Civil society open letter to the Department of Trade and Industry (DTI) regarding the Draft National Policy on Intellectual Property (IP) of South Africa, 2013

This is a joint letter from academics, experts, civil society and advocacy organisations working on intellectual property issues to improve access to affordable medicines and advance global health. We are writing in support of a number of proposed reforms to South Africa's intellectual property law as it relates to access to medicines, and to offer specific recommendations to further improve the recently published **Draft National Policy on Intellectual Property (DNPIP), 2013** (Government Gazette Vol. 579 No. 36816).

South Africa's Department of Trade and Industry (DTI) has expressed its intention that reform of the intellectual property system will balance patients' rights with those of patent-holders. Given South Africa's high burden for both communicable and non-communicable diseases, this is a positive step towards addressing the current imbalance in the system in a manner conducive to social and economic welfare, the protection of public health, and the transfer and dissemination of technology, especially in sectors of vital importance to socio-economic and technological development. The DNPIP proposes several reforms that would make use of pro-public health flexibilities allowable under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Many other countries, including India and Argentina, have already incorporated TRIPS flexibilities into their national laws, and others, like Brazil, are initiating comparable pro-health patent law reforms. These countries and others have also implemented TRIPS-compliant flexibilities to procure more affordable medicines and to strengthen domestic pharmaceutical capacity. We think that intellectual property law reforms are essential for South Africa to meet its human rights obligations, including the right to health and the right of access to medicines.

Below we outline several recommendations to ensure the proposed IP reforms will positively impact access to medicines by preventing excessive patenting and other barriers to generic entry in order to allow competitive price reductions on medicines and medical technologies (including diagnostic tools). Where valid patents do exist that price medicines out of reach, we provide recommendations for improving measures to mitigate this.

Recommendations:

1. **Patentable Subject Matter Exclusions and Patentability Criteria:** Chapter 2 of the DNPIP notes that South African legislation should enact stricter criteria for granting a patent, and exclude from patentability "diagnostic, therapeutic and surgical methods...including new uses of known products." We support these principles, but recommend that additional criteria also be put in place in South Africa, to exclude from patentability or to clarify lack of inventive step with respect to new forms of known medicines or their components (salts, polymorphs, esters and other derivatives), new dosages and formulations, and new combinations of known medicines or components. These exclusions from patentability or clarifications of inventive step are all compliant with Article 27.1 of TRIPS, and countries such as India, Argentina and the Philippines have already put such criteria in place. Strict subject matter exclusions and patentability criteria prevents originator pharmaceutical companies from obtaining multiple patents on the same drug—a practice known as "patent evergreening," which keeps medicine prices high by preventing the entrance of generic competitors. Additionally, a high standard of innovation should incentivise investment in true innovations—new molecular entities and new classes of medicines. Given that the majority of the most important pipeline antiretrovirals are derivatives of known compounds,[1] we believe that implementing stricter patentability criteria is critical in ensuring more affordable access. Both DNA and cDNA sequences should also be explicitly excluded from patentability, as they are products of nature[2]—cDNA sequences in particular are relevant to developing therapeutic products. Adopting this exclusion is essential if South Africa is to develop a rich biotechnology/biosimilars sector. In addition the DNPIP must reject the introduction of utility model patents in South Africa in regard to pharmaceutical products, which grant exclusive rights to pharmaceutical companies for incremental changes to products, undermining innovation and blocking access to generic equivalents.

