INTELLECTUAL PROPERTY CONSULTATIVE FRAMEWORK, 2016

AS APPROVED BY CABINET ON 6 JULY 2016

Notice 581 of 2016 GG 40262 of 9 September 2016

SUBMISSION

by

Adams & Adams

COMMENTS FROM A LEGAL PERSPECTIVE

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A. BACKGROUND INFORMATION

1. Status of South Africa's IP laws

Some of South Africa's intellectual property (IP) laws go back many years (1978 for the Patents Act and the Copyright Act; 1976 for the Plant Breeders' Right Act; 1941 for the Merchandise Marks Act). But even the IP laws of more recent date (namely the Trade Marks Act, 1993, the Designs Act, 1993, and the Counterfeit Goods Act, 1997) have been in existence for two decades. With the rapid developments taking place in the areas of science and technology and innovation, and also in the legal field, revision and updating of these laws have become necessary.

Government has indicated its intention to embark on a comprehensive IP laws revision and updating process. The revision of the IP laws will entail the adjustment of the laws to reflect and to fit in with the current economic, developmental and public interest conditions of South Africa as a developing country, and to reflect the developmental objectives identified in the National Development Plan (NDP). The updating of the laws will also ensure that the country's IP laws embody and/or provide for legal developments since the IP laws were enacted. The formulation of a national IP Policy would be the first step to initiate and steer that process.

It must be understood that such an IP Policy, and also recommendations on amendments of the IP laws put forward in such an IP Policy, as such do not constitute law and do not constitute updates or amendments of the different IP laws – an IP Policy is merely the formulation of the strategic policy position that Government intends to take on various IP-related issues when the IP laws are revised and amended.

The finalisation and adoption of such an IP Policy does not entail a Parliamentary process; the IP Policy (once finalised, taking into account the comments submitted by interest groups) will be approved by Cabinet. The policy positions and recommendations set out in the IP Policy will thereafter have to be implemented (ie enacted into enforceable laws) by way of the passing of new laws or by way of amendments to the different IP laws currently in force. This will entail one or more Parliamentary procedures and may thus be a lengthy process.

2. Publication of the IP Consultative Framework

An IP Consultative Framework was published in the GG 40262 of 9 September 2016 under Notice 581 of 2016, and interested persons were invited to submit comments to the Department of Trade and Industry (**the dti**) by 30 September 2016. In the IP Consultative Framework document (IP Framework) it is clearly stated (par 1. iii) that the purpose of the document is not to prescribe South Africa's IP Policy position, but to put forward the perspective of **the dti** on IP issues by way of a consultative instrument to facilitate relevant engagement with governmental partners and society at large. The IP Framework will thus constitute a starting point for the formulation of a national IP policy, and will serve as a tool to achieve the formulation of South Africa's IP Policy by way of a coordinated approach.

For a consultative process to be fair, inclusive and creditable, it is important that sufficient time be afforded for proper consultation to take place. The IP Framework was only officially published in the GG for public comment in the second week of September 2016; with the cut-off date stipulated as 30 September 2016, this only allowed about 3 weeks for public comments to be compiled and submitted. There is some concern that the opportunity for consultation on the IP Framework was insufficient in that not all industry sectors were directly approached or were aware of the need for commentary, and in that insufficient time was allowed for industries outside the pharmaceutical industry and for the public at large to consider and comment on the IP Framework.

A&A holds the view that specific advantages are to be gained when the opportunity is created for more extensive public consultation, when sufficient timeframes are allowed for further rounds of public consultations, and when all industry sectors are invited to comment on the development of an instrument of national importance such as the IP Policy. For these reasons A&A welcomed the opportunity to participate in the Workshop on the Consultative Framework for IP held on 28-30 September 2016, and so to take note of the various points made and considerations outlined; and also the announcement that the period for comments on the IP Framework has been extended to 14 October 2016.

3. Submission by Adams & Adams

Adams & Adams (A&A) is a law firm specialising in IP law and practice and has been in operation for more than 100 years. A&A submits below its comments on the IP Framework, and also expresses its commitment to participate in any further consultative initiatives in order to pursue the stated objectives of the IP Framework, namely to follow a coordinated approach to IP to achieve a balanced outcome, and to promote the well-being of South Africa and its people.

Since the IP professionals of A&A are also members of the SA Institute for IP Law (SAIIPL), and indeed participated in the drafting of the submission on the IP Framework made by SAIIPL, A&A supports and endorses the position put forward in the submission on the IP Framework made to **the dti** by SAIIPL.

1. PURPOSE OF THE IP CONSULTATIVE FRAMEWORK

[IP Framework paragraph 1. i - ix]

The IP Framework sets out (par 1) the general purpose of the consultative process, namely to follow a co-ordinated and balanced approach to IP, to provide for public as well as inter-departmental government engagement, and to take into account national developmental priorities and also international developments and guidelines.

1.1 A&A supports the general purpose and objectives. In particular A&A submits the following general remarks:

- It is agreed that a comprehensive and inclusive IP Policy for South Africa would be advantageous and indeed necessary to ensure a coordinated and strategically aligned approach to intellectual property issues by public sector as well as private sector bodies, across all fields of innovative activity. The policy should be subject to regular review to allow for future changes.
- It is agreed that IP cuts across different areas of private sector enterprise and Government responsibility. Therefore it is necessary to consider issues relating to IP in South Africa within a broader perspective, ie to take into account policy objectives of different Government Departments; private sector initiatives and interests; other areas of law and practice; and a variety of diverse national objectives such as to promote research and development, trade and commerce, technology transfer, education, socio-economic needs, agriculture, health and access to medicines, international and regional relations, etc.
- It is also agreed that IP has a very specific international and regional interface. For that reason, international and regional instruments, the activities of international and regional bodies, and international and regional relations, including trade agreements and trade practices, have to be taken into account.
- It is further agreed that the IP Policy needs to take note of, and where possible accommodate, national needs, priorities and objectives, specifically also national priorities and needs which may be viewed as presenting or potentially leading to national emergencies, such as the need for the people of South Africa to have access to effective health care and affordable medicines, and the potential threat of pandemic diseases and treatment-resistant illnesses.

Accordingly, and although different considerations apply to different forms of IP in view of the differences in nature, scope and protection of different forms of IP; and the diversity in the general usages and strategic advantages to be obtained from the different forms of IP, the proposition of a coordinated, inclusive, cross-cutting approach to the formulation of an IP Policy is supported.

1.2 A&A also supports and endorses the position outlined in par 1. i and recognised in par 1. ix, namely that IP is an important instrument in promoting innovation and creativity, research and development, technology transfer and industrial capacity, and thus to attract investment and to stimulate economic growth; and furthermore, that a balance has to be struck between the expectations of the creators of IP, the interests of the investors in IP, and the needs of the users of IP.

It is generally accepted that IP is an incentive to encourage innovative endeavours to find solutions for existing and new problems, including to search for and find new and improved and affordable medicines to treat prevalent diseases, in particular also resistant diseases, and so to address national health issues (identified as a high priority objective). The structuring of the IP system in such a manner as to achieve this objective, without detracting from the incentive value of IP to the creators of IP, and the economic interests of the investors in IP, would have merit. This role of IP is in fact recognised in Art 7 of TRIPS.

1.3 The role of IP as a factor for attracting investment and enabling technology transfer – and thus to stimulate economic growth – has been recognised in par 1. ix.g. In order to optimise this factor, it will be important to ensure that the IP system is structured in such a manner as to achieve a balanced outcome, as stated in par 1. v and par 1. ix.f. This approach is supported by A&A.

1.4 The importance of aligning South Africa's IP dispensation with the country's approach to international, regional and sub-regional organisations, as indicated in par 1. viii and par 1. ix.h, is accepted, on the understanding that South Africa will retain its national sovereignty in the area of IP.

1.5 Furthermore, the point of departure as stated in par 1. vii and par 1. ix.a, namely that the provisions and general ethos of South Africa's Constitution should be respected and adhered to, is supported. This is indeed essential from a legal perspective. In this context certain principles are of particular relevance, namely that people may not arbitrarily be deprived of property (section 25) – bearing in mind that IP is property; and that the people have the right of access to health care (section 27). Taking into account that the ethos of the Constitution is one of a balancing of rights, as recognised in section 36 of the Constitution in the context of the limitation of rights, a balanced IP system would be necessary.

1.6 Finally, a particular point raised at the Consultative Workshop, namely that an IP system should also aim to recognise and respect human rights, presented a challenging new perspective to be taken into account. In this regard reference will have to be made, when assessing the merits of the IP system and/or a proposed change to the IP system, to the principle of respecting, protecting, promoting and fulfilling the human rights of all people, as stated in section 7(2) of the Constitution.

Recommendation 1: In supporting the formulation of a comprehensive and cross-cutting IP Policy Framework putting forward appropriate legislative changes to be effected in order to modernise and improve the IP dispensation of South Africa, A&A thus recommends that any legislative changes to be made to South Africa's IP laws, and in particular also the patent law, should strive for a balanced outcome, ie should be structured so as to improve the IP system without detracting from its sound legal foundation and its underlying role and function, namely –

- to serve as an incentive to encourage innovative and creative endeavours, and also research and development work to find solutions for challenges and problems, in the interest of the people;
- to attract investment in local industries and manufacture, so to stimulate economic growth, in the interest of the country;
- to support and confirm South Africa's adherence to its Constitutional values (including the recognition of human rights), and its international and regional responsibilities, and thereby to confirm and maintain the importance of the rule of law also in the field of IP.

