

Ministerie van Economische Zaken, Landbouw en Innovatie

> Retouradres Prins Clauslaan 8 2595 AJ Den Haag

President House of Representatives of the States General Postbus 20018 2500 EA The Hague

Datum 13 August 2012 Betreft Reaction to study 'Harnessing IPR for Development Objectives'

Dear Madam President,

With reference to the answers to the questions in Parliament of 31 January 2012<sup>1</sup> on patents, I am sending you, also on behalf of the Minister of Economic Affairs, Agriculture and Innovation and the State Secretary for European Affairs and International Cooperation, the further reaction, as promised, to the main conclusions and recommendations of the report entitled 'Harnessing Intellectual Property Rights for Development Objectives'.<sup>2</sup>

The report is the result of the Schokland agreement between the Ministry of Foreign Affairs and the MDG-profs Platform, a partnership between Dutch knowledge institutes and ministries, aimed at giving knowledge institutes a greater role in realising the Millennium Development Goals (MDGs). The Platform's aim is to document the relationship between intellectual property rights (IP) and the realisation of MDGs and make policy recommendations. The emphasis in the report was on Africa (notably Uganda and South Africa) and the Netherlands.

The report's recommendations are partly directed at Dutch actors like the Dutch Government and Dutch knowledge institutes. The other part is directed at African government authorities, knowledge institutes and the groups in society involved. Attachment 1 presents a survey of recommendations aimed at the Dutch actors.<sup>3</sup>



- Parliamentary session 2011/12, Appendix 1356
- <sup>2</sup> http://www.wotro.nl/nwohome.nsf/pages/NWOP\_8QUN2G
- <sup>3</sup> 'Harnessing Intellectual Property Rights for Development Objectives' p. 409 tot en met p. 415 and p. 417 424 (recommendations)

Plantaardige Agroketens en Voedselkwaliteit cluster

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Bijlagen 1

### Summary of present letter

This letter discusses the report's main conclusions and recommendations. The recommendations and the reactions to them are explained first.

Section 1 details the relevant Dutch policy and the Dutch position on IP in international forums like the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) and the International Union for the Protection of New Varieties of Plants (UPOV). Section 2 describes the Dutch approach in relation to the context of domestic policy. The following items will be discussed:

- Awareness of the possibilities of humanitarian use licenses, patent pools;
- 2) Management of publicly funded research;
- 3) Access to research publications (open access);
- 4) Valorisation policy.

In Section 3, examples are given of concrete actions contributing to better access to seed and propagating stock for food production and to pharmaceutical drugs to promote health in developing countries. This in support of MDG 1 (eradicate extreme poverty and hunger) and 6 (combat HIV/AIDS, malaria and other diseases).

### The report's recommendations

In essence the report's recommendations for Dutch actors are based on two key principles:

- When setting up IP systems in developing countries the country's level of development and the local context should be taken into account; in Chapter 1 (International) this is discussed in further detail.
- MDGs should be considered when setting national and international research and innovation agendas; in Chapter 2 (National) this is discussed in further detail.

I support the report's key principles, conclusions and recommendations, notably:

## 1. International

A properly functioning IP system is vital to stimulate innovation and to enable access to and transfer of technology and thus economic development. For a properly functioning IP system the country's level of development and the local context should be taken into account. This is why scope has been created under the WTO for a flexible IP system. This means that a balance must be struck between the interests of those entitled to the IP and the public interests served by the use of, and access to the developed products and the (further) application and development of the innovations involved.

I agree with the report's conclusion that developing countries should be given the scope if they so desire to make use of the flexibility provided under the TRIPS Agreement, including the special regime for the least Plantaardige Agroketens en Voedselkwaliteit cluster Plantgezondheid/Fytosanitaire Martkttoegang

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developed countries (LDCs)<sup>4</sup> in the context of which these countries should make their own choices. This is a stance championed in international forums for some time and this will continue.

### 2. National

I recognise the importance of Dutch research policy that takes account of the importance for developing countries of access to the knowledge and innovations relevant to them.

I also recognise the fact that many of the relevant Dutch actors do not seem to be fully aware of the possibilities provided by the IP system in the exercise of IP rights, like humanitarian use licenses (HULs), patent pools and access to research publications (open access). I will, if the opportunity arises, draw their attention to these possibilities and point out their importance.

Below I will explain this in more detail.

