisions of the TRIPs Agreement within their own legal system and practice. WTO Members may also implement in their laws more extensive protection than is required by the TRIPs Agreement, provided that they comply with the provisions set forth therein.<sup>10</sup>

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<sup>8</sup> The TRIPs Agreement requires patents to be available for any inventions, whether products or processes. The protection for process patents would not prevent the manufacture of patented products by a process of reverse engineering, where a different process or method from that which has been patented is used. Therefore, in countries where national legislation required only process patent protection, before the TRIPs Agreement entered into force (and subject to transition periods) generic manufacturers were able to make generic versions of patented products.

<sup>9</sup> WTO, WIPO, WHO, “Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade”, *supra*, p. 54.

<sup>10</sup> Article 1 of the TRIPs Agreement.



The inclusion of '*TRIPs-plus*' provisions in the IP Chapters of FTAs has been championed by the countries and territories that are home to most originator pharmaceutical companies (such as the EU, Switzerland and the US) since the conclusion of the TRIPs Agreement, with the clear objective of ensuring that FTA partners would implement, in their domestic legislation, a level of IP protection similar to that which is applied in their own territories.

Together with the proliferation of the negotiation and conclusion of FTAs, this trend risks leading to the creation of new international standards of IP established through bilateral rather than multilateral negotiations and to the adoption of domestic laws providing for higher levels of IP protection,<sup>11</sup> with potential effects on the generic and biosimilar sector where such tighter IP protection is aimed at, or has the effect of, preventing generic and biosimilar competition and delaying the entry of generic and biosimilar products into the market. Overall, this process runs the risk of altering the balance between the encouragement of investment and the need to ensure competition and technology transfer that must inform IP systems.

Against this background, the IGBA supports the maintenance of a balanced approach with respect to the regulation of IPRs in trade agreements, based on the standards established by the TRIPs Agreement. In addition, the IGBA believes that negotiations concerning IPRs should not seek to harmonise IPR frameworks, but recognise the different approaches taken by the negotiating parties with respect to IPR protection.

Relevant IP provisions that are frequently found in trade agreements and/or that have been identified as bearing particular importance to the generic and biosimilar industries include: patentability standards and '*best mode*' requirements; patent linkage; regulatory review ("*Bolar*") clause; data exclusivity; extension of the duration of the rights conferred by patents; and enforcement of IPRs.

The main issues and relevant recommendations for each of these IP areas are indicated below. The IGBA is available to discuss each aspect in greater detail and to provide further information on how it considers that its specific interests could be best reflected in trade agreements.

## 5.2 Patents

A patent gives its owner an exclusive right to prevent others from exploiting the patented invention for a limited period of time without authorisation, subject to a number of exceptions. A patent is not automatically available for eligible inventions, and is subject to the filing of an application in each jurisdiction in which the inventor (or other eligible person) seeks protection.<sup>12</sup>

Patents are normally granted when five main criteria are met: (i) the patent application must relate to patentable subject matter; (ii) the claimed subject matter must be new; (iii) it must involve an inventive step; (iv) it must be industrially applicable; and (v) the invention must be properly disclosed.<sup>13</sup>

<sup>11</sup> See R. Valdés and R. Tavengwa, WTO, Economic Research and Statistics Division, Staff working Paper ERSD-2012-21, 31 October 2012, p. 40. The authors argue that the non-discrimination requirement of the TRIPs Agreement, together with the distinct '*hub-and-spoke*' architecture of IP provisions, leads to a '*ratchet-like*' process whose effect is to incrementally tighten countries' domestic IP regulations, and which feeds back into the international arena (as countries would want to include in future FTAs the standards resulting from commitments that they made under previous agreements). See also WTO, WIPO, WHO, "*Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade*", supra, p. 84.

<sup>12</sup> WTO, "*A Handbook on the WTO TRIPS Agreement*", edited by A. Taubman, H. Wager and J. Watal, 2012, Cambridge University Press, p. 96.

<sup>13</sup> Ibid.

These requirements are reflected in the TRIPs Agreement, which provides for a general framework with respect to patentability requirements. In particular, the TRIPs Agreement requires that patents be made available for any inventions, whether products or processes, in all fields of technology (subject to certain allowed exclusions), provided that such inventions are new, involve an inventive step and are capable of industrial application.<sup>14</sup> The TRIPs Agreement also contains certain flexibilities, in the form of permissible exclusions from patentability, set forth in Articles 27.2 and 27.3.<sup>15</sup>

FTAs may seek to modify these standards in a manner that would alter the competitive relationship between generic and biosimilar medicines and originators' products.

A number of FTAs covering patentability contain provisions limiting the permissible exclusions from patentability. In other FTAs, the standards of patentability appear more relaxed, which may lead to an increased number of patents being granted for not-so-innovative products.<sup>16</sup>

The IGBA believes that the standards on patentable subject matter, novelty, inventive step and industrial applicability, as well as disclosure, as reflected in the TRIPs Agreement, are instrumental to ensure the proper functioning of the patent system, and contribute to the achievement of the overall balance between the various interests at stake, preventing instances of misuse/abuse.

In this light, the IGBA is of the view that provisions on patentability<sup>17</sup> should appropriately reflect the language set forth in the TRIPs Agreement in relation to the criteria that apply to patentable subject matter and the permitted exclusions from patentability, and should not seek to modify the standards set by the TRIPs Agreement in relation to patents.

