DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013

General Notice 918 of 2013 GG 36816 of 4 September 2013

EXTRACTS FROM SUBMISSION MADE

by

Innovative Pharmaceutical Association of South Africa (IPASA)

FOCUS ON MATTERS OF IP AND PUBLIC HEALTH

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1. **GENERAL SUPPORT FOR IP POLICY**

When the Draft National Policy on IP was published for comment, IPASA made a comprehensive submission. From the comments submitted, it is clear that IPASA supported the Government initiative to formulate a coherent and inclusive national policy on IP, and that IPASA indeed endorsed and supported many of the policy statements and policy recommendations put forward in the draft IP Policy document. Where it held a different view, the IPASA position was submitted in a rational and constructive manner.

In the submission made by IPASA, IPASA's support for the general approach and the broad objectives of the Draft IP Policy was repeatedly expressed, and the need for a comprehensive but a balanced IP policy was emphasised:

On p.3: In formulating a national policy position on IP, it is necessary to consider IP-related issues within a broader perspective, taking into account national needs and policy objectives of different Government Departments, private sector initiatives and interests, related areas of law and practice, and broader national objectives. It is also agreed that IP has a strong international interface, so that international instruments, international developments, international and regional relations, and bi-lateral and multi-lateral trade agreements have to be taken into account.

On p.5: A strong IP system with integrity and credibility of IP rights granted under the system, and a system which complies with the norms and principles of international instruments, such as TRIPS, will assist in achieving and realising the objectives.

On p.5: A balanced IP system, striking a fair balance between the rights and interests of the creators of IP, the opportunities afforded the users of IP, the needs of the public at large, the confidence of investors, and the goals of the country and of Government will be instrumental in achieving the objectives.

On p.5: The most important objective of IP is to foster, promote and reward innovation in order to attract investment, ie to stimulate research, innovation, creativity and the development of

new and better products, so as to build confidence in the South African economy and to encourage the inflow and retention of capital, ultimately to contribute towards economic growth and increased trade. This will result in growth in employment, in the alleviation of poverty, in improved health care, and in economic security and socio-economic stability.

On p.6: The policy statement that IP should promote research, development and innovation in all sectors is endorsed. In order to achieve the objectives of economic development and increased innovation, a strong IP system is in fact an enabling factor, not a barrier. The prospect of obtaining IP protection is a driving force behind R&D work, the cost of which (particularly in the pharmaceutical field) is very high. A lower level of IP protection would discourage R&D and innovation projects.

On p.6: The objective of addressing national issues such as public health, food and education is supported. The role of other factors (other than IP) in achieving these objectives must also be recognised, such as the efficacy of health services, the availability of medicines to persons in need, the access to health practitioners, etc in order to address public health needs.

On p.6: It is expressly stated as an objective that the policy should improve access to IP-based essential goods, particularly in the area of health, thus including medicinal products. This objective appears to envisage the implementation of legislative and/or administrative mechanisms to enable easier access, eg by way of reduced pricing, enhanced procurement measures, or by providing for easier access to licensed rights (compulsory licences). The development of an effective and legally justifiable access base would be supported.

On p.6: Another objective of the IP Policy is the compliance with international treaties of which South Africa is a member. In structuring an IP system, also in the area of pharmaceutical inventions, it will be important to comply with the provisions of the WTO Agreement on Trade-Related aspects of IP Rights (TRIPS), taking into account TRIPS flexibilities but also TRIPS obligations. The optimal use of TRIPS flexibilities is supported. However, eroding or diminishing the current IP system in an arbitrary manner, eg by removing from the definition of patentable inventions certain medicine-specific categories of inventions (the exclusion of which is not envisaged in TRIPS), will not serve to bring the IP system in line with TRIPS but will instead undermine confidence in the system and will be a disincentive to investment and to R&D.

On p.6: The arbitrary use of TRIPS flexibilities as a means to reduce or eliminate or weaken pharmaceutical patents will result in unforeseen negative consequences across all industrial sectors, and ultimately throughout the South African economy. In addition, such a discriminatory policy would be unfair, in contravention of TRIPS obligations, and unconstitutional.

2. ISSUES TO BE ADDRESSED

The interface between IP and Public Health was the primary focal area for the pharmaceutical industry; the IPASA submission therefore primarily addressed policy issues within that focal area.

