

DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013

General Notice 918 of 2013 GG 36816 of 4 September 2013

SUBMISSION

by

Innovative Pharmaceutical Association of South Africa (IPASA)

FOCUS ON MATTERS OF IP AND PUBLIC HEALTH

Contact Information:

PO Box 2008 Houghton, 2041

Tel: +27 (0)11 880 4644 Fax: +27 (0)11 880 5987

Chief Operating Officer

Val Beaumont E-mail: val@ipasa.co.za

Health Projects & Information Manager

Shakira Ramlakhan E-mail: shakira@ipasa.co.za



CONTENTS

A.	EXECUTIVE SUMMARY	i - viii
B.	SUBMISSION	
I.	PRELIMINARY REMARKS.....	3
II.	OBJECTIVES AND BACKGROUND OF THE IP POLICY	4
	Submissions by IPASA	4
III:	ISSUES TO BE ADDRESSED	7
	PART 1: Procedure for patentability.....	8
	Policy recommendations.....	8
	Submissions by IPASA	9
	PART 2: Requirements for patentability	16
	Policy recommendations.....	16
	Submissions by IPASA	16
	PART 3: Parallel importation and compulsory licences.....	23
	Policy recommendations.....	23
	Submissions by IPASA	23
	PART 4: Voluntary licensing and technology transfer.....	31
	Policy recommendations.....	31
	Submissions by IPASA	31
	PART 5: TRIPS flexibilities, bi-lateral trade agreements (BITs), related matters.....	37
	Policy recommendations.....	37
	Submissions by IPASA	37
	PART 6: Patents and public health	41
	Policy recommendations.....	41
	Submissions by IPASA	41
	PART 7: Data protection	45
	Policy recommendations.....	45
	Submissions by IPASA	45
	PART 8: Relevance of generic medicines	50
	Policy recommendations.....	50
	Submissions by IPASA	50
	PART 9: Patent term restoration.....	53
	Policy recommendations.....	53
	Submissions by IPASA	53

DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY, 2013
General Notice 918 of 2013 GG 36816 of 4 September 2013

SUBMISSION

by

Innovative Pharmaceutical Association of South Africa (IPASA)

FOCUS ON MATTERS OF IP AND PUBLIC HEALTH

EXECUTIVE SUMMARY

I. PRELIMINARY REMARKS

1. Need for an encompassing National IP Policy

In the opening remarks of the document published under GN 918/2013 (the 'Policy document'), setting out the background to the drafting of a National Policy on Intellectual Property, it is stated that South Africa does not have a clear Intellectual Property (IP) policy with the result that Government Departments that deal directly or indirectly with IP approach the system differently. IP is cross-cutting in nature, and cuts across the areas of inter alia trade, science, agriculture, research and development, manufacture and health. To ensure coherence in Government's approach to and handling of IP, there is a need for a coordinated approach.

A coordinated approach to IP by the different Departments would entail substantial benefits from a practical perspective. Furthermore, a clearly delineated National IP Policy for South Africa would have the additional advantage of ensuring a coordinated and strategically aligned approach to IP issues by public sector as well as private sector entities and bodies across all fields of innovative activity, and would enable a better understanding and appreciation by the general public, as the users of IP-related products, of the importance of IP.

In formulating a national policy position on IP, it is therefore necessary to consider issues relating to IP 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 the diversity of broader national objectives. It is also agreed that IP has a strong international

interface, so that international instruments, international developments, international and regional relations, including bi-lateral and multi-lateral trade agreements have to be considered.

2. Need for an in-depth further study of IP Policy issues

It is necessary to place on record the fact that the time allocated for interested persons to study the Policy document with its wide-ranging and diverse statements and recommendations, and to prepare and submit comments, was totally inadequate. The Policy document addressed a wide range of complex and important issues, issues not only important to Government, to industry and to IP users and practitioners, but issues of particular general public interest.

It is expected that a National Policy on Intellectual Property, once rendered into final form, will shape and determine South Africa's IP regime for many years to come. It is of critical importance, therefore, that the Policy should not be finalised and concluded until such time as a further opportunity for external consultation and external input has been provided.

It is proposed that **the dti** should consider appointing a Task Team composed of experts in the field of IP law and practice and representatives of different industry sectors, with the specific mandate to consider all submissions made in response to the invitation published under GN 918/2013 as well as all other relevant considerations, and on the basis of all that to formulate a proposed policy document for submission to and consideration by **the dti** and for ultimate approval by Cabinet.

II. **OBJECTIVES AND BACKGROUND OF THE IP POLICY**

1. Broad objectives noted by IPASA

The broad objectives of the IP Policy (as set out on p.4 of the Policy document) in general aim to stimulate the economy of South Africa and to empower its citizens.

It is submitted that 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.

It is also submitted that 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.

It is emphasised, as recognised in the Policy document, that the most important objectives 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. These outcomes will result in growth in employment, in the alleviation of poverty, and in economic security and socio-economic stability.

Each of the recommendations of the Policy document must be measured against these objectives to assess whether such recommendation contributes to or detracts from these objectives.

The fact that it is also expressly stated that IP should promote research, development and innovation in all sectors is therefore endorsed. It must be emphasised that, 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 for research and development (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.

The broad objectives of stimulating the economy, engendering confidence and attracting investment, and promoting research and development are accordingly supported. The objective of addressing national issues such as public health, food and education is likewise supported. The role of other factors (other than IP) in achieving these objectives must, however, 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.

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

Another objective is stated to be 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. Thus the optimal use of TRIPS flexibilities would be 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 erode confidence in the system and will be a disincentive to investment and to R&D.

The arbitrary use of TRIPS flexibilities as a means to weaken the patent system and to reduce or eliminate pharmaceutical patents will result in unforeseen negative consequences across all industrial sectors, and ultimately throughout the South African economy. It can be expected that this will result in a loss of confidence in and damage to the South African economy. In addition, such a discriminatory IP policy would be unfair, in contravention of TRIPS obligations, and unconstitutional.

IPASA confirms that an appropriately drafted and implemented IP policy should encourage medicines innovation, investment and economic development, consistent with South Africa's national imperatives and international obligations. IPASA believes that the Draft National Policy on Intellectual Property (the Policy) represents an important step towards achieving these goals. IPASA applauds the Policy's intent to establish a more robust patent system, and supports the proposal to develop more extensive enforcement remedies and to support trade secret protection. IPASA is concerned, however, that the Policy may overly restrict patentable subject matter and may not offer adequate data protection to pharmaceutical innovators.

There are also concerns about the Draft Policy's failure to provide for patent term restoration; its proposal to connect the marketing regulatory and patent databases; and its proposals endorsing parallel importation of pharmaceuticals; the intention to regulate technology transfer relating to pharmaceuticals; and the use of compulsory licensing to facilitate market entry of generic drugs. These proposals could harm prospects for further development of, and investment in, research and development and enhanced manufacture in South Africa's innovative biopharmaceutical industry.

2. Concluding remarks by IPASA

The broad objectives of stimulating the economy, engendering confidence and attracting investment, and promoting research and development are supported. It must be emphasised that, in order to achieve these objectives, a strong IP system is in fact an enabling factor, not a barrier.

The prospect of obtaining IP protection is a driving force for R&D work, the cost of which in the pharmaceutical field is very high.

The role of non-IP factors in achieving this objective must be recognised, such as *inter alia* the efficacy of health services, availability of medicines to persons in need, access to health practitioners. Note must also be taken of the fact that less than 1.5% of medicines required for general health care (ie medicines on the Essential Drugs List) are under patent; the major percentage of these medicines are freely available.

However, a cautionary remark must also be made: Eroding the parameters of patentable subject matter in the current IP system in an arbitrary manner, for example removing from the definition of patentable inventions certain medicine-specific categories of inventions, will inadvertently diminish confidence in the system, thus resulting in a questionable incentive to investment and to R&D.

A strong IP system encompassing integrity and credibility of IP rights will be the driver in achieving the policy objectives.

III. **ISSUES TO BE ADDRESSED**

The Draft National Policy on Intellectual Property, 2013 (as set out in the Policy document) deals with IP-related matters over a wide spectrum of areas, covering not only issues relating to the protection and enforcement of IP but also issues arising from the interfaces between IP and Public Health; IP and Competition, Public Policy-Making and Technology Transfer; IP and Institutional Capacity; IP and International Architecture, etc. Although the interface between IP and Public Health is the primary focal area for the pharmaceutical industry, several of the other areas that interface with IP are also relevant to the industry.

For ease of reference, issues addressed in the Policy document in different chapters have been grouped together on the basis of their relevance to specific topics; these topics will be dealt with in numbered sequence in PARTS 1 – 9 below. Different policy positions and recommendations, dealt with in different chapters of the Policy document, will therefore be grouped together and addressed together in topical context in PARTS 1 – 9 below.

PART 1: Procedure for patentability (pages 8 – 15)

The Policy document in Chapter 1, dealing with Patents in part a), as well as in Chapter 2, dealing with IP and Public Health, and in Chapter 8, dealing with Institutional Capacity, addresses various aspects of the current law and practice regarding the granting of patents, and contains several recommendations relating to the current procedure for the granting of patents.

Under this heading the following issues are *inter alia* addressed:

- the establishment of a substantive search and examination system, including
 - the need for non-discrimination and TRIPS compliance
 - the additional capacity and resource requirements, and the resultant cost and time delays
- the introduction of pre- and post-grant opposition procedures
- the use of a ‘hybrid’ system, ie both a depository and a substantive search and examination system, including
 - the risk of discrimination and TRIPS contravention.

PART 2: Requirements for patentability (pages 16 – 22)

The Policy document in Chapter 2, dealing with IP and Public Health, also addresses several aspects of the current law and practice regarding the granting of patents which are of particular importance to the pharmaceutical industry. Some of these aspects relate to the patentability of inventions, and two recommendations of particular relevance to the pharmaceutical industry are put forward.

Under this heading the following issues are addressed:

- the restriction of what will constitute patentable inventions, including
 - the relevance and importance of incremental innovation
 - the importance of new medical uses of known substances
- the recognition of indigenous knowledge.

PART 3: Parallel importation and compulsory licences (pages 23 – 30)

In Chapter 1, in the section dealing with Patents, and in Chapter 2, dealing with IP and Public Health, two important issues are addressed, namely the issue of parallel importation, and that of compulsory licences.

Under this heading the following issues are addressed:

- the legalisation and/or facilitation of parallel importation, including
 - the nature of parallel importation, generics and counterfeits
 - the role of exhaustion of rights
 - the relevance of price differentials
 - the potential disadvantages of and risk to the patients
- the facilitation and use of compulsory licensing, including
 - TRIPS and compulsory licensing.

PART 4: Voluntary licensing and technology transfer (pages 31 – 36)

In Chapter 1, in the section dealing with Patents, and in Chapter 5, dealing with a variety of matters in the fields of IP, Competition, Public Policy-Making, Compulsory Licensing and Technology Transfer, a number of issues relating to voluntary licensing and technology transfer are addressed that are of relevance to the pharmaceutical industry.

Under this heading the following issues are addressed:

- the role of voluntary licensing and regulations/guidelines on licensing, including
 - the nature of voluntary licences and existing legislative provisions
 - licences under the IPR Act
- the importance of technology transfer, including
 - the use of technology transfer in licences.

PART 5: TRIPS flexibilities, bi-lateral trade agreements (BITs) and related matters (pages 37 – 40)

In Chapter 1, in the section dealing with Patents, and in Chapter 5, dealing with a variety of matters in the fields of IP, Competition, Public Policy-Making, Compulsory Licensing, and Technology Transfer, a number of issues relating to TRIPS flexibilities and bi-lateral trade agreements are addressed that are of relevance to the pharmaceutical industry.

Under this heading the following issues are addressed:

- the need to incorporate TRIPS flexibilities into the Patents Act, including
 - the difference between TRIPS flexibilities and TRIPS-plus provisions
 - the principles of the Doha Declaration
- the risk inherent in bi-lateral trade agreements.

PART 6: Patents and public health (pages 41 – 44)

In Chapter 2, dealing with IP and Public Health, and in Chapter 10, dealing with IP and Development, a number of issues relating to public health are addressed. Naturally these are important to the pharmaceutical industry.

Under this heading the following issues are addressed:

- the need for amendment of the Patents Act to be amenable to public health, including
 - the nature of amenable amendments
- the facilitation of the market entry of generic medicines, including
 - the benefit provided by the Bolar provision
 - the possibility of quick approval by the MCC
- the advantage of the integration or sharing of databases, including
 - the disadvantage of pre-approval of patents by the regulatory authority.