### ***SUMMARY OF KEY RECOMMENDATIONS – PATENTS***

- ✓ Ensure that provisions on patentability reflect the language of the TRIPs Agreement in relation to the criteria that apply to patentable subject matter and the permitted exclusions from patentability.

<sup>14</sup> Article 27.1 of the TRIPs Agreement.

<sup>15</sup> Article 27 of the TRIPs Agreement allows Members to exclude inventions from being granted a patent (that otherwise complies with other substantive requirements) on three grounds: (i) ordre public or morality; (ii) methods of treatment; and (iii) plants and animals.

<sup>16</sup> S. Musungu, South Centre, C. Oh, World Health Organization "The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?", Study 4C, Geneva, Switzerland, Commission on Intellectual Property Rights, Innovation and Public Health, p. 31. The authors note that new innovative medicines are rare, yet pharmaceutical patents "number in thousands each year", which raises questions as to the number of patents that may be granted for minor modifications.

<sup>17</sup> Provisions addressing issues related to patentable subject matter are found in a number of FTAs and appear a standard feature of agreements concluded by the US, EU FTAs, on the other hand, do not normally cover such area.

### 5.3 ‘Best mode’ requirement

The TRIPs Agreement requires WTO Members to oblige patent applicants to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. In addition, patent authorities may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date (or, where priority is claimed, at the priority date of the application).<sup>18</sup> Therefore, under the so-called ‘best mode’ requirement, if there are several ways in which the invention may be put into practice, the applicant can be required to disclose the one which is most practicable.

‘Best mode’ requirements are not a common feature of trade agreements. However, the IGBA believes that the ‘best mode’ requirement would make a significant contribution to enhancing knowledge dissemination and would play a decisive role in establishing the level of inventiveness legally required for a patent, with clear effects on innovation and competition. For this reason, the IGBA calls for the systematic inclusion of ‘best mode’ requirements in trade agreements.

#### SUMMARY OF KEY RECOMMENDATIONS – ‘BEST MODE’ REQUIREMENT

- ✓ Ensure that trade agreements systematically require Parties to provide for ‘best mode’ requirements in their legislation.

### 5.4 Patent linkage

‘Patent linkage’ refers to requirements linking regulatory approval of pharmaceutical products to the patent status of the products. Patents on pharmaceutical inventions and regulatory approval for pharmaceutical products are normally granted by separate agencies (patent offices and health regulators, respectively). However, certain jurisdictions’ domestic laws link regulatory approval (which is based on an evaluation of safety and efficacy of the pharmaceutical product) to the patent status of the pharmaceutical product. Therefore, under a patent linkage mechanism, the marketing authorisation will not be granted to a generic medicinal product until the patent is found to have expired or to be invalid or not to be relevant to the generic medicine. This has the consequence of considerably delaying the market entry of generic products. In countries where patent linkage is applied, the regulatory authority effectively acts as a patent enforcement agency, as patent linkage prevents that authority from granting marketing authorisation to a generic medicine where it appears that there is a valid patent still in existence.<sup>19</sup>

<sup>18</sup> Article 29.1 of the TRIPs Agreement.

<sup>19</sup> C. Garrison, “Exceptions to patent rights in developing countries”, UNCTAD - ICTSD Project on IPRs and Sustainable Development, August 2006, p. 60.

Patent linkage requirements are present, in relevant part, in Canada, the US and Japan, as well as in few other jurisdictions, *inter alia*, as a result of the conclusion of FTAs, notwithstanding the fact that patent linkage is not a requirement of the TRIPs Agreement. In Canada and in the US<sup>20</sup>, for example, the mechanism provides for an automatic injunction (*i.e.*, an automatic stay of approval) up to 24 and 30 months, respectively, subject to the patentee's filing of a suit within a specified timeframe of receiving the notice. On the other hand, patent linkage requirements are not allowed in the EU, where they are considered by the European Commission to be contrary to EU competition law.<sup>21</sup>

Provisions requiring countries to implement patent linkage requirements within their domestic legislation are found in a number of trade agreements and are a common feature of agreements involving the US. However, inasmuch as they prevent the registration and authorisation of generic medicines until a patent has been found by the competent authorities to be invalid or in fact not relevant to the generic medicine, patent linkage requirements considerably delay market entry of non-originator products.

Patent linkage requirements stand to be particularly problematic in negotiating frameworks involving countries with little IPR enforcement '*experience*' and no patent linkage requirements in place. Inasmuch as the functioning of the patent linkage mechanism relies on the ability of domestic systems to quickly assess the existence or the validity of a patent, before granting regulatory approval, patent linkage requirements imposed on countries whose systems do not currently meet such standards are likely to pose significant challenges and to result in additional burdens and further delays and impediments on trade in pharmaceutical products.

Therefore, the IGBA is of the view that the inclusion of patent linkage provisions in trade agreements must clearly be avoided. Furthermore, recent multinational initiatives such as the Pat-INFORMED database also constitute a threat to neutral and objective procurement decisions.

Where patent linkage provisions are part of trade negotiations, the IGBA strongly calls for negotiators to ensure that such provisions not be formulated in mandatory terms, that they be limited as to the scope of the patents that are covered, and that they be balanced by appropriate '*safeguards*' to prevent abuse.

