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the dti

Department:
Trade and Industry
REPUBLIC OF SOUTH AFRICA

EXPLANATORY MEMORANDUM

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Trade and Industry
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EXPLANATORY MEMORANDUM TO THE RATIFICATION OF THE WORLD TRADE ORGANISATION'S DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT AND PUBLIC HEALTH

1. BACKGROUND

The TRIPS Agreement lays down only minimum standards of protection of intellectual property rights (IPR), which domestic IPR protection legislation exceeded even before South Africa signed the TRIPS Agreement in 1995. The South African IPR legislation is based on European legislation. Under the apartheid regime, South Africa undertook trade commitments during the Uruguay Round as a developed country. Although other WTO members were willing to grant it 'transition' status in 1995, the European Union insisted that South Africa take on the obligations of developed countries. However, this did not present the South African government with immediate implementation problems in the case of the TRIPS Agreement, as it already had minimum standards of protection.

In November 2001 at the Doha meeting of WTO members, South Africa together with other developing countries such as Brazil and India demanded the reassessment of the TRIPS Agreement. This was to ensure that they could either produce affordable generic drugs (compulsory licensing) or buy them from elsewhere (parallel imports) at reasonable prices, especially in a national health emergency situation. It was argued during the meeting that developing countries cannot afford to pay the exorbitant prices demanded by the developed countries' pharmaceutical companies for the drugs which these companies have developed and produced, which often include the only effective treatment for national health emergencies such as the HIV/Aids pandemic.

A separate Declaration on the TRIPS Agreement and Public Health (Declaration) was thereafter adopted in 2001 and a subsequent Decision on the Interpretation of Paragraph 6 reached in 2003. The Declaration recognised the gravity of the public health problems afflicting many developing and least developed countries. It was accepted that the TRIPS

Agreement should be interpreted and implemented in a manner supportive of members' right to protect public health and to gain access to essential medicines. Members were given more flexibility in utilising parallel import mechanism and in the granting of compulsory licences. Members were further permitted to determine through their own national legislations the grounds upon which such licences are to be granted, and to decide what constitutes a national public health emergency. On 6 December 2005, WTO members approved the Protocol Amending the TRIPS Agreement making permanent a decision on patents and public health originally adopted in 2003.

South Africa, despite having played a leading role in this process, has to date not yet submit its Instrument of Acceptance of the Protocol to the WTO. Other developing countries such as China, India and Brazil have accepted the Protocol of Amendment and have incorporated the amendment into their domestic laws. The flexibilities embedded in the Protocol of Amendment have also not been fully implemented in the Medicines Act as well as the Patents Act with the result that the benefits that flow from the Declaration are not being utilised.

By accepting the Protocol, a country expresses its consent to be bound by the Protocol on the international plane. Effectively, this means expressing its consent that all WTO Members are entitled, but not required, to use the flexibilities on public health if they so wish. It does not bind countries to take any positive action. Many countries have already accepted the Protocol without taking any domestic legislative action.

South Africa is at liberty not to incorporate the Declaration into domestic law. The importance of ratifying the Declaration is that South Africa adds to the number of countries that are required in order for the amendment to enter into force. Once the TRIPS amendment has been accepted by two thirds of WTO members, it becomes WTO law.

Given that South Africa is a party to a number of human rights treaties including the International Covenant on Economic, Cultural and Social Rights, which recognises the right to the "highest attainable standard of physical and mental health" as well as being bound by Section 27 of the Constitution which recognises the right of access to health care, the utilisation of such flexibilities to improve access to medicines must be viewed as an affirmative obligation on Government. Proper implementation of the TRIPS flexibilities would not only increase access to medicines for the poor but would also provide growth opportunities to the domestic pharmaceutical industry in that South African generic

companies will be able to produce medicines at more affordable prices for domestic consumption as well as for export to third countries.

2. LEGAL IMPLICATIONS

The Protocol Amending the TRIPS Agreement was submitted to the State Law Advisors at Departments of Justice and Constitutional Development, and of International Relations and Cooperation. The Office of Chief State Law Adviser at the Department of Justice and Constitutional Development and the Department of International Relations and Cooperation advised that the Protocol be taken through the ratification process in line with Section 231 (2) of the Constitution before the Instrument of Acceptance of the Protocol Amending the TRIPS Agreement is submitted to the WTO.

It should be noted that acceptance does not create any obligation on the part of countries that accepted the Protocol to use the flexibilities, nor to implement it in its domestic law. South Africa is therefore at liberty not to incorporate the flexibilities set out in the Protocol Amending the TRIPS Agreement into domestic law.