### 1. INTERNATIONAL

# 1.1 WTO Trade Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement under the WTO is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. In this context and under additional agreements and negotiations a number of flexibilities have been adopted. These flexibilities are often subject to a number of preconditions, laid down in the relevant articles. In negotiations on trade liberalisation or EU economic partnerships the Government has always emphasised the importance of the flexibilities under the TRIPS Agreement for developing countries and will continue to do so. In this respect the Government has also indicated that the level of development of the countries concerned and that a measure of restraint should be exercised in adopting provisions that go beyond the TRIPS' requirements.<sup>5</sup>

Preferably such provisions should have a demonstrably positive impact and must be at the request of the LDCs themselves. It should be noted that not all LDCs are the same. A one-size-fits-all approach is out of the question here. In some cases major economic interests (trade relations, Plantaardige Agroketens en Voedselkwaliteit cluster Plantgezondheid/Fytosanitaire Martkttoegang

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<sup>&</sup>lt;sup>4</sup> Under article 66.1 of the TRIPS Agreement LDCs shall not be required to apply its provisions, other than Articles 3, 4 and 5, for a transitional period. Under article 66.2 developed WTO countries shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDCs. All other articles including the flexibilities therein apply to all WTO members irrespective of their economic status.

<sup>&</sup>lt;sup>5</sup> Parliamentary session 2010/11, 22 112, 1195 (BNC fiche to Communication on Intellectual Property).

the level of industry/innovation and the level of fakery/piracy) may raise a country's level of ambition with respect to protecting and enforcing IP rights. This is set out in the policy document '*De ontwikkelingsdimensie van prioritaire internationale publieke goederen*'.<sup>6</sup>

Concerning WTO-TRIPS I will:

- Continue to emphasise the importance of the flexibilities under the TRIPS Agreement.
- Assist developing countries if they so desire in formulating and implementing an effective *sui generis* system to protect their intellectual property rights (article 27.3 under b of the TRIPS Agreement).
- Adopt a positive stance on extending the period of transition for LDCs (which is due to expire on 1 July 2013), provided the requirements of article 66.1 of the TRIPS Agreement are met.
- In negotiations on bilateral or regional trade liberalisation between the EU and LDCs urge for an approach in line with the TRIPS Agreement.
- Incorporate the requirements of article 31 of the TRIPS Agreement with respect to compulsory licensing in the 1995 Patents Act. Preparations are in progress and the full article will be incorporated with the next amendment.

# 1.2 World International Property Organization (WIPO)

With respect to WIPO, I would like to indicate that on the adoption of the WIPO Development Agenda and its 45 recommendations in 2007 WIPO members have committed themselves to the Development Agenda and its implementation.

The recommendations are aimed at increasing LDCs' knowledge of intellectual property rights and putting them to better use, and at making WIPO more development-friendly. A number of these recommendations were implemented directly, the rest are being realised through projects of the WIPO Development Committee set up in 2007. Many of these projects are directly related to the WIPO report recommendations like the use of flexibilities, MDGs and WIPO's contribution to them. Our approach of endorsing the MDGs and integrating them where relevant in WIPO policy sufficiently meets the recommendations and does not need further revision

# **1.2** International Union for the Protection of New Varieties of Plants (UPOV)

In developing countries there is a great need to develop crops for local market demand and for non-primary agriculture. The potential contribution better varieties can make to food security and better income is quite substantial. These opportunities are not used to the full as there are too few incentives in place to develop traditional varieties and produce good propagating material.

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<sup>&</sup>lt;sup>6</sup> Parliamentary session 2011/12, nr. 32 605, n 57

For developing countries it is very important there are sufficient incentives in place to develop new varieties, for agricultural production for export and for domestic production and the local market.

Following on the agreements made under TRIPS developing countries are encouraged to put in place an efficient system for the protection of varieties. In this respect I believe that UPOV 1991 cannot be applied to all developing countries but that a differentiated approach is desired.

For export purposes modern varieties are best. Without them the country's supply will be less competitive in export markets. However, if plant breeders find their rights are not properly protected they will not develop or supply such varieties. A plant breeder will want protection under the UPOV 1991.

Local breeders however need protection for varieties grown for the local or regional market. Local plant breeders need protection in their own country to further employment and food security. Countries should make their own choices in this respect.