One example of such '*safeguards*' concerns the provision of clear incentives for generic manufacturers to challenge patents. This could be done through a requirement to provide a period of marketing exclusivity for the first generic applicant that challenges a patent, similarly to what foreseen in the *US Drug Price Competition and Patent Term Restoration Act* of 1984 (usually referred to as the "*Hatch-Waxman Act*"). There are relevant international precedents that allow for this and other appropriate '*safeguards*' to accompany patent linkage provisions.<sup>22</sup>

<sup>20</sup> Note that in the US patent linkage does not apply to biosimilars.

<sup>21</sup> In its Pharmaceutical Sector Inquiry (Final Report adopted on 8 July 2009), the European Commission recognised that the EU's regulatory framework for approval of pharmaceutical products does not allow authorities to take the patent status of the originator medicine into account when deciding on marketing authorisations of generic medicines. Therefore, patent linkage is considered by the Commission an anti-competitive instrument to delay generic and biosimilar medicines entry into the market and, as such, subject to EU competition rules. As result, EU trade agreements do not contain patent linkage requirements.

<sup>22</sup> The *United States – Colombia Trade Promotion Agreement* (US-Colombia FTA), signed 22 November 2006 (entered into force on 15 May 2012), the *United States – Panama Trade Promotion Agreement*, signed 28 June 2007 (entered into force on 31 October 2012) and the *United States – Peru Trade Promotion Agreement*, signed 12 April 2006 (entered into force on 1 February 2009).

The IGBA considers that these '*safeguards*' would still not compensate for the added complexity and cost of patent linkage requirements to domestic health systems. This is why the IGBA is of the opinion that, where patent linkage requirements are included in trade agreements, they should be clearly non-mandatory and allow for flexibility with respect to implementation of both the linkage mechanism and the '*safeguards*' at the domestic level.

Trade agreements must also clearly state that patent linkage requirements do not apply to biologics. Given the early stage of competition in the biologic industry and the constantly evolving scientific and regulatory landscape surrounding biologics, the IGBA strongly believes that the establishment of complex and layered IP protection for biologics (including patent linkage requirements) is largely premature.

#### ***SUMMARY OF KEY RECOMMENDATIONS – PATENT LINKAGE***

- ✓ Ensure that trade agreements do not include provisions on patent linkage requirements.
- ✓ Where present, patent linkage provisions must be non-mandatory;
- ✓ Where present, patent linkage provisions must be limited as to the scope of the patents that are covered;
- ✓ Where present, patent linkage provisions must be balanced by appropriate '*safeguards*' to prevent abuse; and
- ✓ Where patent linkage provisions are present, appropriate language must clarify that patent linkage does not apply to biologics.

## 5.5 Regulatory review (“Bolar”) clause

The regulatory review clause (also called “Bolar”<sup>23</sup> or “early working” exception) allows generic and biosimilar manufacturers to use a patented invention during the period of patent term without the consent of the patent holder for the purposes of developing information to obtain marketing approval from health regulatory authorities.

The rationale for this requirement lies in that, during the process of obtaining marketing authorisation, the applicant has to produce a first batch of the product (generic and biosimilar medicines manufacturers need to use patented material to submit their approval request for purposes of bioequivalence requirements), which may be considered an infringement of a related patent.<sup>24</sup> Therefore, by allowing generic producers to be in a position to market their versions as soon as the patent expires, the regulatory review clause favours market entry by competitors immediately after the end of the patent term and ensures timely access to generic medicines.

The regulatory review clause set forth in Section 55.2(1) of the Canadian *Patent Act* was found to conform to the requirements of Article 30 of the TRIPs Agreement (on exceptions to the exclusive rights conferred by a patent) by the WTO Dispute Settlement Body in the dispute *Canada – Pharmaceutical Patents*.<sup>25</sup> The Canadian version of the regulatory review clause covers activities seeking product approvals under both domestic and foreign regulatory procedures. However, the scope of the regulatory review clause varies according to relevant national legislation.

The regulatory review clause is an important provision that facilitates the production and introduction of generic and biosimilar medicines into the market on the date of patent expiry. Without such a clause, generics and biosimilars manufacturers would only be able to start their bioequivalence and other testing after patent expiry. A number of countries explicitly provide for the regulatory review clause in their legislation.<sup>26</sup>

Generally, few FTAs include regulatory review clauses. Such clauses that do exist are mainly for purpose of restricting the scope of the exception. For example, a number of agreements contain provisions requiring that the exportation of a product covered by the regulatory review clause be only permissible for purposes of obtaining marketing approval in the country from which the export originates.

<sup>23</sup> The name “Bolar” comes from the US court case *Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858 (1984), concerning the manufacturing of generic medicines. In that case, the court held that US law did not allow for the experimental use of a patented chemical. Shortly after the ruling, the US Congress enacted the *Hatch-Waxman Act*, permitting use of patented products in experiments for the purpose of obtaining FDA approval.

<sup>24</sup> WTO, WIPO, WHO, “Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade”, supra, p. 174.

<sup>25</sup> *Canada – Patent Protection of Pharmaceutical Products*, DS114.

<sup>26</sup> The WIPO established that, up to 2010, 48 countries provided for the regulatory review clause, while in other countries the regulatory review clause is considered to fall within the scope of the general research exemption and, in other cases, it has been developed through case law (see WIPO Secretariat, “Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels”, Committee on Development and Intellectual Property (CDIP), Fifth Session, Geneva, April 26 to 30, 2010, CDIP/5/4 REV, p. 23).

Similar provisions should be avoided.<sup>27</sup> On the contrary, the IGBA strongly supports the inclusion of a broad regulatory review clause that covers imports and exports and does not provide for a time limit.

