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Ambassador JM Matjila
Director General
Department of International Relations and Cooperation
460 Soutpansberg Road
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Dear Ambassador Matjila,

I am pleased to forward, for your information, the letter addressed to the Director General for Trade and Industry, Mr Lionel October, that Mr. Rupert Schlegelmilch, Director for Services and Investment, Intellectual Property and Public Procurement at the Directorate – General for Trade, sent regarding the Draft National Policy on Intellectual Property.

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Yours sincerely,

Roeland van de Geer
Head of Delegation

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EUROPEAN COMMISSION
Directorate-General for Trade

Directorate B - Services and investment, Intellectual Property and Public Procurement
The Director

Brussels, 17 OCT. 2013
B.3/ACJ/SH

Mr Lionel October
Director-General
Department of Trade and Industry
Republic of South Africa

Dear Mr October,

I refer to the "Draft National Policy on Intellectual Property" of the Republic of South Africa, which was published on 5 September 2013, and would like to offer comments, in the spirit of our dialogue as established by the Trade, Development and Cooperation Agreement.

In the annex attached to this letter you will find more detailed comments from my services on the draft policy. I would though like to make some general comments here.

Firstly, let me highlight that we are pleased that there is already a standard of commitment to intellectual property protection and enforcement that exists between us under the European Union – Republic of South Africa Trade, Development and Cooperation Agreement[1], not to mention under the Agreement on Scientific and Technological (S&T) Cooperation between the European Community and the Republic of South Africa. [2]

I also welcome the broad objectives of the Policy that you outline at the outset of this document, such as the development of a legal framework on IP and its contribution to development, stronger enforcement mechanisms, and the promotion of research, innovation and public awareness.

Indeed, as ministers declared at the Regional Preparatory Meeting for Africa in Dar es Salaam in March 2013 ahead of the Annual Ministerial Review of the UN Economic and Social Council: "policymakers in Africa should redouble efforts to develop their legal and policy frameworks, including their intellectual property legislation and policy, so as to release the region's untapped potential" - we share this goal of untapping creativity and encouraging innovation. A well-developed IP regime will help in leveraging the trade potential of intellectual assets, safeguard health and safety, tax revenues and jobs by

[1] Article 46(1) TADC: "The Parties shall ensure adequate and effective protection of intellectual property rights in conformity with the highest international standards. The Parties apply the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) from 1 January 1996 and undertake to improve, where appropriate, the protection provided for under that Agreement."
[2] http://ec.europa.eu/research/iscp/pdf/st-agreement-1997-south-africa.pdf#view=fit&pagemode=none

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combating IPR infringement more effectively and improve legal certainty, and helping the environment to be more conducive to inward investment and technology transfer.

In regard to your draft national policy, I would like to make some specific comments:

- I must emphasise that the EU and its Member States fully fulfil their international obligations, such as in regard to the World Trade Organisation (WTO) and its Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). I therefore strongly disagree with the view that we have failed to meet our commitments under Article 66.2 of TRIPS, and point you to our annual submissions to the WTO which detail our substantial activities.

- Also, the claim that "generally bilateral trade agreements undermine the inclusion" of TRIPS flexibilities and exceptions is contradicted by the EU's bilateral trade agreements, which reaffirm these flexibilities, as is also the case with the European Union – Southern African Development Community Economic Partnership Agreement currently being negotiated.

Policy on intellectual property must strive to find a balance between encouraging innovation and ensuring protection of the public interest. This is at the heart of our approach.

I sincerely hope you take these comments and those attached in the annex into consideration as you continue forward in the formulation of your intellectual property policy, and look forward to further communication with you in the near future.

Rupert SCHLEGELMILCH

cc: Ambassador Jerry Matthews Matjila, Director General of the Department of International Relations and Cooperation

ANNEX:

EU comments on South Africa's "Draft National Policy on Intellectual Property, 2013"

Data Protection (pps 13, 22)

"... multinational pharmaceutical companies have lobbied their Governments... to put pressure on the governments of developing countries not to disclose information from clinical trials to third parties such as generic companies... the costs for developing generics will be so high that it will frustrate access to public health."

"There should be no general or blanket data protection of information that is at the disposal of the medicines regulatory authority, the Medicines Control Council (MCC), but rules on unfair trade practices and protection of confidential information relevant for competitiveness should be in place."

