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SECTION27 SUBMISSION ON THE DEPARTMENT OF TRADE AND INDUSTRY'S COPYRIGHT AMENDMENT BILL 2015

16 SEPTEMBER 2015

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INTRODUCTION

1. SECTION27 is a public interest law centre that uses and develops the law to advance human rights. It conducts research, advocacy and litigation to achieve its goals, which include a focus on the right to have access to health care services in general and medicines of proven quality, safety and efficacy in particular. SECTION27 also has strong focus on the social determinants of health including, in particular, equal access to quality basic education.

2. SECTION27's primary interest in intellectual property policy and law reform flows from its understanding of the manner and extent to which patent protection has been used to undermine access to medicines. As part of the "Fix the Patent Laws" campaign with Médecins Sans Frontières ("MSF") and the Treatment Action Campaign ("TAC"), SECTION27 has worked for many years to limit the negative impact of intellectual property on public health. However, the contents of the Copyright Amendment Bill 2015[1] ("Amendment Bill") also have a profound impact on the accessibility of learning and other reading materials for people and children with print disabilities.

3. SECTION27 welcomes the release of the Amendment Bill. The Amendment Bill provides an opportunity to bring to the attention of the Department of Trade and Industry ("DTI") aspects of copyright law reform which have relevance to or an impact on access to medicines and patent law reform as well as access to reading and learning material protected by copyright for people and children with print disabilities.

4. Aspects of this Bill also form part of the Draft National Intellectual Property Policy ("NIPP"). SECTION27 urges the DTI to finalise the NIPP in order to ensure a streamlined law reform process.

[1] Government Gazette notice No. 39028.

SUMMARY OF KEY RECOMMENDATIONS

5. We welcome the DTI's call for concrete suggestions in order to improve the Amendment Bill. Amongst others, this submission makes the following recommendations:

5.1. On the implications of copyright protection for pharmaceutical package inserts:

5.1.1. Section 2 of the Copyright Act should be amended to incorporate a clear boundary of protected subject matter – including the exclusion of factual information and methods of operation from copyright protection;

5.1.2. Section 12 of the Copyright Act should be amended to expand the general exceptions from the protection of a literary work such as a medicine package insert;

5.1.3. The inclusion of a new type of right of reproduction; and

5.1.4. The inclusion of a limited defence to copyright infringement.

5.2. On the definition of parallel importation of goods:

5.2.1. The removal of any conflation with trade mark protection; and

5.2.2. Given that there is a conflation with trade mark protection in the Amendment Bill, we would like to ensure that there is no conflation with patent protection in this regard. We urge the DTI to consider in terms of the draft NNIP and subsequent patent law reform, separately from the 1978 Act, our specific joint recommendations dealing with parallel importation in respect of international, branded and generics medicines as well as those manufactured under compulsory license.

5.3. On the Intellectual Property Tribunal:

5.3.1. The jurisdiction of the proposed Intellectual Property Tribunal should be limited to copyright disputes;

5.3.2. The role of the Intellectual Property Tribunal as a forum of first instance should be clarified; and

5.3.3. The appointment of members to the Intellectual Property Tribunal, including the Chairperson, should be limited to legally qualified persons since each member can potentially preside over proceedings.

5.4. On disability and access to reading and learning material protected by copyright:

5.4.1. The human rights aims of the Amendment Bill, and in particular, the impact of the Amendment Bill with regard to learners' rights to access to basic education, equality and access to information should be incorporated within the Preamble of the Amendment Bill;

5.4.2. The definition of "disability" in the Amendment Bill should be amended so as to ensure, as in section 19D, it includes *all* people with disabilities;

5.4.3. Section 19D of the Amendment Bill should be finalised, enacted and implemented in its current construction;

5.4.4. Building on the enactment and implementation of section 19D of the Amendment Bill, further immediate and consistent measures to ensure people with print disabilities have improved access to reading and learning materials should be taken including:

5.4.4.1. The ratification of the Marrakesh Treaty to Facilitate Access to Published Works for Persons who are Blind, Visually Impaired, or Otherwise Print Disabled ("Marrakesh Treaty");

5.4.4.2. Ensuring improved access to appropriate adapted learning and reading materials to learners with disabilities in schools and students with disabilities in tertiary education institutions. This should be prioritised as a matter of urgency; and

5.4.4.3. Proactive, comprehensive and coordinated measures must be taken to ensure the digitisation of reading and learning materials, most especially in South Africa's nine official indigenous African languages to alleviate the consequences of the "book famine" faced by people with disabilities in South Africa.