2.1 Procedures for patentability

(a) Substantive search and examination system

IPASA is not opposed to the principle of a substantive search and examination system; however, certain repercussions must be borne in mind:

On p.9: It is not correct to assume that the current system generally results in weak patents, or that a search and examination system will necessarily result in the issuance of stronger patents than those issued under the current registration system.

On p.9: Such a system will demand high costs and substantial human resource capacity. Capacity building would include, as a pre-requisite to the implementation of a substantive search and examination system, adequate human resources, and an administrative, technical, and intellectual property regulatory infrastructure to avoid backlogs and to ensure that the entire system runs effectively and efficiently. Investment in building this infrastructure will only be justified if proceedings are fair and are resolved within a reasonable time frame.

(b) Outsourcing the search and examination function

On p.13: Outsourcing the search and examination function does not necessarily provide a solution; there would still be a significant cost factor and a time-delay factor. Furthermore, the credibility of the outcome on patentability would depend on the credibility and independence of the external service provider used.

On p.13: A serious problem facing the pharmaceutical industry in Brazil is the requirement for the health regulatory agency (ANVISA) to approve all patent applications claiming pharmaceutical products and/or processes. This is in addition to the substantive examination conducted by Brazil's patent office (INPI). This 'dual examination' is incompatible with Brazil's obligations under the anti-discrimination provisions of Art 27.1 of TRIPS. In addition, ANVISA and INPI do not apply the same patentability requirements, thus generating uncertainty for patent applicants and undermining incentives for innovation.

(c) Use of a 'hybrid' system

The use of a 'hybrid' system (ie substantive search and examination for inventions in some fields of technology, but deposit and registration for inventions in other fields of technology), would be a contravention of the non-discriminatory provision of TRIPS:

On p.9: Such differentiation poses a risk of contravening the non-discrimination principle of TRIPS Art 27.1. There would be discrimination if only pharmaceutical patents are to be examined, while applications in other areas of technology are merely registered. There would also be discrimination if only foreign patent applications are examined, while locally originating applications are merely registered.

(d) Pre- and post-grant opposition

The introduction of pre-grant and post-grant opposition proceedings may not achieve the positive outcomes as expected:

On p.10: The introduction of pre-grant opposition proceedings has the potential to lead to unnecessary delays and undermine development of a robust intellectual property system. Such proceedings may be used inappropriately to delay the granting and enjoyment of valid patent rights.

On p.13: As regards pre- and post-grant opposition, it is emphasised that the expected additional cost factor as well as the potential delay factor would have a negative impact on the cost of medicines, as well as on the early availability of medicines.

On p.13: As regards post-grant opposition, the Patents Act already provides for post-grant revocation. This existing procedure is very similar to post-grant opposition; introducing provisions for post-grant opposition in addition to post-grant revocation would be a duplication.

(e) Search and examination plus pre-grant opposition

The use of a search and examination system in combination with a pre-grant opposition system would be a duplication and cause time delays:

On p.9: If a search and examination system is introduced so as to ensure that no 'invalid' inventions (ie lacking novelty and inventiveness) are patented, there does not seem to be any justification for a pre-grant opposition provision.

On p.10: Before an integrated system is introduced, combining search and examination with pre- and post-grant opposition, a thorough cost and benefit analysis should be conducted.

2.2 **Requirements for patentability**

(a) Diagnostic, therapeutic and surgical methods of treatment not to be patentable

Methods of medical treatment are already excluded from patent protection in SA:

On p.22: Diagnostic, therapeutic and surgical methods of treatment are already excluded from patentability in South Africa. This is in line with TRIPS Art 27.3(a), although this provision in

TRIPS is only a permissive exclusion and not an obligatory exclusion. This is a so-called TRIPS flexibility.

(b) New uses of known products not to be patentable

New medical uses of known substances or compounds provides an important possibility for treating advanced diseases:

On p.16: Through scientific advancements in the understanding of diseases, and through continued R&D, important new uses for known medicines are discovered. In addition, new combination therapies utilising combinations of existing drug products provide advanced treatments for a wide range of conditions with substantial benefits to public health. These types of innovations are achieved through intense R&D; yet they can be seen as new medical uses of known products.