Cabinet approved that the Protocol Amending the TRIPS Agreement be submitted for ratification.

3. IMPLEMENTATION AND MONITORING

the dti will act as the Competent Authority responsible for overseeing the implementation of the Protocol on behalf of the South African Government. There is no financial implication for South Africa in accepting the Protocol Amending the TRIPS Agreement.

The dti is currently in the process of finalising the IP Policy and the implementation of the flexibilities on public health as contained in the TRIPS Agreement Amendment is being dealt with in this process. Consultations will be undertaken with all interested parties to consider the amendment of the Patents Act and Medicines Act to incorporate the flexibilities on public health.

4. OBJECTIVE

The objective of the TRIPS Amendment is to clearly set out the flexibilities available under the TRIPS Agreement to member states seeking to protect public health by gaining access to essential medicines.

Annex 1

Declaration on the TRIPS Agreement and Public Health

Adopted on 14 November 2001

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Annex 2

Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

Decision of 30 August 2003

WORLD TRADE ORGANIZATION

WT/L/540
2 September 2003

(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

   (a) "pharmaceutical" product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[1];

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* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

[1] This subparagraph is without prejudice to subparagraph 1(b)

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[4] has made a notification[5] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[1];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[6];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

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[2] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[3] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

[4] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[5] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

[6] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[7] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving

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[7] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

[8] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[9] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be

part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

ANNEX 3

PROTOCOL AMENDING THE TRIPS AGREEMENT

6 DECEMBER 2005

GENERAL COUNCIL

WT/L/641
8 December 2005

Amendment of the TRIPS Agreement

Decision of 6 December 2005

See also:
» Press release: Members OK agreement to make health flexibility permanent

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

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PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization:

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

Notes:

1. This subparagraph is without prejudice to subparagraph 1(b). back to text

2. It is understood that this notification does not need to be approved by a WTO body in order to use the system. back to text

3. Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States. back to text

4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties. back to text

5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system. back to text

6. This subparagraph is without prejudice to Article 66.1 of the Agreement. back to text

7. The Importer may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system. back to text

8. It is understood that this notification does not need to be approved by a WTO body in order to use the system. back to text

9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system. back to text

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT back to top

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT back to top

1. For the purposes of Article 31bis and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included [1];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of

public non-commercial use. It is noted that some Members will not use the system as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s)[4] has made a notification[5] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[6];

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex[6];

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[7] the following information:

– the quantities being supplied to each destination as referred to in indent (i) above; and

– the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT back to top

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

ANNEX 4

DIRCO LEGAL OPNION

international relations
& cooperation

Department
International Relations and Cooperation
REPUBLIC OF SOUTH AFRICA

OFFICE OF THE CHIEF STATE LAW ADVISER (INTERNATIONAL LAW)
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15steenkampt141001
File: 10/16/3/3
RO428/2015

Ms N Mtshali
Email: mtshalin@dirco.gov.za

RATIFICATION OF THE PROTOCOL TO AMEND THE TRADE RELATED ASPECTS ON INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT

1. Your request for legal advice dated 8 October 2015, under reference 18/1/7/WTO/TRIPS, refers.

2. Please be advised that we have reviewed the Protocol from an international law perspective. We have specifically been asked to advise on whether this Protocol falls within the scope of section 231(2) or 231(3) of the Constitution of the Republic of South Africa, 1996, which would determine whether the Protocol would have to be submitted to Parliament for approval before it can be ratified, or whether the Protocol only needs to be tabled in Parliament for information purposes within a reasonable time after it has been signed.

3. It appears from the DTI's letter dated 21 August 2015 that it is of the opinion that the Protocol should be classified as an agreement falling within the scope of section 231(3) as an agreement of a technical, administrative or executive nature, due to the following reasons:

   3.1. The Protocol will not have an effect on South Africa's domestic legislation and there is no obligation on South Africa to incorporate the Protocol into its domestic legislation; and
   3.2. Since the TRIPS Agreement forms part of Annex 1A of the Marakesh Agreement, its ratification would not fall within the purview of section 231(2) of the Constitution.

4. We note that the State Law Advisers at the Department of Justice and Constitutional Development ("DOJ&CD") are of the opinion that this Protocol falls within the scope of section 231(2) of the Constitution, being an agreement that requires Parliamentary approval before it can be can be ratified, for the following reasons:

   4.1. The TRIPS Agreement forms part of Annex 1 to the WTO Agreement, which was ratified by South Africa after Parliamentary approval was obtained, which means that the Protocol would amend the agreement as approved by Parliament; and

4.2. The content of the Protocol, as read with the TRIPS agreement cannot be considered to be technical, administrative or executive in nature, as required by section 231(3) of the Constitution.