2. **Patent Examination System:** In order for subject matter exclusions and stricter patentability criteria to be applied effectively, it is essential that South Africa examines pharmaceutical patent applications to determine whether they meet these requirements. Chapter 1 of the DNPIP recommends the use of a substantive search and examination system to determine whether applications, especially in the pharmaceutical sector, are valid or not. We strongly support this system, as it would effectively prevent multiple patents being filed on minor variations to known compounds. However we note that in the long run this should be a single system, not approached in conjunction with the current depository registration system as suggested in the DNPIP. If a

[1] *See* http://www.i-mak.org/roadmap/.
[2] *See e.g. Association for Molecular Pathology v Myriad Genetics* from the most recent term of the U.S. Supreme Court.

phased-in approach is deemed necessary, it is essential that pharmaceuticals be among the first product areas to be examined. The cost effectiveness of establishing a substantive patent examination system can be offset with filing, application and renewal fees that can meet the one time cost of upgrading infrastructure and the ongoing human resources needed to administer such a system as seen in the case of the Indian Patent Office which has consistently generated a revenue surplus since inception[3].

3. **Pre- and Post-Grant Patent Opposition:** Chapter 1 of the DNPIP notes that South Africa should provide for a pre- and post-grant opposition mechanism within national law to enable third parties to oppose weaker patents that fail to meet patentability standards. This is an important additional check to ensure that only true innovation is rewarded with patent protection. In India a third party (including generic manufacturers, researchers, civil society organisations, and other interested persons and entities) can oppose a patent while the application is pending, and for one year after it is granted. This is done by submitting evidence to the patents office detailing why the patent should not be granted. We support the implemention of an opposition procedure system in South Africa which would simplify the process for challenging patents and allow the patent office to benefit from the inputs of various stakeholders. In addition, we believe that South Africa should adopt an extended time-period for post-grant opposition with respect to pharmaceutical patents adopted during the non-examination period. South Africa has granted a much higher rate of pharmaceutical patents than other countries, including the United States and European countries.

4. **Access to Patent Information:** In addition, it is essential for South Africa to improve the transparency surrounding patent applications in order to support a patent opposition mechanism (as well as compulsory licensing provisions). All applicants must be required to disclose the International Nonproprietary Name (INN) of the pharmaceutical subject matter applied for, either at the time of filing or subsequent to it becoming available, to prevent applicants from obfuscating the subject matter being applied for. This practice is commonplace and increases the difficulty in identifying patents and patent applications that relate to a specific medicine. As well as complicating the opposition procedure, lack of clarity with respect to patents covering medicines also adds significant transaction costs for generic companies attempting to make a *freedom to operate* decision that will ultimately be borne by the procurer. In addition all patent and filing information must be made publicly accessible through a user-friendly mechanism. This is essential to ensure the success of a patent opposition mechanism that relies on third parties using this information to challenge weak patents.

5. **Improved Access Flexibilities:** Chapter 1 and 2 of the DNPIP acknowledges the need to modify existing legislation and regulations to address the difficulties in utilising both compulsory licensing and parallel importation measures which have resulted in neither provision being successfully used to date on a pharmaceutical product. We support these amendments and recommend additional criteria to support their effective use:

i. **Compulsory Licensing**: Compulsory licenses must be authorised in cases where: medicine prices prohibit access, supply is inadequate to need, there is a need for multiple suppliers to avoid stock-outs and shortages, the patent holder has refused to grant a voluntary license on reasonable terms, the medicine is an “essential facility,” there is a need for a novel fixed dose combination medicine comprising ingredients patented by multiple rights holders, or the medicine is not being adequately worked in South Africa. In addition to these grounds, there should be specific allowance of compulsory licensing to remedy anti-competitive behaviour, as authorised by TRIPS Article 31(k), and a more general “public interest” ground for compulsory licenses. On top of this, South Africa should set up a simple, expeditious administrative procedure for hearing applications for compulsory licenses, clarify and regulate royalty rates and specify time periods for negotiations. The DNPIP must also clearly differentiate between compulsory licensing and public non-commercial use (or government use) and emergency or urgent need licenses, which do not require prior notification or negotiation with the patent holder (though notification and payment of adequate compensation is required after-the-fact) and can be used by governments to provide medicines in the public sector or be granted in the case of a public health emergency.

ii. **Parallel Importation:** Legislation must be qualified by the principle of international exhaustion to allow for the importation of medicines into South Africa if the medicines have been placed on the market anywhere in the world by the patent owner, or by any party authorised to use the invention. Such amendments should allow the parallel importation of both branded and legitimately produced generic medicines, as in the case of Kenya and the Philippines. Moreover it is essential that South Africa revise its

[3] *See http://www.tac.org.za/community/files/file/WhySAneedsanexaminationsystem.pdf*

regulatory framework to rectify the overly narrow grounds for parallel importation and to streamline procedures so as to eliminate the need for a full registration procedure.