On p.17: A blanket refusal to recognise patents for new uses of existing substances would be inconsistent with Art 27.1 of TRIPS, which requires that 'patents shall be available for any inventions … provided that they are new, involve an inventive step and are capable of industrial application'. Although TRIPS provides (Art 27.2 and 27.3) a list of the types of subject matter that can be excluded from patent coverage, this list does not include new uses of known products.

On p.21: The patentability of the new medical use of a known substance (so-called first medical use) is expressly permitted in South Africa. TRIPS has no provision on this issue; more specifically, TRIPS does not exclude from patentability new medical uses of known substances.

On p.21: Through scientific advancements in our understanding of diseases, and through continued R&D, important new uses for medicines are discovered. For example, 30 years after its original approval to treat patients with advanced breast cancer, researchers discovered that Nolvadex (tamoxifen) helps those diagnosed with bipolar disorder during the manic phase of the disease. Evista (raloxifene) was initially developed to treat osteoporosis, but was later approved to reduce the risk of invasive breast cancer in postmenopausal women.

(c) Incremental innovation not to be patentable

The true meaning of incremental innovation (also referred to as 'evergreening') must be properly understood; also the advantages of incremental or continuing innovation must be appreciated:

On p.18: The reference to the application of strict rules to patenting may be indicative of an intention that the level of patentability should be lifted, so that incremental inventions (ie inventions based on but constituting improvements of existing basic inventions) should not be patentable.

On p.18: South African law, in line with TRIPS Art 27.1, requires an invention, in order to be patentable, to be new, inventive and industrially applicable. These requirements and the relevant standards apply to all inventions, also to incremental improvements based on basic inventions. South African law prescribes absolute novelty as a requirement for patentability. The South African requirement for inventiveness is the same strict requirement applicable in most developed countries.

On p.18: The criteria of novelty and inventiveness also apply to improvements on basic inventions, so that insignificant changes will not be patentable. It should be remembered that an improvement patent covers only the improvement; protection in respect of the basic invention expires with the basic patent.

On p.18: It must be pointed out that there is a continuing need for improved, adapted and more effective medicines, ie for beneficiation of existing medicines. Beneficiation by implication requires incremental innovation and advancement on basic inventions and concepts.

On p.19: Incremental innovation in the pharmaceutical field can improve the safety, therapeutic effect or method of delivery of an existing medicine or vaccine, or improve the efficiency with which it can be manufactured, with positive outcomes for public health.

On p.20: It is emphasised that, although discoveries of new chemical entities (ie basic inventions) are extremely valuable, important innovations are in fact based on such prior inventions through continued R&D on improved drug delivery methods, formulations and effectiveness, all of which greatly benefit patients.

On p.21: Patentability of new formulations or new molecular forms of active ingredients should not be abolished *per se*. Extensive R&D is often required to improve a molecular form or the formulation of an existing medicine, and the modified product generally has improved efficacy. As long as the criteria of novelty and inventiveness are complied with, patentability should be available.

2.3 **Parallel importation and compulsory licences**

The Doha Declaration, 2001 of the WTO confirmed that countries have the right to determine the legal parameters for compulsory licences and parallel importation:

On p.23: Paragraph 5 of the Doha Declaration of 2001 confirmed that TRIPS flexibilities included the right of countries to grant compulsory licences and the freedom to determine the grounds on which such licences may be granted, as well as the freedom to establish their own national regimes for exhaustion of rights and the legality of parallel importation.

On p.24: The Doha Declaration must be viewed within the context of the critical issues that were addressed at that time, ie the gravity of the pandemic diseases that were afflicting developing and least-developed countries. Legislative measures considered then, to permit compulsory licences and to legalise parallel imports, were intended as measures to address these health crises.

On p.24: Legalising parallel imports and facilitating compulsory licences only in respect of pharmaceutical patents and not other technologies would constitute a contravention of the non-discrimination provision in TRIPS Art 27.1.

(a) Legalisation of parallel importation in line with WTO Doha decision

On p.24: Facilitating and thus expanding South Africa's parallel importation of pharmaceutical products would pose clear risks to patients. International experience demonstrates that parallel importation encourages and facilitates the sale of counterfeit, sub-standard, or uncontrolled pharmaceuticals. It is extremely difficult to police the supply of medicines once the chain of supply from manufacturer to authorised importer is broken.

