MSF South Africa

3rd Floor, Orion Building
49 Jorissen Street
Braamfontein, Johannesburg
Tel: +27 (0) 11 403 4440/1/2
PO Box 32117
Braamfontein 2017
office-joburg@joburg.msf.org
www.msf.org.za

DOCTORS WITHOUT BORDERS (MSF) SUBMISSION ON THE DEPARTMENT OF TRADE AND INDUSTRY'S COPYRIGHT AMENDMENT BILL 2015

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Introduction

1. Doctors Without Borders (MSF) is an international medical humanitarian organisation with operations in South Africa and 62 other countries, which provides impartial medical assistance to those affected by armed conflict, epidemics, natural disasters or exclusion from healthcare. In order to perform our medical operations, MSF needs sustainable access to medicines, vaccines, diagnostics and other medical supplies that are affordable and suitable for resource-poor settings.

2. Recognising the negative impact that intellectual property protection often has on access to and affordability of medicines, MSF welcomes the opportunity to comment on the Copyright Amendment Bill, insofar as it relates to areas that will impact on access to medical technologies in South Africa. We further request the opportunity to make a presentation to the Portfolio Committee on Trade and Industry during public hearings on the Copyright Amendment Bill.

3. MSF jointly launched the Fix the Patent Laws campaign in South Africa with the Treatment Action Campaign (TAC) and SECTION27 in 2011, and the coalition has since expanded to include 15 patient groups in South Africa working across a variety of disease areas. The Fix the Patent Laws campaign advocates for reform of South Africa's Patents Act of 1978 and other relevant legislation to fully adopt legal flexibilities allowed under the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), in order to protect health. Legislative reform should ensure an appropriate balance is struck between meeting international obligations to provide intellectual property protection on medical technologies, and the constitutional right of people living in South Africa to have access to healthcare services.

4. During 2013, the Department of Trade and Industry (DTI) released for public comment a draft National Intellectual Property Policy (NIPP) that committed to full adoption of the TRIPS flexibilities to protect health and the public interest.[1] [2] MSF, together with TAC and SECTION27 provided a joint submission of recommendations on the draft NIPP.[3] Despite promises from the DTI that a final NIPP would be released by the end of 2014, no finalised policy has been forthcoming.

5. On 17 March 2014, the DTI informed the Parliamentary Portfolio Committee on Trade and Industry that bills have been drafted for approval by Minister of Trade and Industry Rob Davies to amend: the Patents Act, Copyright Act, Counterfeit Goods Act, Trade Marks Act, Designs Act, Merchandise Act, Unauthorized Use of Emblems Act, and Performers' Protection Act.[4] As stakeholders were informed by the DTI that the objective of the NIPP was "to develop a legal framework on IP"[5], the July 2015

[1] http://www.fixthepatentlaws.org/?p=657,
[2] http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf
[3] http://www.fixthepatentlaws.org/?p=764
[4] https://pmg.org.za/committee-meeting/20514/
[5] http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf

release of the Copyright Amendment Bill ("the bill") to reform the Copyright Act, prior to the release of the finalised NIPP was surprising.

6. As South Africa embarks on the process of reforming its laws which govern the protection of intellectual property, it is essential that the NIPP is urgently finalised to ensure coherence between the DTI's vision of reform—as initially laid out in the draft policy—and eventual promulgation of new laws, regulations and practice.

7. This submission focusses on the following areas:
    A. The aims of the bill
    B. The definition and practice of parallel importation
    C. The scope, intent and inclusiveness of the proposed IP Tribunal
    D. The proposal to place pharmaceutical product package inserts and database compilations outside the scope of copyright protection

The aims of the Copyright Amendment Bill

8. The Preamble of the bill sets forth a number of objectives, which primarily list the topics of the proposed amendments. It does not, however, expand significantly on the constitutional obligations or moral principles that should govern interpretation of the Act in the future. As such, we recommend including additional purposes that outline the intention of the bill to "promote the spirit, purport and objects of the Bill of Rights" in terms of section 39(2) of the Constitution.