Let us recall that WTO members as part of the TRIPS Agreement agreed (Article 39.1) that in order to prevent unfair competition, as defined in Art.10bis of the Paris Convention, members shall protect undisclosed information and data submitted to governments and governmental agencies. The protection of such data, therefore, is an international obligation.

Although lengths of protection vary internationally, what is important is to construct a balanced policy between encouraging the creation of innovative drugs and ensuring public health. As the WHO recognises, "access without innovation would mean a declining capacity to meet an evolving global disease burden".[3]

Patent extension (p14)

"The extension of patents by its nature is not good as it extends the lifespan of a patent..."

This statement neglects the fundamental rationale behind extensions. Patent term extension (called a "supplementary protection certificate" (SPC) in the EU) is a tool to compensate for any excessive delay in granting the first marketing approval in a country, which often lead to a reduction of the effective patent term. This is a measure that aims at putting on equal footing in terms of patent protection pharmaceutical and other innovative products as marketing approvals (MA) - that considerably reduce the period of time during which an innovative medicine can be commercialised - are generally not necessary for the latter.

Plant variety protection (p20)

The Plant Varieties Act is not adverse to access to technology because the 'breeder exemption' authorises access by other breeders to the improved protected variety for further breeding, without the authorisation of the right holder. Therefore the new technology, which in this case is a plant variety, is further accessible for breeding advancement in order to response various challenges such as climate change.

Also, plant breeders rights (PBR) are not at the expense of other traditional agricultural system or natural plants because:

[3] http://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm

- it is not possible to protect a discovery from the wild; a breeder needs to further develop the plant material into a variety;

- it is only possible to protect new varieties, which have not been commercialised before (1 year in the country);

- PBR does not restrict or affect the marketing of traditional varieties.

Agriculture and genetic resources (p.25)

"The TRIPS Agreement provides that member states must apply for some sort of IP protection to plant varieties either as patents or other kinds of protection, namely sui generis. It has been found that the sui generis of plant varieties protection (PVP) has not been effective at encouraging research on crops in general and the kind of crops grown by poor farmers in particular. The PVP is designed for commercial farmers from developed countries and poses a threat to the practices of many farmers in developing countries of reusing, exchanging and reselling seeds. UPOV is not suitable for developing countries that do not have significant commercial culture."

This statement indicates that PVP was not able to encourage breeding activities in crops in general. However, the following data contradict this:

- Number of genera and species protected by UPOV Members: + 3000.
- Practical experience for DUS testing by UPOV Members: + 2580 genera and species.
- Cooperation agreements between UPOV members: + 1900;
- UPOV Test Guidelines for around 295 genera and species provide guidance for more than 90% of application for plant breeders' rights.

PVP does not affect the practices of many farmers of reusing, exchanging and selling seeds of local tradition varieties. For country which are members of UPOV 1991, there is an optional mechanism, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a new protected variety for the planting of a further crop - subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society. This option is only for new protected varieties and does not regulate traditional varieties.

The aim of UPOV is to provide and promote an effective system of plant variety protection with the aim of encouraging the development of new varieties of plants for the benefit of society. In addition, the compulsory exceptions for research, for further breeding, and for private and non-commercial use by farmers, gardeners indicates that the case of subsistence farmers is also considered.

We would suggest that the Recommendation be amended as: "The PVP system of South Africa in currently conform to UPOV 1978 should be amended accordingly to UPOV 1991, in order to introduce the optional exception on farm saved seed which permit farmers, on their own farms, to use part of their harvest of a new protected variety for the planting of a further crop - subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society."

In addition the clear exemption for private and non-commercial use will cover the case of subsistence farmers.

Technology transfer (p30)

"Recent analysis of 2006 country reports to the TRIPS Council concluded that developed countries have generally failed to meet their obligations in relation to Article 66.2."

We would suggest that the recent annual submissions that the European Union has made to the WTO in regard to its fulfilment of obligations under Article 66.2 demonstrates that the statement above is wholly incorrect. Without even mentioning EU Member State programmes, a few examples of EU programmes over the last few years include the European and Developing Countries Clinical Trials Partnership (EDCTP), CAAST-NET, IST-Africa Initiative, the Science and Technology – Europe Africa Programme (ST-EAP).