2. STRATEGY OF THE IP CONSULTATIVE FRAMEWORK

[IP Framework paragraph 2. i - vii]

2.1 The strategy to be followed in the IP Framework as set out (par 2) is supported, including that a balance is to be struck between issues of urgency to be addressed immediately; issues requiring medium term assessment; and the need for continuous monitoring and evaluation. This will then play out as a three-pronged approach: the policy proposals (and probably also the ensuing legislative changes) pertaining to the issues identified as immediate issues will be proceeded with without delay; the policy proposals (and any legislative changes that may be proposed) pertaining to issues identified as medium term issues will proceed over time; but the monitoring and evaluation of all policy proposals and legislative changes will continuously take place.

2.2 The intersection between IP and public health, with all of its related and sometimes problematic aspects, has been identified as the immediate issue to be addressed. A&A wishes to point out that, from a legal perspective it would be important, when addressing this issue, for a proper investigation to be made as to the true effect of patents on the availability of and the access to essential medicines, and thus on public health. It is widely accepted and frequently argued by groups criticising and indeed attacking the current South African patent system, that patents provide a barrier to the access to medicines, particularly affordable medicines. However, it is seldom recognised that patents also provide the incentive for research and development work in order to find the medicines needed for public health.

The wide-spread need of people (particularly poor people) to have access to the provision of effective health care, effective medical treatment, and effective medicines. This broad topic was extensively discussed at the Consultative Workshop. The provision of effective health

care is a matter of national priority to be addressed by governments – IP plays no part in that factor. Likewise, the provision of effective medical treatment relates to the availability of appropriately trained medical practitioners; again a national educational matter – IP plays no part in this factor. However, part of effective health care and effective medical treatment is the access to appropriate medicines; of relevance in this regard is the availability of such medicines, and thus the issue of local manufacture or importation – IP is relevant where local manufacture and/or importation will require licensing by IP right holders. Furthermore, another underlying aspect of effective health care and medical treatment is the availability of new and effective medicines to treat the increasingly resistant diseases – this is where IP becomes even more relevant, inasmuch as IP rights are viewed as one (and perhaps the most important) incentive for R&D to find new and effective medicines.

Reference has been made at the Consultative Workshop to other potentially effective incentives to stimulate R&D regarding, and also manufacture of, new medicines; mention was made of tax breaks and similar concessions, tender preferences, funding, etc. However, there are also protagonists and interest groups that view IP rights (particularly patents) not as an incentive but as a barrier and stumbling block to prevent access to medicines. When assessing this issue, it should be taken into account that this view may not be factually correct.

Several studies have been conducted and reports published which indicate that in fact only a small percentage of the medicines on the List of Essential Medicines of the WHO are still covered by patents. As part of a proper prior investigation and assessment, and before legislative changes to the patent system are effected, it would be important to determine what percentage of the medicines currently needed for purposes of the treatment of patients in South Africa are still under patents.

This notwithstanding, the importance of the need to provide access to medicines for the people in need of treatment is recognised and confirmed. It is thus recognised and confirmed that it is in the public interest that access by the public to patented medicines must be facilitated; however, it is equally important to recognise that it is also in the public interest that valid patents should be effectively enforced and infringement should not be sanctioned, so that the rights granted to patentees will be respected and the credibility of the patent system maintained. This will be necessary in order to derive the long-term and ongoing economic and social benefits that the patent system can deliver.

Recommendation 2: A&A recommends that any proposed amendment and adjustment of the patent laws as part of the country's endeavours to address public health and to facilitate access to medicines, should be preceded by, and should take into account, an appropriate study and assessment of the actual role of patents in resolving these issues, particularly the need for access to medicines. Note should also be taken of international studies already conducted in this regard.

3. INTER-MINISTERIAL COMMITTEE ON IP

[IP Framework paragraph 3. i - v]

The establishment of an Inter-Ministerial Committee (IMC) to ensure that the cross-cutting aspect of IP is adequately dealt with, is supported. Although it is appreciated that such a committee would necessarily be composed of government officials, it is suggested that provision should be made (eg in the terms of reference of the IMC or as part of its operational plan) for the IMC to consult with and/or obtain input from industry and business and also from the legal sector involved with IP work.

Recommendation 3: A&A recommends that provision should be made in the operational and functional plan and/or guidelines for the IMC, for consultation with, or input to be obtained from, industry, business and the legal profession engaged in areas of IP.

4. IMMEDIATE ISSUES TO BE ADDRESSED

[IP Framework paragraph 4]

An overview is given of the manner in which the immediate issues are to be addressed, grouped under three sub-headings, namely domestic review; international best practice; and international commitments. The domestic review wil entail consideration of 10 patent-related sub-issues on which policy positions need to be formulated, and in regard to which legislative changes may be proposed, as set out in par 4.1.1 – 4.1.10 of the IP Framework document.

The 10 patent-related issues identified as issues of immediate importance are supported. However, it is presumed that, as part of a long-term objective and the formulation of an encompassing IP policy instrument, review of other patent-related issues and also other IP laws and related issues will in due course be addressed.

4.1 Immediate domestic review

[IP Framework Paragraph 4.1 i - iv]

By way of an introduction to the discussion of the 10 patent-related issues, reference is made, in the introductory paragraphs i – iv, to the global dialogue around the potentially negative impact of IP rights on public health, culminating in the Doha Declaration, and specifically to the statement in paragraph 4 of Doha that the TRIPS Agreement does not prevent member countries from taking measures to protect public health but that TRIPS should indeed be interpreted and implemented to protect public health and to promote access to medicines.

It may be mentioned that TRIPS Art 8 in fact expressly recognises the right of countries to adopt measures necessary to protect public health, provided such measures are consistent with the provisions of TRIPS. It is important that this qualifying statement should be borne in mind.

It may further be mentioned that Doha paragraph 4 then reaffirms that, to achieve this (ie to protect public health), member countries may make use of the relevant TRIPS flexibilities. It is stated in the IP Framework (par 4.1 iii) that the South African government has not made optimal use of these flexibilities; it will be necessary to outline the manner in which and/or the legal provisions by which such optimal use could be made.

In paragraph 5 of Doha the relevant flexibilities are identified, namely –

- the granting of compulsory licences (as provided for in TRIPS Art 31 and as already provided for in the Patents Act s 56; the grounds for granting such a licence and the procedure may require adjustment);
- the right to determine what constitutes a national emergency (as referred to in TRIPS Art 31(b); this possibility has not yet been used by South Africa); and
- the right to determine the ambit of exhaustion of rights (as stipulated in TRIPS Art 6; currently the statutory position in South Africa has been determined in s 45 of the Patents Act as national exhaustion, but this may require adjustment).

Recommendation 4.1: A&A recommends that it would be necessary, in order to ensure that optimal use is made by South Africa of TRIPS flexibilities, as suggested in the IP Framework, that the appropriate flexibilities be identified and that an assessment be made as to the manner in which optimal use of such flexibilities could be made, so as to enhance the current legal IP dispensation in South Africa in order to address the health-related needs of the country, but without eroding the certainty and efficacy of the current patent system.

4.1.1 *Local manufacture and export*

[IP Framework paragraph 4.1.1 i - v]

In sub-paragraphs i – v the potential for growth in the domestic pharmaceutical sector is outlined, particularly the potential advantages of stimulating local manufacture. In the submission by the SAIIPL (paragraphs 18) – 24)), the factors that currently impede the objective of growing the local manufacture of pharmaceutical products are comprehensively explained. It is argued that these factors do not relate to the current patent dispensation; in fact, the point is made that local manufacture would be boosted by strong domestic IP protection, and the warning is sounded that inadequate local IP protection (and therefore also the continuous threat to the current level of protection) would discourage local innovation and local manufacture and could indeed encourage relocation to more attractive jurisdictions.

A&A supports and endorses the importance of, and the need to encourage, local research in the pharmaceutical field and also local manufacturing of active pharmaceutical ingredients and pharmaceutical products in general, and also endorses the proposition that the country's IP regime should support and complement these objectives. However, from a legal perspective A&A agrees with the points made by the SAIIPL, namely that it is not the current patent dispensation (and patent rights as such) that constitutes the primary barrier to these activities and objectives; the potentially restrictive effect of patent rights is only

one factor of relevance. In fact it is the current threat to the continued availability of patent protection for pharmaceutical products in South Africa that constitutes a disincentive to the funding and establishment of these activities by the private sector, and thus constitutes a barrier to achieving these objectives.

At the Consultative Workshop the importance of local R&D and local manufacture in the medicines field was considered and discussed. It was pointed out that the primary objective with the promotion of local manufacture was to improve access to the medicines. However, from a commercial perspective, increased local manufacture would reduce foreign imports and consequently impede foreign competition, also pricing competition. This would lead to price increases. It was also pointed out that adequate funding was the main stumbling block in the way of increased local manufacture; and that adequate production supplies was the main uncertainty if local manufacture inhibited the importation of generic equivalents.

As regards enhancement of local R&D, the point was made at the Consultative Workshop that, from a legal perspective, consideration should be given to the introduction into the law of an express and sufficiently broad research exception, to permit R&D for non-commercial purposes and as part of the clinical testing and development of new medicines. The introduction into the Patents Act of an express and appropriately formulated research exception is supported.