In particular, the IGBA considers that the regulatory review clause in trade agreements should be informed by the following core drivers:

- It should be mandatory;
- It should be articulated so as to encompass all actions (e.g., the manufacture, construction, use or sale of the patented invention) related to the development and submission of information that is required in the country where the generic/biosimilar manufacturer will use the patented invention;
- Limitations that were to render the regulatory review clause moot (such as those mentioned above) should be avoided; and
- The flexibilities provided by the TRIPs Agreement regarding exceptions to patent rights (including that the regulatory review clause operates automatically, without consent of the patent holder) should apply to the regulatory review clause.

#### **SUMMARY OF KEY RECOMMENDATIONS – REGULATORY REVIEW (“BOLAR”) CLAUSE**

- ✓ Ensure that trade agreements require Parties to implement a regulatory review clause;
- ✓ Ensure that the regulatory review clause covers all actions related to the development and submission of information that is required in the country where the generic/biosimilar manufacturer will use the patented invention; and
- ✓ Provisions limiting the scope of the regulatory review should be avoided.

<sup>27</sup> See, for example, Article 15.9(5) of the *Dominican Republic – Central America – United States Free Trade Agreement* (US-CAFTA-DR). Similar provisions appear in a number of other US FTAs, such as the US-Colombia FTA, the *Agreement between the Government of the United States of America and the Government of the Sultanate of Oman on the Establishment of a Free Trade Area* (US-Oman FTA) and the *Free Trade Agreement between the United States of America and the Republic of Korea* (KORUS FTA), *inter alia*. By providing that export by a generic (or biosimilar) manufacturer of a product, which is otherwise covered by the regulatory review clause, is only allowed for purposes of regulatory approval in the country from which the export originates, these provisions force generic companies to carry out tests and production of quantities necessary for marketing approval country by country in the event of export, rendering the system impracticable (S. Musungu, C. Oh, *supra*, p. xii and 31).



## 5.6 Exclusivity periods

### a. Data Exclusivity

Data protection covers the test or other data submitted to regulatory authorities for purposes of regulatory approval. This is an IPR which is distinct from patents. While patents cover the ‘invention’ contained in the pharmaceutical product, test data protection covers the information (e.g., pharmacological and toxicological tests and clinical trials) submitted to regulatory authorities for purposes of regulatory approval.<sup>28</sup> In some jurisdictions, test data protection is implemented through requirements establishing data exclusivity periods.

The rationale for data exclusivity is to ‘compensate’ the applicant (originator) for the efforts made to undertake the clinical trials and produce test data. However, data exclusivity delays market entry of non-originator products, as it will not be possible to rely on the data produced for purposes of obtaining marketing authorisation for the same medicinal product.

In particular, data exclusivity refers to a period of exclusivity granted to originators of pharmaceutical products during which the test data developed for purposes of regulatory approval may not be relied upon by a generic and biosimilar manufacturer in the application for the marketing authorisation for the same medicinal product. Data exclusivity may run in parallel to patent protection for approved pharmaceutical products. However, it would continue to apply in situations where, *inter alia*, the patent has already expired, is about to expire, or where the validity or relevance of the patent to the non-originator product is challenged.<sup>29</sup> This results, in most situations, in data exclusivity effectively delaying the entry of generic (and, where applicable, biosimilar) medicinal products into the market because manufacturers of such products are required to wait until the protection period expires before submitting their application for marketing authorisation for their products.<sup>30</sup>

The TRIPs Agreement requires WTO Members to protect clinical data submitted for regulatory approval against disclosure and “*unfair commercial use*”, which refers to acts of unfair competition. In particular, Article 39.3 of the TRIPs Agreement requires WTO Members to protect such test or other data when:

- The data has not been disclosed;
- The submission of test data is mandatory;
- The products utilise new chemical entities; and
- The origination of the test or other data has required a considerable effort.

<sup>28</sup> WTO, WIPO, WHO, “Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade”, supra, p. 65.

<sup>29</sup> WTO, WIPO, WHO, “Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade”, supra, p. 63.

<sup>30</sup> Distinct from data exclusivity is the concept of “*market exclusivity*”, which refers to a period of exclusivity during which generic and biosimilar manufacturers may not market their products. In general terms, during market exclusivity, manufacturers of generic and biosimilar medicines may not market a generic version of the originator’s pharmaceutical product, but their application for marketing authorisation may be submitted and processed if data exclusivity has expired. This distinction does not appear to be clearly and consistently reflected in trade agreements: whereas the EU refers to protection of data for purposes of obtaining a marketing authorisation, US agreements appear rather focussed on the ability to market the product (for example, in the KORUS FTA: “...the Party shall not permit third persons...to market the product...on the basis of the information [...]”). Through data exclusivity requirements, negotiating countries are likely to attempt inserting in trade agreements terms of protection that cover data and marketing exclusivity periods contemplated under their legislation.



Such undisclosed test data needs to be protected:

- Against unfair commercial use; and
- Against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.<sup>31</sup>

A number of countries have interpreted this requirement as an obligation to establish data exclusivity regimes, and are requesting that data exclusivity requirements appear in FTAs, so as to bind FTA participants to put in place similar frameworks in domestic laws. However, data exclusivity is not a requirement of the TRIPs Agreement and any interpretation that justifies the introduction of data exclusivity requirements on the basis of the TRIPs Agreement must be clearly rejected. What the TRIPs Agreement requires is a form of test data protection so as to prevent “*unfair commercial use*” of the data by third parties, a concept that refers to acts of unfair competition, and not to create a form of exclusivity. This interpretation is also clearly endorsed by the WHO.<sup>32</sup>

In light of the above, the IGBA is of the view that trade agreements should not contain provisions concerning the protection of test or other data that go beyond the requirements of the TRIPs Agreement, or should defer the regulation of such matters to the domestic legislation of the Parties involved.