6. **IP Enforcement:** Chapter 9 of the DNPIP discusses the seizure of generic medicines by customs agents. We recommend that the difference between generic medicines, counterfeit medicines that misuse a properly registered trademark, and unregistered, unsafe, and substandard medicines that mislabel their ingredients or do not meet applicable safety, efficacy and quality standards be recognized and that these categories of medicine be treated differently and appropriately to help mitigate any improper seizures or destruction of generic drugs and to counteract counterfeit drugs and redress true threats to public health.

7. **Competition Policy:** Chapter 5 of the DNPIP discusses the relationship between IP and competition law. The DNPIP acknowledges that competition law may be used to counteract the potentially negative effects of patent protection on public health. Under TRIPS countries are able to regulate practices they consider to be anti-competitive, including—but not limited to—anti-competitive licensing practices. South Africa should explore greater regulation of voluntary licenses in the pharmaceutical sector to avoid this. Furthermore South Africa must make use of a range of remedies to address anti-competitive practices, including compulsory licensing. As TRIPS does not define anti-competitive practices, South Africa has significant flexibility to determine for itself what conduct in relation to exclusive rights in IP is to be considered anti-competitive for the purposes of the Competition Act. We strongly recommend that references to compulsory licensing as an exception to an exclusive right be removed from the text as compulsory licensing is an integral part of the principle of balance that lies at the heart of patent protection.

8. **Patent Exceptions:** South Africa must adopt into national law broader limited exceptions to patent rights for the purposes of commercial and non-commercial research and education. Such exceptions are fully authorised by TRIPS Article 30 and have been previously implemented by countries such as Brazil.

9. **Data Exclusivity:** Chapter 1 of the DNPIP refers to data exclusivity as a hindrance to generic competition, but we recommend that data exclusivity be removed completely from the text. TRIPS Article 39.3 refers to undisclosed test or other data that is submitted to governments for the purpose of obtaining marketing approval and that it takes considerable effort to originate, and requires protection against "unfair commercial use" of such data.[4] This is distinguishable from data, marketing or regulatory exclusivity such as that granted in the United States and Europe, which prevents medicines regulatory authorities from referring to or relying on test data submitted by the rights holder (for a specified period of time) in order to register their generic equivalents. Data exclusivity serves no purpose other than to provide firms with *de facto* market exclusivity when they are unable to legitimately obtain a patent. It prevents generics from entering the market and allows firms to set monopoly pricing on medicines that do not meet patentability standards. TRIPS Article 39.3 does not require data exclusivity, which is now widely accepted as a TRIPS-plus measure that negatively impacts on access to medicines. Data exclusivity goes beyond data protection into the realm of pseudo-monopoly and should be avoided.

We urge the Department of Trade and Industry to take on board our recommendations to improve the proposed reforms of the Draft National Policy on IP. Despite expected opposition from the US, EU and the pharmaceutical industry, these reforms must be rapidly adopted through the legislative process in order to enable improved access to quality and affordable medicines. By pursuing the reforms discussed in the DNPIP, South Africa is exercising its lawful right to use TRIPS-compliant flexibilities to fulfill its constitutional obligations and protect the right to health of its people.

Yours sincerely,

[4] *See* http://www.searo.who.int/entity/intellectual_property/data-exclusively-and-others-measures-briefing-note-on-access-to-medicines-who-2006.pdf