STRUCTURE OF THIS SUBMISSION

6. In this submission, we address in substantial detail the issues set out above. We, therefore, consider the following:

   6.1. The international and constitutional law context of copyright protection with reference to the public health flexibilities in international law available to South Africa and also South Africa's obligations under international law;
   6.2. The implications of copyright protection for pharmaceutical package inserts with reference to the requirements of the Medicines Control Council and South African, English and United States case law;
   6.3. The shortcomings in the definition of the parallel importation of goods;
   6.4. The problems arising out of the proposed establishment of the Intellectual Property Tribunal; and
   6.5. The importance of comprehensive, coordinated and proactive measures being taken to ensure improved access to reading and learning materials for people with print disabilities in accordance with the purpose of section 19D of the Amendment Bill and South Africa's constitutional obligations.

THE INTERNATIONAL AND CONSTITUTIONAL LAW CONTEXT

7. As a party to the Berne Convention for the Protection of Literary and Artistic Works ("Berne Convention"),[2] South Africa is obliged to provide copyright protection "in as effective and uniform a manner as possible".[3]

[2] Berne Convention for the Protection of Literary and Artistic Works of September 9, 1886, completed at PARIS on May 4, 1896, revised at BERLIN on November 13, 1908, completed at BERNE on March 20, 1914,

8. The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), through Article 9.1, gives effect to the Berne Convention[4] by stating that signatories under TRIPS must comply with the substantive provisions of the Berne Convention.

9. The Berne Convention clearly allows a degree of flexibility in the incorporation of its provisions into the national laws of contracting parties by virtue of the wording: "in as effective and uniform a manner as possible".[5]

10. South Africa is also a party to the United Nations Convention on the Rights of Persons with Disabilities ("UNCRPD"), which it has ratified. The UNCRPD therefore places various binding obligations on the government, including taking proactive measures to ensure that people with disabilities have access to reading and learning materials. These obligations, and South Africa's constitutional obligations with regard to the rights of people with print disabilities to basic education, access to information and equality, must be interpreted in light of the Marrakesh Treaty which South Africa claims to be "enforcing" despite its current failure to sign or ratify it.[6]

11. According to section 39(1)(b) of the Constitution,[7] international law must be considered when interpreting the Bill of Rights. Reference to international law here "include[s] binding as well as non-binding law".[8] International laws must, therefore, be used "as tools of interpretation".[9] Foreign law may also be considered in terms of section 39(1)(c) of the Constitution.[10] We have, therefore, made reference to case law from other jurisdictions. In this submission, we also provide guidance with reference to case law on the importance of the consistency of legislation with the Bill of Rights in

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revised at ROME on June 2, 1928, at BRUSSELS on June 26, 1948, at STOCKHOLM on July 14, 1967, and at PARIS on July 24, 1971, and amended on September 28, 1979.

[3] Preamble of the Berne Covention 1886.

[4] Specifically the Paris Act of 1971.

[5] Preamble of the Berne Covention 1886.

[6] See, for example, "Treat our disabled people with dignity" (December 2013) available at http://www.gov.za/blog/treat-our-disabled-people-dignity.

[7] Constitution of the Republic of South Africa, 1996.

[8] *S v Makwanyane and Another* 1995 (3) SA 391 at p413 per Chaskalson P.

[9] Ibid at p414.

[10] *Makwanyane* (n 8) at p415.

order to "promote the spirit, purport and objects of the Bill of Rights" in terms of section 39(2) of the Constitution.