On p.25: Parallel importation means the importation into South Africa of a genuine product obtained by a third person in another country from a legitimate source, but without the authority of the patent holder to import.

On p.26: It must be pointed out that parallel importation is the importation of a genuine product; the importation by a third party of a generic product or an infringing product or a counterfeit product is not parallel importation; this would be infringement.

On p.26: In practice, the main motivation for parallel importation on the part of the unauthorised importer is to benefit from price differentials: manufacturing costs in some countries are lower than in others, so that the selling price in the country of importation may be higher than the purchasing price in the country of manufacture. The objective with parallel importation is therefore often a profit motive: the importer aims to profit from price differentials; the importer does not aim to make more affordable products available to the people in the country of importation.

On p.27: It is important to recognise that parallel importation (permitted on the basis of international exhaustion of patent rights) will benefit the parallel trader as opposed to the consumer.

On p.28: A further issue is that parallel importation also entails safety risks:

- since the importation of the so-called 'genuine' product is not handled by the patent holder or his licensee themselves, there is a risk that the product may be tampered with, thus negatively affecting its quality;

- since there is no accountability or control over the importation of the so-called 'genuine' product, there is a risk that counterfeit products (poor quality products illegally bearing the brand name of the genuine product) may be imported.

(b) Compulsory licensing should be aligned with the WTO Doha Decision

On p.29: Compulsory licences are dealt with in detail in the South African Patents Act and in TRIPS. In South Africa a compulsory licence may be granted on an application to Court by any interested person who can show that the rights under a patent are being abused, without the consent of the right holder.

On p.29: Resorting to compulsory licences is not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by pharmaceutical companies better ensure that current and future patients have access to innovative medicines.

On p.29: The law of South Africa already provides for compulsory licences on grounds that would be applicable to the abuse also of pharmaceutical patents, eg –

- that the patented invention is not being worked in South Africa to an adequate extent;
- that the demand for the patented product in South Africa is not being met to an adequate extent and on reasonable terms;
- that by reason of the refusal of the patentee to grant a licence on reasonable terms, industry is being prejudiced and it is in the public interest that a licence should be granted;
- that the demand in South Africa for the patented product is being met by importation, and the price asked by the patent holder is excessive in relation to the price in the countries where the product is being manufactured.

2.4 **Voluntary licensing and technology transfer**

Regulations/guidelines on voluntary licensing should be developed:

On p.31: IPASA confirms that fair and equitable licensing guidelines developed by way of an inclusive consultation process would be useful. However, IPASA submits that licensing guidelines or regulations should not be used in a manner to limit market access.

On p.33: A code of good practice or guidelines on licensing practices could be of value to ensure that relevant issues are considered and addressed. Although guidelines on licensing, ie principles that would envisage voluntary application, could be useful and indeed beneficial, regulations in the form of peremptory principles should be expected to discourage licensing. A code of good practice would be useful.

On p.32: Within the pharmaceutical industry voluntary licensing activities have existed for many years; the practice has resulted in a series of collaborative programmes between

international drug manufacturers and domestic companies – some in South Africa – to initiate a framework of technology transfer to get medicines to those who need them.

On p.32: IPASA would support an initiative to develop models for, and to encourage, technology transfer within industry sectors, and between public and private sectors.

On p.35: At present there are no provisions in the Patents Act to compel or regulate the transfer of technology within the context of a voluntary licence. Prescribing or regulating certain levels of technology transfer could be a disincentive to the granting of voluntary licences. The transfer of technology to a licensee is a voluntary matter; prescriptive regulations to prescribe or compel a licensor to transfer technology would interfere with the freedom to contract. However, appropriate incentives, such as funding, tax concessions, or guaranteed purchasing/sales contracts could facilitate and indeed encourage licensing.

On p.36: Voluntary and royalty-free licences already granted by pharmaceutical companies are indicative of the industry's commitment to the principles of the Policy document and, moreover, the industry's commitment to addressing the global health cause. These voluntary licences generally entail an authorisation given by the patent holder to a generic company to make the patented product as if it were a generic, making it cheaper to buy.

2.5 **TRIPS flexibilities**

South Africa must make optimal use of TRIPS flexibilities in its patent law, and must avoid or remove TRIPS-plus provisions:

On p.37: IPASA supports the principle of making optimal use of TRIPS flexibilities in a manner so as to stimulate research and innovation also in the field of pharmaceuticals, and in a manner to encourage the pharmaceutical innovator companies to find and develop new medicines to treat prevalent diseases.