DISCUSSION

5. South Africa ratified the Agreement Establishing the World Trade Organisation ("WTO Agreement") on 2 December 1994 and it entered into force for South Africa on 1 January 1995. Ratification of the WTO Agreement also meant the acceptance by South Africa of a number of other legal instruments which are attached as Annexures to the WTO Agreement. The WTO Agreement distinguishes between two groups of Agreements in this regard. In terms of Article II(2) and (3) of the WTO Agreement, all the agreements listed in Annexures 1, 2 and 3 of the are integral parts of the WTO Agreement and shall be binding on Member States (i.e. automatic acceptance by States upon ratification of the WTO Agreement), while Annexure 4 agreements are only binding upon those Member States who have accepted them (i.e. acceptance independent from the ratification of the WTO Agreement).

6. The TRIPS Agreement is listed in Annexure 1C of the WTO Agreement, making it an integral part of the WTO Agreement and meaning that it became binding on South Africa on the date of entry into force of the WTO Agreement for South Africa (1 January 1995). The TRIPS agreement was therefore, together with the WTO Agreement, accepted as a section 231(2) Agreement (subject to Parliamentary approval) by South Africa.

7. The Protocol we were asked to consider amends the TRIPS Agreement by inserting Article 31bis after the current Article 31 in the TIPS Agreement and by inserting the Annex to the TRIPS Agreement after the current Article 73 of that Agreement. These amendments are substantive amendments to the obligations of Member States under the TRIPS Agreement.

8. The Protocol is open for acceptance by Members (in terms of Article 3 thereof) and the entry into force procedure is the same as that indicated in paragraph 3 of Article X of the WTO Agreement (in terms of Article 4 of the Protocol). Article X(3) of the WTO Agreement provides as follows:

   "Amendments to provisions of this Agreement, or of the Multilateral Trade Agreements in Annexes 1A and 1C, other than those listed in paragraphs 2 and 6, of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it. The Ministerial Conference may decide by a three-fourths majority of the Members that any amendment made effective under this paragraph is of such a nature that any Member which has not accepted it within a period specified by the Ministerial Conference in each case shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference."

9. The fact that the Protocol itself makes provision for its entry into force in terms of Article X(3) of the WTO Agreement, suggests the General Council's concurrence that the Protocol alters the rights and obligations of Member States and therefore makes provision for Member States to expressly accept the amendments made by the Protocol.

10. Consequently, since the Protocol will alter South Africa's obligations under the TRIPS Agreement (regardless of whether such alterations would have to be incorporated into South Africa's domestic legislation or not), and since the TRIPS Agreement is a section 231(2) agreement in terms of the Constitution that had to be approved by Parliament before it could have been ratified, we are of the view that South Africa's obligations under the TRIPS Agreement cannot be amended without first obtaining Parliament's approval.

CONCLUSION

11. We therefore agree with the DOJ&CD and conclude that the Protocol falls within the ambit of section 231(2) of the Constitution, requiring Parliamentary approval for acceptance. Parliament's approval needs to be obtained before the Protocol can be accepted.

12. In order to obtain Parliamentary approval the Protocol needs to be certified by this Office. The documentation required for certification consists of:
    - two copies of the President's Minute;
    - two copies of the Explanatory Memorandum setting out the purpose of the Agreement and proposed date of signature;
    - two copies of the finally agreed text of the Agreement;
    - two copies of the legal opinions from the State Law Advisers at the Department of Justice and Constitutional Development and this Office;
    - Completed certification form (attached herewith)
    - all documentation in folder Z137.

13. A Presidential Minute must then be obtained by the line function Department. Once the President has signed the Minute, the Protocol cannot be amended in any way.

14. Following the process to obtain the Presidential Minute, the Protocol must be submitted to Parliament in the following manner :

    14.1. Approach the relevant cabinet portfolio committee :

    The line function department must prepare a Cabinet Memorandum. The various Cabinet Committees may have their own requirements for the format of Cabinet Memoranda. The usual headings required are: Subject; Purpose; Summary; Discussion; Organisational and Personnel Implications; Financial Implications; Communication Implications; Constitutional Implications; Other Departments/Bodies consulted; Recommendations.