Recommendation 4.1.1: A&A recommends that a study be conducted to determine the reasons for the perceived decline in local research and development, and also the decline in local manufacture, in the pharmaceutical industry; and that different initiatives be investigated in order to encourage and enable local research on new active pharmaceutical ingredients (APIs) and new medicines, and to encourage and enable local manufacture of such APIs and their inclusion in pharmaceutical products, taking into account the role of patent rights. In this context it should be borne in mind that patent rights do not constitute a barrier to non-commercial research and development work, and do not necessarily constitute an unsurmountable barrier to commercial manufacture (eg licences may be granted, and the procedure for such licences could be simplified).

4.1.2 *Substantive Search and Examination*

[IP Framework paragraph 4.1.2 i - iv]

The issue of the implementation in South Africa of a substantive search and examination (SSE) procedure has already been considered and extensively debated at several public and stakeholder meetings and workshops. It is understood that a decision has already been taken by **the dti** and CIPC to implement an SSE procedure, and that 20 prospective patent examiners have already been appointed by CIPC.

In implementing an SSE system, a number of aspects will have to be borne in mind:

(a) As stated in the IP Framework (sub-par 4.1.2 ii - iii), it would be important in selecting a specific model, to ensure that such model would be consistent with the non-discrimination provision of TRIPS Art 27.1. As stated (sub-par 4.1.2 iii), Art 27.1 provides that a discriminatory measure may not relate to a specific field of technology, and the argument has been raised that the introduction of an SSE procedure only in respect of pharmaceutical patents would amount to discrimination relating to a specific field of technology. However, it has been held (by a WTO Dispute Resolution Panel) that there is a clear distinction between 'differentiation' and 'discrimination', and that 'differentiation' would be a legitimate measure and would not constitute 'discrimination'. It is not entirely clear whether the implementation of an SSE procedure only in respect of patent applications relating to pharmaceutical inventions (ie falling within a specific field of technology) would be found to be 'differentiation' and not 'discrimination'.

Even if the decision is taken that the SSE system is to be implemented in respect of patent applications in all sectors of technology, it is necessary to point out that such SSE System must be properly structured and set up: a poorly implemented SSE system could have far-reaching negative effects throughout all economic sectors, and could in particular be detrimental to the growth and general competitiveness of the South African R&D sector by inhibiting the local filing of patent applications in respect of R&D outcomes. This means that South African applicants would be carrying the brunt of the negative consequences of an ineffective SSE system. A badly implemented SSE is also likely to have a negative effect on local manufacture and foreign direct investment.

Based on current patent filing statistics, and taking into account the examination systems in other comparable countries (such as Brazil), it is estimated that the number of patent examiners will have to be between 150 and 200 in order to avoid unduly long delays and examination backlogs. If only 20 examiners are appointed and trained per annum, as is currently the case, it will take between 8 and 10 years to reach the minimum number of examiners for the SSE system to operate effectively in the South African patent filing environment.

For a fully-fledged SSE system, annual salary costs alone would be substantial. It is therefore imperative that **the dti** will make the necessary long-term financial commitments and that appropriate financial resources will be provided for the SSE system. It is expected that, as part of the implementation and maintenance of an effective SSE system, there will be an additional cost burden and additional processing delays placed on patent applicants. It is submitted that all of these factors should be taken into account in the implementation plans for the SSE system.

(a) It must be pointed out that appropriate training of the prospective patent examiners will be essential. Although the prospective examiners will be persons with good qualifications in different fields of technology, they will not necessarily have any knowledge or experience in the

field of patent law. This means that the prospective patent examiners will not only have to be trained in regard to search and examination methodology – training that may effectively be provided by officials of examining offices in other countries – but, more importantly, will have to be instructed and trained on the specific legal principles and criteria that apply in South Africa in respect of novelty, inventiveness, industrial applicability, interpretation of patent claims, validity assessment, etc. This aspect has also been mentioned in the SAIIPL submission (par 4.1.2 - 27)). It is not clear that officials and/or examiners at foreign examining offices will be able to do this South Africa-specific legal training, unless the patent laws of such countries have similarities with South African law. It is possible that officials at international bodies dealing with, and thus familiar with, the patent laws of different countries (and thus also of South Africa) may be able to assist in this regard.

(b) As also pointed out in the SAIIPL submission (par 4.1.2 - 28)), the prospective examiners will have to be trained (and CIPC will have to be prepared to bear the costs that may ensue) to respond to review and appeal procedures in which the findings of the examiners are challenged. It is expected that there will be an increase in patent litigation involving CIPC as the body represented by the Registrar of Patents, and thus the patent examiners, and an increase in the concurrent costs.

Recommendation 4.1.2: A&A recommends that the prospective South African patent examiners, who would all be highly qualified in different scientific and technical fields, would have to undergo intensive training in South African patent law and the specific principles and criteria set out in South African patent law, as interpreted and amplified by court decisions, including the interpretation and assessment of novelty; inventiveness applicability in industry, trade or agriculture; the exclusions from patentability; the selection of applicable prior art; the interpretation of patent claims and the assessment of patent claims against the applicable prior art; and the statutory exceptions and exclusions from patentability; etc. In addition, some training in regard to general legal principles would be helpful, such as the assessment of legal personality, assignment of rights, enforcement of rights, etc.

4.1.3 *Patent opposition*

[IP Framework paragraph 4.1.3 i - ii]

The IP Framework outlines the advantages of introducing patent opposition proceedings, and the disadvantages of the current revocation proceedings.

(a) It is not clear whether the IP Framework has in mind opposition proceedings to take place by way of an intervention by a third party (the 'opposer') in the course of and as part of the substantive examination process. This seems to be the case, since reference is made to relevant information to be presented to the examiners by the third party (ie the 'opposer'). From a legal perspective such a proposal cannot be supported.

The substantive examination process is a procedure between the patent applicant and the examiner, in the course of which the patent examiner will raise objections or queries

regarding the patent application, and the applicant will be afforded an opportunity to respond. It would not be fair and justifiable to permit a third party (the 'opposer') to intervene in this process. For instance, would the applicant be required to respond to the submissions/objections made by the opposer? Would the examiner be required to accept and apply the submissions/objections put forward by the opposer?

In the submission by the SAIIPL (par 4.1.3 29) - 33)) this issue is dealt with in detail. A&A supports the SAIIPL arguments and recommendation, namely that only the presentation of third party observations during the examination process could be supported, without any obligation on either the examiner or the applicant to respond; but that third party intervention by way of opposition cannot be supported.

(b) If, as another alternative, the IP Framework has in mind the introduction of pre-grant opposition proceedings (as existed under the previous Patents Act, 1952), ie to provide for third party intervention once the examination process has been concluded and the patent application has been accepted but before the patent is actually granted, this would be acceptable from a legal perspective.

However, although legally acceptable, this would not mean that a pre-grant opposition procedure would necessarily be an enhancement of the South Africa patent system. For instance, it can be expected that such an opposition procedure could become a protracted process that would cause delays – particularly also since any prescribed period for the notification of an intention to lodge an opposition could itself be extended, and so cause even further delays. Furthermore, it is not clear whether the hearing officer of such a pre-grant opposition would be an examiner (either the same examiner who had examined the application, and who could be perceived to be biased, or a different and presumably unbiased examiner); or whether an independent judicial officer, or the Registrar himself, would be the hearing officer.

Whatever the position eventually may be, provision would have to be made for the finding of such hearing officer to be taken on review and/or appeal – all of which would entail costs and cause delays.

(c) Furthermore, there should be recognition of the difference between a pre-grant opposition process and a post-grant opposition process. Although no express reference has been made to the introduction of a post-grant opposition process, it should be borne in mind that there is very little difference between post-grant opposition and revocation proceedings (the latter already provided for in the Patents Act, s 61), except that the current revocation proceedings entail a judicial process in the Court of the Commissioner, while a post-grant opposition process would probably take place before a hearing officer and not the Court. These aspects will have to be clarified.

In order to avoid abuse of any proposed opposition proceedings, provision for interim protection measures will be essential to be considered as part of any opposition system.

Furthermore, if the patent dispensation is changed to provide for a substantive examination procedure, and/or to provide for a pre- or post-grant opposition procedure, appropriate measures will have to be included in the patent law to avoid frivolous attacks on granted patents.

Recommendation 4.1.3: A&A recommends that, in order to address the perception created by stakeholder groups (not entirely justified), that the current patent system permits 'weak' patents to be granted, the most important first step is for an effective and credible SSE procedure be introduced, carried out by duly qualified and duly trained patent examiners; and as a possible second step, that the existing revocation procedure be restructured and/or adjusted to make it more accessible and cost effective and less time-consuming, but to remain a judicial procedure. It is submitted that the proposed pre-grant opposition procedure and a possible post-grant opposition procedure, both heard by an administrative official, cannot be supported; such procedures would cause delays and will lack credibility.

4.1.4 *Patentability criteria*

[IP Framework paragraph 4.1.4 i- ii]

Reference is made in the IP Framework to TRIPS Art 1 (which requires member countries to give effect to the provisions of TRIPS and which allows countries to implement in their laws more extensive protection than is required by TRIPS); to Art 7 (which stipulates that the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer of technology in a manner conducive to social and economic welfare and a balance of rights and obligations); and to Art 8 (which allows member countries to adopt measures to protect public health and nutrition and to promote the public interest, provided such measures are consistent with the provisions of TRIPS; and to adopt appropriate measures that may be needed to prevent the abuse of IP rights by rights holders, provided such measures are consistent with the provisions of TRIPS).