On p.38: Lowering the levels of patent protection that have been in place in South Africa since prior to TRIPS, eg by excluding certain patentable subject matter, is not contemplated in the Doha Declaration and cannot identified as a TRIPS flexibility but would indeed be contrary to the spirit of TRIPS.

On p.39: It is necessary to have clarity about two concepts: what are TRIPS flexibilities? and what is the link between TRIPS flexibilities and TRIPS-plus protection?

- TRIPS flexibilities are provisions of TRIPS that provide legal space for individual countries to structure their IP laws in accordance with their own legal, developmental, economic and national needs.
- TRIPS flexibilities exist where TRIPS has a permissive (not a mandatory) requirement or takes no position.

- TRIPS-plus protection is present when the patent law of a country grants more protection under a patent than the mandatory minimum requirements of TRIPS.
- TRIPS-plus protection is also seen in cases where TRIPS provides flexibility but a country affords a higher level of protection rather than a lower level.

On p.39: It is up to individual countries to structure their patent laws within the space allowed by TRIPS flexibilities so as to achieve the desired objective envisaged for their patent systems, taking into account that –

- ideally a balanced outcome must be achieved;
- patents in general, and pharmaceutical patents specifically, are important to encourage pharmaceutical companies to undertake R&D work in order to provide new medicines to treat diseases;
- access to the medicines resulting from R&D work is important;
- both TRIPS compliance and access to affordable medicines must be achieved.

On p.40: IPASA agrees with and supports the general principles and the approach to public health as set out in the Doha Declaration. However, lowering the levels of patent protection that have been in place in South Africa since prior to TRIPS, eg by excluding certain patentable subject matter, is not contemplated in the Doha Declaration and is not identified as a TRIPS flexibility but would indeed be contrary to the spirit of TRIPS.

2.6 **Patents and public health**

The Patents Act should be amended to be amenable to public health issues, eg to facilitate the entry of generics:

On p.41: It is not clear what patent-related amendments would be regarded as 'amenable' to issues related to public health. For example, IPASA would have concerns if such 'amenable' amendments would include an amendment to require patent pre-approval by the regulatory authority before a pharmaceutical patent is granted by the patent office; or an amendment that would restrict the definition of 'patentable invention' in the field of pharmaceuticals, eg to exclude new medical uses of known substances.

On p.42: The Bolar provision has been incorporated in South Africa's patent law specifically to facilitate the entry of generic substitutes into the market. However, if the recommendation of 'quick approval of generics' for marketing authorisation is intended to legalise the use by the MCC of the dossiers compiled by the innovator companies (including all of the confidential proprietary data and clinical trial information in respect of the original medicine) in order to grant 'quick approval of generics', this recommendation has to be opposed. Such a recommendation would reflect a policy position contrary to, and in contravention of, TRIPS Art 39.3.

On p.43: The Policy appears to identify the current provisions in the Patents Act in so far as they relate to pharmaceutical products, and patent protection afforded to pharmaceutical products, as primary stumbling blocks in addressing public health problems. It is submitted that such an approach tends to ignore other more relevant issues, such as inadequate service delivery and management of hospitals in the public health sector; inadequate resources in the health area, such as clinics, doctors, nurses, etc; ineffective use of public funding in the health sector, etc.

On p.43: There should be incentives to pharmaceutical companies to search for and develop more effective remedies. It is universally accepted that the possibility of patent protection is such an incentive. If the possibility of effective patent protection is removed, there would be a risk of less R&D work being done to find effective cures for prevalent diseases. And without innovative new medicines being developed, there would be no generics.

On p.44: The Policy statement that 'quick approval of generics by the MCC is necessary' raises serious concerns. If this statement is intended to encourage, or indeed authorise the MCC, for purposes of approving generics, to make use of the dossier compiled and submitted by the innovator company for purposes of the marketing authorisation of the original medicine, it is foreseen that serious consequences could follow. These dossiers contain confidential and proprietary data on efficacy and on the related clinical trials generated by the innovator companies at great cost and over lengthy period of time. To encourage or indeed authorise the MCC to make use of this data would be a contravention of TRIPS Art 39.3.

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12 February 2014