PART 7: Data protection (pages 45 – 49)

In Chapter 1, in Part a) dealing with Patents and in Part h) dealing with Trade Secrets, a number of issues relating to the protection of confidential information and confidential data are addressed. These issues are important to the pharmaceutical industry.

Under this heading the following issues are addressed:

- the obligation to protect data in terms of TRIPS Art 39.3, including
 - the ambit of protection required by TRIPS Art 39.3
 - the absence of data protection in South Africa
- the importance of data protection, including
 - that data protection does not prevent marketing approval
 - that data protection must not be discriminatory.

PART 8: Relevance of generic medicines (pages 50 – 52)

In Chapter 1, in the section dealing with Patents, and in Chapter 2, dealing with IP and Public Health, a number of issues relating to the role of generic medicines are addressed. Naturally these issues are important to the pharmaceutical industry.

Under this heading the following issues are addressed:

- the need to facilitate the market entry of generic medicines, including
 - the nature of generic medicines
 - the use of the Bolar provision (early working provision)
 - the risk to patients
- the proposal of quick approval of generics by the MCC, including
 - the statement that market entry of generics should not be frustrated by data protection.

PART 9: Patent term restoration (pages 53 – 56)

The Policy document in part a) of Chapter 1 (section x) on p.11 -12), deals with the issue of patent term extension/restoration. This is a matter of particular importance to the pharmaceutical industry, in the light of the time delays that impact on the effective period of exclusive rights afforded by pharmaceutical patents.

Under this heading the following issue is addressed:

- the encouragement for transparency regarding the registration system of the MCC, including
 - the pressure on Government to provide for patent term extension/restoration
 - the need for patent term extension/restoration to compensate for regulatory delays.

B. SUBMISSION

I. PRELIMINARY REMARKS

1. Need for an encompassing National IP Policy

In the opening remarks of the document published under GN 918/2013 (the 'Policy document'), setting out the background to the drafting of a National Policy on Intellectual Property, it is stated that South Africa does not have a clear Intellectual Property (IP) policy with the result that Government Departments that deal directly or indirectly with IP approach the system differently. IP is cross-cutting in nature, and cuts across the areas of inter alia trade, science, agriculture, research and development, manufacture and health. To ensure coherence in Government's approach to and handling of IP, there is a need for a coordinated approach.

These statements are of particular relevance not only to the pharmaceutical industry but also to many other industries, the activities of which fall within the areas of responsibility of different Government Departments and which thus have to deal with, and comply with the requirements of, different Departments. A coordinated approach to IP by the different Departments would therefore entail substantial benefits from a practical perspective. Furthermore, a clearly delineated National IP Policy for South Africa would have the additional advantage of ensuring a coordinated and strategically aligned approach to IP issues by public sector as well as private sector entities and bodies across all fields of innovative activity, and would enable a better understanding and appreciation by the general public, as the users of IP-related products, of the importance of IP.

In formulating a national policy position on IP, it is therefore necessary to consider issues relating to IP 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 the diversity of broader national objectives. It is also agreed that IP has a strong international interface, so that international instruments, international developments, international and regional relations, including bi-lateral and multi-lateral trade agreements have to be considered.

The comments that follow below are submitted by the Innovative Pharmaceutical Association of South Africa (IPASA) and represent the views of IPASA. Individual pharmaceutical companies and other bodies representing the pharmaceutical industry are expected to submit separate submissions setting out their comments.

2. Need for an in-depth further study of IP Policy issues

It is necessary to place on record the fact that the time allocated for interested persons to study the Policy document with its wide-ranging and diverse statements and recommendations, and to prepare and submit comments, was totally inadequate. The Policy document addressed a wide

range of complex and important issues, issues not only important to Government, to industry and to IP users and practitioners, but issues of particular general public interest.

It is expected that a National Policy on Intellectual Property, once rendered into final form, will shape and determine South Africa's IP regime for many years to come. It is of critical importance, therefore, that the Policy should not be finalised and concluded until such time as a further opportunity for external consultation and external input has been provided.

It is proposed that **the dti** should consider appointing a Task Team composed of experts in the field of IP law and practice and representatives of different industry sectors, with the specific mandate to consider all submissions made in response to the invitation published under GN 918/2013 as well as all other relevant considerations, and on the basis of all that to formulate a proposed policy document for submission to and consideration by **the dti** and for ultimate approval by Cabinet.

II. OBJECTIVES AND BACKGROUND OF THE IP POLICY

The broad objectives of the IP Policy (as set out on p.4 of the Policy document) in general aim to stimulate the economy of South Africa and to empower its citizens. Specific objectives are set out; these are generally supported, including –

- 1.1 to engender confidence and attract investment
- 1.2 to create an environment conducive to economic opportunities to empower South African citizens
- 1.3 to promote research, development and innovation in all sectors
- 1.4 to ensure that IP laws are aligned with the level of development and innovation in South Africa
- 1.5 to improve national compliance with international treaties of which South Africa is a member
- 1.6 to enhance access to foreign and local technology and to develop a strategy on technology transfer to build domestic capacity and skills
- 1.7 to efficiently apply an IP system alongside other Government policies
- 1.8 to enhance the function and capacity of IP regulatory and registration departments
- 1.9 to develop an IP Policy that addresses emerging issues relating to IP and that recognises national issues such as public health, food, education
- 1.10 to introduce a public health perspective into IP laws and to improve access to medicines
- 1.11 to improve access to IP-based essential goods and services, eg for education, health, food
- 1.12 to develop an overall transfer of technology strategy aimed at building domestic capacity and skills.

Submission by IPASA

It is submitted that 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.

It is also submitted that 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.

It is emphasised, as recognised in the Policy document, that the most important objectives 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. These outcomes will result in growth in employment, in the alleviation of poverty, and in economic security and socio-economic stability. Each of the recommendations of the Policy document must be measured against these objectives to assess whether such recommendation contributes to or detracts from these objectives.

It is thus essential that IP be viewed from the perspective of the potential benefits which IP holds for South Africa rather than from a protectionist point of view. In order for the South African economy to move from a resource-based economy to a knowledge-based economy, and in order to avoid disinvestment, de-industrialisation and the flight of capital, and in order to advance research and technology in South Africa it is imperative that the IP Policy should encourage and protect South African research and innovation in a cost effective and enforceable manner. For the same reasons the ability must be enhanced of South African-based research institutions to protect innovations in South Africa and abroad and to commercialise those innovations. At the same time the IP Policy should encourage foreign companies and entities to bring their research and innovation outcomes to South Africa, to obtain effective protection under South African laws, and to exploit and commercialise their IP in South Africa to the benefit of the country and its people.

The achievement of the broad objectives is in the national interest; however, there may be different viewpoints as to the manner in which these objectives should be achieved. IP is indeed seen as a tool to be used to enable the achievement of the broad objectives in regard to economic and trade development; the IP system must not only be moulded to suit the developmental environment of the country but also to enable the objectives to be realised. In this regard it is expressly stated as an objective that national IP laws must be appropriate to the level of development and innovation of South Africa. Although an implication of this latter statement may be seen as an intention that the level of IP protection should be lowered, it is trusted that this is in fact not the case; a strong IP protection system is generally viewed as a tool to enhance innovation, technology development and ultimately economic growth.

The fact that it is also expressly stated that IP should promote research, development and innovation in all sectors is therefore endorsed. It must be emphasised that, 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 for research and development (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.

The broad objectives of stimulating the economy, engendering confidence and attracting investment, and promoting research and development are accordingly supported. The objective of addressing national issues such as public health, food and education is likewise supported. The role of other factors (other than IP) in achieving these objectives must, however, 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.

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

Another objective is stated to be 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. Thus the optimal use of TRIPS flexibilities would be 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 erode confidence in the system and will be a disincentive to investment and to R&D.

The arbitrary use of TRIPS flexibilities as a means to weaken the patent system and to reduce or eliminate pharmaceutical patents will result in unforeseen negative consequences across all industrial sectors, and ultimately throughout the South African economy. It can be expected that this will result in a loss of confidence in and damage to the South African economy. In addition, such a discriminatory IP policy would be unfair, in contravention of TRIPS obligations, and unconstitutional.

III. ISSUES TO BE ADDRESSED

The Draft National Policy on Intellectual Property, 2013 (as set out in the Policy document) deals with IP-related matters over a wide spectrum of areas, covering not only issues relating to the protection and enforcement of IP but also issues arising from the interfaces between IP and Public Health; IP and Competition, Public Policy-Making and Technology Transfer; IP and Institutional Capacity; IP and International Architecture, etc. Although the interface between IP and Public Health is the primary focal area for the pharmaceutical industry, several of the other areas that interface with IP are also relevant to the industry.

Accordingly, this submission will primarily address the subject matter as set out in CHAPTERS 1, 2, 5, 7, 8, 9, 10 and 14 of the Policy document in so far as this relates to pharmaceutical and health-related matters, will provide explanatory information relevant to the viewpoints of the pharmaceutical industry, and will comment on the various policy recommendations put forward in these chapters of the Policy document.

For ease of reference, issues addressed in the Policy document in different chapters have been grouped together on the basis of their relevance to specific topics; these topics will be dealt with in numbered sequence in PARTS 1 – 9 below. Different policy positions and recommendations, dealt with in different chapters of the Policy document, will therefore be grouped together and addressed together in topical context in PARTS 1 – 9 below.

IPASA confirms that an appropriately drafted and implemented IP policy should encourage medicines innovation, investment and economic development, consistent with South Africa's national imperatives and international obligations. IPASA believes that the Draft National Policy on Intellectual Property (the Policy) represents an important step towards achieving these goals. IPASA applauds the Policy's intent to establish a more robust patent system, and supports the proposal to develop more extensive enforcement remedies and to support trade secret protection. IPASA is concerned, however, that the Policy may overly restrict patentable subject matter and may not offer adequate data protection to pharmaceutical innovators. There are also concerns about the Draft Policy's failure to provide for patent term restoration; its proposal to connect the marketing regulatory and patent databases; and its proposals endorsing parallel importation of pharmaceuticals; the intention to regulate technology transfer relating to pharmaceuticals; and the use of compulsory licensing to facilitate market entry of generic drugs. These proposals could harm prospects for further development of, and investment in, research and development and enhanced manufacture in South Africa's innovative biopharmaceutical industry.

PART 1: Procedure for patentability

The Policy document in Chapter 1, dealing with Patents in part a), as well as in Chapter 2, dealing with IP and Public Health, and in Chapter 8, dealing with Institutional Capacity, addresses various aspects of the current law and practice regarding the granting of patents, and contains several recommendations relating to the current procedure for the granting of patents. These are set out below.

Policy recommendations:

- 1.1 Government should consider approving the establishment of a substantive search and examination system of patent applications to ensure the patenting of strong technologies (p.8, p.12).
- 1.2 South Africa should consider adopting the search and examination system of patent applications to co-exist with the current registration system (ie a non-examining depository system) of patents system (p.11).
- 1.3 The Patents Act should be amended to have both pre- and post-grant opposition procedures to effectively foster the spirit of granting stronger patents (p.10).
- 1.4 The search and examination system should be introduced with other complementary systems, such as pre- and post-grant opposition procedures and capacity building, for an efficient system (p.11).
- 1.5 South Africa should adopt a multi-faceted approach in so far as the registration of patents is concerned; that is, it should use the depository (registration) system, a substantive search and examination system, and the utility patent system (ie the granting of utility models or petty patents for lower-level technologies) (p.32).
- 1.6 Government must coordinate universities and research institutions that have competencies to evaluate patent applications (p.33).

The Policy document also recommends that a cost and benefit analysis should be conducted before implementing some of the patent-related recommendations, and sounds a warning that official fee structures may have to be adjusted:

- 1.7 A cost and benefit analysis should be conducted through the Regulatory Impact Assessment (RIA) process, and benchmarks should be based on similar economies such as India, Brazil and Egypt. Benefits should not only be calculated in monetary terms, as access to public health does not necessarily translate into monetary value (p.11).
- 1.8 South Africa should adopt a multi-tiered or differentiated fees structure on IP matters without compromising service delivery and value for money (p.33).

Submissions by IPASA

In response to the recommendations set out above, IPASA makes the following submission for consideration by Government:

Ad recommendation 1.1:

IPASA is not opposed to the principle underlying the recommendation for the development of a substantive search and examination system. However, it is not correct to assume that the current system generally results in weak patents, or that a search and examination system will result in the issuance of stronger patents than those issued under the current registration system. IPASA is also not convinced that the implementation of such a system will be practical nor indeed feasible. Such a system will demand high costs and substantial human resource capacity. Sustained investment in building this infrastructure will only be justified, however, if proceedings are fair and are resolved within a reasonable time frame. For this reason, 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 a backlog and to ensure that the entire system runs effectively and efficiently.