I intend to promote the innovative capacity of local seed and plant development systems by means of joint programmes and the transfer of plant developing and plant breeding knowledge. The Netherlands will continue its efforts to improve global access to genetic resources for plant breeding and plant breeding research. Knowledge institutes and the sector could make substantial contributions here. The Netherlands' approach is in line with the 'World Seed Project', an initiative taken at the 2nd World Seed Conference in 2009, in which five international organisations (FAO, ISF, ISTA, OECD and UPOV) collaborate with a number of developing countries to strengthen their seed sectors.

With respect to UPOV the Wetherlands will:

- Urge for greater scope for the 'private and non commercial use exemption' in UPOV 1991 than is currently the case. This will allow small farmers that use protected varieties to trade their surpluses on the market and exchange seed among themselves.
- Request scope for a differentiated approach to seed systems in European bilateral and regional free trade agreements with developing countries with the emphasis on effective enforcement.
- Contribute through public research to the knowledge and improvement of local seed and breeding systems in developing countries, including the transfer of knowledge on developing and enforcing plant breeders' rights in line with the local context.
- Develop in cooperation with the sector one or more projects on differentiated seed systems and crops for Sub-Sahara Africa as part of the top sector Horticulture and Propagating Stock agenda.

## 2. NATIONAL

2.1 National IP policy and raising awareness

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I believe improvements can be made in raising knowledge, awareness and application in IP instruments in a development context. It would seem that potential for the application of the Humanitarian Use Licences, mentioned earlier, and patent pools in public-private partnerships with developing countries are not widely known.<sup>7</sup> These instruments generally provide better starting points for developing countries to obtain access and use of knowledge and technology protected by IP rights.

Organisations like the World Health Organization (WHO) for medicine and the Consultative Group on International Agricultural Research (CGIAR) for agriculture, have further developed IP instruments like these and made them available to be used in public-private partnerships. I would like to point out that these are not off-the-shelf instruments, but tailored to meet the needs of every new research consortium and partnership. Knowledge and awareness can contribute significantly to this process.

A centre of expertise would help provide assistance to research consortiums and public-private partnerships in exploring the Freedom to Operate (FTO)<sup>8</sup>, and in designing HULs and patent pools. It could also raise awareness of the development dimension in publicly financed research programmes being undertaken by the Netherlands Organisation for Scientific Research (NWO), technology foundation STW, the Royal Netherlands Academy of Arts and Sciences, and associated knowledge institutes, Top Sectors of the Dutch economy and large technological institutes. As we currently have a caretaker government, I will refer the decision on a centre of expertise to the new Minister.

# 2.2 National IP policy and government-led research

I recognise the importance of Dutch research policy accommodating the need for developing countries to gain access to relevant knowledge and innovation. Where possible, our public responsibility will enable us to refine our policy to further the realisation of MDGs. This is highly appropriate for the development, application and dissemination of knowledge relevant to development supported by the Ministry of Foreign Affairs, including the knowledge platforms recently introduced by the Ministry. These knowledge platforms for the four key areas in development cooperation policy and a fifth for innovative intervention strategies bring Dutch researchers and knowledge institutes and

Humanitarian Use Licences (HULs) are intended to achieve the greatest social impact of publicly financed and patented technologies, often including royalty free availability for further development. One example is the ABSB project (www.sourcewatch.org/index.php?title=U.S.\_Promotion\_of\_Ag\_Biotech\_in\_Egypt). Patent pooling allows patent holders to voluntarily share their high-potential medicines or technologies in a pool with the aim of simplifying complex licence negotiations and increase competition, reducing legal obstacles and development costs and harmonising standards. One example is the Medicines Patent Pool (www.medicinespatentpool.org).

<sup>8</sup> Freedom to Operate: research or specific action, like commercialisation of a product, can be carried out without infringement of the intellectual property rights of others.

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researchers from developing countries and international organisation together to design a common research agenda, to share the latest knowledge and their experiences and to relate the results to policy makers and make use of them in practice.

On condition that the interests of the holders' rights to IP are not infringed upon, we will work to:

- promote active contribution by research institutes and funding organisations to making innovations available to developing countries in Top Sectors of Horticulture & Propagating Materials and Agro & Food including the association Top consortiums for Knowledge and Innovation.
- ensure that NWO pays extra attention in its subsidy conditions to IP policy that contributes to the realisation of MDGs. This may be achieved for instance by standard inclusion of HULs in licensing contracts with developing countries and subsidy beneficiaries.
- Encourage all NGOs that receive public funding and conduct research, including the CGIAR, to apply HULs where they own or obtain the eligible IP rights or when they commission research and do not obtain IP rights including the right to sub-licences for humanitarian purposes.