The most recent summary of activities from 2012-13 has just been submitted, and should be published by the WTO imminently.

Copyright, software and internet (p32)

"Many developing countries have joined international treaties in the copyright area, but can hardly show benefits that flow from such treaties."

UNCTAD itself has described the benefits that flow, for example, from the WIPO Copyright Treaty: "Article 6(1) of the [WIPO Copyright] Treaty provides an exclusive right to authorize the making available to the public of originals and copies of works through sale or other transfer of ownership, that is, an exclusive right of distribution. Such a right, surviving at least until the first sale of copies, is a powerful tool in the fight against piracy because it makes it possible for the officials in charge of enforcement to seize illegal copies where they find them in the marketplace, in addition to having to track down the person responsible for the act of reproduction, who often will not be the person offering the copies for sale to the public." [4]

"Access to the internet in developing countries is limited and impacted upon by various factors. In this regard, the 'fair use' principle under copyright regime may be limited by or severely restricted by forms of technological protection, e.g. encryption that restricts access more severely than that under copyright principles. This is clearly demonstrated by the EU and US jurisdictions."

Technological protection measures are applied to restrict acts which are not authorised by the right holder of the protected subject matter. In EU law we have a list of permitted exceptions rather than a general fair use provision. There is no "conflict" with copyright principles.

Patent reform (p34)

"Industrialised nations in the main from the GATT system days used to control the system and this is no exception to the WTO system."

The WTO is a consensus-driven organisation.

Institutional architecture (p36)

[4] http://www.unctad.org/en/docs/ditctab20103_en.pdf

"Seizures of generic drugs are taking place under the pretext of seizure of counterfeiting"... "EU countries are the main culprits"

This is a gross generalisation of detentions that took place five years ago and have not reoccurred. Over the past four years no cases of EU customs detaining generic medicines in transit have been reported. EU customs do not detain generic medicines "under the pretext of seizure of counterfeiting".

"The World Customs Union (WCU) is being persuaded to deal with the enforcement of IP. WCU is not an enforcement agency on IP matters, but the private sector of the developed countries are initiating a decision-making body in an undemocratic way to deal with IP issues."

We understand that the document intends to refer to the World Customs Organization (WCO). The EU and its Member States are members of the WCO and actively cooperate within the WCO with other members of that international organisation. The EU, together with many other WCO members, including developing countries, consider that IPR border enforcement by customs is an important element in the fight against IPR infringements; and that the WCO must address this customs matter.

Members of the WCO are free to democratically discuss and express their point of view on any customs related issue, such as IPR border measures, and the EU in particular is not aware of efforts to develop a "decision-making body" concerning IP enforcement, and in particular of such a body initiated by the private sector.

In that regard, it might be interesting to note that South Africa held the chair of the Counterfeiting and Piracy Group (CAP) within the WCO in 2010/2011.

"UNCTAD per se is not convinced that the IP system is working for the good of trade and economic development for developing countries."

In fact, UNCTAD has stated the opposite. The 2010 UNCTAD Creative Economy report notes for example that, "It is widely recognized that any analysis of the creative economy must consider the role of intellectual property, which is a key ingredient for the development of the creative industries in all countries. Intellectual property law is a major policy tool and part of the regulatory framework around the creative industries. If properly managed, it can be a source of revenue for both developed and developing countries." [5]

We would also, as another example, make reference to conclusions from the 2010 OECD study on Policy Complements to the Strengthening of IPRs in Developing Countries: "The results of the macro-level assessment provide a clear indication of the inter-relationships between indicators of economic performance and protection of three main types of intellectual property (patents, copyright and neighbouring rights and trademark rights). Moreover, the significance of the results across the system of equations points to a virtuous circle, whereby improvements in the IPR environment are associated with improved economic performance – in particular with respect to FDI – and, in turn, further improvements in the IPR environment." [6]

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[5] http://www.unctad.org/en/docs/ditctab20103_en.pdf

[6] http://www.oecd-ilibrary.org/policy-complements-to-the-strengthening-of-iprs-in-developing-countries_5km7fmwz85d4.pdf?itemId=/content/workingpaper/5km7fmwz85d4-en

It is worth noting that the Common Market for Eastern and Southern Africa (COMESA) has put intellectual property at the core of its growth strategy. In its draft IP policy of May 2013, it recognizes that "in a 'knowledge-based and innovation-driven economy' the generation, creation, innovation and management of knowledge through IP play a crucial role in wealth creation and national development".