See also the further remarks and submissions under the heading Background information and remarks by IPASA below.

Ad recommendation 1.2:

IPASA submits that the problem with such a 'hybrid' system will lie in the designation of fields of technology and/or origin of applications to be either deposited or examined. Any such differentiation poses a risk of contravening the non-discrimination principle of TRIPS Art 27.1. There would be discrimination, and thus a contravention of TRIPS Art 27.1, 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, or vice versa.

Accordingly, in regard to the proposal for a 'hybrid' system, the risk of contravention of the non-discrimination principle of TRIPS Art 27.1 should be emphasised: patent rights shall be available and enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally made.

Ad recommendation 1.3:

IPASA submits that, 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. The justification for pre-grant opposition is primarily to serve as a substitute for an examination procedure, ie to ensure that the patentability (novelty and inventiveness) of the invention and the potential validity of the patent are assessed before the patent is granted.

IPASA submits that the proposal that has the potential to lead to unnecessary delays and undermine development of a robust intellectual property system, is that of the introduction of pre-grant opposition proceedings. Such proceedings may be used inappropriately and often frivolously to delay the granting and enjoyment of valid patent rights.

As regards the proposal for a post-grant opposition procedure, the Patents Act already provides in s.61 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.

Ad recommendation 1.4:

IPASA submits that, before an integrated system combining search and examination with pre- and post-grant opposition, a thorough cost and benefit analysis should be conducted, as recommended in Policy Recommendation 1.7.

Ad recommendation 1.5:

IPASA again submits that a multi-faceted approach may entail the risk of discrimination, and thus a contravention of TRIPS Art 27.1, if only pharmaceutical patents are to be examined, while applications in other areas of technology are merely registered.

The recommendation that provision should be made for the granting of utility models is supported.

Ad recommendation 1.6:

As indicated above, IPASA confirms that capacity building and investment will be critical for implementing effective substantive search and examination procedures. However, it is not clear that academic and research institutions could be used to provide this capacity.

Ad recommendation 1.7:

IPASA supports the Policy recommendation that an encompassing cost and benefit analysis would be informative and indeed beneficial.

Ad recommendation 1.8:

IPASA submits that a differentiated fee structure (that provides for a reasonable 'search and examination' fee that is dedicated solely to investment in search and examination resources) would help provide resources for building the infrastructure to support this patent granting process. Such a system should not, however, compromise efficiency. Unreasonable delays in patent examination will discourage innovation and investment in building this system. IPASA also believes that patents that undergo a substantive search and examination should be entitled to a presumption of validity during the examination period. In addition, it is suggested that the implementation of a compensatory measure be considered, such as a patent term adjustment system to allow patent

holders to effectively enjoy their rights where the substantive search and examination system leads to delays in the issuance of a patent.

Background information and remarks by IPASA

Substantive search and examination

At present the granting of patents in South Africa does not entail a substantive search and examination procedure; a so-called depository system is used. Although the Patents Act requires (s. 34) the Registrar to examine patent applications, the Regulations prescribe (reg. 41) that only a formal examination is required, ie to ensure that all formal requirements have been complied with. The perception appears to be that such a non-examining system results in the granting of ‘weak’ or invalid patents, ie patents for ‘invalid’ inventions lacking the necessary novelty and inventiveness requirements set by the Patents Act.

Search and examination systems are generally used in developed countries but have been implemented also in several developing countries such as Brazil, China, India and Egypt. The experience has shown that such a system requires extensive technical capacity within the registration authority, and has significant cost and time-delay implications. For example, in Brazil a team of more than 700 technical staff is used to carry out the search and examination function, and the average period used for the search and examination of a patent application is close to 10 years.

If a substantive search and examination system is introduced, this will have to be in respect of all areas of technology to avoid contravening the non-discrimination principle of TRIPS Art 27.1. This would require even more extensive and diversified technical capacity in the Registry staff, with significant cost implications. This would not only increase the patenting costs but would also introduce a substantial time-delay factor, and thus serve as a disincentive, particularly for smaller businesses.

In the area of pharmaceutical products, patents in South Africa are generally in line with patents in other countries where substantive search and examination systems apply. Therefore, the South African patents for pharmaceuticals are already ‘strong’ patents. In this regard, s.43(4) of the Patents Act allows any person to obtain from the patent applicant any search report issued in another country for the same patent. Since this may be relied on by third parties to revoke the South African patent in terms of s.61 of the Patents Act, patent applicants are motivated to ensure that their South African patents are brought into a form as allowed in examining countries, ie to be ‘strong’ patents.

In assessing the potential advantages of a search and examination system, it should also be taken into account that a large number of South African patents are allowed to lapse within a few years of application. A review of renewal patterns of South African patents has revealed that in the 8th year after application only approximately 40% of granted patents are maintained, only 20% by year 15, and less than 10% in the last year. In addition, only a very small number of South African patents are

ever enforced. During enforcement proceedings the validity of the patent is almost inevitably assessed by a judicial officer with the benefit of expert evidence and legal argument, and only patents found to be valid are enforced. A heavy onus is thus placed on patent owners to maintain only valid and enforceable patents on the patents register. The current system makes sure that the onus to ensure that commercially valuable patents are rendered into valid form (ie brought in alignment with corresponding patents in other countries) and are maintained on the register (ie by paying the annual renewal fees) is placed on patent owners, so that the parties with a commercial interest in the patent spend the necessary costs on only those limited numbers of patents that are of commercial importance. The patent registry is not burdened with the cost and capacity requirements to ensure that only valid patents are on the register. In addition, the judicial system is not burdened with the costs and capacity requirements for assessing the validity of patents which are not of any commercial importance.

As indicated above, a search and examination system of patents will result in additional capacity requirements at the patent office, a significant increase in costs for all patent applicants, and delays in the prosecution of patent applications. Inevitably this will have a negative impact on the costs for securing rights to all South African and foreign inventions. There are initiatives in South Africa that encourage innovation especially amongst SMEs. The success of these initiatives is promoted by a low-cost patent system. Introducing a search and examination system would substantially increase the costs of prosecuting an application (by at least four to five fold) and would thus discourage local inventors and SMEs from obtaining protection. In short, the patent system may become inaccessible to a larger section of the economy in South Africa. Since foreign applicants and large local businesses would generally have the required funds and expertise to deal with the increased costs of patent prosecution, the introduction of a search and examination system would have less of an effect on these entities.

Furthermore, TRIPS Art 62 requires reasonable protection procedures to be carried out within a reasonable period of time, which are governed by principles of fairness and equity, and which are not unnecessarily costly. In addition TRIPS Art 27 requires that there shall be no discrimination between different fields of technology; Art 3 requires that all applicants, whether foreign or local are treated equally (national treatment); and Art 4 requires that foreign nationals from all countries are also treated equally (most-favoured-nation treatment). In addition, South Africa's own constitution protects against unfair discrimination between parties and property.

It is thus crucial that a search and examination system shall apply equally to patent applications filed by foreign or local applicants and in all technology fields. In addition, in order for the examination system to be creditable, it will have to be effective, consistent and reliable. Duplications during examination must be avoided as this will result in duplication of efforts and resources and will result in an escalation of costs and delays and will undermine confidence. As required by TRIPS and the constitution, all administrative actions during examination will have to be subject to judicial review.

Finally, 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. The justification for pre-grant opposition is primarily to serve as a substitute for an examination procedure, ie to ensure that the patentability (novelty and inventiveness) of the invention and the potential validity of the patent are assessed before the patent is granted.

Pre- and post-grant opposition

As regards the proposal for a post-grant opposition procedure, the Patents Act already provides in s.61 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.

When considering the merit of introducing a provision for pre- and post-grant opposition, an important issue would be the nature of such a procedure: would it be a proper judicial process, or a hearing and decision by a designated official acting as a hearing officer? It should be pointed out that the nature of the procedure would determine its credibility; a judicial procedure would be necessary to ensure credibility. A decision by a designated official would be open to question. Further, as already pointed out, the current revocation provision (Patents Act s.61) is equal to a post-grant opposition; this is a creditable judicial procedure in a court of law.

As regards pre- and post-grant opposition, it should be 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.

Outsourcing evaluation functions

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. In this regard the use of different South African institutions and entities, such as universities and research institutions, may also entail an element of uncertainty and lack of credibility: there would be no guarantee that the same level of critical assessment would consistently apply in the case of different institutions being used to carry out this function. This would erode the integrity and credibility of South African patents and may indeed have a greater negative impact than the allegation of 'weak' patents resulting from a non-examining system.

It is generally accepted that one of the most serious problems facing the pharmaceutical industry today in Brazil was created when Article 229-C was introduced into the patent law by a 1999 amendment. This requires the health regulatory agency (ANVISA) to approve all patent applications

claiming pharmaceutical products and/or processes. This review 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.

As the law is currently implemented in Brazil, ANVISA analyses the patent application before INPI does, and only those applications that receive ANVISA's approval are submitted to INPI. The patent applications that do not receive ANVISA's approval are extinguished without the proper examination of the patent authority, and the applicant can only demand the protection through the Brazilian courts. This administrative flow causes further significant and duplicative examinations that unduly and unfairly impede pharmaceutical patent applications.

Brazil and India have only recently adopted protection for pharmaceutical patents and patents take several years to mature to grant in these countries (since 2001 between 8 to 10 years in Brazil). Despite a lack of historic patent protection and a strong generic manufacturing sector, general access to essential medicines in India and Brazil is much lower than in South Africa. The historic protection of new and inventive pharmaceutical inventions in South Africa has resulted in better access to medicines in South Africa compared to Brazil, India and Egypt and this protection should be maintained in order to ensure the high levels of access to medicines required in South Africa.

Possible 'hybrid' systems

In the light of the high cost and technical capacity factors inherent in a search and examination system, the use of 'hybrid' systems is being considered, ie a deposit system to co-exist with a search and examination system. The problem with such a 'hybrid' system will lie in the designation of fields of technology and/or origin of applications to be either deposited or examined. Any such differentiation poses a risk of contravening the non-discrimination principle of TRIPS (Art 27.1), and also the principles of national treatment (Art 3) and most-favoured-nation treatment (Art 4), as pointed out above.

In assessing the use of a 'hybrid' system, the main consideration would be that such a system should be structured and operated on a non-discriminatory basis; there would be discrimination, and thus a contravention of TRIPS Art 27.1, if only pharmaceutical patents are to be examined, while applications in other areas of technology are merely registered. There would also be discrimination and a contravention of TRIPS Art 3 if only foreign patent applications are examined, while locally originating applications are merely registered, or vice versa.

Accordingly, in regard to the proposal for a 'hybrid' system, the risk of contravention of the non-discrimination principle of TRIPS Art 27.1 and the national treatment principle of TRIPS Art 3 should be emphasised: patent rights shall be available and enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally made.

Cost and benefit analysis

A cost and benefit analysis would be a useful tool, provided it is executed in a transparent and credible manner, to determine the consequences of changing the current deposit system. As regards the overall benefits of a cost and benefit analysis, it must be pointed out that a steep increase in patenting costs in South Africa could be a disincentive to filing and commercialising the invention in South Africa.

The issue of a multi-tier or differentiated fee structure is not entirely clear. Reference is made in the document (p.23) that most of the IP comes from foreign companies. If a differentiated fee structure envisages higher filing fees for applications originating in foreign countries, there could be a risk of discrimination and thus a contravention of TRIPS Art 27.1, unless the higher fees can be justified on the basis of additional administrative work required in such cases.

It is accepted that the filing and prosecution fees will have to be increased if a substantive search and examination system is introduced to cover the additional costs involved.

An alternative option that may be considered to reduce the number of applications to be subjected to a search and examination process, is to empower the Registrar to require from an applicant to provide him with the results of a search and examination procedure carried out in respect of a corresponding application in another country (ie based on and somewhat similar to the current provision of s.43(4)).

Where an applicant provides the Registrar with information regarding the outcome of examination in another examining country, on which the Registrar can rely in granting a patent, the cost to the Registry would be lower and a lower fee would be justified, while the outcome would be a patent with demonstrated validity.

However, where a differentiated fee structure refers to the need for substantive examination in cases where there cannot be reliance on such an examination in another country, a higher fee would be justified.

It is not clear what the position of all the different users of the IP system would be on the issue of a differentiated fee structure, in the light of a possible perception of a discriminatory system. This would be a matter for thorough consultation with all stakeholders.

PART 2: Requirements for patentability

The Policy document in Chapter 2, dealing with IP and Public Health, also addresses several aspects of the current law and practice regarding the granting of patents which are of particular importance to the pharmaceutical industry. Some of these aspects relate to the patentability of inventions, and two recommendations of particular relevance to the pharmaceutical industry are put forward. These are commented on below.