The definition and practice of parallel importation

9. Parallel importation is recognised by Article 6 of the TRIPS Agreement. As it relates to medical technology, parallel importation allows the importation and resale in a country of a product that has been legitimately put on the market in the exporting country. Parallel importation does not require the consent of the intellectual property holder, and can allow for more affordable access to a product sold at a lower price—or available under a license—in a different market.

10. In the DTI Draft NIPP, recommendations note that:
    "South Africa should facilitate in its legislation the ability to import patented products if it can get them cheaper in other jurisdictions," and *"South Africa should amend its legislation to address issues of parallel importation and compulsory licensing in line with the Doha Decision of the WTO on IP and public health."*

11. While South Africa's current laws provide for parallel importation, this flexibility has not been used to support access to more affordable medicines. This is in part due to overly burdensome procedures outlined in regulations promulgated with respect to the Medicines Act 101 of 1965. More detailed recommendations on how to improve other legislative framework relevant for parallel importation of medical technologies

are outlined in the joint submission by MSF, TAC and SECTION27, to the DTI on the draft NIPP.[6]

12. In addition to recommendations on parallel importation made by MSF, TAC and SECTION27 with respect to the Patents Act of 1978, it is critical that the definition of parallel importation is consistent across all legislation relevant to intellectual property reform, and designed in a way to facilitate parallel importation when it is in the public interest to do so. Below, we define the shortcomings of the current definitions of parallel importation in the bill, as well as how to better safeguard the right to conduct parallel importation, through amendments to the bill and further proposed amendments to the original Copyright Act of 1978

Shortcomings of the current definition of parallel importation in the bill

13. Parallel importation is defined in Section 1 (g) of the Copyright Amendment Bill as follows:

> *"'parallel importation of goods', also known as "gray market goods" refers to genuine branded goods that are imported into a market and sold there without the consent of the owner of the trademark."*

14. The proposed definition is problematic for several reasons, and should be deleted. Firstly, it creates unnecessary confusion regarding the extent of products to which parallel importation applies. Secondly, it conflates copyright protection with trademark protection—a trend which continues later in the bill, when the specific right of parallel importation is defined.

15. Use of the term "genuine branded products" to identify eligibility for parallel importation may be interpreted, in the context of medicines, as limited to originator/biologic products. However, parallel importation is also permissible with generic/biosimilar medicines, or on medicines produced under compulsory or government use licenses.

16. Parallel importation is permissible across different forms of intellectual property, be it copyright, trademark, or patents. As mentioned above, parallel importation is conducted without the consent of the intellectual property rights holder, regardless of the form the IP takes. Conflation between copyright and trademarks (or any form of IP) in the bill's definition is problematic, as a poor and inaccurate definition could be abused by rights holders to block parallel importation of more affordable goods, even when making imported goods more affordable is in the public interest.

17. Confusion of copyright, trademark and patent rights in relation to parallel importation could have a detrimental effect on access to medicines, as it could create reluctance within the Department of Health to risk an action that could result in lengthy and expensive legal challenges.

[6] http://www.fixthepatentlaws.org/?p=764

18. We recommend deleting this definition, and instead defining the specific right to conduct parallel importation at a later point in the bill, by revising proposed Section 12A.

Defining the right to conduct parallel importation

19. Section 12A of the Copyright Amendment Bill states:

> *"(7) Notwithstanding any provision of this Act, parallel importation of trademarked goods is allowed in relation to-*
>
> *(a) goods that have been exhausted to be resold in the area from which the goods originate; and*
>
> *(b) the extent to which the owner of the trademarked goods can control the distribution of trademarked goods."*

20. The current language of Section 12A(b) proposes an unnecessary limitation upon parallel importation—in fact is in contradiction to the purpose of parallel importation—and again conflates copyright with trademark. This does not serve the purpose of facilitating parallel importation, especially when it is in the public interest to do so—such as when medicines must be accessed more affordably.