It is not clear how these TRIPS provisions relate to patentability criteria; the patentability criteria are set out in Art 27, namely novelty, inventiveness, and industrial applicability – subject to the right of member countries to exclude certain inventions from patentability. It is also not clear in what way the IP Framework intends to make use of TRIPS flexibilities to adjust the patentability criteria in order to address the public health concerns. Is the intention to make the patentability criteria stricter? It is also not clear which TRIPS flexibilities are to be used for this purpose.

Although TRIPS sets out the three criteria for patentability, TRIPS does not set out the tests or the standards to be applied to assess novelty, inventiveness and industrial applicability; such tests and standards appear to be the only flexibilities available and applicable to patentability criteria.

It is suggested in the IP Framework that international best practice should be considered in developing an appropriate approach to the patentability criteria. It would be important to give further consideration to this suggestion in the context of the South African position:

(a) Novelty requirement

In terms of the Patents Act, a very strict novelty requirement currently applies, ie absolute novelty. A patent will only be valid if it complies with this strict novelty requirement. The introduction of any flexibility could only mean that the novelty requirement would become less strict, ie to make it easier for a valid patent to be obtained even if the invention is not absolutely new. It is not clear that this is what government would like to achieve. Furthermore, to implement different novelty requirements for inventions from different technology sectors would be a contravention of TRIPS Art 27.1.

(b) Inventiveness requirement

In terms of the Patents Act, the test for inventiveness entails the judgement of a person skilled in the art; this test appears to be objective and in line with the position in other countries. It is not clear what adjustment is to be considered.

More information would be required in order for this aspect of the IP Framework to be properly considered. It is possible that this aspect has been raised in the IP Framework as a result of the allegations frequently made by parties attacking the credibility of the South African patent system, namely that the absence of a substantive search and examination procedure results in the granting of 'weak' patents, inter alia by allowing incremental innovative inventions to be patented, thereby allowing 'ever-greening'. What these parties fail to recognise and/or admit, is that the validity of any granted patent may be challenged, eg by way of revocation proceedings, or by way of a counter-claim when the patent holder tries to enforce the patent. This reality ensures that patent applicants would be reluctant to file patent applications and obtain patents in cases where the patentability criteria are not met and invalidity is likely to ensue – even in the absence of a substantive search and examination assessment.

(c) Types of inventions

Although TRIPS Art 27.1 provides for 'any inventions, whether products or processes, in all fields of technology' to be eligible for patenting, Art 27.2 and 27.3 allows member countries to exclude from patentability certain inventions. All of the categories of inventions that may be excluded have been excluded by the Patents Act. So, this flexibility has been used. The type of invention that is generally referred to by parties attacking the patent system, relates to the use of a known substance or composition in a new method of treatment of humans or animals, which is permitted in terms of s 25(9) of the Patents Act.

It is submitted that there is no evident TRIPS flexibility that could be used in order to remove this type of invention from patentability.

(d) Incremental innovation

The reference in the IP Framework to a need for the patentability criteria to be reconsidered may be indicative of an intention that the level of patentability should be lifted, so that incremental inventions (ie inventions based on existing basic inventions but constituting improvements of existing basic inventions) should not be patentable.

As part of the attack on the current patent system by certain parties, the allegation is made that the current system allows 'ever-greening' to take place since incremental innovations are patentable: it is thus argued that improvement inventions, ie incremental innovations, should not be patentable since this leads to 'ever-greening'. This seems to imply that the patentability criteria should be made stricter. It is important that the true meaning of the concept of incremental innovation, and the true meaning of the concept of 'ever-greening', must be properly understood; and it is important that the underlying reason for incremental innovation, and thus the advantages of incremental or continuing innovation as part of a patent system, must be appreciated.

First it must be pointed out that the objection against the patentability of incremental inventions is based on a misunderstanding of the legal position. The South African criteria of novelty and inventiveness as applicable to basic inventions also apply to improvements on basic inventions, so that insignificant improvements or changes of basic inventions (ie improvements or changes which lack novelty and/or inventiveness) will not be patentable. It should further be remembered that an improvement patent covers only the improvement; protection in respect of the basic invention expires with the expiry of the basic patent – there is no 'ever-greening' of the basic patent.

It must further be pointed out, in the context of pharmaceutical patents, 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. Beneficiation by way of 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.

In this context it must be emphasised that, although discoveries of new chemical entities (ie new basic inventions) are extremely valuable, many important innovations are in fact based on prior inventions through continued R&D, eg on improved drug delivery methods, and improved formulations and effectiveness, all to the benefit of the patients. Therefore, patentability of new formulations or new molecular forms of active ingredients should not be abolished *per se*. Extensive R&D is often required to improve a molecular form or the formulation of an existing medicine, and the modified product generally has improved efficacy. As long as the patentability criteria of novelty and inventiveness are complied with, patentability should be available.

(e) Relevance of human rights

As mentioned above (par 1.6), a particular point was raised at the Consultative Workshop, namely that an IP system should also aim to recognise and respect human rights. This means that, in order to achieve this objective, the current IP system, and particularly the patent system, will have to be adjusted to provide for the principle of respecting, protecting, promoting and fulfilling the human rights of all people, as stated in section 7(2) of the Constitution. This approach presents a challenging new perspective to be taken into account; it would be necessary to determine how this objective is to be achieved in the context of the current patent system, ie which of the currently applicable legal criteria will have to be adjusted to accommodate this objective.

The Constitution sets out (in Chapter 2) a comprehensive list of basic human rights; however, not all of these rights are relevant to the protection of IP rights. The following human rights are deemed to be relevant:

- the right to equality: everyone has the right to equal protection and benefit of the law; the State may not unfairly discriminate directly or indirectly against anyone
- the right to an environment that is not harmful to their health or well-being
- no one may be deprived of property except in terms of a law of general application, and no law may permit arbitrary deprivation of property
- everyone has the right to have access to health care services
- everyone has the right of access to information held by the State, and information held by another person that is required for the exercise or protection of any rights
- everyone has the right to administrative action that is lawful, reasonable, and procedurally fair
- everyone has the right to have any dispute that can be resolved by the application of law decided before a court or another independent and impartial tribunal.

It may be pointed out that some of these basic rights have already been recognised in the Patents Act, also as a patentability criterion, eg in s 25(4)(a), s 36; as a principle of just and fair administrative action, eg in s 16; as a principle for the resolution of disputes, eg in s 28; as a principle to provide access to information, eg in s 43(4);

It would also be necessary to ensure that the right not to be deprived of property in an arbitrary manner will be recognised in the application of legal provisions providing for compulsory licences under patents, and for State acquisition and use of patents.

Recommendation 4.1.4: A&A submits that the current patentability criteria as set out in the Patents Act are compliant with TRIPS Art 27 and are also in line with international best practice. It is recommended that careful consideration be given to the potential negative consequences of any changes to the patentability criteria, eg to provide for different novelty or inventiveness requirement for inventions from different technology sectors; to provide

that improvement inventions (ie incremental innovations) will not be patentable; or to provide that new medical uses of known compounds or substances will not be patentable.

It is further recommended that it should be borne in mind that the flexibilities provided for in TRIPS Art 8 envisage the adoption of special measures (not the adjustment of patentability criteria), while Art 7 emphasises the need to ensure a balance of rights and obligations in the protection and enforcement of IP rights.

4.1.5 *Disclosure requirements*

[IP Framework paragraph 4.1.5 i-ii]

Reference is made (par 4.1.5 i) to the disclosure requirement asset ou in TRIPS Art 29, ie that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This requirement is virtually repeated verbatim in the Patents Act (s 32(3)(b)). Non-compliance with this requirement (again repeated verbatim) is a ground for the patent to be revoked (s 61(1)(e)).

It is accordingly submitted that the disclosure requirement as stipulated in TRIPS is substantially complied with.

A point that was raised in the Consultative Workshop related to the cancellation by way of a legislative amendment in 2002, of the requirement, previously set out in s 32(3)(c)), for the applicant to disclose in the complete specification the best method of performing the invention known to the applicant at the time when the specification is filed. It may be explained that this amendment was made in order to render the disclosure requirement as set out in s 32 compliant with the peremptory requirement of TRIPS Art 29. Prior to the 2002 amendment, s 32 only required the complete specification fully to describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed. The ambit and clarity of the disclosure, ie to enable a skilled person to perform the invention, was not stipulated; this was added to comply with TRIPS.

It should be noted that the only peremptory provision of TRIPS Art 29 is reflected in the current s 32; Art 29 then contains a permissive provision, namely that member countries may require the applicant to indicate the best mode for carrying out the invention known to the inventor. This permissive requirement of TRIPS constitutes a TRIPS flexibility; the merit of introducing this requirement into the Patents Act should be carefully considered. In this context it should be taken into account that the patent system (as indeed all IP rights) is based on the *quid pro quo* principle: in return for the exclusive IP rights afforded the IP holder, the IP holder has the obligation to provide to the public sufficient information regarding the IP to enable the public to make use of that information and to build on that information to create further IP, when the period of exclusivity expires and the information falls in the public domain. Therefore, the granting of IP rights by the State is often described as social contracts; the IP right is granted and in return the innovative concept must be disclosed to enable the innovation to be carried out by the public once the IP right expires.