Policy recommendations:

- 2.1 South African legislation should allow strict rules to apply to patenting as competition principles may be undermined. This should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as is the case under the TRIPS Agreement (p.21).

- 2.2 Where indigenous knowledge is used in developing patents, there should be disclosure of the origin of the genetic resource or knowledge, prior informed consent, benefit-sharing or co-ownership of the patents (p.21).

Submissions by IPASA

In response to the recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 2.1:

IPASA emphasises that, through scientific advancements in the understanding of diseases, and through continued research and development, important new uses for known medicines are discovered. In addition, new combination therapies utilising 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 research and development and entail new medical uses of known products.

IPASA strongly encourages the policy makers of South Africa to recognise the significant health, scientific, and commercial benefits of incremental innovations and new uses for existing pharmaceuticals. Patent applications for new improvements, upgrades, and next generation products should be reviewed in accordance with internationally recognised patentability criteria; the policy position should also be applied consistently among all technology dependent sectors. The

failure to provide patents for ‘new uses of known products’ may reduce investments in research, resulting in fewer treatments for unmet medical needs.

IPASA further submits that a blanket refusal to recognise patents for new uses of existing substances would be inconsistent with Art 27.1 of TRIPS. Art 27.1 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 the TRIPS Agreement 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, as proposed in the Policy document. Art 27.1 also requires that ‘patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology’. Additional hurdles to patentability that fall disproportionately on the pharmaceutical sector and/or on inventions made in other countries would be contrary to, and a contravention of, this obligation.

See also the further remarks and submissions under this heading Background information and remarks by IPASA below.

Ad recommendation 2.2:

IPASA supports this recommendation, but points out that the recognition of the use of indigenous resources and/or knowledge, has already been addressed in South African law (Patents Act s.30(3B) and reg 44A). The patent applicant is already required to disclose any use made of indigenous knowledge and to confirm that prior informed consent and benefit-sharing have been complied with.

Thus the current provisions of the Patents Act in regard to the use of indigenous knowledge are supported as giving due recognition to the use of indigenous resources and indigenous knowledge.

Background information and remarks by IPASA

Incremental innovation

Strong proposals have been made by activist groups that the requirements for a patentable invention should be stricter, so as to prevent incremental innovation leading to the patenting of insignificant modifications and the unjustified extension of patent monopolies, and thus to prevent ‘evergreening’.

Although this is not expressly stated in recommendation 2.1, 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.

The fact is that South African law, in line with TRIPS Art 27.1, generally 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. Unlike the position in some countries, South African law prescribes (Patents Act s.25(5), (6)) absolute novelty as a requirement for patentability. The South African requirement for inventiveness (Patents Act s.25(10)) is the same strict requirement applicable in most developed countries.

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

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. Incremental innovation and advancement on basic inventions and concepts should be encouraged and, if new and inventive, should be protected in all technology fields, since continued advancement results in the introduction of new, better and cheaper products.

A recent joint study was carried out by WTO, WIPO and WHO (*Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade – WTO, WIPO, WHO 2013*). This study concluded that access to medicines is a complex issue touching on many issues outside of the patent system.

This study pointed out that –

- access to medicines has to be seen in the broader context of the need for innovation and effective regulation (p.30); merely to leverage enhanced access to the stock of existing, proven medicines is insufficient (p.32);
- there is a continuing need for new, adapted and more effective medicines; access is not a static equation – an integral feature of appropriate access strategies must be a recognition of the value of targeted and appropriate innovation, both for major new breakthrough products but also for adaptations to, and improvements of, existing technologies (p.35);
- the mere existence of IP rights on a product is not a barrier to, nor its absence a guarantee of, access to that product (p.171).

For illustration of these principles it should be noted that, from the WHO list of essential medicines, more than 95% of essential medicines were once patented (thus came from research and innovation) but that at present less than 1.4% of these essential medicines remain under patent (It is unlikely that currently there are any patents on these essential medicines in Africa and Southern Africa). Yet, access to these essential medicines remains problematic in most countries and it is difficult see how the patent system can be held responsible for the lack of access to these essential medicines.

The study further illustrates that 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 (p.130); it is thus important to judge every individual invention claimed in a patent on its own merits. The mere fact that an innovation is incremental is not a ground for refusing the granting of a patent. In fact, in most cases innovation is incremental by nature since technology normally progresses in incremental steps (p.131). For these reasons it is important that a patent must be available if the patentability criteria of novelty, inventive step, and industrial applicability are met (p.131).

If patent protection for new and inventive incremental innovations in the pharmaceutical field is limited, investment (in clinical trials, product registration, infrastructure, distribution channels, training of medical personnel, education, creating awareness) by pharmaceutical companies in South Africa in respect of new products and remedies is likely to be delayed and in some cases products and remedies may never reach the South African market. This will result in a lack of access for South Africans to these latest medical advancements and the accompanying health benefits.

It is emphasised that, although discoveries of new chemical entities (ie basic inventions) are extremely valuable, important innovations based on such prior inventions continue later with research and development on improved drug delivery methods, formulations and effectiveness, all of which greatly benefit patients. Following the discovery of a new drug class, research-based pharmaceutical firms expend significant resources making important improvements in the safety, efficacy, selectivity, and utility of drugs within such a class, leading to substantial progress over time. For example, with respect to specific drug products, new formulations have been developed from known medications or compounds that are easier to use, lead to greater patient compliance, and have fewer side effects. Without incentives for investment into these technologies, these new treatments would not be available to patients.

Government is strongly encouraged to recognise the significant health, scientific, and commercial benefits of incremental innovations and new uses for existing pharmaceuticals. Patent applications for new improvements, upgrades, and next generation products should be reviewed in accordance with internationally recognised patentability criteria, and should be applied consistently among all technology dependent sectors. The failure to provide patents for ‘new uses of known products’ may reduce investments in research and development, resulting in fewer treatments for unmet medical needs.

TRIPS takes no position on the standards to be applied to determine novelty and inventiveness. TRIPS also does not expressly exclude incremental inventions from patentability. The provision in TRIPS Art 27.2, namely that countries may exclude from patentability inventions the commercialisation of which must be prevented inter alia to protect human health, is generally understood as a basis to prohibit the patenting of harmful products.

However, since the issue of the proposed limitation on the patentability of incremental inventions is not expressly addressed in the recommendation 2.1, is seen as an indication that Government does not propose to introduce such a limitation. This position is supported.

New molecular forms and formulations

Activist groups have also specifically urged Government to exclude from patentability inventions in the form of new molecular forms of active ingredients, eg crystalline forms, and new formulations of medicinal products. Unlike the legal position eg in India, new molecular forms of active ingredients and new formulations are not excluded from patentability in South Africa, provided such molecular

forms or formulations are new and inventive. The activist groups proposed that the South African law should be amended to adopt the approach as in India.

It is submitted that patentability of new formulations or molecular forms of active ingredients should not be abolished *per se*. Extensive R&D is often required to improve a molecular form or 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. Removing the possibility of patent protection for improvements that are new and inventive will discourage further R&D to find improved medicines, also in cases of resistant illnesses where the existing medicines are no longer effective.

Again this specific issue, ie the patentability of modifications of existing basic inventions, is not expressly addressed in the recommendation 2.1. It seems, therefore, that Government does not propose to place a restriction on the patentability of such modifications of basic inventions. This position is supported.

New medical use of known substances

Activist groups have further proposed that an invention that comprises the new medical use of a known substance should not be patentable, even if such new medical use complies with the requirements for patentability. The patentability of the new medical use of a known substance (so-called first medical use) is expressly permitted in South Africa (Patents Act s.25(9)). TRIPS has no provision on this issue; more specifically, TRIPS does not exclude from patentability new medical uses of known substances.

The patentability of second and further medical uses of known substances is not expressly prohibited in South Africa and is in practice allowed, provided such further medical use is new and inventive. TRIPS has no provision to exclude such patents.

Through scientific advancements in our understanding of diseases and through continued research and development, important new uses for medicines are discovered. For example, 30 years after its original approval in 1977 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 by the US FDA to reduce the risk of invasive breast cancer in postmenopausal women. In addition, new

combination therapies utilising existing drug products have advanced treatments for a wide range of conditions with substantial benefits to public health. These types of innovations are achieved through intense research and development. The resultant products are all new applications of known substances.

As regards that part of the recommendation 2.1 proposing that South African legislation should be amended so that new uses of known substances would no longer be patentable, it is submitted that this proposal should be reconsidered and not further pursued. It is emphasised that many highly effective medical products are based on new uses of known substances. If such inventions will no longer be patentable, R&D work focussed on such new applications will be discontinued, to the detriment of patients. It is emphasised that TRIPS does not exclude from patentability the new medical uses of known substances.

Methods of treatment

It may be mentioned that the recommendation 2.1 is not entirely clear: diagnostic, therapeutic and surgical methods of treatment are already excluded from patentability in South Africa (Patents Act s.25(11)). 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. Accordingly, in this respect the recommendation is already part of South African law.

Disclosure of indigenous resources

This issue of recommendation 2.2, ie the recognition of the use of indigenous resources and/or knowledge, has already been addressed in South African law (Patents Act s.30(3B) and reg 44A). The patent applicant is already required to disclose any use made of indigenous knowledge and to confirm that prior informed consent and benefit-sharing arrangements have been complied with. The current provisions of the Patents Act in regard to the use of indigenous knowledge are supported as giving due recognition to the use of indigenous resources and indigenous knowledge.

PART 3: Parallel importation and compulsory licences

In Chapter 1, in the section dealing with Patents, and in Chapter 2, dealing with IP and Public Health, two important issues are addressed, namely the issue of parallel importation, and that of compulsory licences. Both these issues are of particular importance to the pharmaceutical industry. Certain recommendations are made; these are dealt with below.

Policy recommendations:

- 3.1 South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha decisions of the WTO on IP and public health (p.12, p.13).
- 3.2 South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions (parallel importation). Parallel importation of IP can also be made under a regional arrangement and, in this regard, South Africa may wish to influence regional integration for the purpose of access to medicine (p.21).
- 3.3 Law enforcement agencies in South Africa should not confiscate/seize generic products in transit on the pretext that they are counterfeits (p.13).
- 3.4 Compulsory licensing should be introduced in South Africa in line with international treaties such as Doha Decision 6 of the WTO negotiations on trade and public health (p.21).

Submissions by IPASA

In response to the recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 3.1:

IPASA understands this recommendation to refer in the first place to paragraph 5 of the Doha Declaration of 2001, which 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. The correctness of this reference to the 2001 Doha Declaration is confirmed.

However, IPASA wishes to point out that the 2001 Doha Declaration must be viewed within the context of critical issues that were addressed at that time, ie the gravity of the pandemic diseases that were afflicting developing and least-developed countries at that time. Legislative measures to permit compulsory licences and to legalise parallel imports were intended as measures to address these health crises.

IPASA submits that reliance on the 2001 Doha Declaration cannot be justified in order to motivate legislative amendments to facilitate parallel imports and compulsory licences in respect of pharmaceutical products in general. Furthermore, 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.

Ad recommendation 3.2:

IPASA submits that 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. Without that link, counterfeit and/or poor-quality goods enter the drug supply lines more easily. Patients often cannot distinguish counterfeit or sub-standard pharmaceutical products from genuine products. Moreover, in the case of product withdrawal or recall, the manufacturer may not be able to identify parallel importers and alert them of recall decisions.

The Policy document itself acknowledges the challenges of monitoring counterfeit medicines and preventing the shipment of medicines to unintended destinations. Any legislative changes or regional arrangements that eliminate or scale back existing regulations on parallel importation will make those challenges more acute. The primary benefits of expanded parallel trade, meanwhile, will likely accrue to intermediaries.

See also the further remarks and submissions under the general heading Background information and remarks by IPASA below, under the sub-headings Parallel importation explained and Price differentials provide benefits.

Ad recommendation 3.3:

IPASA confirms that a generic product is not necessarily a counterfeit product (ie illegally bearing the same or confusingly similar brand name as the genuine product). However, IPASA also emphasises that a generic product is not the genuine product.

Ad recommendation 3.4:

IPASA points that, as a basis for expanding the grounds for compulsory licenses, the Policy document invokes Paragraph 6 of the Doha Declaration, which recognised that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement, and instructed the TRIPS Council to find a solution. A 2003 decision of the WTO General Council announced the implementation of Paragraph 6 and submitted a proposed amendment to TRIPS that entail a dual export/import compulsory licence model. The 2003 decision set forth detailed criteria for countries seeking to qualify as an eligible importing member. Significantly, Paragraph 6 may only be invoked on a case-by-case basis, and only after South Africa has determined that it has insufficient manufacturing capacity for the specific product that it seeks to import. The Policy document says generally that 'South Africa seems to be having a problem with manufacturing capacity'. This will have to be factually established. More detailed analysis would thus be required before South Africa could invoke Paragraph 6 of the Doha Declaration. If South Africa did meet the WTO's requirements, South Africa would need to give proper notification to the TRIPS Council of the products and quantities needed, and to take measures to prevent re-exportation, as set forth by the WTO General Council.