However, the IGBA recognises the practice followed by some developed countries to systematically require the inclusion of data exclusivity obligations in their international trade agreements.

In these negotiating instances, the IGBA strongly calls for the inclusion of provisions that would limit as much as possible the scope and length of data exclusivity requirements and that would reflect the standards of the TRIPs Agreement (*e.g.*, that the protection of data be granted only where the origination of such data involves considerable efforts).

Trade agreements should also not address data exclusivity requirements for biologics, and should certainly not provide for any special or additional requirement leading to longer data exclusivity periods for biological medicines.

### ***b. Market Exclusivity***

The IGBA is concerned by the development that recent trade agreements have prescribed minimum periods of market exclusivity, a period that extends beyond the data exclusivity period and restricts the market entry of biosimilars to a set period of time. In the United States, for example, biosimilar manufacturers cannot submit applications based on an original biologic for four years after marketing approval of the reference biologics and are further restricted from receiving regulatory approval for an additional eight years.

<sup>31</sup> See Article 39.3 of the TRIPs Agreement. See also WTO, “*A Handbook on the WTO TRIPS Agreement*”, *supra*, p. 128.

<sup>32</sup> See WHO, “*Briefing Note on Access to Medicines*”, March 2006.

The dedicated provision on biologics, mostly related to market exclusivity, which was agreed in the context of the negotiations of the Trans-Pacific Partnership (TPP) Agreement, was suspended by the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) by the remaining TPP parties, without the US. This can be considered an important signal against dedicated provisions on market exclusivity for biologics. The IGBA strongly opposes the inclusion of additional requirements leading to longer market exclusivity period for biological medicines in the negotiated United States, Mexico, and Canada Agreement.

### ***SUMMARY OF KEY RECOMMENDATIONS – EXCLUSIVITY PERIODS***

- ✓ Ensure that trade agreements do not contain data exclusivity requirements or other exclusivity periods that go beyond the requirements of the TRIPs Agreement, or ensure that trade agreements defer the regulation of such matter to domestic legislation of the Parties involved;
- ✓ Where data or other exclusivity requirements are present:
  - Ensure that appropriate provisions be included to limit the scope and length of the exclusivity;
  - Data exclusivity provisions are not to extend to instances where the submission of data from the originator company is not required according to the domestic legislation applicable in the Parties' territories;
  - Ensure that the protection of data is granted only where the origination of such data involves considerable efforts; and
  - Where exclusivity is provided for biologics, it should not exceed the exclusivity periods provided for chemical drugs.

## ***5.7 Extension of the duration of the rights conferred by patents***

National laws establish the term of protection that patents grant. This term must respect the mandatory standard envisaged by Article 33 of the TRIPs Agreement, which requires that the protection granted by patents last twenty years from the date of the filing of the patent application.

Some countries' legislation<sup>33</sup> provides for the possibility to request and obtain, for pharmaceutical products covered by patents, an extension of the patent protection term beyond the twenty years requirement established by the TRIPs Agreement. The rationale for this extension is to compensate patent holders for regulatory delays occurred in the marketing approval process.

<sup>33</sup> WTO, WIPO, WHO, "Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade", supra, p. 183.

For example, in the EU, a supplementary protection certificate (hereinafter, “SPC”) may be conferred by an EU Member State to extend the terms of a national patent or an EU patent in that country.<sup>34</sup> In this context, the IGBA supports current discussions on the systematic introduction of a ‘*manufacturing waiver*’ in all domestic legal frameworks where there is additional patent protection, as well as in all trade agreements. Such a waiver should not only apply to the manufacturing for export, but also to the manufacturing for stockpiling products for the domestic market ahead of the end of the patent term.

Provisions addressing the extension of the duration of patent rights (hereinafter collectively referred to as ‘*patent term extensions*’) are becoming a standard feature in FTAs concluded by the EU and the US. The TRIPs Agreement does not require WTO Members to provide for additional extension of patent rights to compensate for the time lost in the regulatory review processes; it only requires that the protection granted by patents be available for twenty years from the filing date. Patent term extensions were discussed in *Canada-Pharmaceutical Patents*. In that dispute, the panel stated that extensions due to regulatory delays should not be considered (at least insofar as the TRIPs Agreement is concerned) as part of the rights derived from patent law.

Patents term extension requirements further delay the entry of generic and biosimilar medicines into the market beyond the term of the patent. For this reason, it is important to ensure that trade agreements do not contain patent term extension provisions and, where they do, that such requirements be formulated in non-mandatory terms and in such a way as to allow governments implementing such provisions to retain flexibilities and limit the scope of the extended protection.

A key priority for the IGBA is to ensure that provisions on patent term extensions, where they exist, allow generic and biosimilar manufacturers to export during the period of additional protection. Enabling generic manufacturers to export pending the extended patent protection term would enhance competition by creating an equal level playing field with manufacturers in countries where patent term extensions do not apply. In recognition of the importance that this provision stands to have on trade in generic and biosimilar products, the export exception has been expressly included in the *Comprehensive Economic and Trade Agreement* (CETA) between Canada and the EU.<sup>35</sup> It must be noted that patent term extensions, that were agreed in the context of the negotiations of the Trans-Pacific Partnership (TPP) Agreement, are suspended by the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) by the remaining TPP parties, without the US. This can be considered an important signal against further patent term extensions. Those suspensions should be made permanent.