21. A recent amendment to Chile Law No. 17.336 on Intellectual Property, Article 18(e) provides model wording to meet the objective of defining the right to conduct parallel importation.[7] We recommend replacing the language of 12A(7) in the bill with a stand-alone section on Parallel Importation (e.g. 12C), along similar lines to the Chile Law, which should state:

> *"Notwithstanding any provisions of this Act, the Trademark Act 194 of 1993, the Counterfeit Goods Act 37 of 1997, the Medicines Act 101 of 1965, or the Patents Act 57 of 1978, the first sale or other transfer of ownership in South Africa or abroad shall exhaust the rights of distribution and importation nationally and internationally in respect of the transferred original or copy."*

22. Consistency should be sought in the definition of the right to parallel importation, across future amendments to the Copyright Act, the Trade Marks Act, the Counterfeit Goods Act, the Patents Act, and the Medicines and Related Substances Act, and other relevant legislation. Modification of the recommended language, modelled on the Chile Law would be suitable for all such legislation.

Further proposed amendments to the Copyrights Act of 1978

23. While not amended by the bill, sections of the original Copyright Act of 1978 are contradictory to the right of South Africa to conduct parallel importation, and must be amended if they are to be in line with the right of South Africa to conduct parallel importation.

[7] http://www.wipo.int/wipolex/en/text.jsp?file_id=270205

24. Section 23(2)(a) of the original Copyright Act of 1978 should be deleted, as it is contradictory to permitting parallel importation, including of more affordable medicines from abroad, by government or other actors. It currently states:

> *"(2) Without derogating from the generality of subsection (1), copyright shall be infringed by any person who, without the license of the owner of the copyright and at a time when copyright subsists in a work*
>
> *(a) imports an article into the Republic for a purpose other than for his private and domestic use."*

25. An amendment should be added to the bill that revises Section 23 (2)(b) and (c) of the Copyright Act of 1978, in order to exempt the situation of parallel importation from being considered as infringement under distribution. We suggest amendments to Section 23(2)(b) and (c) of the original act to read (with the assumption that our recommendation for a Section 12C on parallel importation be adopted):

> *"(b) except for those derived from parallel importation under Section 12C, sells, lets, or by way of trade offers or exposes for sale or hire in the Republic any article;*
>
> *(c) except for those derived from parallel importation under Section [12C], distributes in the Republic any article for the purpose of trade, or for any other purpose, to such an extent that owner of the copyright in question is prejudicially affected"*

26. Finally, Section 28(2) and (5) of the Copyright Act of 1978 must be amended, as the current wording could allow a South African rights holder to block lawful parallel importation of copyrighted goods. We suggest amendment to Section 28(2), and addition of Section 28(5) to read:

> *"(2) This section shall apply to any copy of the work in question made outside the Republic, the making of which constituted an infringement of copyright in the country in which the article was made.*
>
> *---*
>
> *(5) This section shall mutatis mutandis apply with reference to an exclusive licensee who has the right to import into the Republic any work published elsewhere which would be an infringing copy of the work in the country in which it was made."*

The scope, intent and inclusiveness of the proposed IP Tribunal

1. The Copyright Amendment Bill establishes an 'Intellectual Property Tribunal' ("IP Tribunal"). In its current form, the Bill establishes a wide breadth of jurisdiction under the IP Tribunal to rule on disputes related to intellectual property and other legislation. The bill outlines the following functions of the Tribunal:
    i. *"must carry out the functions and exercise the powers assigned to it by or in terms of the provisions of this Act or any legislation";*

ii. *"may adjudicate any application or referral made to it in terms of [the 1978] Act, Companies Act, 2008 or any legislation…"; and*
iii. *"may adjudicate any application or referral made to it by any person, institution or regulatory authority where the dispute which is the subject of the application or referral relates to intellectual property rights".*

27. The scope of jurisdiction of the IP Tribunal in the current bill is overly wide and will impact on types of intellectual property for which legislative reform is still underway. The overly wide scope of disputes to be dealt with by the Tribunal highlights the challenges inherent in embarking on legislative reform prior to the finalisation of the NIPP, and reiterates the need to establish a clear framework for reform, as well as the values, principles and objectives of reform.