Background information and remarks by IPASA

Parallel importation explained

Parallel importation is the importation of genuine goods into South Africa without the consent of the right holder. In other words, parallel importation is the importation into South Africa by a person other than the patent holder, and without the express authorisation of the patent holder, of a genuine product that is subject to patent rights in South Africa. Parallel importation thus 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.

The disposal of a patented product by or on behalf of the patent holder gives the purchaser certain rights; in South Africa the purchaser acquires the right to use or dispose of the product purchased –

Patents Act s.45(2). It is noteworthy that s.45(2) does not give the purchaser the right to export or to import the product purchased. It is also noteworthy that s.45(2) does not state that the disposal of the patented product by or on behalf of the patent holder anywhere in the world shall give the purchaser the rights contemplated in s.45(2). Since the South African Patents Act only has territorial effect, it must be accepted that s.45(2) must be interpreted to state that the disposal of the patented product in South Africa gives the purchaser in South Africa the rights mentioned in s.45(2).

Exhaustion of rights

The principle, ie that the disposal of a patented product by or on behalf of the patent holder gives the purchaser certain rights in respect of the product purchased, is known as the principle of the exhaustion of rights: once the patent holder has received his remuneration by selling the product, his patent rights in respect of that product are exhausted. A debate which has been ongoing throughout the world even since prior to TRIPS, is whether patent law should provide that the sale of a patented product should result in the total international exhaustion of rights, or only in limited national exhaustion in accordance with national law. Since no consensus could be reached, TRIPS Art 6 takes no position on the issue of exhaustion of rights.

As indicated above, it is noteworthy that in South Africa this concession under s.45(2) does not include the right to the purchaser to import the patented product; it thus seems that s.45(2) does not contemplate the total exhaustion of rights. It is further noteworthy that s.45(2) does not refer to the disposal of the patented product by the patent holder anywhere in the world; again it seems that s.45(2) does not contemplate total international exhaustion of rights.

If the exhaustion of rights in terms of South African law is indeed limited, parallel importation would constitute infringement. A legislative amendment would thus be necessary to legalise parallel importation into South Africa.

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.

Price differentials provide benefits

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. By sourcing the patented product from a country where manufacturing costs are lower, the parallel importer aims to be more competitive in the country of importation, and to capture the market and/or to secure supply contracts; the parallel importer does not necessarily aim to benefit the people in the country of importation.

It is thus 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, and may affect all economic sectors and impact a host of issues, including beneficiation, imports, exports, research and development investment, manufacturing growth, foreign direct investment etc.

The costs of medicines is generally driven in different countries by different factors, such as direct and indirect input costs, labour costs, electricity costs, state subsidies and incentives, taxes, rebates, import duties and transport costs. Importantly, the quality of medicines may also differ from country to country, which factor also influences costs. Effective public sector procurement of medicines on tender, such as the system used in South Africa, often results in the supply of medicines to the public sector at cost or even below cost. This remains the most effective method to control costs of medicines in the public sector.

This means that, in order for parallel importation to benefit the people in need of more affordable quality medicines, several aspects of such parallel importation will have to be controlled.

Furthermore, it is important to recognise that parallel importation (or international exhaustion of patent rights) will benefit the parallel trader as opposed to the consumer, and may affect all economic sectors and impact a host of issues, including beneficiation, imports, exports, research and development investment, manufacturing growth, foreign direct investment etc.

Risks to patients

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.

Expanding South Africa's laws to legalise the 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. Without that link, counterfeit and/or poor-quality goods can enter the drug supply lines more easily. Patients often cannot distinguish counterfeit or sub-standard pharmaceutical products from genuine products. Moreover, in the case of product withdrawal or recall, the manufacturer may not be able to identify parallel importers and alert them of recall decisions.

The Policy document itself acknowledges the challenges of monitoring counterfeit medicines and preventing the shipment of medicines to unintended destinations. Any legislative changes that eliminate or scale back existing legislative regulations on parallel importation will make those challenges more acute. The primary benefits of expanded parallel trade, meanwhile, will likely accrue to intermediaries, ie the parallel traders.

As mentioned above, the unauthorised importation of a generic product must be differentiated from parallel importation: the unauthorised importation of a generic product made by a generics manufacturer (ie not the patent holder), and where the generic product falls within the patent claims, would constitute infringement. However, it should be noted that a generic product is not necessarily a counterfeit product (ie illegally bearing the same or confusingly similar brand name as the genuine product).

Compulsory licences

Unlike the measure of uncertainty in regard to exhaustion of rights, compulsory licences are dealt with in detail in the South African Patents Act and in TRIPS. Compulsory licences are granted (by the Court in terms of South African law) to third parties on certain specified grounds, without the consent of the right holder; in general a compulsory licence does not allow for the terms and conditions to be negotiated, nor for the royalties payable to be agreed upon. 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 (Patents Act s.56).

Activist groups argue that the grounds provided for in the South African Patents Act for granting compulsory licences are inadequate, and that the prescribed procedure is too complicated and costly. Government is urged to change the law so that additional health-related grounds for compulsory licences are prescribed by legislation, and so that the procedure is simplified.

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. There is also concern about apparent inaccuracies and misunderstandings that appear to underpin the reasoning reflected in the Policy document. For example, statements incorrectly imply that compulsory licences are widely used by other governments, developing and developed, including the United States. For example, the legal authority to issue a compulsory licence under a US patent is very limited, and the US government has never issued a compulsory licence on a biopharmaceutical product. These statements, therefore, should not be used to justify easier and quicker issuance of compulsory licences.

As indicated above, the law of South Africa (Patents Act s.56) 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 (s.56(2)(a));
- that the demand for the patented product in South Africa is not being met to an adequate extent and on reasonable terms (s.56(2)(c));
- 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 (s.56(2)(d));

- 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 (s.56(2)(e)).

TRIPS and compulsory licences

TRIPS makes specific reference to compulsory licences in Art 31 and to the procedures, terms and conditions to be adhered to, including that –

- each case is to be considered on its individual merits;
- a compulsory licence should only to be granted if the proposed user/licensee has made efforts to obtain a voluntary licence and such efforts have not been successful;
- such a compulsory licence shall be non-exclusive and non-assignable;
- the use shall be authorised predominantly for the supply of the domestic market.

The position in South Africa in terms of s.56 is in line with TRIPS.

It must be borne in mind that compulsory licensing can only provide a solution to the need for access to medicines if the prospective licensee has local manufacturing capacity. TRIPS Art 31 provides that a compulsory licence shall predominantly provide for the domestic market. South African law (Patents Act s.56(4)(a)) likewise permits the Court to preclude the prospective licensee from importing.

TRIPS Art 31*bis* (which envisages a double licence model to benefit developing countries without manufacturing capacity) has not yet been introduced in South Africa.

PART 4: Voluntary licensing and technology transfer

In Chapter 1, in the section dealing with Patents, and in Chapter 5, dealing with a variety of matters in the fields of IP, Competition, Public Policy-Making, Compulsory Licensing and Technology Transfer, a number of issues relating to voluntary licensing and technology transfer are addressed that are of relevance to the pharmaceutical industry. Certain recommendations are made; these are dealt with below.

Policy recommendations:

- 4.1 Regulations/guidelines on licensing should be developed to encourage the utilisation of patents. The Minister may issue a code of good practice as such guidelines (p.14).
- 4.2 South Africa must put systems in place that encourage foreign companies to transfer technology to domestic companies. Incentives/tax breaks may be devised to achieve this (p.29).
- 4.3 Technology transfer contracts should be standardised to regulate restricted/prohibited technologies subjected to export controls and maximum percentages (p.8, p.11).
- 4.4 South Africa must develop models that encourage technology transfer intra-industry/sector/firm and intra-public and private sectors. Common definitions should be developed on what constitutes technology transfer, and policies that enhance technology transfer must be put in place. There is a need to agree on common comparable metrics for measuring the extent to which incentives on technology transfer have their intended effect (p.28).
- 4.5 South Africa should strive to achieve technology transfer models that would encourage technology transfer to LDCs (p.28).

Submissions by IPASA

In response to the recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 4.1:

IPASA confirms that fair and equitable licensing guidelines developed by way of an inclusive consultation process would be useful. However, IPASA submits that the research-based pharmaceutical industry believes that licensing guidelines or regulations should not be used in a manner to limit market access. Restrictive national manufacturing or technology transfer requirements would raise national treatment concerns, among other issues, under TRIPS rules (as set out for example in Art 3 of TRIPS), and could have lasting implications for market access and patient health.

In particular it is strongly recommended that the Competition Commission should not be given the power to exert licensing pressure on IP owners, or to require technology transfer as a condition of market access.

Ad recommendation 4.2:

IPASA submits that voluntary and royalty-free licences are already granted by pharmaceutical companies; this is indicative of the industry's commitment to the principles verbalised in the recommendation 4.2 and, moreover, its 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.

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.

IPASA supports the use of metrics for measuring the effectiveness of various technology transfer incentives, such as tax breaks, to identify the most effective models for technology transfer.

Ad recommendation 4.3:

IPASA submits that, before steps are taken to standardise or regulate licensing and/or technology transfer contracts in the area of pharmaceutical products and manufacturing processes, an inclusive consultation process would be necessary. Further information would also be required in regard to 'restricted' and 'prohibited' technologies referred to in the Policy recommendation.

Ad recommendation 4.4:

IPASA would support an initiative to develop models for, and to encourage, technology transfer within industry, sectors and business entities, and between public and private sectors. Again an inclusive consultation and planning process would be desirable. As indicated above, there are many examples and models within the pharmaceutical industry of collaborative programmes and licensing projects entailing technology transfer.

On international level, the GHIT initiative is a prime example of cooperation between different stakeholders. The Global Health Innovative Technology (GHIT) project was launched in Japan and offers drug companies a model for developing products not likely to provide fast returns but nevertheless important to address neglected diseases.

The use of comparable metrics for measuring the effectiveness of incentives and models for technology transfer could be useful.

Ad recommendation 4.5:

IPASA needs to point out that, although technology transfer to LDCs would be a factor to stimulate and enhance innovation so as to create a viable technology base in those countries, and ultimately to promote economic development, the practical problem would often be the lack of manufacturing capacity in those countries. Many issues will have to be addressed and many problems resolved in the context of technology transfer to LDCs.

Background information and remarks by IPASA

Voluntary licences

These policy statements appear to refer to voluntary licensing of patents. Voluntary licences are based on consensual agreements between the patent holder and a third party, and may cover manufacturing rights, selling and distribution rights, exporting and importing rights, etc. Access to technology generally forms part of such a licence.

In general a voluntary licence allows for the terms and conditions to apply, as well as the royalties to be paid, to be negotiated and agreed upon. This includes the rights granted to the licensee, eg the right to manufacture and/or the right to import, and in some cases also the right to export. When manufacturing rights are granted, the licence agreement will generally also provide for the licensor to supply the necessary manufacturing information and the corresponding technology information.

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 to encourage licensing as a way of using patented technology, regulations in the form of peremptory principles should be expected to discourage licensing. A code of good practice would be useful.

Voluntary licences are recognised by the Patents Act (s.57), and the Regulations provide (reg 62) that such a licence and may be recorded against the patent concerned. In the absence of a condition to the contrary, a licence to exercise a patented process carries with it the right to make, use or dispose of the patented product; there is no mention that the licence would be deemed to include the right to export/import the patented product (Patents Act s.58). This has to be expressly agreed upon.

TRIPS Art 40 deals with contractual licences and recognises that certain IP licensing practices or conditions restrain competition and impede the transfer of technology, and allows countries to specify in their laws licensing practices/conditions that constitute an abuse of IP rights.

Prohibited conditions in licences

Certain conditions in a licence are prohibited; if included in a licence such conditions will be deemed to be null and void (Patents Act s.90). These include –

- to prohibit or restrict the licensee from using any product (whether patented or not) supplied by any other person;
- to require the licensee to acquire from the patent owner (or his nominee) any product not protected by the patent;
- to require of the licensee to observe a specified minimum resale price;
- to prohibit the exercising or disposing of the patented product in any country where it is not patented.