    14.2. The Protocol must be considered by Parliament (National Assembly and National Council of Provinces) :

    14.2.1.1. The line function Department must prepare an Explanatory Memorandum setting out the history, objectives and implications of the agreement;
    14.2.1.2. The legal opinions from the State Law Advisors of both Departments (DOJ&CD and DIRCO) must be included;
    14.2.1.3. It must be stated whether the agreement contains any self-executing provisions in terms of section 231(4) of the Constitution;
    14.2.1.4. The projected financial and other costs of the agreement must be set out;
    14.2.1.5. The Explanatory Memorandum must contain all other information needed to take an informed decision.

    14.3. Since the Protocol requires an Instrument of Acceptance, such Instrument of Ratification must be deposited with the Depository:
    14.3.1.1. The Line Function Department must prepare the Instrument of Acceptance (the South African Treaty Section can assist with the finalisation of the Instrument);
    14.3.1.2. The Minister of International Relations and Cooperation or the President must sign the Instrument of Ratification (the South African Treaty Section will assist in this regard); and
    14.3.1.3. DIRCO will send the Instrument of Ratification to the relevant depository through the diplomatic channels.

    14.4. The Agreement must be deposited with the Treaty Section at DIRCO :
    The documents required are :

    - A certified copy of the agreement;
    - The President's Minute or Parliamentary authorisation; and
    - Copy of the signed Instrument of Acceptance.

15. It is trusted that our comments would be of assistance to you.

TANIA STEENKAMP HEFER
STATE LAW ADVISER (IL)

PRETORIA
14 October 2015

ANNEX 5

DOJ LEGAL OPNION

the doj & cd

Department:
Justice and Constitutional Development
REPUBLIC OF SOUTH AFRICA

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Date: 19 August 2015

Mr L October
Director-General
Department of Trade and Industry
Private Bag X84
Pretoria
0001

Dear Mr October

Attention: Ms Verushka Gilbert

LEGAL OPINION ON TAGGING OF PROTOCOL AMENDING THE AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: YOUR UNNUMBERED MINUTE DATED 14 JULY 2015

BACKGROUND

1. According to the submission received from the Department of Trade and Industry (the "Department") South Africa ratified the World Trade Organisation Agreement (the "WTO Agreement") on 1 January 1995. By ratifying the WTO Agreement, South Africa also became a party to the Agreement on Trade Related Aspects of Intellectual Property Rights (the "TRIPS Agreement"), since the TRIPS Agreement is an annexure to the WTO Agreement.

2. We are further informed that through a decision of the General Council of the World Trade Organisation (the "WTO") of 30 August 2003, a separate declaration on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration") was adopted. A subsequent decision was reached by the General Council on 6 December 2005 on the amendment of the TRIPS Agreement and paragraph 6 of the Doha Declaration. A Protocol on the adoption of paragraph 6 of the Doha Declaration (the "Protocol"), which was adopted by consensus as the Protocol amending the TRIPS Agreement, is now open for ratification. The Declaration essentially amends the TRIPS Agreement to address the challenge of access to medicines by granting special pharmaceutical manufacturing capabilities, referred to as the "Paragraph 6 System". The 2005 Protocol thus makes permanent the decision originally adopted in 2003. In order for South Africa to fully implement the flexibilities contained in the Protocol, it has to be ratified. It appears that the changes to the TRIPS Agreement will be effected when two thirds of WTO members have accepted the Protocol. The original date for acceptance of the Protocol was until 1 December 2007. However, the deadline has since been extended to 31 December 2015 through a General Council decision of 26 November 2013. To date, 55 WTO Members have already accepted the Protocol.

3. A Member State is required to deposit an "instrument of acceptance" which indicates that it accepts the Protocol. As indicated above, the Protocol shall only take effect upon acceptance by two thirds of the Members. Thereafter the Protocol shall take effect for each other Member upon acceptance by it. We are informed that it is permissible for Members to accept the Protocol but not to take any positive domestic legislative action. Thus accepting the Protocol does not create any obligation for a Member to use the System, nor to implement it in its domestic law.

4. The Department is of the view that since the TRIPS Agreement forms part of Annex 1 A of the Marrakesh Agreement its ratification would not fall within the purview of section 231(2) of the Constitution of the Republic of South Africa, 1996 (the "Constitution") in respect of requiring approval by both Houses of Parliament. The Department accordingly holds the view that it therefore constitutes an agreement falling within the purview of section 231(3) of the Constitution. The

Department further opines that in light of the above-mentioned, it would be sufficient for Cabinet to merely consider the ratification of the Protocol amongst other actions for the "instrument of acceptance". The Department, however, envisages that once the flexibilities inherent to the amendment are formally incorporated into specific legislation (e.g. such as the South African Patents Act), that this process should involve Parliamentary oversight.