The level of disclosure should therefore be sufficient to enable the public to build on that information to create new innovations; in practice this would enable technology transfer. There is no clear reason to justify a further requirement that an innovator (or a patent applicant) should disclose the best mode for carrying out the innovative concept.

Recommendation 4.1.5: A&A recommends that the current disclosure requirement as set out in the Patents Act s 32(3)(b) be retained as is; this requirement is compliant with the peremptory provision of TRIPS Art 29. It is also submitted that this level of disclosure is in line with the underlying basis for patents, namely the *quid pro quo* principle, namely that the disclosure should be sufficient for a person skilled in the art to carry out the invention, ie to understand the invention.

A&A submits that the objective of continuing innovation and the transfer of technological advancement would be achieved by a disclosure requirement as set out in s 32(3)(b).

4.1.6 *Parallel importation*

[IP Framework paragraph 4.1.6 i-iii]

The IP Framework refers to the fact that TRIPS in Art 6 gives member countries the flexibility to determine their own regimes in regard to exhaustion of IP rights. The provisions in the different IP laws of a member country in regard to the exhaustion of that IP right will thus determine the legal position in regard to parallel importation.

(a) Position of TRIPS on parallel importation

TRIPS takes a neutral position on the issue of the exhaustion of IP rights, and thus on the legality or otherwise of parallel importation. Art 6 of TRIPS states that nothing in TRIPS shall be used to address the issue of the exhaustion of IP rights. In Art 28.1(a) of TRIPS reference is also made to this fact by way of footnote 6 specifically linked to the importation right under patents. It is clear, therefore, that TRIPS does not give any indication of a preferred position in regard to the exhaustion of rights, and thus in regard to the legitimacy of parallel importation (ie in cases where the patent holder did not authorise the importation). This is interpreted that TRIPS leaves it to the national laws of a country to determine the position in regard to exhaustion of rights and parallel importation; Art 6 of TRIPS certainly cannot be interpreted to legalise parallel importation.

(b) Position of the Patents Act on parallel importation

The position on parallel importation under South Africa's IP laws differs in respect of the different types of IP. At present the Patents Act appears to provide only for national exhaustion of rights. In terms of s 45(1) the patent holder gets in South Africa the exclusive right to exclude other persons from carrying out certain actions in regard to the patented invention, *inter alia* of disposing of the patented product. In terms of s 45(2) the disposal of the patented product by the patent holder (or his licensee) gives the purchaser the right to use or dispose of that product. There is no wording to indicate that section 45(2) intends to apply also to the disposal of the patented product in other countries; or that the patented product purchased may be exported or imported. The wording seems to indicate that it is the intention of the legislature

that only the national right will be exhausted by the sale in South Africa, and only in regard to the use or resale (not the importation) of the product sold.

Therefore, the Patents Act appears to address only the sale of the patented products in South Africa, ie only provides for national exhaustion; and it does not appear to limit the exclusive importation right of the patent holder once the patented article has been sold. This interpretation is based on the wording of s 45(2), namely that the disposal of a patented article by the patentee shall only give the purchaser the right 'to use, offer to dispose of, and dispose of that article'. The provision does not give the purchaser the right to make, to exercise, or to import the patented invention (which exclusive rights are granted to the patentee by s 45(1)). Accordingly, it is submitted that parallel importation is not permitted by the Patents Act. This is confirmed in footnote 19 of the IP Framework.

Accordingly, on the basis of section 45, it is submitted that the South African patent holder has the right, in terms of the Patents Act, to prohibit parallel imports; in fact, that parallel importation without the authority of the patent holder will constitute an infringement of the patent.

(c) Position of the Medicines Act on parallel importation

Reference is also made in the IP Framework to the provision in s 15C of the Medicines Act, 1965 which authorises the Minister of Health to prescribe the conditions on which a patented medicine may be imported by a person other than the patentee. It must be noted that this provision does not permit parallel importation of medicinal products in general; it merely permits parallel importation of a specific medicine on the basis of a specific permit issued by the Minister of Health. In terms of this provision parallel imports can therefore take place legally, but a permit first has to be obtained and the stipulated conditions have to be observed, eg that the imported product must be a genuine product (not a generic).

(d) Misconceptions in regard to parallel importation

Parallel importation means the importation into South Africa of a genuine product obtained by a third person in another country from a legitimate source, but without the authority of the patent holder to such third party to import the product into South Africa. It must be emphasised 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.

The concept of 'parallel importation' thus refers to the (unauthorised) importation of genuine products into country A, which products are protected by a patent in country A, but without the licence or authority of the patent holder in country A. These products may have been obtained legitimately from the patent holder in another country, or from a licensee of the patent holder, but without the right of importation into country A. Even where the patent holder in country A has not authorised the importation of the genuine products, his consent may be implied if his rights in respect of the products had been 'exhausted' by the sale of the products in such other country.

In the absence of express authorisation by the patent holder, the legality or otherwise of parallel imports thus depends on whether or not the patent holder's right has been exhausted internationally by the sale of the patented products in a specific country. As indicated above, TRIPS takes no position on the issue of exhaustion of rights; national *vis-à-vis* international exhaustion depends on the national law of a specific country. As indicated above, South Africa's Patents Act only provides for national exhaustion of rights.

(e) Risks posed by parallel importation

It is submitted that the implementation of international exhaustion of rights regime in South Africa, ie the legalisation of parallel importation, could have very negative consequences for South Africa in all fields of technology. In the first place, if South Africa becomes a primary country of importation, that would impact negatively on any aspirations for the country to boost its local manufacturing capacity; this has already happened in the textile industry. In addition, if products are being imported instead of being manufactured locally, that would impact negatively on the local beneficiation prospects, on exportation prospects, on R&D investments, and trade deficits would probably be increased.

It must further be taken into account that facilitating and thus expanding South Africa's parallel importation of pharmaceutical products could pose other 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.

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. It is thus important to recognise that parallel importation is likely to benefit the parallel trader as opposed to the consumer.

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.

Recommendation 4.1.6: A&A recommends that the current legal dispensation of national exhaustion of patent rights, and the current illegitimacy of parallel importation, be retained so as to provide a safeguard against potentially abusive practices. In the case of medicines, a system of permitted parallel importation is already in existence under the Medicines Act; this system could be refined so that it becomes more attractive to potential legitimate users.

4.1.7 *Exceptions*

[IP Framework paragraph 4.1.7 i-iii]

Reference is made in the IP Framework of the use of limited exceptions, as envisaged in TRIPS Art 30, as a means of striking a balance between the rights of creators and users of IP. As already indicated above, A&A supports the underlying principle of a successful IP system as the need to find a proper balance of rights and obligations, as envisaged in TRIPS Art 7.

The proposal put forward in the IP Framework, that consideration should be given to the introduction of an appropriate research exception, is supported. From the IP Framework it seems that the envisaged research exception is focussed on the pharmaceutical sector, ie based on the exception proposed by the WHO to address public health needs in developing countries; however, it is suggested that a research exception should be considered in a wider context. Although it is generally accepted that the exclusive rights granted by the patent system are aimed at giving the patent holder the right to exclude a collection of commercial activities, and that activities of a non-commercial nature (such as academic research activities) would not necessarily be prohibited, this is not expressly so stated in the Patents Act.

Therefore, A&A supports the proposal that the introduction into the Patents Act of an express research exception should be considered. Such an exception should be limited to the use of the material disclosed in the patent specification for non-commercial, and particularly for academic, research purposes.

This means that such an exception should be formulated and interpreted not to extend to the clinical and other confidential data submitted in support of an application for the market authorisation of a new pharmaceutical or agricultural chemical product. Such clinical and other test data is generally not disclosed, whereas the information in a patent specification is disclosed to the public. TRIPS Art 39 addresses the protection of such undisclosed data, and expressly provides that such data shall be protected against disclosure and, where disclosure is necessary in the public interest, that such data shall be protected against unfair commercial use. It is submitted that there does not appear to be a sound reason for a research exemption to apply to such data.

Recommendation 4.1.7: A&A recommends that consideration be given to the introduction into the Patents Act of a carefully drafted research exemption, to permit non-commercial use of the material disclosed in a patent specification for research purposes; and further, that it should be stated that the exemption does not apply to the use of confidential test or other data submitted for purposes of marketing authorisation of pharmaceutical or agricultural chemical products.

4.1.8 *Voluntary licences*

[IP Framework paragraph 4.1.8]

In the IP Framework a brief reference is made to the role of voluntary licences, and the statement is made that voluntary licences may not always provide the required level of access to patented pharmaceutical products.

It is submitted that the value of voluntary licences as a method of providing access to patented material, coupled with technology transfer, should not be disregarded. The use of voluntary licensing entails several advantages and, moreover, the Patents Act and other statutes already contain provisions regulating and improving the voluntary licensing system, thereby creating a workable and effective system. Some of these features are set out below:

- voluntary licences are based on consensual agreements between the patent holder and a third party, and may cover various activities such as manufacturing, selling and distribution, exporting and importing
- 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
- voluntary licences are recognised by the Patents Act and Regulations and may be recorded against the patent concerned – reg 62
- in the absence of a condition to the contrary, a licence to manufacture a patented product carries with it the right to use or to dispose of the patented product; it is noteworthy that no reference is made to importation – s 58(a)
- 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 patent product; again there is no mention of export/import of the product – s 58(b)
- certain restrictive conditions in a licence are prohibited – s 90
    - to prohibit or restrict the licensee from using any product (whether patented or not) supplied by any other person – s 90(1)(a)
    - to require of licensee to observe a specified minimum resale price – s 90(1)(d)
    - to prohibit the exercising or disposing of the patented product in any country where it is not patented – s 90(1)(e)
- the refusal to grant a voluntary licence on reasonable terms, whereby the trade or industry or the establishment of any new trade or industry is prejudiced, is a ground to obtain a compulsory licence – s 56(2)(d)
- the Competition Act 89 of 1998 applies to IP-related transactions, and prohibits
    - restrictive horizontal practices, eg directly/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 excessive prices to the detriment of consumers, or refusing to give a competitor access to an essential facility – s 8

- TRIPS 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 – Art 40.