# 2.3 National IP policy and open access

I am in favour of free access to research publications and where possible to the results of publicly-funded research. One exception would be when it concerns private participants who must be given the opportunity to earn back their investment by establishing their IP rights. In these cases differentiation could be applied in exercising their rights, for instance in applying HULs to benefit developing countries.

In concrete terms we will work towards ensuring

- that the open access principle will be adopted as far as possible across the board in the publication of research financed from public funding in scientific journals, and where possible from research data and results.
- encourage open access publicity policy by Ministries for results of policy supporting research. The costs resulting from open access publication for the author or research institute, would be included when awarding the contract.

# 2.4 National IP policy and valorisation

In 2010 the Ministries of Economic Affairs, Agriculture and Innovation; and Education, Cultural Affairs and Science set up a valorisation programme aimed at strengthening and securing the infrastructure in and around knowledge and educational institutes. This is intended to ensure knowledge is better exploited and will lead to innovations beneficial to the economy and society, for instance in new products, services and processes, and new commercial activity. Plantaardige Agroketens en Voedselkwaliteit cluster Plantgezondheid/Fytosanitaire Martkttoegang

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Under the 2008 *Valorisatieagenda*, knowledge organisations, government and the private sector committed to developing a shared set of indicators for education, entrepreneurship and valorisation. The national valorisation committee which stimulates implementation of the *Valorisatieagenda* plays a role here. The State Secretary for Education, Culture and Science has agreed with institutes of higher education that they will contribute to this indicator development, with the aim of achieving a good set of indicators by 2016. Some steps have already been taken to develop indicators.<sup>9</sup> Valorisation is intended to cover a wide area of knowledge from all disciplines, from fundamental, practical and applied research and all forms of its exploitation for economic and societal benefits. This would logically include the exploitation of knowledge from the Netherlands beyond our borders.

### 3. Access to food and medicines; other activities

The report is primarily directed to MDGs 1 (Eradicate extreme poverty and hunger) and 6 (Combat HIV/AIDS, malaria, and other diseases). In relation to access to food and medicine, I believe that this is not possible without ensuring responsible use of food and medicines in the developing country concerned.

It is important for instance to have reasonably priced good quality medicines available, as well as the necessary logistics, infrastructure, level of knowledge, sufficient doctors, storage facilities and controls on use of medicines as well as healthcare infrastructure. Similar conditions apply to propagating material for food production.

To accelerate the development of medicines and access to them, the Netherlands is supporting seven Product Development Partnerships (PDPs) for neglected diseases, the Tropical Disease Research Programme, the Global Fund for Aids, Tuberculosis and Malaria and the Global Alliance for Vaccines and Immunisation.

In order to build the capacity of African research institutes in the area of medicines, the Netherlands is supporting the European and Developing Countries Clinical Trials Partnership (EDCTP) and the Council on Health Research for Development (COHRED). We are also supporting the production of the Access to Medicines Index, which ranks pharmaceutical producers by analysing their performance on providing access to medicines.

In the area of medical products specifically geared to reproductive health the Netherlands also supports the United Nations Population Fund's Global Programme for Reproductive Health Commodity Security and the Universal Access to Female Condom programme. Plantaardige Agroketens en Voedselkwaliteit cluster Plantgezondheid/Fytosanitaire Martkttoegang

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<sup>&</sup>lt;sup>9</sup> See EU study: 'A Composite indicator for Knowledge Transfer', Finnen et al (2011)

The Netherlands also supports the Integrated Seed Sector Development programme started in 2010 in several African countries to increase access to high-value seed and propagating material. This programme addresses the African Union Commission's wish to improve local, national seed systems.

As an extension to this I will also aim to promote participatory breeding programmes for the development and use of quality propagating material and seed that is adapted to local conditions and wishes.

In addition, the State Secretary for European Affairs and International Cooperation and I support the Access to Seeds Foundation to encourage the private sector to improve access to quality propagation material for developing countries. This could be achieved for instance by drawing up an Access to Seeds Index, along the lines of the Access to Medicine Index. Early results based on discussions with stakeholder representatives and the sector are positive and give us confidence for the future.

Yours faithfully,

Henk Bleker Minister for Agriculture and Foreign Trade Plantaardige Agroketens en Voedselkwaliteit cluster Plantgezondheid/Fytosanitaire Martkttoegang

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