LEGAL QUESTION

5. In view of the above, the Department requests our opinion on the question whether the Protocol falls within the ambit of section 231(2) or section 231(3) of the Constitution.

DELIBERATION

Provisions of the WTO Agreement

6. Since the TRIPS Agreement is contained in Annex 1 C to the WTO Agreement, and since certain Articles of the WTO Agreement, like that providing for amendments, are also applicable to, *inter alia*, the TRIPS Agreement we regard it expedient, as a point of departure, to consider the relevant provisions of the WTO Agreement.

7. The relevant paragraphs of Article X of the WTO Agreement, which provides for amendments, read as follows:

"1. Any Member of the WTO may initiate a proposal to amend the provisions of this Agreement or the Multilateral Trade Agreements in Annex 1 by submitting such proposal to the Ministerial Conference. The Councils listed in paragraph 5 of Article IV may also submit to the Ministerial Conference proposals to amend the provisions of the corresponding Multilateral Trade Agreements in Annex 1 the functioning of which they oversee. Unless the Ministerial Conference decides on a longer period, for a period of 90 days after the proposal has been tabled formally at the Ministerial Conference any decision by the Ministerial Conference to submit the proposed amendment to the Members for acceptance shall be taken by consensus. Unless the provisions of paragraphs 2, 5 or 6 apply, that decision shall specify

whether the provisions of paragraphs 3 or 4 shall apply. If consensus is reached, the Ministerial Conference shall forthwith submit the proposed amendment to the Members for acceptance. If consensus is not reached at a meeting of the Ministerial Conference within the established period, the Ministerial Conference shall decide by a two-thirds majority of the Members whether to submit the proposed amendment to the Members for acceptance. Except as provided in paragraphs 2, 5 and 6, the provisions of paragraph 3 shall apply to the proposed amendment, unless the Ministerial Conference decides by a three-fourths majority of the Members that the provisions of paragraph 4 shall apply.

2. ...

3. Amendments to provisions of this Agreement, or of the Multilateral Trade Agreements in Annexes 1A and 1C, other than those listed in paragraphs 2 and 6, of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance by it. The Ministerial Conference may decide by a three-fourths majority of the Members that any amendment made effective under this paragraph is of such a nature that any Member which has not accepted it within a period specified by the Ministerial Conference in each case shall be free to withdraw from the WTO or to remain a Member with the consent of the Ministerial Conference.

4. Amendments to provisions of this Agreement or of the Multilateral Trade Agreements in Annexes 1A and 1C, other than those listed in paragraphs 2 and 6, of a nature that would not alter the rights and obligations of the Members, shall take effect for all Members upon acceptance by two thirds of the Members.".

8. It is clear from the above quoted provisions that, any Member of the WTO may initiate a proposal to amend the provisions of the WTO Agreement or the Multilateral Trade Agreements in Annex 1 by submitting such proposal to the Ministerial Conference. For a period of 90 days after the proposal has been tabled formally at the Ministerial Conference (unless the Ministerial Conference decides on a longer period), any decision by the Ministerial Conference to submit the proposed amendment to the Members for acceptance shall be taken by consensus. It is further clear that amendments to provisions of the WTO Agreement, or any of the

Multilateral Trade Agreements in Annexes 1A and 1C, which includes the TRIPS Agreement, of a nature that would alter the rights and obligations of the Members, shall take effect for the Members that have so accepted them upon acceptance by two thirds of the Members and thereafter for each other Member upon acceptance thereof by it. Furthermore, amendments to provisions of the WTO Agreement or of the Multilateral Trade Agreements in Annexes 1A and 1C, of a nature that would not alter the rights and obligations of the Members, shall take effect for all Members upon acceptance by two thirds of the Members. The decision of the General Council of 6 December 2005 also specifically provides that the Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

9. Article XII of the WTO Agreement provides for accession and reads as follows:

"1. Any State or separate customs territory possessing full autonomy in the conduct of its external commercial relations and of the other matters provided for in this Agreement and the Multilateral Trade Agreements may accede to this Agreement, on terms to be agreed between it and the WTO. Such accession shall apply to this Agreement and the Multilateral Trade Agreements annexed thereto.

2. Decisions on accession shall be taken by the Ministerial Conference. The Ministerial Conference shall approve the agreement on the terms of accession by a two-thirds majority of the Members of the WTO.