It is further pointed out that the potential value as a licensing tool, of a further voluntary licensing model already provided for in the Patents Act, should not be overlooked. The Patents Act makes provision, in s 53, for a patent holder to endorse the patent in the official register with the words 'Licences of Right'. With such an endorsement, any person is entitled as of right to a licence under the patent on such conditions, in the absence of agreement, as determined by the Commissioner of Patents. It is submitted that this model, already provided for in the Patents Act, could be used as a basis for the creation of a so-called Medicines Patent Pool (referred to in par 4.1.9 iii of the IP Framework) as part of the Government's efforts to negotiate access to affordable medicines.

Recommendation 4.1.8: A&A recommends that the value and potential usefulness of the diversity of provisions and models in regard to voluntary licences already contained in the Patents Act, should not be overlooked, and that optimal use should be made of these provisions and models.

4.1.9 *Compulsory licences*

[IP Framework paragraph 4.1.9 i-v]

The IP Framework states, in par 4.1.9 i, that compulsory licences are regarded as one of the most important policy tools to ensure that IP rights do not unduly restrict access to essential innovations. As also mentioned, this issue has become one of the most debated and contested items of discussion. Since compulsory licences are generally granted without the consent of the patent holder, so that such granting may be contentious, it is important that the current legal model for compulsory licences should be considered, so as to determine where changes and improvements could be made without undermining the credibility of the patent system.

Some of the features of the current compulsory licence system are set out below:

- compulsory licences are granted by the Court 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 by the parties, nor for the royalties payable to be determined by the parties, although the Patents Act contains certain provisions that regulate these aspects – s 56(4), (5), (7)

- a compulsory licence may be granted on an application to Court by an interested person who can show that the rights under a patent are being abused – s 56

- patent rights are deemed to be abused *inter alia* if –

  - the patented invention is not being worked in South Africa on a commercial scale or to an adequate extent within a specified period, and there is no satisfactory reason for such non-working – s 56(2)(a)

  - 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)

  - by reason of the refusal of the patent holder to grant voluntary licences on reasonable terms, the trade or industry of the country or of any class of persons, or the establishment of any new trade or industry is being prejudiced, and it is in the public interest that a licence should be granted – s 56(2)(d)

  - 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)

- it is evident that these grounds could be used as a basis for compulsory licences in respect of medicinal products; however, the court process is complicated and the onus of proof substantial

- in granting a compulsory licence, the Court may stipulate that the licensee will be precluded from importing the product manufactured in another country

- there is no express reference to the fixing of the applicable royalty rate by the Court

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

  - each case to be considered on its individual merits; this is the case under s 56

  - only to be granted if the proposed user/licensee has made efforts to obtain a voluntary licence and such efforts have not been successful; this is listed as a type of abuse – s 56(2)(d)

  - such a licence shall be non-exclusive and non-assignable; stipulated in s 56(5)

  - the use shall be authorised predominantly for the supply of the domestic market; importing may be prohibited (s 56(4)(a)), export not prohibited

  - the patent holder shall be paid adequate remuneration in the circumstances of each case

- TRIPS has also introduced a special dual compulsory licensing model to address compulsory licensing in respect of pharmaceutical products in developing countries without adequate manufacturing capacity – Art 31*bis*.

Many arguments have been advanced in support of the use of compulsory licensing as a tool or mechanism for accessing medicines at lower prices, particularly in a developing country like South Africa; some of the arguments are set out below:

- compulsory licensing allows a country to license the manufacture of a patented medicine to a third party, even when the patent holder refuses to grant a licence, and when there are good reasons to do so, eg when the Government considers the price of that medicine to be too high
- compulsory licensing may be a bargaining tool in price negotiations with patent holders who are also producers of patented medicines
- compulsory licensing presupposes local manufacture and may not be an effective tool if South Africa has a problem in regard to manufacturing capacity, whether for generic or innovative medicines; it should then rather resort to parallel importation, or implement the dual licensing model of TRIPS Art 31*bis*
- a compulsory licence does not deprive the IP holder of the ownership of the IP right; it should not be treated as direct expropriation; it constitutes an exception to the exclusive right
- on the other hand, a compulsory licence does deprive the patent holder of the right to exclude third parties from commercially exploiting the patented invention.

It has also been argued that the current compulsory licensing model as set out in the Patents Act has many shortcomings and could be improved, so as to make the model easier to use. Some of the negative features identified are set out below:

- the grounds for granting compulsory licences are inadequate
- the procedure for obtaining a compulsory licence is too complicated
- additional health-related grounds for compulsory licences must be prescribed
- optimal use must be made of TRIPS provisions relating to national emergencies
- provisions to implement the dual compulsory licence model of TRIPS Art 31*bis* must be introduced into the patent law.

It is submitted that the very nature of a compulsory licence must be borne in mind, namely that such a licence is granted against the will of the patent holder and in fact deprives the patent holder from his just reward for his time and innovative effort to produce the patentable invention – a reward contemplated in terms of the *quid pro quo* principle on which the patent system is based. It must also be borne in mind that a compulsory licence deprives the patent holder of his right to exclude third parties from commercially exploiting his patented invention – a right expressly provided for by TRIPS Art 28 and by the Patents Act s 45; and deprives the patent holder of his right to enjoy the whole profit and advantage accruing by reason of the invention – a right expressly provided for in the Patents Act s 45. It has also been pointed out that the prospect of compulsory licences being granted may make voluntary licensing more attractive.

Recommendation 4.1.9: A&A recommends that, although the current compulsory licence model should be reconsidered and if necessary adjusted in order to make it more functionally effective in the context of the current need for access to affordable medicines, the provision should be retained that compulsory licences will only be granted in cases where the patent rights are being abused, or where there are compelling public interest circumstances warranting the granting of such a licence; and furthermore, that the granting of compulsory licences will continue to be subject to judicial review. In effect A&A thus recommends that the compulsory licensing provisions should remain compliant with TRIPS Art 31.

4.1.9.1 Judicial process

[IP Framework paragraph 4.1.9.1 i-ii]

The IP Framework points out that the current judicial process for the grant of a compulsory licence as provided for in the Patents Act is protracted and expensive; a more streamlined and accessible administrative process should be considered.

Although A&A agrees that TRIPS does not require a judicial process, A&A wishes to point out that TRIPS Art 31 emphasises the need for judicial supervision and has two references to the need for judicial review: Art 31(i) requires that any decision to authorise a compulsory licence shall be judicial review, and Art 31(j) requires the remuneration under a compulsory licence to be subject to judicial review.

Recommendation 4.1.9.1: A&A thus recommends that any new process for the granting of compulsory licences must be subject to judicial review.

4.1.9.2 Adequate remuneration

[IP Framework paragraph 4.1.9.2 i-ii]

The IP Framework points out that the current provisions in the Patents Act for the granting of a compulsory licence do not contain any guidelines as to adequate remuneration; guidelines for determining adequate remuneration should be considered.

A&A appreciates this point but wishes to point out that TRIPS Art 31(j) requires that any remuneration awarded shall be subject to judicial review.

Recommendation 4.1.9.2: A&A agrees that the proposed guidelines on adequate remuneration would be useful, but recommends that any decision taken regarding remuneration, or any award made for remuneration to be paid, should be subject to judicial review.

4.1.9.3 Government use

[IP Framework paragraph 4.1.9.3 i-ii]

The IP Framework refers to the provision in TRIPS Art 31(b) that public non-commercial use of the subject matter of a patent shall not be subject to the requirement of prior negotiations with the patent holder, and then refers to the current provision in the Patents Act regarding State use, stating that the Act goes beyond the requirements of TRIPS.

It is not clear what kind of 'non-commercial use' the IP Framework has in mind; the use of patented subject matter for the manufacture of medicinal products can hardly be seen as 'non-commercial use'. This notwithstanding, A&A wishes to point out that the provision in the Patents Act s 4 does not expressly deal with 'non-commercial use'; s 4 deals with the use of an invention by the State for public purposes. A&A submits that such use would be subject to the requirement of preceding negotiations with the patent holder, but failing agreement such use for public purposes can be permitted on conditions determined by the Commissioner.

Recommendation 4.1.9.3: A&A recommends that consideration be given to an appropriate amendment of the Patents Act to provide for State use of a patented invention without the need for prior negotiation with the patent holder, but only in cases of a national emergency, or in circumstances of extreme urgency, or in cases public non-commercial use, as contemplated in TRPS Art 31(b). It should be made clear that the legal validity of any decision authorising such use would remain subject to the requirement of judicial review, as contemplated in TRIPS Art 31(i).