28. The scope of the Tribunal established by this bill should be limited to dealing with disputes related to the protection of copyright. To avoid confusion regarding the functions of the Tribunal, all references to the IP Tribunal in this bill should be replaced with "Copyright Tribunal"

29. Finally while the scope of the Tribunal established by this bill should be limited to copyright, it is essential that the Tribunal is established to protect the rights of all people living in South Africa and not simply the commercial rights of companies holding copyright protections. To this effect, dispute proceedings must be transparent and allow participation of third parties providing evidence or arguments in favour of the public interest. It is extremely problematic that in Section 29(I)(1) of the bill, the right to participate in a hearing is limited to the Commission, Applicant, Respondent, and "*any other person who has a material interest in the hearing, unless, in the opinion of the presiding member of the Tribunal, such interest is adequately represented by persons participating at the hearing.*"

30. To ensure that the Tribunal protects public interest of people living in South Africa, and provides them the right to participate in hearings, section 29(I)(1) of the bill must be expanded to include other persons and organisations that are able to provide input on the impact of dispute rulings on public interest, including health matters.

The proposed placement of pharmaceutical package inserts and database compilations outside the scope of copyright protection

31. Currently there is no reference in the bill to excluding pharmaceutical package inserts from the scope of copyright protection. This is problematic as claims of copyright protection have previously been used as a tactic in South Africa to prevent a generic pharmaceutical company from utilising close copies of the package inserts

used by an originator company.[8] The need for exclusion of package inserts from copyright was addressed by stakeholders in comments on the NIPP.[9]

30. Section 15(1) the Medicines and Related Substances Act 1965 and the Regulation 9 of the General Regulations on the Act require that all medicines - including generic medicines – are "accompanied by a package insert".[10] Package inserts provide information on a medicine, including but not limited to the ingredients found in the medicine, how to administer the product, and any known side effects of the medicine. It is in the public interest that such information be provided on pharmaceutical products.

31. A generic medicine "is a pharmaceutical product … intended to be interchangeable with an innovator [or originator] product".[11] Generic manufacturers must prove their products are interchangeable or therapeutically equivalent to the innovator product. It is unreasonable to expect producers of identical or bio-equivalent medicines to avoid replicating portions of the originator product's package insert text and design, when the products themselves must be the same, or substantially the same.

32. To avoid copyright infringement, many generic manufactures in South Africa are currently forced to spend an inordinate amount of time and resources to develop unique package inserts.[12] This acts to delay companies' registration of more affordable generic medicine, and could mean that the additional costs involved in avoiding copyright infringement are passed on to consumers and the Department of Health.

33. In the United Kingdom, most Commonwealth countries and the United States, package inserts and the expressions and content within are placed outside the scope of copyright protection, as it is recognised that certain ideas or information can be expressed only in one or a limited number of ways.[13] In the U.S. this is known as the "merger doctrine", where the expression is considered inextricably merged with the idea.[14] We recommend South Africa adopt a similar legal standard, in particular through our recommendation for the addition to the bill of a section 2A(3) below.