3. Accession to a Plurilateral Trade Agreement shall be governed by the provisions of that Agreement."

10. Upon scrutiny of the provisions of Article XII, it is clear that any state or separate customs territory possessing full autonomy in the conduct of its external commercial relations and of the other matters provided for in the WTO Agreement and the Multilateral Trade Agreements may accede to the WTO Agreement, on terms to be agreed upon between such state or territory and the WTO. Such accession shall apply to the WTO Agreement, as well as the Multilateral Trade Agreements annexed thereto.

11. Furthermore, the relevant paragraphs of Article XVI of the WTO Agreement provides as follows:

"1. This Agreement shall be open for acceptance, by signature or otherwise, by contracting parties to GATT 1947, and the European Communities, which are eligible to become original Members of the WTO in accordance with Article XI of this Agreement. Such acceptance shall apply to this Agreement and the Multilateral Trade Agreements annexed hereto. This Agreement and the Multilateral Trade Agreements annexed hereto shall enter into force on the date determined by Ministers in accordance with paragraph 3 of the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations and shall remain open for acceptance for a period of two years following that date unless the Ministers decide otherwise. An acceptance following the entry into force of this Agreement shall enter into force on the 30th day following the date of such acceptance.

2. A Member which accepts this Agreement after its entry into force shall implement those concessions and obligations in the Multilateral Trade Agreements that are to be implemented over a period of time starting with the entry into force of this Agreement as if it had accepted this Agreement on the date of its entry into force.

3. Until the entry into force of this Agreement, the text of this Agreement and the Multilateral Trade Agreements shall be deposited with the Director-General to the CONTRACTING PARTIES to GATT 1947. The Director-General shall promptly furnish a certified true copy of this Agreement and the Multilateral Trade Agreements, and a notification of each acceptance thereof, to each government and the European Communities having accepted this Agreement. This Agreement and the Multilateral Trade Agreements, and any amendments thereto, shall, upon the entry into force of this Agreement, be deposited with the Director-General of the WTO.

4. Each Member shall ensure the conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements."

12. Scrutiny of the above quoted provisions reveals firstly that the acceptance shall apply to the WTO Agreement, as well as the Multilateral Trade Agreements annexed thereto. It further reveals that each Member of the WTO shall ensure the

conformity of its laws, regulations and administrative procedures with its obligations as provided in the annexed Agreements.

Provisions of the Protocol

13. The relevant provisions of the Protocol read as follows:

"1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.
2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.
3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.
5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.
6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.".

14. The Annex to the Protocol contains Article 31 *bis*. which is to be inserted after Article 31 of the TRIPS Agreement and which provides as follows:

"Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall

not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.
3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).".

15. The Annex to the TRIPS Agreement to be inserted in that Agreement further provides as follows:

"1. For the purposes of Article 31bis and this Annex:
(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;
(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the

Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex;

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website the following information:

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of

technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.
7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.".

Discussion of procedure to be followed with regard to the Protocol

16. Section 231 of the Constitution provides for international agreements and reads as follows:

> "231.(1) The negotiating and signing of all international agreements is the responsibility of the national executive.
>
> (2) An international agreement binds the Republic only after it has been approved by resolution in both the National Assembly and the National Council of Provinces, unless it is an agreement referred to in subsection (3).
>
> (3) An international agreement of a technical, administrative or executive nature, or an agreement which does not require either ratification or accession, entered into by the national executive, binds the Republic without approval by the National Assembly and the National Council of Provinces, but must be tabled in the Assembly and the Council within a reasonable time.
>
> (4) Any international agreement becomes law in the Republic when it is enacted into law by national legislation; but a self-executing provision of an agreement that has been approved by Parliament is law in the Republic unless it is inconsistent with the Constitution or an Act of Parliament.
>
> (5) The Republic is bound by international agreements which were binding on the Republic when this Constitution took effect.".

17. The provisions of section 231 of the Constitution were discussed comprehensively by the Constitutional Court in the case of *Glenister v President of*

the Republic of South Africa and Others *2011 (3) SA 347 (CC)*. The court remarked as follows at p375 with regard to the approval of international agreements:

"[89] The constitutional scheme of s 231 is deeply rooted in the separation of powers, in particular the checks and balances between the executive and the legislature. It contemplates three legal steps that may be taken in relation to an international agreement, with each step producing different legal consequences. First, it assigns to the national executive the authority to negotiate and sign international agreements. But an international agreement signed by the executive does not automatically bind the Republic, unless it is an agreement of a technical, administrative or executive nature. To produce that result, it requires, second, the approval by resolution of Parliament.