<sup>34</sup> The relevant legislation is contained in *Regulation (EC) No 469/2009 of the European Parliament and of the Council* of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1, as amended). The US relevant legislation is contained in 35 US Code § 156 on “*Extension of patent term*”.

<sup>35</sup> *Comprehensive Economic and Trade Agreement*, signed on 26 September 2014, available online at: <https://international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng>

### ***SUMMARY OF KEY RECOMMENDATIONS – PATENT TERM EXTENSIONS***

- ✓ Ensure that trade agreements do not contain requirements that extend the terms of the protection granted by patents;
- ✓ Where patent term extensions are present, appropriate language must be included to allow governments implementing such provisions to retain appropriate flexibilities in the implementation of such requirements;
- ✓ Where patent term extensions are present, a specific export exception must be included to allow manufacturers of non-originator products to export during the period of additional protection; and
- ✓ In all domestic legal frameworks where additional patent protection exists, as well as in all trade agreements, a '*manufacturing waiver*' must be introduced. Such a waiver should not only apply to the manufacturing for export, but also to the manufacturing for stockpiling products for the domestic market ahead of the end of the patent term.

## **5.8 Enforcement of IPRs**

The TRIPs Agreement introduced multilateral provisions on enforcement of IPRs, an area of regulation that had not been extensively covered by previous conventions. The TRIPs Agreement requires WTO Members to ensure that IPRs be effectively enforced under their laws, and that penalties punish and deter violations.

The provisions on enforcement are informed by the twofold objective of safeguarding the rights of IP owners while avoiding barriers to legitimate trade. With respect to trade in pharmaceutical products, this objective is reflected in the need to ensure that free trade in legitimate medical products, including generic and biosimilar medicines, is not subject to unnecessary legal barriers to prevent movements of medicines between countries.

The standards established by the TRIPs Agreement with respect to enforcement cover civil and administrative procedures and remedies, provisional measures, special requirements related to border measures, and criminal procedures.

In particular, the TRIPs Agreement requires WTO Members to make available civil judicial procedures and remedies, including injunctions, damages and orders for the disposal of goods, with respect to all IPRs (including patents and test data protection) covered by the TRIPs Agreement.<sup>36</sup> The TRIPs Agreement also requires Members to ensure that judicial authorities have the authority to order provisional measures to prevent infringements from occurring – for example by preventing the entry into the channels of commerce in their jurisdiction of imported goods suspected of infringing IPRs and to preserve evidence.

<sup>36</sup> The TRIPs Agreement provides that, where administrative procedures are available against IPR infringements, they must conform to the principles set forth for civil procedures.

Border measures substantially enable customs authorities to suspend the release into free circulation of the goods suspected to infringe IPRs. In relevant part, the TRIPs Agreement requires that border measures be available for at least counterfeit trademark and pirated copyright goods. However, availability of border measures for infringements of other IPRs, such as patents is optional, as it is for suspected infringing goods destined for exportation and goods in transit, *inter alia*.

The TRIPs Agreement requires that criminal procedures be available (at least) in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. The TRIPs Agreement does not require that criminal procedures be applied to patent or test data infringements.

Certain negotiating partners have placed an increased emphasis on ensuring that FTAs contain robust mandatory disciplines on IPR enforcement, which go beyond the requirements of the TRIPs Agreement. From the perspective of the generic and biosimilar pharmaceutical industries, provisions on IPR enforcement are crucial to ensure that instances of IPR infringements are properly addressed and sanctioned. However, it is equally important to ensure that IPR enforcement does not create unnecessary barriers to legitimate trade in generic and biosimilar medicines.

In this respect, the IGBA considers that agreements placing excessive emphasis on patents may impact the balance achieved by the TRIPs Agreement and run counter to the objectives that need to inform IPR enforcement action. For this purpose, the IGBA calls for maintaining the flexibilities provided in the TRIPs Agreement with respect to enforcement measures.

In particular, the IGBA considers that patents should not be made subject to border measures and criminal enforcement.

In addition, border measures should not apply to transit goods. Border measures applicable to transit goods could threaten legitimate trade in generic and biosimilar medicines, especially where claims are based on alleged trademark violations (which may occur in the pharmaceutical field inasmuch as companies may choose brand names for medicines that sound inevitably similar, in that they are derived from International Nonproprietary Names).

Lastly, the IGBA considers that trade agreements should contain an explicit reference to the right of generic and biosimilar manufacturers to be compensated for damages suffered pursuant to enforcement actions, to constitute a safeguard against abuse of enforcement.

#### **SUMMARY OF KEY RECOMMENDATIONS – ENFORCEMENT OF IPRs**

- ✓ Maintain the flexibilities of the TRIPs Agreement with respect to enforcement measures applicable to patents; and
- ✓ Include an explicit reference to the right of generic and biosimilar manufacturers to be compensated for damages suffered pursuant to enforcement actions, so as to introduce a safeguard against abuse of enforcement.