4.1.9.4 Compulsory licences for export

[IP Framework paragraph 4.1.9.4]

The IP Framework refers to the ongoing discussions and negotiations regarding the compulsory licence model permitting export, as incorporated in TRIPS Art 31*bis* which was the outcome of the implementation of paragraph 6 of the Doha Declaration. The continued engagement of South Africa in the further refinement of the Art 31*bis* is supported. In this regard it is pointed out that South Africa has not yet taken any legislative steps to implement the Art 31*bis* model.

4.1.9.5 Compulsory licences to remedy anti-competitive practices

[IP Framework paragraph 4.1.9.5 i-iii]

The IP Framework refers to the provisions in TRIPS Art 31(k) to the granting of compulsory licences to remedy anti-competitive practices, and in particular that compliance with the TRIPS requirements of prior negotiation and of limitation to supply the domestic market is not required. It is then stated that the omission expressly to provide for such licences shows that full advantage of the TRIPS flexibilities has not been taken in the current legal dispensation.

Although some of the circumstances outlined in s 56(b) of the Patents Act as constituting abuse of patent rights in fact also constitute anti-competitive practices, A&A supports a proposal that s 56 should be amplified to recognise anti-competitive practice as a ground for the granting of a compulsory licence. Further appropriate provisions specifically applicable to the granting of a compulsory licence on that ground can be incorporated, such a no need for prior negotiation with the patent holder; the authorisation of exports; the anti-competitive practice to be taken into account as a factor in determining remuneration; and the reliance on possible recurring of such practices to refuse termination of the licence.

4.1.10 *IP and competition*

[IP Framework paragraph 4.1.10 i-ix]

The IP Framework sets out the need to prevent patents from 'illegitimately extending market power' and argues that the principles of competition law could be used to achieve this. Detailed reference is then made to relevant provisions in TRIPS, in the Patents Act, and in the Competition Act, and the conclusion is put forward (par 4.1.10 vii) that competition law is an important instrument to achieve an appropriate balance between the interests of the creators and users of IP.

A&A agrees with the relevance and potential role of competition law in addressing anti-competitive market practices such as restrictive horizontal practices, restrictive vertical practices, and abuse of a dominant position in the market – all dealt with in Chapter 2 of the Competition Act. As regards the point raised that the prohibitive costs for making use of the procedures available under the Competition Act, the SAIIPL correctly points out in its submission that a complaint lodged with the Competition Commission does not necessarily entail costly litigation; the Commission carries out the necessary investigation.

Recommendation 4.1.10: A&A is in agreement with and supports the recommendation in par 4.1.10 ix of the IP Framework, namely that guidelines regarding the interface between IP and competition should be developed, taking into account international best practice and in consultation with stakeholders.

4.2 **International best practice – a BRICS perspective**

[IP Framework paragraph 4.2 i-iii]

The position is put forward in the IP Framework that, in addressing the issues identified and dealt with in detail in paragraph 4.1, regard should be had to international best practice and in particular the information to be obtained from the BRICS countries. However, the unique features of South Africa should ultimately determine the IP policy position taken. This approach is supported.

4.3 **International commitments**

[IP Framework paragraph 4.3 i-x]

This section primarily deals with South Africa's international commitments arising from the country's membership of IP-related international treaties and conventions. From a national IP Policy perspective it is of particular importance that the country should comply with and give effect to its commitments.

1. South Africa's membership of multilateral treaties

In paragraph 4.3 i six multilateral IP-related treaties are listed of which South Africa is a party.

- Three of these treaties provide for substantive protection of different species of IP, namely the Berne Convention (copyright), the Paris Convention (patents, trade marks, designs), and the TRIPS Agreement (seven types of IP, including patents, trade marks, designs, copyright, lay-out designs of integrated circuits, geographical indications, and undisclosed information/trade secrets).
- Two of the six listed treaties provide for international filing or deposit procedures, namely the Patent Cooperation Treaty (patent applications), and the Budapest Treaty (deposit of micro-organisms).
- The sixth listed treaty, the WIPO Convention, provides for the establishment of WIPO as the successor of BIRPI (the United International Bureau for the Protection of Intellectual Property), the international organisation to take responsibility for the promotion and protection of IP.

In addition to the listed treaties (on substantive protection of IP, on international filing procedures, and on WIPO), there is a further category of international treaties on the classification of different species of IP, namely the Locarno Agreement on the International Classification of Designs, the Nice Agreement on the International Classification of Goods and Services for Marks, the Strasbourg Agreement on the International Patent Classification, and the Vienna Agreement on the International Classification of Figurative Elements of Marks. South Africa is not a party to any one of these treaties, but has implemented the provisions of the Locarno Agreement (Designs Act, 1993: s 7, reg 9, Sch 3); and of the Nice Agreement (see Trade Marks Act, 1993: s 11, reg 4, Sch 3).

The abovementioned treaties are all administered by WIPO, with the exception of the TRIPS Agreements which is administered by WTO. In addition to acceding to the WIPO Convention establishing WIPO, and so becoming a member country of WIPO, South Africa has also signed the WTO Agreement establishing the WTO, and is thus a member country of WTO.

There are also international IP-related treaties negotiated and administered by other international organisations, to some of which South Africa is a party, such as the Convention on Biological Diversity administered by UNEP (United Nations Environment Programme) (South Africa became a party in November 1995), with its Cartagena Protocol (South Africa became a party in November 2003), and its Nagoya Protocol (South Africa became a party in January 2013). As a member country SA is obliged to give effect to certain requirements in regard to the patenting of inventions derived from the use of indigenous biological resources, including to acknowledge the use of traditional knowledge and to provide for benefit-sharing agreements. This was dealt with by the Patents Amendment Act, 2005, amending the Patents Act, 1978: s 2, 30 and 61; reg 22, 33A, 67B; Sch 2.

Another such treaty is the UPOV Convention of UPOV (the International Union for the Protection of New Varieties of Plants), requiring member countries to provide for protection of new plant varieties (South Africa became a party in November 1977). This is dealt with in the Plant Breeders' Rights Act, 1976.

Recommendation 4.3(1): It is recommended that recognition should be given in the IP Policy to all of the treaties of which South Africa is a member – not only the WIPO and WTO treaties; as a member South Africa has certain obligations to be given effect to in its national laws. Even in those cases where South Africa is not a party of the treaty but has implemented the systems of the treaty in its national laws, such as the classification systems, certain obligations have been created for South Africa by its own national laws.

2. Membership of further treaties to be considered

In paragraph 4.3 v it is suggested that SA should analyse the WIPO treaties of which the country is not yet a member to determine whether membership would be beneficial. This suggestion is supported. However, SA should also investigate whether there are other IP-related treaties not administered by WIPO but by other international bodies, membership of which would also be beneficial. One such other treaty is the UNESCO (UN Educational, Scientific and Cultural Organisation) Convention on the Protection of the Diversity of Cultural and Artistic Expressions. Nevertheless, it is submitted that, from an IP Policy perspective, the WIPO treaties would be the most relevant instruments.

In the first place, although SA has not yet acceded to the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Corporations (1961), most of the provisions of this Convention have been incorporated in the Copyright Act, 1978 and the Performers' Protection Act, 1967. The effect of this is that the nationals of other convention countries (to which protection has been extended in terms of s 37 of the Copyright Act) enjoy full protection in SA under the Copyright Act in respect of phonograms and broadcasts, and probably also under the Performers' Protection Act in respect of performances, but SA nationals are not entitled to similar protection as required by the Rome Convention in other convention countries, since SA is not a member of Rome.

In the second place, although SA has not acceded to the Locarno and Nice classification agreements but has implemented in its national laws the classification systems under the Locarno Agreement (designs) and the Nice Agreement (trade marks), it is not clear why accession to these agreements should not take place. Furthermore, since substantive search and examination of patent applications is being introduced, it would seem that accession by South Africa to the Strasbourg Agreement (classification of patents) and formal implementation of its classification system would be advisable.

In the third place, specific consideration should be given to international instruments relating to geographical indications (GIs). (Reference is made in paragraph 4.3.2 to the protection of geographical indications (GIs); this topic will be dealt with in more detail further below.) However, in the context of multilateral treaties, WIPO has negotiated an international instrument specifically dealing with GIs, ie the Lisbon Agreement for the Protection and International Registration of Appellations of Origin. SA has not acceded to this treaty; in fact, to date only 28 countries are members of the Lisbon Agreement.

Although the TRIPS Agreement does not expressly refer to the Lisbon Agreement, TRIPS requires (in Art 22 - 24) that member countries shall provide the legal means to prevent the use of false or misleading GIs, and to enter into negotiations to increase the protection of GIs. In this context the Lisbon Agreement may be of relevance to South Africa.

Recommendation 4.3(2): (i) It is recommended that accession to the Rome convention on performers and producers of phonograms should be considered.

(ii) It is recommended that accession to the Locarno, Nice and Strasbourg classification agreements should be considered.

(iii) It is recommended that consideration be given to the potential benefits of accession to the Lisbon Agreement on the protection of GIs.

3. Other instruments relevant to public health and IP

In paragraphs 4.3 vi-vii the IP Framework deals with IP-related international instruments that emanated from the WHO. Specific reference is made to the Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPA-PHI) (2011); this was based on the report by the Commission on IP Rights, Innovation and Public Health (CIPIH) (2006). These instruments were followed by a trilateral study conducted by WHO, WTO and WIPO and a joint instrument was issued on Promoting Access to Medical Technologies and Innovation: Intersections between Public health, IP and Trade (PM-MTI) (2012).