[90] The approval of an agreement by Parliament does not, however, make it law in the Republic, unless it is a self-executing agreement that has been approved by Parliament, which becomes law in the Republic upon such approval, unless it is inconsistent with the Constitution or an Act of Parliament. Otherwise, and third, an 'international agreement becomes law in the Republic when it is enacted into law by national legislation'.

[91] **The approval of an international agreement, under s 231(2) of the Constitution, conveys South Africa's intention, in its capacity as a sovereign State, to be bound at the international level by the provisions of the agreement. As the Vienna Convention on the Law of Treaties provides, the act of approving a convention is an 'international act . . . whereby a State establishes on the international plane its consent to be bound by a treaty'. The approval of an international agreement under s 231(2), therefore, constitutes an undertaking at the international level, as between South Africa and other States, to take steps to comply with the substance of the agreement. This undertaking will, generally speaking, be given effect by either incorporating the agreement into South African law, or taking other steps to bring our laws in line with the agreement, to the extent they do not already comply.**

[92] An international agreement that has been ratified by resolution of Parliament is binding on South Africa on the international plane. And failure to observe the provisions of this agreement may result in South Africa incurring responsibility towards other signatory States. An international agreement that has been ratified by Parliament under s 231(2), however, does not become part of our law, until and unless it is incorporated into our law by national legislation.". (Our emphasis.)

(See also *Azanian Peoples Organisation (Azapo) and Others v President of the Republic of South Africa and Others 1996 (4) SA 671 (CC)* at paragraph [26] on 688A/B-C/D.)

18. Paragraph 5.5 of the *Manual on Executive Acts of the President of the Republic of South Africa* (the "*Manual*"), stipulates that agreements of a technical, administrative or executive nature, refer to agreements which are departmentally specific and which are not of any major political or other significance. The agreements generally have no financial consequences and do not affect the domestic law of both parties. With regards to the determination of whether an agreement is of a technical, administrative or executive nature, **Erika de Wet** in **Shelton, International Law and Domestic Legal Systems: Incorporation, Transformation and Persuasion**, at pp. 567-593, states as follows:

"The Constitution does not give any indication of which agreements would qualify as a technical, administrative or executive. The internal practice which has developed within the Office of the Chief State Law Adviser is to consider as "technical" those agreements which do not have major political significance; do not require additional budgetary allocation from Parliament over and above the budget provided by particular government department; and agreements which do not impact domestic law. They are often of a bilateral nature and concern routine agreements for which a single government department is responsible for implementation. ..."

19. According to chapter 5 (paragraph 5 on p 44) of the *Constitutional Handbook for Members of the Executive* (the "*Constitutional Handbook*"), technical, administrative or executive agreements are agreements which-

(a) are departmental specific;

(b) are of no major political or other significance;

(c) have no financial consequences; and

(d) do not affect domestic laws.

20. As regards agreements requiring approval by Parliament, paragraphs 5.4, 5.6 and 5.7 of the *Manual* provides as follows:

"5.4 Section 231(2) of the Constitution provides that all international agreements shall bind the Republic only after they have been approved by resolution of both Houses of Parliament. The exceptions are: (1) agreements of a technical, administrative or executive nature, or (2) those which do not require accession or ratification. The result is that Parliament is required to approve only agreements which require "ratification or accession" and which are not of a technical, administrative or executive nature.

5.6 **Departments should not lightly determine that such agreements requiring ratification or accession are "technical, administrative or executive". Failure to allow Parliament to ratify an agreement might result in a defect in the conclusion of the agreement.**

5.7 Although there is no rule as to which types of agreement require ratification or accession, this requirement is generally stated in the text of the agreement. As a general guideline this applies normally to multilateral agreements, although in some cases such a procedure could also be required for bilateral agreements."
(Our emphasis.)

21. J Dugard, **International Law. A South African Perspective**, (3rd Ed), at pp. 408 -409 remarks as follows with regard to formal and multilateral agreements such as the TRIPS Agreement:

"**Formal agreements, particularly multilateral agreements, normally require ratification in addition to signature.** This requires the representative of the state subsequently to endorse the earlier signature. This provides the state with an opportunity to reconsider its decision to be bound by the treaty and, if necessary, to effect changes to its own law to enable it to fulfil its obligations under the treaty. In practice treaties generally indicate whether ratification is required, but where this is not done the intention of the parties will have to be ascertained from the surrounding circumstances. Although a state is not bound by a treaty that it has signed but not ratified, it is obliged to refrain from acts which would defeat the object and purpose of such a treaty until it has made clear its intention not to be bound by the treaty.