## 6. The Inclusion of Provisions to Prevent Misuse/ Abuse of IPRs and Anti-Competitive Practices in International Trade Agreements

Competition policy is relevant to the legal framework for intellectual property protection, and the role that it plays in providing “*checks and balances*” to IPRs has been recognised in international agreements and national laws. Legal provisions on competition are an integral and complementary part of IP frameworks. The recognition of the legitimate role that competition law and policy stand to play *vis-à-vis* IPRs is an important element of the overall balance embodied in the TRIPs Agreement, and it has been reflected, to a significant extent, in the IP Chapters of a number of FTAs.

The protection of IPRs has been recognised as particularly important to the pharmaceutical sector because of, *inter alia*, the impact that it has on health concerns. At the same time, it is generally acknowledged that competition, particularly between originators and competing generic and biosimilar medicines manufacturers, is essential in order to keep public health budgets under control and to increase access to medicines to the benefit of patients.

A number of anti-competitive and abusive practices have been identified as being most harmful to the generic and biosimilar sector. As recognised by the European Commission in its Pharmaceutical Sector Inquiry Report, they include strategic patenting,<sup>37</sup> patent litigation,<sup>38</sup> interventions before national regulatory authorities<sup>39</sup> and life-cycle strategies for follow-on products.<sup>40</sup> The overall effect of such practices is to delay generic and biosimilar entry into relevant markets.<sup>41</sup> In this context, the IGBA strongly condemns the recent instances of originator companies that have prevented or impeded access to reference products, in particular in Canada and the US.

The TRIPs Agreement contains a number of provisions on competition law and policy, which reflect the concerns regarding potential abuse of IPRs protected by the agreement. In relevant part, Article 8.2 states that appropriate measures, which are consistent with the provisions of the TRIPs Agreement, may be needed to prevent abuse of IPRs by right holders or the resort

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<sup>37</sup> This is the case of originator companies filing for numerous patent applications for the same medicine (in addition to the base patent), with the aim of creating several layers of ‘defence’ against competition from generic manufacturers. This practice leads to a multitude of patents and patent applications, creating so-called “*patent clusters*” and impeding or delaying access of generic medicines to the market (WTO, WIPO, WHO, “*Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade*”, supra, p. 198).

<sup>38</sup> This anti-competitive practice concerns litigation proceedings initiated by manufacturers of originator products in multiple jurisdictions, which can cause a deterrent to the entry of generic and biosimilar medicines, irrespective of the final outcome. In addition, in some cases, courts may grant injunctions in favour of patent holders while litigation is pending and before the ultimate determination of validity of the patent is made. The Pharmaceutical Sector Inquiry conducted by the European Commission noted that, while the majority of court cases were initiated by originator companies, generic companies won the majority of cases in which a final judgment was delivered (WTO, WIPO, WHO, “*Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade*”, supra, p. 199).

<sup>39</sup> This practice concerns submissions made by originator companies before national authorities when generic companies apply for marketing authorisation and/or pricing and reimbursement status for their medicines. These interferences often lead to delays in generic market entry (for a time span that was quantified by the European Commission as an average of 4 months).

<sup>40</sup> These practices concern the behaviours, put in place by originators, to attempt switching patients of their medicines, which are facing imminent loss of exclusivity, to a so-called second generation, or follow-on, medicine. Where the launch takes place in time to allow patients to switch to the second-generation medicine before generic companies enter the market, the probability that generic companies will be able to gain a significant share of the market decreases significantly.

<sup>41</sup> See, for a complete overview, the European Commission Pharmaceutical Sector Inquiry Report, 8 July 2009 (the relevant documents can be consulted at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry>)

to practices that unreasonably restrain trade or adversely affect the international transfer of technology. This provision is not necessarily concerned only with competition law violations, but with the more general concept of ‘*abuse*’ of IPRs, which is especially relevant to the generic and biosimilar sector.

A number of FTAs contain provisions that are similar to those found in the TRIPs Agreement. In particular, a fair number of FTAs contain provisions in the IP Chapter that guard against abuse by right holders. IP-specific competition provisions vary from agreement to agreement and may range from a general reaffirmation of the principles in Article 8 of the TRIPs Agreement to more detailed provisions addressing abuse of IPR.

These provisions are certainly useful to restate the general principle that countries that are Parties to agreements may act to avoid IPR misuse/abuse and should systematically be established in trade agreements. However, they are formulated in broad terms, leaving important issues to be decided at the national level.<sup>42</sup>

In this light, to address the anti-competitive and abusive practices that are most harmful to the generic and biosimilar sector, the IGBA strongly believes that trade agreements should include a set of binding provisions on competitive safeguards. One particular way in which binding provisions against anti-competitive and abusive practices can be included in FTAs is through the insertion of a competitive safeguard provision, with a list of practices that constitute misuse/abuse of IPRs and that are most harmful to the generic and biosimilar sector (in line with the relevant precedent offered by the Reference Paper on Telecommunications Services<sup>43</sup> with respect to anti-competitive practices in the telecommunications sector).

In addition, trade agreements could also include provisions that consider as grounds for patent revocability a determination of anti-competitive behaviour issued by relevant judicial and administrative authorities.<sup>44</sup>

The IGBA would be glad to engage more closely with negotiators and stakeholders, and remains available to provide more detailed information on its positions and on how it considers that treaty language could best reflect these specific objectives.

### ***SUMMARY OF KEY RECOMMENDATIONS – COMPETITIVE SAFEGUARDS***

- ✓ Include a set of binding provisions on competitive safeguards to protect against IPR misuse/abuse; and
- ✓ Include provisions that call for considering a determination of anti-competitive behaviour issued by relevant judicial and administrative authorities as grounds for patent revocability.