When considering the way forward with IP, particularly patents, in the context of public health issues and access to medicines, it would be important to refer to the information provided in all three of these international instruments although they do not constitute treaties. As a member of all three of these international bodies, South Africa should take cognisance of the principles identified and recommendations put forward in these instruments. Some of these will be referred to below.

(i) Patents have an incentive function: In the absence of patent protection inventors would be unable to gain appropriate returns from their intellectual creations, with negative consequences for society (CIPIH p 32). IP rights are an important incentive for the development of new health care products (GSPA-PHI par 23, 33). The role of patents in the context of the search for new medicines and the access to these medicines is critical (PM-MTI Chap II and III).

(ii) Patent laws, policies and practices are relevant: Patent laws (eg prescribing patentability criteria), patent practices (eg effective substantive examination), and patent policies (eg understanding of and approach to incremental innovation) have an influence on the stimulation of R&D, the disclosure of information, and the availability of and access to new products and technologies. TRIPS has built-in flexibilities of which optimal use can be made by individual countries. An appropriate balance of rights and obligations is important.

Certain IP-related principles are referred to in these instruments, which should be taken into account particularly by developing countries when structuring their IP legal frameworks. Included are the following: IP rights are an incentive for the development of health care products (GSPA-PHI Context – par 7); the so-called TRIPS flexibilities and the specific TRIPS provisions that affirm that member countries should implement TRIPS in a manner to protect public health and access to medicines (GSPA-PHI Context – par 8); the need to promote transfer of technology (GSPA-PHI Elements – element 4); the management of IP to contribute to innovation and promote public health (GSPA-PHI Elements – element 5).

The joint WHO/WTO/WIPO report (PM-MTI) also makes frequent reference to the role of patents in dealing with public health issues; it recognises that the IP system is at the centre of the debate on innovation and access to medicines (PM-MTI Executive Summary p 12-14); it analyses the medical R&D costs and the relevance of patents in stimulating innovation (PM-MTI Chap III sections A and D).

Recommendation 4.3(3): Since important information and guidelines regarding the structuring of national patent laws, the patentability criteria, and the prosecution procedures can be obtained from the instruments emanating from the WHO and from the joint study by WHO/WTO/WIPO, it is recommended that these instruments be taken into account in formulating an IP Policy for South Africa. It should be borne in mind, however, that these instruments are not treaties or agreements in terms of which SA has specific compliance obligations.

4. The role of bilateral and regional agreements

Reference is made in paragraphs 4.3 viii-ix to the role of multilateral IP forums and bilateral and regional agreements in shaping South Africa's IP position and obligations, and the point is made that standards of IP protection beyond the minimum requirements of TRIPS are extracted from countries entering into bilateral and regional agreements. It is stated as crucial that particularly developing countries should not erode the gains made in regard to the recognition of TRIPS flexibilities as a legitimate tool in structuring IP laws and policies. This position is supported.

Recommendation 4.3(4): It is recommended that, when South Africa is engaged in the negotiation of an IP-related bilateral or regional agreement, particular attention should be devoted to the importance of assessing and, if possible, avoiding agreeing to clauses that would extract IP-related obligations exceeding the obligations that the country is obliged to give effect to in terms of international conventions of which it is a party, such as TRIPS, the Paris Convention, the Berne Convention, etc.

5. Geographical indications (GIs)

[IP Framework paragraph 4.3.1]

In paragraph 4.3.1 extensive reference is made to the issue of the protection of geographical indications (GIs). The point is made in paragraph 4.3.1 i that SA does not have dedicated statutory provisions or a specific registration system dealing with GIs; reference is made to a number of statutes with provisions relevant to GIs; and to certain legislative initiatives that would affect GIs which are under way.

It is correct that South Africa has a number of statutes with provisions relevant to GIs, such as the Trade Marks Act, 1993 with provisions allowing GIs to be registered as certification marks (s 42) or collective marks (s 43). However, registration as either of these types of marks does not reflect all of the criteria typical of a GI as set out in the TRIPS Agreement (Art 22) and/or in the Lisbon Agreement (Art 2). The Merchandise Marks Act, 1941 prohibits the use of false trade descriptions, and a false trade description is defined (s 1) as a trade description that is false in a material respect in indicating eg the country or place in which any goods were made or produced. However, this prohibition does not provide for a registration system for GIs. The Liquor Products Act, 1989 prohibits (s 11) the use of the name of any country or a word or expression in a manner to indicate that a liquor product is a product of a country other than the true country of origin thereof. However, again this does not provide for a registration system for GIs.

Reference is also made to draft regulations on GIs published by the Department of Agriculture Forestry and Fisheries; it would be important to ascertain what these draft regulations will entail, what the ambit of the provisions would be, and what progress has been made.

The main problem has indeed been identified: South Africa does not have a dedicated statutory registration system, aligned with applicable international instruments, for the registration and protection of GIs. It is submitted that such a dedicated registration and protection system is in fact essential in order to safeguard and protect this important national asset. This was illustrated when it came to the attention of **the dti** and the Rooibos Council in 2103 that a French company had filed applications in France for the registration as trade marks in its own name of terms and expressions containing the word ‘Rooibos’ in different combinations. When a SA law firm was instructed to oppose and cancel these applications and registrations, the argument was raised that the name ‘Rooibos’ was not legally protected in SA. Therefore there was no legal basis to prohibit the registration of this name in other countries. In order to deal with this problem, the Minister of **the dti** had to publish a prohibition in terms of the Merchandise Marks Act to prohibit the unauthorised use of the name ‘Rooibos’ and so to protect the name ’Rooibos’.

Therefore, it is submitted that the enactment of appropriate legislation to provide for a dedicated registration and protection system for GIs must be prioritised.

In setting up such a registration system it would be important to find agreement on the term to be used to designate such an indication, ie either 'appellation of origin' (AO) or 'geographical indication' (GI), as well as the definition of an AO/GI, since there are subtle differences in the definitions used in the TRIPS Agreement and in the Lisbon Agreement.

The Lisbon Agreement defines an appellation of origin as 'the geographical name of a country, region, or locality which serves to designate a product originating therein, the quality or characteristics of which are due exclusively or essentially to the geographical environment, including natural and human factors'. The negative feature of this definition is that it only covers geographical names (so that a name such as 'Rooibos' would not qualify); the positive feature is that it recognises not only the natural factors of the region but also human factors to be attributable for the characteristics of the product.

The TRIPS Agreement defines geographical indications as 'indications which identify a good [product] as originating in the territory of a Member [country], or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin'. The negative feature of this definition is that it only recognises the geographical factor (and not human factors) as attributable for the characteristics of the product; the positive feature is that it covers all indications of origin and not only geographical names.

Therefore, it is suggested that, in drafting dedicated South African legislation, a definition be formulated combining the positive features of both these definitions.

In paragraph 4.3.1 vi reference is made to the Lisbon Agreement for the protection of Appellations of Origin; it has already been recommended in **Recommendation 4.3(2)(iii)** above that South Africa should consider acceding to this Agreement.

Recommendation 4.3(5): (i) It is recommended that appropriate legislation be enacted to provide for a dedicated registration and protection system for GIs/AOs.

(ii) It is recommended that consideration be given to the formulation of an appropriate definition of the concept to be protected as a GI/AO, and to include the positive features of the definitions of both the TRIPS and the Lisbon Agreements.

Reference is also made in paragraph 4.3.1 v to a bilateral GI Protocol with the EU that South Africa has agreed to conclude. In an earlier trade agreement between SA and the EU certain GIs were identified and certain obligations and/or prohibitions in regard to the use thereof were stipulated. This created certain obligations for SA, eg to discontinue the use of terms such as 'champagne', 'sherry' and 'port' on products emanating from SA. In order to make a positive contribution to the formulation of a national IP Policy also addressing the issue of GIs in the context of bilateral trade agreements and/or protocols, further information will have to be obtained in regard to the negotiations regarding a bilateral GI Protocol, and also any negotiations regarding other bilateral agreements, and that careful consideration should be given to the terms and conditions to be stipulated in such agreements and protocols.

5. IN-BUILT AGENDA

5.1 Medium term

[IP Framework paragraph 5.1 i-x]

Extensive reference is made in this paragraph to the WIPO Development Agenda which inter alia recommends that WIPO should provide assistance to countries to develop and improve their IP systems and policies. Reference is specifically made to the assistance given by WIPO to a number of developing countries. The intention is also that WIPO should give assistance with the development and improvement of the institutional IP capacity, infrastructure and other facilities.

The proposal is made that the IMC should work together with the WIPO Secretariat in order to benefit from WIPO assistance. This proposal is supported.

An initial list of substantive issues has been set out as proposed topics to be addressed, and it is stated that this will happen also in cooperation with other expert institutions. It is submitted that the list may have to be amplified, and that it would be essential to involve also South African stakeholders and interest groups in the work to be done.

5.2 Monitoring and evaluation

[IP Framework paragraph 5.2.1 i-ii]

Reference is made to certain legislative projects that have already been commenced or concluded, such as certain amendments to the Copyright Act, and legislation to protect Indigenous Knowledge (IK) and Traditional Knowledge (TK). It is proposed that it would be important to continue to monitor and evaluate any further developments in regard to these projects. This proposal is supported.

Adams & Adams
October 2016