A state may later become a party to a treaty in whose negotiation it did not participate, and which it did not sign, by means of accession, provided that the original parties accept that such states may accede to the treaty. Multilateral law-making treaties that seek to achieve a large measure of universality generally include an accession clause. For instance, the International Covenant on Civil and Political Rights provides that it shall be open to accession, *inter alia*, by any member state of the United Nations.

While it is not difficult to identify an international agreement subject to ratification or accession, in practice, it may prove difficult to identify an agreement of a technical, administrative or executive nature which comes into force on signature alone. All will depend upon the intention of the parties which must be ascertained from the circumstances surrounding the conclusion of the treaty. The practice of the government law advisors is to treat agreements of a routine nature, flowing from the daily activities of government departments' as not requiring parliamentary approval. **Where, however, there is any doubt, the agreement is referred to Parliament.**". (Our emphasis.)

(With regard to the highlighted parts see also **M Olivier**, Informal international agreements under the1996 constitution, SAYIL Vol. 22, 1997, p63 at p 64.)

22. When considering the TRIPS Agreement and the Protocol against the background of the above, it must first be borne in mind that both the TRIPS Agreement and the Protocol amending it are international agreements in their own right with regard to which the same procedure as that followed with regard to all other international agreements must be followed. South Africa ratified the WTO Agreement, which ratification according to the WTO Agreement also applied to the Multilateral Trade Agreements in Annex 1, including the TRIPS Agreement. The ratification in essence entailed an approval by resolution in both the National Assembly and the National Council of Provinces of, *inter alia*, the TRIPS Agreement. Amendments to the TRIPS Agreement, such as that contained in the Protocol, will upon acceptance become part of the TRIPS Agreement as approved by resolution in both the National Assembly and the National Council of Provinces. The amended document will then be different from the document approved by Parliament without Parliament having approved it. For this reason, we are of the view that it would not suffice for protocols amending the TRIPS Agreement to bind the Republic without approval by the National Assembly and the National Council of Provinces, by merely tabling it in the Assembly and the Council within a reasonable time.

23. Further to the above, it must be borne in mind that section 231(2) of the Constitution provides that all international agreements shall bind the Republic only after they have been approved by resolution of both Houses of Parliament, the only exceptions being agreements of a technical, administrative or executive nature, or

agreements which do not require accession or ratification. When taking into account the content of the TRIPS Agreement and the Protocol, as well as the previous ratification, we are of the view that it could not be argued that the Protocol would fall within the ambit of agreements of a technical, administrative or executive nature. Furthermore, according to chapter 5 of the *Constitutional Handbook*, technical, administrative or executive agreements are agreements which are departmentally specific, of no major political or other significance, which have no financial consequences and do not affect domestic laws. From our analysis of the TRIPS Agreement and the Protocol, it is clear that the amendment in question falls within th epruview of section 231 (2) of the Constitution. Our view is informed by the fact that, the Department according to its submission envisages that the flexibilities inherent to the amendment of the TRIPS Agreement will in future have to be formally incorporated into specific legislation (e.g. such as the South African Patents Act), and that this process should involve Parliamentary oversight.

24. South Africa ratified the WTO Agreement, which ratification according to the WTO Agreement also applied to the Multilateral Trade Agreements in Annex 1, including the TRIPS Agreement. The TRIPS Agreement, as well as the Protocol are furthermore multilateral agreements. In view hereof, and taking cognisance of the warning in paragraph 5.6 of the Manual that departments should not lightly determine that such agreements requiring ratification or accession are "technical, administrative or executive" we are of the opinion that the Protocol should rather follow the route provided for by section 231(2) of the Constitution.

25. The Department's attention is, however, also drawn to *paragraph 5.21* of the *Manual* which obliges the Department of International Relations and Cooperation to confirm whether or not an international instrument is "technical, administrative or executive" in nature.

CONCLUSION

26. In view of our above discussion and taking into account that South Africa ratified the WTO Agreement, which ratification according to the WTO Agreement also applied to the Multilateral Trade Agreements in Annex 1, including the TRIPS Agreement, as well as the fact that both the TRIPS Agreement and the Protocol are multilateral agreements, we are of the opinion that the Protocol falls within the purview of section 231(2) of the Constitution.

Yours sincerely,

FOR THE CHIEF STATE LAW ADVISER

R MAKUYA// WJJ NEL// SM MASAPU// E DANIELS