The South African Competition Act, 1998 applies to IP-related transactions, and prohibits

- restrictive horizontal practices, eg directly or indirectly fixing a selling price – s.4;
- restrictive vertical practices, eg fixing a minimum resale price – s.5;
- abuse of a dominant position, eg charging an excessive price to the detriment of consumers, or refusing to give a competitor access to an essential facility – s.8.

It is evident, therefore, that there are already in place many legislative and regulatory provisions to ensure that voluntary licences comply with certain principles.

Licences under the IPR Act

In the case of patents based on R&D carried out with public funding, the Act on IP Rights from Publicly Financed R&D, 2008 (the IPR Act) already deals with commercialisation (also through licensing) of such patent technology. Such licences are already subject to certain rules and principles.

Barriers to knowledge transfer, co-operation and joint research projects with South African publicly-funded institutions should be avoided or at least limited. In this regard ownership provisions in respect of IP created in the course of R&D collaborations with publicly financed recipients (including universities and research councils) as provided in the IPR Act may have to be reviewed. There are many examples where local and foreign companies have simply withdrawn cooperation and funding of research at such recipients, and have channelled same to either private institutions in South Africa or to foreign universities or research councils.

It is strongly argued that unnecessary barriers to investment in research and development in the creation of IP in South Africa should be limited. In this regard exchange control provisions currently applicable to the assignment to foreign entities of IP created in South Africa may have to be

reviewed. There are many examples where local and foreign companies have simply moved R&D activities out of South Africa to avoid exchange control provisions.

Technology transfer

The success of voluntary licensing of domestic entities as a method of exploiting a patented invention depends on whether such entities have manufacturing ability and manufacturing capacity. The Patents Act already requires (s.32(3)) a complete patent specification to sufficiently describe, ascertain and, where necessary, to illustrate or exemplify the invention and the manner in which it is to be performed so as to enable a person skilled in the art to perform the invention. This means that the patent specification already discloses the essential technology relevant to the invention.

A licence grants to the licensee the right to exercise the invention as described and illustrated in the specification. Generally a licensee will be identified on the basis of the ability of the licensee to perform and carry out the invention. Further technology information and know-how, ie the best method known to the patentee for carrying out the invention, would in appropriate circumstances be provided to the licensee, generally to ensure that a product of the required standard and quality will be produced. The transfer of further technological information and know-how to the licensee would be a matter for negotiation and agreement between the parties.

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 over and above the level of technological disclosure required in the patent specification should be a matter of negotiation and agreement between the parties to a voluntary licence.

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 of domestic entities and, where appropriate, the transfer of technology over and above the technological information disclosed in the patent specification.

The Policy document recommends the development of models for encouraging technology transfer, in particular from foreign companies to domestic firms. To identify the most effective models for technology transfer, the Policy document recommends the use of metrics for measuring the effectiveness of various technology transfer incentives, such as tax breaks. It is also recommended

that South Africa should not enter into bi-lateral trade agreements that would restrict or undermine any flexibilities available to the country under TRIPS to require or encourage technology transfer.

IPASA wishes to point out that voluntary and royalty-free licences already granted by pharmaceutical companies are indicative of the industry's commitment to the principles verbalised in 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. Pharmaceutical companies also make use of non-assert declarations, where a patent holder decides and declares not to enforce certain patents in certain cases, allowing a generic version of that product to be produced. However, for generics to be successfully used, they still need product quality assurance and economically-viable markets in which to operate, where business costs are reasonable.

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 and some in India, for example – to initiate a framework of technology transfer to get medicines to those who need them. For example, many people in least-developed countries (LDCs) and low-income countries (LICs) have gained access to life-saving antiretrovirals for HIV/AIDS treatment in part because of access initiatives that do not rely on the enforcement of intellectual property rights. Differential pricing and capacity building systems are also put into place. Some examples of pharmaceutical companies making voluntary concessions under their patent rights include the following:

- A pharmaceutical company has halted patent filing and enforcement in LDCs, and also does not enforce existing patents for its antiretrovirals in sub-Saharan Africa, thus allowing generics to be produced and to reach 70% of all people living with HIV in those countries.
- Another pharmaceutical company granted royalty-free licences in respect of its ARV Efavirenz to five South African generic manufacturers.
- Yet another pharma company created the Diflucan Partnership in 2000 to provide treatment for two AIDS-related fungal infections in developing countries; millions of Diflucan treatments have been distributed free of charge to governments and NGOs in developing countries.

It is submitted that the expertise of pharmaceutical companies is needed and has indeed been made available to help those in need of medicines in underdeveloped countries, and to make available company-owned technologies for the sake of the people in need of medicines.

PART 5: TRIPS flexibilities, bi-lateral trade agreements (BITs) and related matters

In Chapter 1, in the section dealing with Patents, and in Chapter 5, dealing with a variety of matters in the fields of IP, Competition, Public Policy-Making, Compulsory Licensing, and Technology Transfer, a number of issues relating to TRIPS flexibilities and bi-lateral trade agreements are addressed that are of relevance to the pharmaceutical industry. Certain recommendations are made; these are dealt with below.

Policy recommendations:

- 5.1 South Africa must change the Patents Act to incorporate patent flexibilities as contained in the TRIPS Agreement after the Doha decisions of the WTO (p.9).
- 5.2 Technology transfer should be conducted within the rules of TRIPS as BITs may be TRIPS-Plus (p.25).
- 5.3 South Africa should not enter into bilateral trade agreements that may negate the gains and discretionary measures attained through multilateral agreements such as TRIPS on patent flexibilities (p.9, p.28).
- 5.4 South Africa must align itself with other developing countries and reject the Roadmap on the PCT as it may lead to policy compromise and introduce TRIPS-Plus requirements that are beyond the checks and balances of national sovereignty (p.31).
- 5.5 South Africa should guard against the concept of a 'World Patent' as it will compromise policy space as granted in TRIPS (p.10).
- 5.6 South Africa should implement the 'IP and Development Agenda' criteria as established by WIPO, eg IP and competition policies should be reconciled and enforced, technology transfer must be monitored and evaluated, IP should be user friendly to small and medium enterprises, and licensing agreements should be used in regard to IP (p.38).
- 5.7 South Africa must not support 'global enforcement and harmonisation of patents' agendas of developed nations that take place out of context and without the benefit of costs and benefit analysis, without monitoring processes, and outside the goals and aims of the 'IP and Development Agenda' (p.38).

Submissions by IPASA

In response to the recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 5.1:

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. In this regard it is confirmed that IPASA agrees with and supports the general principles and approach to public health issues as set out in, and as addressed by international bodies pursuant to, the Doha Declaration.

In this regard IPASA refers to the joint study carried out by WTO, WIPO and WHO dealing inter alia with the intersection between public health, IP and trade (the report was published in 2013), as referred to in more detail in PART 2: Requirements for patentability above.

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 as expressed in Art 65.5.

Ad recommendation 5.2:

IPASA is in agreement with the principle that technology transfer should take place within the rules of TRIPS, ie in a non-discriminatory manner as contemplated in Art 27.1, and to least-developed countries as contemplated in Art 62.2 and as referred to in the Doha Declaration Paragraph 5.

Although appropriate incentives could be put in place to encourage technology transfer, it is submitted that prescribing or regulating technology transfer in a mandatory or prescriptive manner could be a disincentive to the granting of voluntary licences.

In this regard IPASA refers to the further remarks and submissions made in PART 4: Voluntary licences and technology transfer above.

Ad recommendation 5.3:

Although a decision on the negotiating of and entering into bilateral agreements with other countries resides with Government on the basis of its strategy on external relations and agreements, IPASA supports the assertion that the formulation of its IP laws and the use of TRIPS flexibilities in its IP laws are matters for decision within the national jurisdiction of South Africa and should not be determined by terms and conditions prescribed by other countries.

Ad recommendation 5.4:

Inasmuch as the PCT Roadmap entails the possible curtailment or removal of the autonomy of South Africa to decide on the granting of patents in accordance with its own national laws, IPASA agrees with the Policy recommendation of not supporting the PCT Roadmap.

Ad recommendation 5.5:

IPASA supports this recommendation.

Ad recommendation 5.6:

IPASA believes that the general principles of the WIPO 'IP and Development Agenda' should be implemented in a manner to encourage innovation and development in South Africa, and so as to stimulate continued investment in R&D projects to find solutions to address the needs of the people of South Africa.

Ad recommendation 5.7:

IPASA agrees that comprehensive cost and benefit analyses and assessments would provide a useful basis for decisions in regard to the appropriateness and practical applicability of international developments within the South African IP environment.

Background information and remarks by IPASATRIPS flexibilities and TRIPS-plus provisions

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.

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.

The principle of making optimal use of TRIPS flexibilities is supported.

Principles of the Doha Declaration

The Doha Declaration, 2001 recognises certain principles and certain problems relating to public health issues, eg –

- the gravity of public health problems afflicting many developing and least-developed countries;
- that IP protection is important for the development of new medicines;
- that there is concern about the effect of IP on prices;
- that TRIPS should not prevent countries from taking measures to protect public health;
- that countries without manufacturing capacity in the pharmaceutical sector would find it difficult to make effective use of compulsory licensing;
- that developed countries are encouraged to provide incentives to promote technology transfer to least-developed countries.

The Doha Declaration, 2001 identifies certain TRIPS flexibilities, eg –

- that countries have the right to grant compulsory licences and to determine the grounds on which such licences are granted;
- that countries have the right to determine what constitutes a national emergency, and that public health crises can constitute national emergencies;
- that countries are entitled to determine their own regime on exhaustion of rights.

The industry 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 as expressed in Art 65.5.

In the context of the Doha Declaration and the efforts made by WTO member countries to arrive at a solution to the pandemic health crises afflicting poor nations, it has to be pointed out that South Africa has taken no steps to implement the system provided for in new TRIPS Art 31*bis* to secure pharmaceutical products to treat the people suffering under South Africa's 'massive disease burden'.

PART 6: Patents and public health

In Chapter 2, dealing with IP and Public Health, and in Chapter 10, dealing with IP and Development, a number of issues relating to public health are addressed. Naturally these are important to the pharmaceutical industry. Certain policy recommendations are made; these are dealt with below.

Policy recommendations:

- 6.1 The Patents Act should be amended to be amenable to issues related to access to public health (p.9).
- 6.2 For IP and health policies to be in tandem, **the dti** and the DoH should reconcile policy stances, eg the need to address pricing of drugs as this may frustrate access (p.21).
- 6.3 IP protection regimes must not contradict public health policies; the two should be balanced (p.21).
- 6.4 South Africa should make provision in its laws that will facilitate the entry of generic competitors as soon as a patent has expired. The Bolar provision is already in the Patents Act. Quick approval of generics by the MCC is necessary (p.21).
- 6.5 The current IP system hardly stimulates research on diseases that affect poor people; therefore public funding for research on health problems in South Africa should be directed and increased. Existing capacities must be enhanced, and IP derived from this research must be controlled, eg through licensing, for the benefit of the country (p.21).
- 6.6 Government departments should integrate their databases so as not to grant patents on medicines that may be expiring as this may undermine access to public health (p.11).

Submissions by IPASA

In response to the policy recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 6.1:

IPASA submits that this Policy recommendation is not clear; it is not clear what patent-related amendments would be regarded as ‘amenable to issues related to access to public health’.

For example, IPASA would have significant 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. Such amendments would not be supported by IPASA.

Ad recommendation 6.2:

IPASA recognises that there is a need to reconcile and align policy stances between different Government departments on issues that are relevant to and/or impact on their respective areas of responsibility. Such alignment could have beneficial outcomes.

Ad recommendation 6.3:

IPASA again confirms that a balanced alignment of policy positions would be desirable, taking into account that the fundamental feature of IP protection is to stimulate innovation and the investment of resources and efforts to find solutions also for the public health needs.

Ad recommendation 6.4:

It is submitted that 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 statement referring to 'quick approval of generics' for marketing authorisation is intended to refer to 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.

Ad recommendation 6.5:

IPASA supports the proposal that public funding should be increased for research on the health problems affecting the people of South Africa.

Ad recommendation 6.6:

Although it is not quite clear exactly what is meant by the proposal in regard to the sharing of databases by Government departments, it is recognised that the sharing between South Africa's regulatory authority and patent office could, however, be appropriately used to help South Africa's regulatory authority take into consideration the patent status of a pharmaceutical product or process when considering the approval of a generic version of a patented drug. This information would help prevent the regulatory authority from approving market access for a generic product when a valid patent for the innovator product is still in force.

However, IPASA would have serious concerns if this proposal is an indication of an intention to make use of the database of the MCC by introducing a patent pre-approval requirement by the MCC before granting a patent in respect of a pharmaceutical product.