"Institutions from developed countries provide advice on IP. It is, however, advisable to cautiously filter such advice as it may undermine the multilateral arrangements and may not be sensitive to IP and development."

The European Commission has a broad development and poverty reduction mandate in its external co-operation. As such, the objectives of trade-related programmes, including IP programmes, relate to the economic development strategies of the partner country concerned. It is important to recall that all assistance is demand-driven from partner countries. Depending on the partner countries' needs, IP technical co-operation can include focus on activities such as:

- To help partner countries to adopt laws and regulations that are compliant with the TRIPS Agreement and supportive to national objectives (economic development, social and health objectives, for example);

- Advice and clarification concerning the flexibilities and options available under the TRIPS Agreement, notably with regard to access to medicines, traditional knowledge and genetic resources, and geographical indications, so that IP protection and enforcement responds to domestic policy objectives. For example, the EU is ready to help partner countries to implement the Doha Declaration on TRIPS and Public Health, and more generally speaking, the EU can provide advice on how to reconcile the need to encourage innovation with the need to protect consumers and competition;

- Advice on how to organise the administrative apparatus, e.g. patent offices, collective management societies.

- To provide training for administrative and judicial staff;

- To increase awareness amongst potential right-holders;

- Training for staff in the administration of IP protection and management methods.

IP and development (p39)

"Developed countries are demanding that 'IP enforcement and harmonisation' should take place without delay... this should be so whether or not benefits accrue to developing countries."

Firstly, the EU seeks to take into account development cooperation objectives in non-development policies. The commitment towards Policy Coherence is embedded in the European Consensus on Development adopted in December 2005.[7] The European Commission reports every two years on progress made on policy coherence for development by the EU in a number of areas, including trade.

Secondly, international harmonisation enables broad alignment of rules and thereby a more predictable IP environment. The continuously growing demand for IP rights puts IP

[7] http://ec.europa.eu/europeaid/what/development-policies/policy-coherence/

offices under strain and risks either affecting the quality of the rights granted or delaying the granting of rights. Better alignment of legislation between one country and another would certainly help, as this would make mutual recognition a possible option, but discrepancies in rules and in quality mean that much remains to be done. Certain cooperation mechanisms are already in place or being developed (based on the Patent Cooperation Treaty – PCT – and/or on initiatives such as Patent Prosecution Highways) to ensure that at least part of one patent office's work (e.g. search work) can be reused by other offices at which an application for the same invention has been filed.

Thirdly, there are good reasons for enforcement to take place in a swift manner. Available evidence suggests that falsified and other substandard medicines, meaning those that are not approved under a regulatory system as being safe and effective, are most prevalent in countries which have weak regulatory and enforcement frameworks. Pirated and counterfeit goods most often are produced with disregard to health, safety and quality requirements. Such products represent a danger to consumers as evidenced by the increasingly frequent seizures of fake medicines, food products, car and plane parts, electrical appliances and toys. This is a significant threat. For example, in April 2013, a customs operation was carried out in 23 African countries by the World Customs Organisation. "More than one billion articles and in particular 550 million doses of illicit, potentially dangerous if not deadly medicines were intercepted including: antibiotics, painkillers, anti-inflammatory drugs, medicines for high blood pressure and diabetes and food supplements." [8]

Also, we would point your attention to the European Union's support for the recent extension (for a further eight years) of the transitional period for least-developed countries to implement the World Trade Organisation's (WTO) Council on Trade Related Aspects of Intellectual Property Rights (TRIPS).

"It is no wonder that the WIPO development agenda may be conflicted as it has to keep the funders happy due to the fact that they are the main users of the system."

WIPO is a consensus-driven organisation – therefore the level of its Member States' contributions cannot be in any way linked to its agenda. We note that in the proposed WIPO Program and Budget for 2014/15, specific development expenditures are again forecast to be over 20% of the total budget.

[8] http://www.wcoomd.org/en/media/newsroom/2013/june/wco-and-iracm.aspx