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[8] https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch2b_trilat_web_13_e.htm
[9] http://napm.co.za/legislative-submissions/
[10] General Regulations made in terms of the Medicines and related Substances Control Act 101 of 1965.
[11] http://www.who.int/trade/glossary/story034/en/
[12] http://napm.co.za/legislative-submissions/
[13] *Compare* Beecham Group plc and SmithKline Beecham Pharmaceuticals (Pty) Ltd v Biotech Laboratories (Pty) Ltd 2002 (holding that a generic company may not copy the safety label of a brand name drug), *with* SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharmaceuticals, Inc., 211 F.3d 21 (2nd Cir. 2000), available at http://biotech.law.lsu.edu/cases/devices/smithkline_v_watson.htm (holding that label information required to meet regulatory requirements do not infringe copyright).
[14] T Endicott and M Spence, "Vagueness in the Scope of Copyright" (2005) 121 LQR 657.

34. Placing package inserts outside the scope of copyright protection is in line with Article 9.2 of the TRIPS Agreement, which states: *"Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such."*

35. Copyright protection of database compilations is also potentially problematic for promoting generic competition and more affordable access to medicines. The MCC may rely on test results of original manufacturers to determine the safety and efficacy of an identical generic medicine—if the database itself is protected under copyright, the MCC could be prevented from relying on the test data within to approve a more affordable generic medicine.

36. In 2010, the Gauteng High Court appeared to permit a non-original production as copyrightable, in *Board of Healthcare Funders v Discovery Health Medical Scheme.*[15] This goes against practice in other jurisdictions, such as the U.S., where non-original productions such as databases are denied copyright protection, and instead considered a compilation of information that does not reflect creative activity, but rather is the outcome of skill and effort.[16] We would recommend that the bill be amended as per below, to allow South African courts to reinterpret databases and other non-original productions as outside the scope of copyright protection.

37. We recommend the addition of a section 2A to the bill, which would place package inserts, and potentially database compilations, outside the scope of copyright protection. Note that subsection (4) is based on S. 12(8) of the present South Africa Copyright Act, and should be relocated to this section. Section 2A should read:

> *2A. Scope of copyright protection*
>
> *(1) Copyright protection extends to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.*
>
> *(2)(a) Tables and compilations which, by reason of the selection or arrangement of their contents, constitute the author's own intellectual creation shall be protected as such by copyright.*
>
> *(b)The copyright protection of tables and compilations shall not extend to their contents and shall be without prejudice to any rights subsisting in those contents themselves.*
>
> *(3) Notwithstanding the provisions of Section 2, no protection shall extend to expression inextricably merged with the idea such that the idea can be expressed intelligibly only in one or a limited number of ways, or when a particular expression is directed by law or regulation such that only one form of expression will meet regulatory requirements, such as on a safety label.*
>
> *(4) Notwithstanding the provisions of Section 2, no protection shall subsist in official texts of a legislative, administrative or legal nature, or in official*

[15] http://www.saflii.org/za/cases/ZAGPPHC/2012/65.pdf
[16] http://www.copyright.gov/title17/

translations of such texts, or in speeches of a political nature or in speeches delivered in the course of legal proceedings, or in news of the day that are mere items of press information, provided that the speeches referred to in this subsection shall have the exclusive right of making a collection thereof."

Conclusion

38. The release of the Copyright Amendment Bill prior to the finalisation of the NIPP highlights the shortcomings of embarking on legislative reform prior to the finalisation of the policy to outline objectives of reform. Reform of the Copyrights Act and other Acts related to the protection of intellectual property must be guided by the intention of achieving the objectives of the Bill of Rights. As reform to other Acts related to the protection of intellectual property is forthcoming, and finalisation of the NIPP is currently underway, the scope of amending the Copyright Act must be limited to related copyright protections and not set any precedent for subsequent IP reform that would be detrimental to the public interest.

39. We once again remind the DTI of the urgent nature of finalising the NIPP and undertaking pro-public health reform of the Patents Act and other Acts related to medicines and medical technologies.

Contact:

Catherine Tomlinson, Parliamentary Liaison, MSF South Africa at
catherine.tomlinson@joburg.msf.org or (+27)76 318 5632