Background information and remarks by IPASANature of amenable amendments

It is not clear what specific amendments of the Patents Act would be amenable to issues relating to public health. Issues relating to public health and to the supply of medicines to the people in need thereof should primarily be addressed (and are addressed) in the public health policies of the appropriate Government department. It is presumed that such patent-related amenable amendments would include –

- the introduction of a search and examination system since this will allegedly prevent weak patent monopolies;

- restricting the definition of ‘invention’ to exclude first and later medical uses of known substances, new molecular forms of active ingredients, and new formulations, etc.

These possible amendments to the Patents Act have specifically been identified in other parts of this submission eg in PARTS 1 and 2 above, and have been considered and addressed in those sections.

The industry fully supports all efforts and initiatives to address public health issues and to improve the health of the people and their access to medicines.

However, the Policy position 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.

Adequate health care and the improvement of the public health depends on various factors, as indicated above. The development of new medicines to address prevalent illnesses, particularly treatment-resistant illnesses, is an important factor to improve public health. This means that 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.

Sharing of databases

The Policy document suggests establishing connectivity between the databases of the Medicines Control Council (MCC) and the IP Commission (CIPC) so that pre-grant information can be shared between the patent office and the regulatory authority before patents are granted. It is proposed that such sharing of information may help align the lifespan (and expiration) of a patent with the introduction of a generic drug. The Policy document suggests the experience of information sharing in Brazil may be informative.

The Policy document recognises that the lack of alignment of the patent process with the regulatory process might lead to approval of a generic medicine while the innovator’s patent is still in force because of South Africa’s ‘Bolar’ (research exemption) provision. It therefore suggests that marketing and stockpiling of generic medicines might need to be curtailed. Separately, it states that generic companies should ‘optimally’ use the South African Bolar provision ‘without resorting to stockpiling and competing with the owner of the patent before expiry’.

In order to fully comment, more information is needed about the proposed integration of databases for the purpose of information sharing. IPASA does not believe that this integration should be used as a mechanism to create additional patentability burdens or elevated standards specific to pharmaceutical inventions. Such burdens may be contrary to TRIPS Art 27.1, which prohibits discrimination in the granting of patents on the basis of field of technology.

For example, IPASA would have significant concerns if the proposed integration of databases included the requirement for patent pre-approval by the regulatory authority that could prevent the granting of pharmaceutical patents by the patent office. This patentability hurdle has been implemented in Brazil, the country the Policy document cites as a relevant example. In fact, the process requiring the regulatory authority's prior consent in Brazil has led to unnecessary delays for the regulatory authority to transmit its prior consent decision on pharmaceutical patent applications back to the patent office for examination. Such a redundant and inefficient process has slowed innovation and patient access to new medicines in Brazil, and would likely have similar consequences if introduced in South Africa.

Information sharing between South Africa's regulatory authority and patent office could, however, be appropriately used to help South Africa's regulatory authority take into consideration the patent status of a pharmaceutical product or process when considering the approval of a generic version of a patented drug. This information would help prevent the regulatory authority from approving a drug for a generic product when a valid patent for the innovator product is still in force.

Permitting, by way of the Bolar provision, what would otherwise be infringing activity prior to expiration of a patent for the purposes of generating information necessary for presenting an application for regulatory approval is consistent with international norms. The Policy document also correctly notes that generic stockpiling and marketing should not be allowed under South Africa's Bolar provision. Strict measures to prevent the stockpiling of generic medicines during the patent term are appropriate. As a WTO panel concluded, stockpiling constitutes a substantial curtailment of patent rights that is inconsistent with TRIPS. Pharmaceutical innovators must have safeguards available to prevent infringing products from being launched upon regulatory approval, but before the relevant patents have expired.

However, the Policy statement that 'quick approval of generics by the MCC is necessary' (on p.21 of the Policy document) raises serious concerns. If this statement is intended to encourage, or indeed authorise the MCC 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 will 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.

PART 7: Data protection

In Chapter 1, in Part a) dealing with Patents and in Part h) dealing with Trade Secrets, a number of issues relating to the protection of confidential information and confidential data are addressed. These issues are important to the pharmaceutical industry. Certain policy recommendations are made; these are dealt with below.

Policy recommendations:

- 7.1 South Africa should remain committed to the protection of data in terms of TRIPS Art 39, but not to the extent that multinationals are demanding as per their Governments, as this could compromise access to health (p.10).
- 7.2 Protection of 'confidential information' from clinical trials on indigenous medicines should be protected through the law of data protection in terms of Art 39.3 of the TRIPS Agreement (p.18).
- 7.3 There should be no general or blanket data protection of information that is at the disposal of the medicines regulatory authority (MCC), but rules on unfair trade practices and protection of confidential information relevant for competitiveness should be in place (p.19).
- 7.4 The MCC should encourage transparency in its registration system, as allegations of regulatory failures are putting strenuous pressure on **the dti** to amend the Patents Act to accommodate patents that may prejudice access to public health (p.12).

Submissions by IPASA

In response to the policy recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 7.1:

IPASA submits that a reasonable period of regulatory data protection, in conjunction with, but distinct from, patent protection, is essential to the development of new medicines. Regulatory procedures that do not protect confidential commercial information associated with innovative research and development from disclosure to third parties may significantly curtail incentives for the private sector to make substantial investments in such projects. Failure to protect the proprietary research data and findings based on clinical trials and other research by innovator companies will, therefore, significantly harm the public health and patient welfare by hindering new pharmaceutical innovations. The protection required by TRIPS Art 39.3 is not only intended to prevent unauthorised disclosure of such proprietary research and other data to third parties, but also to prevent unfair commercial use thereof, eg use by the regulatory authority to facilitate or expedite the marketing authorisation of generics.

Ad recommendation 7.2:

In order to comply with TRIPS, data protection cannot be provided in a discriminatory manner. To provide data protection only in relation to the indigenous knowledge forming the basis of traditional medicines, and not in relation to the clinical and efficacy information confirming and forming the basis of the marketing registration of innovative medicines, would be discriminatory and would contravene Art 39.3 and Art 27.1 of TRIPS. Consistent with its TRIPS obligations, South Africa should provide data protection in respect of all proprietary confidential data for all medicines, -regardless of whether such medicine is an innovative medicine or a traditional medicine.

Ad recommendation 7.3:

The requirements of TRIPS Art 39.3 are clear and are in fact mandatory: member countries of WTO/TRIPS shall protect undisclosed test or other data which is required to be submitted for purposes of marketing approval of pharmaceutical products (without exception), and such protection shall be against disclosure and against unfair commercial use. Disclosure will only be permitted where it is necessary to protect the public, and even then it is necessary to ensure that the data is protected against unfair commercial use.

It is submitted, therefore, that the policy position as set out would be contrary to TRIPS Art 39.3 and cannot be supported.

Ad recommendation 7.4:

It is submitted that data protection *per se* does not prohibit generic companies from seeking marketing authorisation and entering the market. Generic manufacturers are free to do the necessary research work and clinical trials in order to compile a dossier for purposes of marketing authorisation. In fact, the Bolar provision provided for in the Patents Act (s.69A) already provides generic companies with a time advantage and allows generic companies to do all such preparatory work and indeed to submit their applications for marketing authorisation during the subsistence of the patent in respect of the original medicine. Data protection would not frustrate such early preparatory work to obtain early market entry as soon as the patent expires; data protection would only prevent the use of the data submitted by the originator company as a basis for the marketing authorisation of the generic. This would be unfair commercial use as prohibited by TRIPS Art 39.3.

Background information and remarks by IPASA

TRIPS requires data protection

The protection of confidential data submitted for purposes of marketing registration against unauthorised disclosure and against unfair commercial use is a mandatory requirement of TRIPS Art 39.3. To date South Africa has not enacted any statutory provision to provide for such protection.

The process of compiling the necessary data on clinical trials and the efficacy of a new medicine in order to obtain marketing registration is a costly endeavour requiring considerable effort. TRIPS Art 39.3 requires this data to be protected in a twofold manner: against disclosure as well as against unfair commercial use. Even though statutory measures are introduced to protect such data against disclosure, it would still be a contravention of Art 39.3 if such data is used in order to expedite market entry of generics, as this would constitute unfair commercial use.

It is emphasised that the protection of confidential data submitted for purposes of marketing registration is not only intended to deal with unauthorised disclosure and thus breach of confidentiality; it is also intended to provide protection against unfair commercial use of such data. This is a mandatory requirement of TRIPS Art 39.3. To permit such confidential data to be used to expedite market entry of generics would constitute unfair commercial use, expressly prohibited by TRIPS Art 39.3.

At present no data protection

South African law currently provides no regulatory data protection. Regulatory data protection generally provides for a defined period of time during which third parties are prohibited from using innovator data to support their own marketing approval applications, without authorisation from the innovator. The Policy document does not express a clear intention to provide regulatory data protection as required by TRIPS Art 39.3. Instead it explicitly rejects the utility of 'blanket data protection' for innovator data and emphasises the importance of 'access to knowledge'. In fact, the Policy document expresses the view that entry of generic medicines should 'not be frustrated *per se* due to the law of data protection'. The Policy document recommends that South Africa should amend the Medicines and Substances Control Act, the Health Practitioners Act, and related health legislation to invoke Art 39.3 of TRIPS only in relation to 'indigenous knowledge in traditional medicines'.

As regards confidential data submitted by pharmaceutical companies for purposes of marketing authorisation, the proposed policy position appears to accept the need for the introduction only of a limited provision on data protection, ie to protect the confidentiality of 'confidential information', apparently only against disclosure. However, no general or 'blanket' data protection appears to be contemplated; the use of such data to expedite market entry of generics would appear to be condoned, although this would constitute unfair commercial use as expressly prohibited by TRIPS Art 39.3.

Importance of data protection

South African laws, including the current confidentiality of information provision in the Medicines and Related Substances Act, may be insufficient to fully protect innovator test and other data in a manner that is consistent with TRIPS Art 39.3, especially the requirement to protect data against unfair commercial use. Unfair commercial use is viewed to include reliance by the MCC on the data submitted by innovators to approve requests by generic competitors to market the same or similar products. In order to comply with TRIPS Art 39.3 South Africa should provide innovative pharmaceutical products with data protection comprising not only protection against unauthorised disclosure but also protection against unfair commercial use, and regardless of whether or not such products are patented. This should prohibit the MCC from granting marketing approval for generics and biosimilars during this data protection period by making use of and relying on the data submitted in respect of the innovative product.

Pharmaceutical research and development is extremely expensive and involves a high risk of failure. The laws of many jurisdictions, including South Africa, permit some applicants for marketing authorisation, generally applicants in respect of generic or follow-up medicines, to skip much of this resource-intensive development process. Such applicants can obtain marketing approval of generic or follow-on medicines on the basis of abridged applications containing much smaller data packages. These subsequent applicants rely indirectly on the pioneering, proprietary data submitted in support of marketing registration applications for the innovative medicines, and they need not include independent data demonstrating safety and effectiveness. The time and effort needed to obtain approval of generics and biosimilars is therefore significantly less than for innovative products; this may constitute unfair commercial use. For this reason it is imperative that innovators receive some period of data protection to create an adequate incentive for investment in research and development and to prevent unfair commercial use being made of their data.

Although patents provide a critical form of protection, they are not sufficient. For the few pharmaceutical inventions that do become approved medicines, a substantial part of the patent life is already lost by the time the products can be marketed. Significant delays in regulatory reviews further erode effective patent protection. In addition, not all aspects of an invention may be patentable, patents can be difficult to enforce, and patents are susceptible to being designed around. Data protection thus provides a measure of certainty necessary for risky investments in new medicines. Irrespective of whether or not strong patent protection is available, a period of data protection ensures that there will be a limited but guaranteed period of time during which competitors will not be permitted to rely on the innovator's proprietary data, thus providing innovators some time to begin recouping investment costs.

Data protection does not prevent marketing approval

It must be understood that data protection does not prohibit other companies from seeking approval for and marketing competing products on the basis of full, independently developed packages of safety and effectiveness data. Nor does data protection impede the free exchange of scientific information in medical, clinical, and academic publications or of conferences. Rather, it provides protection against the use of an innovator's proprietary data by a commercial competitor for a discrete, limited period of time.

Moreover, the presumption that strong data protection impedes generics is not supported. For example, the United States provides five years of regulatory data protection for small molecule drugs and 12 years of regulatory data protection for biologics, but also has 84% generic drug market penetration. For these reasons, nearly every developed nation recognises the importance of providing a period of regulatory data protection.