<sup>42</sup> WTO, “A Handbook on the WTO TRIPS Agreement”, supra, p. 133.

<sup>43</sup> Negotiating Group on Basic Telecommunications, Reference Paper, available at: [https://www.wto.org/english/tratop\\_e/serv\\_e/telecom\\_e/tel23\\_e.htm](https://www.wto.org/english/tratop_e/serv_e/telecom_e/tel23_e.htm)

<sup>44</sup> The inclusion of this provision appears most suitable in trade agreements concluded with the US and other countries that normally require or suggest inclusion of disciplines on patentability in trade agreements (this is not the case, for example, for the EU).



## 7. The Inclusion of Appropriate Frameworks on Incentives for Generic and Biosimilar Medicines

Countries may include frameworks to incentivise the access of generic and biosimilar medicines in their markets. Such incentives may be granted to encourage challenges of weak or invalid patents, stimulating competition and innovation, as well as to increase savings for national health care systems and facilitate access to affordable medicines.

The US introduced provisions establishing a legal incentive to promote generic competition through the Hatch-Waxman Act. In particular, in the US, the first company (or companies) that files a generic application containing a patent challenge certification may be rewarded with 180 days of generic market exclusivity. This mechanism, referred to as Hatch-Waxman exclusivity, has been, since its implementation, a driver of early generic access and has contributed greatly to the number of patent challenges in the US. As a result, while having the biggest originator pharmaceutical market in the world and very high levels of intellectual property protection, the US has also the highest level of generic utilisation in the world (i.e., over 89% of all prescriptions dispensed in the US are generics<sup>45</sup>). The US experience, therefore, provides an example as to why incentives for generics to challenge weak or invalid patents should be part of a balanced IPR regime. A similar mechanism was recently introduced in South Korea.

There are several features of the US market that explain the success of the Hatch-Waxman exclusivity system of incentivisation. These features are not present in other countries, so that generic incentivisation needs to be provided in different forms. Market exclusivity periods (of the kind provided by the Hatch-Waxman Act) are most suitable for countries with a patent linkage system. Incentivisation through pricing and reimbursement policies could apply in countries without patent linkage systems (e.g., the EU).

Providing for a clear framework for incentives is particularly relevant in countries with both patent linkage and high data protection, as it would allow balancing of the protection granted to originators through patents and other IPRs, and stimulating challenges of weak patents.

In light of these objectives, the IGBA calls for the inclusion, in trade agreements, of a framework providing for appropriate incentives to generic and biosimilar competition. The formulation of such a requirement must take stock of the divergences among IPR systems and the different negotiating contexts that are relevant to the pharmaceutical sector, and be adaptable and sufficiently flexible to suit all relevant frameworks.

The IGBA remains available to discuss further details of its proposal with negotiators and relevant stakeholders.

### ***SUMMARY OF KEY RECOMMENDATIONS – INCENTIVES***

- ✓ Include a framework for appropriate incentives to increase generic and biosimilar competition and grant access to generic and biosimilar medicinal products.



## 8. Conclusions

**In conclusion, the IGBA recommends that:**

### ***Fostering regulatory convergence of the requirements for the approval of generic and biosimilar medicines, and recognition of compliance inspections***

- Trade agreements establish appropriate frameworks to promote regulatory cooperation in generic and biosimilar medicines and the mutual recognition of compliance inspections. The purpose of cooperation is to achieve convergence of requirements with respect to the authorisations of generic and biosimilar medicines and agree on mechanisms to avoid unnecessary and duplicative inspections;
- Regulatory cooperation and regulatory convergence rest on a set of core principles and objectives that are to be systematically embedded in trade agreements. These principles include increased transparency requirements and participation in decision-making processes, where the objectives must provide for the reduction of unnecessary barriers to trade that result from avoidable divergences of regulatory requirements, partly also through a commitment to participate in the process on international standardisation and through mechanisms that institutionalise regulatory exchanges. These principles and objectives need to be restated and properly spelled out in trade agreements;

### ***The regulation of intellectual property rights in trade agreements***

- Trade agreements should not seek to provide for IPR protection that results in delayed entry of non-originator products into the market and hampers patient access to generic and biosimilar products;
- Instead, trade agreements should seek a balanced approach with respect to the regulation of IPRs, based on the standards established by the TRIPs Agreement;
- With respect to negotiations concerning countries and territories where the level of IP protection is already high, negotiations concerning IPRs do not seek to harmonise IPR frameworks, but recognise the different approaches taken by the negotiating parties with respect to IPR protection; and
- In all domestic legal frameworks where additional patent protection exists, as well as in all trade agreements, a 'manufacturing waiver' must be introduced.

***The inclusion of provisions to prevent misuse/abuse of IPRs and anti-competitive practices in international trade agreements***

- Trade agreements contain binding provisions to prevent misuse/abuse of IPRs and anti-competitive practices affecting generic and biosimilar products; and

***The inclusion of appropriate frameworks on incentives to generic and biosimilar medicines***

- Trade agreements provide a framework to incentivise access of generic and biosimilar medicines.
  - The IGBA believes that, if implemented, the key principles and recommendations outlined above and described in greater detail in the preceding sections would bring substantial improvements to the regulatory environments affecting generic and biosimilar medicines, stimulating trade and increasing patient access to high quality generic and biosimilar medicines.
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# TRADE PRINCIPLES:

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## GENERIC AND BIOSIMILAR MEDICINES

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INTERNATIONAL GENERIC AND  
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