Data protection must not be discriminatory

Art 39.3 of TRIPS requires governments to protect innovative pharmaceutical product data submitted for government review against unfair commercial use and disclosure. Providing effective regulatory data protection would be an important component of fulfilling this obligation. The Policy document recommends that Art 39.3 of TRIPS should be invoked only in relation to 'indigenous knowledge in traditional medicines'. This interpretation appears to recognise the importance of such protection for at least a subset of products – ie traditional medicines – but impermissibly and in a discriminatory manner narrows South Africa's obligation to protect all pharmaceutical data from unfair commercial use to that subset. Consistent with its TRIPS obligations, South Africa should provide data protection in respect of data for all medicines, whether the covered product is a traditional medicine or not, which would prevent the MCC from granting marketing approval for generic or biosimilar medicines that rely on innovator data during the regulatory data protection time period.

PART 8: Relevance of generic medicines

In Chapter 1, in the section dealing with Patents, and in Chapter 2, dealing with IP and Public Health, a number of issues relating to the role of generic medicines are addressed. Naturally these issues are important to the pharmaceutical industry. Certain policy recommendations are made; these are dealt with below.

Policy recommendations:

- 8.1 Generic companies should optimally use the Bolar provision without resorting to stockpiling and competing with the owner of the patent before expiry of the patent (p.13).
- 8.2 South Africa should make provisions in its laws that will facilitate the entry of generic competitors as soon as the patent has expired on a particular medicine. The Bolar provision is already in the Patents Amendment Act (2002). Quick generic approval should be given by the MCC, which currently has backlogs (p.21).
- 8.3 Entry of generic medicines into the South African market should not be frustrated on the basis of data protection (p.19).
- 8.4 Education and awareness must be intensified among law enforcement agencies that generics are not counterfeit medicines (p.13).
- 8.5 Law enforcement agencies should not confiscate/seize generics in transit under the pretext that they are counterfeits (p.13).

Submissions by IPASA

In response to the policy recommendations set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 8.1:

IPASA points out that the Bolar provision, also referred to as the early-working provision and which allows generic companies to carry out all necessary preparatory work to apply for and obtain marketing authorisation during the subsistence of the patent in respect of the original medicine, has been part of the South African Patents Act (s.69A) since 2002. There is no reason to believe that, after more than 10 years, generic manufacturers would not be aware of this provision, or would not be making optimal use of the concession under this provision, in order to get ready for early market entry.

Ad recommendation 8.2:

As regards the reference to the concession provided in the Bolar provision to facilitate the early entry to the market of generic competitors, IPASA repeats its comments under recommendation 8.1 above. As regards the reference to quick generic approval to be given by the MCC, IPASA wishes to

place on record its concerns. If the reference to 'quick approval of generics' for marketing authorisation is intended to refer to 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.

This has also been pointed out by IPASA under recommendation 6.4 in Part 6 above.

Ad recommendation 8.3:

This recommendation expressly states that data protection should not frustrate market access of generics. This implies that, even if data protection provisions were to be introduced into South Africa's laws, as expressly required by TRIPS Art 39.3, such protection should not prevent the MCC from making unfair commercial use of the proprietary data of innovator companies to expedite the market entry of generics. IPASA submits that this would be a blatant contravention of TRIPS Art 39.3.

Ad recommendation 8.4:

IPASA confirms that generics per se are not counterfeits. However, during the subsistence of the relevant patent generics would be infringements. Furthermore, one should not rule out the possibility that generics themselves may be counterfeited.

IPASA thus supports the policy position that awareness by law enforcement agencies and the public in regard to generic medicines would be important. Although it is correct that generics are not counterfeits, it must be pointed out that there may also be risks in the trade in generics, eg that generics may also be copied and their quality compromised.

Ad recommendation 8.5:

IPASA confirms that law enforcement agencies should act in accordance with the law of the country. However, it must be pointed out that the importation of generics during the subsistence of the patent in respect of the innovator medicine would constitute infringement.

Background information and remarks by IPASA

There should be a clear understanding that, during the subsistence of the relevant patent, a generic medicine is an infringement of the patent in respect of the original medicine. Although generics are not counterfeits they are nevertheless infringements of the relevant patents. It is accepted that, upon the expiry of the relevant patent, generic equivalents may be freely made and distributed.

It should also be understood that generic medicines would not exist without the prior existence of the original patented medicine. The very existence of generic medicines is dependent upon the development of the original medicines by way of a costly R&D process, followed by comprehensive clinical trials and a strict assessment as part of the marketing registration process.

Generic medicines are viewed as being less costly than the original medicines and thus more accessible to those in need. Early market access for generics is thus promoted. Generic medicines already enjoy the early-working concession (Bolar provision, Patents Act s.69A); a further benefit of early marketing access is being proposed by the non-application of data protection provisions as required by TRIPS Art 39.3.

The concession to generics in the form of the Bolar provision already benefits generics by enabling early marketing registration and thus early market entry. By not applying data protection principles within the marketing registration process, ie by not prohibiting the unfair commercial use of the confidential data submitted in respect of the original medicine in order to expedite the marketing registration of the generic medicine, would constitute yet another benefit to generics.

The concessions already made in favour of generics (the early working under the Bolar provision) and the further concessions proposed to be made (data protection should not delay market access) are tipping the scale in favour of generics and may be seen as discriminatory.

Risks to patients

An important aspect of the importation of generics would be the possible safety risks to patients:

- measures will have to be in place to ensure that the generic products being imported will be of the appropriate quality and efficacy, and to ensure that there is no risk that the products will be tampered with;
- measures will have to be in place to monitor and deal with the risk that counterfeit generics may be imported (without the authority or knowledge of the generics manufacturer).

PART 9: Patent term restoration

The Policy document in part a) of Chapter 1 (section x) on p.11 -12), deals with the issue of patent term extension/restoration. This is a matter of particular importance to the pharmaceutical industry, in the light of the time-delays that impact on the effective period of exclusive rights afforded by pharmaceutical patents.

The Policy document makes a general policy recommendation in regard to transparency in respect of allegations of regulatory delays, but does not include a recommendation expressly stating that patent term extension will be considered. A general statement is made (p.12 of the Policy document) that the 'extension of patents by its nature is not good as it extends the lifespan of a patent and delays the entry into the market of generics. In an ideal world, patent extension should not be allowed in developing countries as it may hinder access to medicines'. However, this statement fails to recognise that this is not an ideal world, and that regulatory delays do in fact erode the effective available period of patent exclusivity.

Policy recommendation:

9.1 The MCC should encourage transparency in its registration system as allegations of regulatory failures are putting strenuous pressure on **the dti** to amend the Patents Act to accommodate patent extension that may prejudice access to public health.

Submission by IPASA

In response to the recommendation set out above, IPASA makes the following submissions for consideration by Government:

Ad recommendation 9.1:

The recommendation encouraging greater transparency by the MCC in its marketing registration system is supported. In particular more information should be obtained in regard to the allegations of regulatory delays in the context of the marketing registration process.

Government is urged to consider conducting an analytical enquiry into the effective lifetime of patents in the pharmaceutical field, ie the effective period of exclusive rights afforded the patent holders of patents in the pharmaceutical field, by researching the following aspects:

- the date of lodgement of an application with the MCC for marketing authorisation in comparison with the date of filing of the corresponding patent application in South Africa;
- the time period that elapses between the date of lodgement of the application for marketing authorisation and the date on which such marketing authorisation is granted;
- whether any generics manufacturers make use of the Bolar provision under the relevant patent during the relevant patent term;

- whether any generics manufacturers apply for, and are granted, marketing authorisation by the MCC for a generic substitute, and the relevant dates.

On the basis of such an enquiry, a fair and creditable decision will be possible in respect of the merit (or demerit) of a provision for patent term extension or supplementary protection certificate in South African law.

Finally, Government through the Department of Trade and Industry is urged to reconsider its position on patent term restoration to encourage the future development and dissemination of innovative new products in South Africa.

Background information and remarks by IPASA

No patent term extension at present

At present there is no provision in the South African Patents Act no 57 of 1978 for any extension of the term of patents, nor for the issue of Supplementary Protection Certificates (SPCs), as this concept is referred to in some countries, even in circumstances where a substantial part of the period of patent exclusivity is lost to the patent holder as a result of circumstances beyond the patent holder's control, such as the need (in the public interest) for prolonged R&D work required to perfect the efficacy of the product, and the necessarily time-consuming process of obtaining marketing authorisation.

It may be mentioned that the previous Patents Act no 37 of 1952 did provide (s.39) for patent term extension; however, this provision was omitted from the present Act.

It is submitted that, for the reasons and considerations which will be set out more fully below, it is necessary for South Africa to give consideration to the introduction into the Patents Act, 1978 of appropriate provisions for the extension of protection in those cases where the effective term of patent exclusivity is substantially reduced by prolonged R&D work, and specifically by time-consuming regulatory approval processes beyond the control of the patent holder, during which the regulatory authorities give due consideration to applications for marketing authorisation before the commercial exploitation of the patented invention can be commenced.

Need for patent term extension

The proposal for the introduction of patent term restoration/extension or SPCs in South African law is based on the hard reality of recent developments in the pharmaceutical field, namely the incremental increase in the cost of R&D work to bring a new medicine onto the market; the rapidly diminishing period of effective market exclusivity under pharmaceutical patents; and the need to find a fair balance between the interests of pharmaceutical patent holders and third party

competitors, such as the manufacturers of generic substitutes or follow-on drugs, in an industry with escalating levels of competition. Such a fair balance needs to be defined against the background of the pressing need for effective and affordable life-saving treatment for the people in poor countries, notably least-developed countries, to combat the so-called 'third-world' or 'neglected' diseases which are assuming pandemic proportions.

Limited forms of extension of term for pharmaceutical patents, such as SPC's, are accepted to be in recognition of, and to provide a balance for, the exceptionally long development time for new medicines, and the time-consuming regulatory processes involved in developing and commercialising new medicines. The aim with such extension is to provide an effective patent marketing life, ie the period of patent protection after marketing authorisation has been obtained and during which the patent holder can endeavour to reap the commercial benefit of the invention and earn a return on the investment made in developing the invention.

Many countries offer patent term restoration or extension of term, or supplementary protection certificates. Patent term restoration/extension generally allows patent holders to recoup a valuable portion of the patent term that elapses and is lost to them while the patented product is in research and development, or during regulatory review for marketing approval, during which period the patented product cannot be marketed. In many countries up to five years of lost time can be recouped.

Both creators of innovative medicines and generic manufacturers have recognised that there are substantial R&D delays and, although this is often denied, substantial regulatory delays in the approval of medicines. This is also the case in South Africa. These delays shorten the effective period available for the use of a patent and, when combined with the present lack of patent term restoration, harms the ability of an innovator to realise the full value of the invention.

The Policy document acknowledges that South Africa's MCC registration system should be more efficient and transparent, so that the reasons for the alleged backlogs can be addressed. While this regulatory backlog continues, patent term restoration remains an even more critical tool for properly incentivising drug development and investment in the innovative biopharmaceutical sector.

Another factor which in practice negatively impacts on the period of patent exclusivity afforded by a pharmaceutical patent, is the implementation in South Africa (Patents Act s.69A) of the Bolar provision by legislation. This provision allows third parties, ie generics manufacturers, during the period of patent protection in respect of the original product to do all necessary preparatory work for, and to submit (and obtain) regulatory authorisation. This enables the generic product to enter the market immediately upon expiry of the patent.

Advances in medical research have led to many important new therapies and vaccines, including medicines to treat HIV/AIDS. It is the private sector that undertakes extensive medicines research and is almost exclusively responsible for conducting the extraordinarily lengthy, costly, and risky development process required to transform discoveries into new medicines that meet requirements for proof of safety and effectiveness imposed by medicines regulatory agencies. An extensive and thorough research and approval process is in the patients' best interests. Yet, because of the significant time it takes to develop and obtain approval for a new pharmaceutical product, the effective patent life for such a product is often reduced substantially, generally to an average of less than 10 years. This is an unfair reduction in patent protection available to pharmaceutical products.

Consequently, the Department of Trade and Industry is strongly encouraged to reconsider its position on patent term restoration to encourage the future development and dissemination of innovative new products in South Africa.

This submission is by IPASA, a trade association representing the following research-based biopharmaceutical companies operating in SA:

Abbot Laboratories, AbbVie, Alcon Laboratories, Allergan Pharmaceuticals, Amgen, AstraZeneca, Baxter Healthcare, Bayer Healthcare, Boehringer Ingelheim, Bristol-Myers Squibb, Covidien, Galderma, GE Healthcare, Janssen Pharmaceutical, Lilly, Merck, MSD, Norgine, Novartis, Novo Nordisk, Takeda, Pfizer, Roche, Sanofi, Servier Laboratories.

For more information, please contact IPASA's Chief Operating Officer, Val Beaumont as below:

Tel: (011) 880 4644

Email: val@ipasa.co.za