IMPLICATIONS OF COPYRIGHT PROTECTION FOR PHARMACEUTICAL PACKAGE INSERTS

12. The Amendment Bill does not address the implications of copyright protection for pharmaceutical package inserts. This issue has been addressed by stakeholders in submissions to the DTI on the draft NIPP.[11]

13. The following will be expanded on before four specific avenues of legislative reform are explored:

    13.1. The requirements of the Medicines Control Council;

    13.2. The case of *Biotech Laboratories (Pty) Ltd v Beecham Group Plc and Another*; and

    13.3. The need for legislative reform.

<u>The requirements of the Medicines Control Council</u>

14. In terms of section 15(1) of the Medicines and Related Substances Act 1965 ("Medicines Act"), all medicines must be registered by the Medicines Control Council ("MCC"). Applications for registration must be in the prescribed form, including "prescribed particulars". The "prescribed particulars" referred to in section 15(1) of the Medicines Act are set out in the General Regulations made in terms of the Medicines Act ("General Regulations").[12] Regulation 9(1) requires that each medicine is "accompanied by a package insert". Sub-regulations 9(1) – (5) stipulate the precise particulars of the package insert. Regulation 9 gives effect to section 35(1)(viii) of the Medicines Act.

[11] See the submission of the National Association of Pharmaceutical Manufacturers, available here: http://napm.co.za/legislative-submissions/.
[12] General Regulations made in terms of the Medicines and related Substances Control Act 101 of 1965.

15. All medicines, including generic medicines, must be "accompanied by a package insert" in terms of regulation 9 of the General Regulations. A generic medicine "is a pharmaceutical product … intended to be interchangeable with an innovator [or originator] product".[13]

16. As such, applications for the registration of generic medicines must prove therapeutic equivalence with the originator product in terms of regulation 2 of the General Regulations.

17. The copyright law implications become apparent through an intersection of regulations 2 and 9. The requirements of therapeutic equivalence in terms of regulation 2 and prescribed particulars in package inserts in terms of regulation 9 result in applicants for registration of generic medicines spending inordinate amounts of resources to avoid copyright infringement of the orginator's package insert.[14]

18. Package inserts, in terms of regulation 9(1)(a) – (s), have to contain information relating to, amongst other particulars, scheduling status, composition, indications and side-effects. Such particulars in a package insert accompanying a generic medicine inevitably need to be the same (or substantially the same) as an orginator's package insert in order for the medicine to meet the overall requirement of therapeutic equivalence.

19. The Registrar of Medicines has also directed that standardised package inserts should be used for multisource medicines ("MSMs"), and that:

> "[t]he most recent approved innovator package insert and/or MCC approved standardised package insert template, if available, should be used as reference for the compilation of MSM package inserts".[15]

[13] See http://www.who.int/trade/glossary/story034/en/.
[14] See Copyright section in the submission of the National Association of Pharmaceutical Manufacturers, available here: http://napm.co.za/legislative-submissions/,
[15] Guidelines: Package inserts for human medicines, paragraph 1.13.

20. It must be noted that producers of generic medicines, including members of the National Association of Pharmaceutical Manufacturers, "fully support" the MCC's requirements in terms of the Medicines Act and General Regulations.[16] Therefore, the Amendment Bill, through copyright law reform, provides ample opportunity to address the difficulties faced by applicants for generic medicines as a result of the implications of copyright protection for pharmaceutical package inserts. We will provide various recommendations below.

The case of *Biotech Laboratories (Pty) Ltd v Beecham Group Plc and Another*

21. *Biotech Laboratories (Pty) Ltd v Beecham Group Plc and Another*[17] provides a clear factual exposition of copyright infringement of an orginator's pharmaceutical package insert.

22. The case exemplifies the limitations of the Copyright Act 1978 ("the 1978 Act") and, therefore, why generic producers are forced to frame legal arguments on very narrow grounds when there is an alleged infringement of the originator's package insert.[18] The net effect is that the limitations of the 1978 Act make generic medicine producers susceptible to copyright infringement of originators' package inserts.

23. In this case, Biotech, the generic producer, was interdicted in the court below and on appeal from infringing the approved package insert of Smith-Kline Beecham, the originator company. Biotech applied for the registration of a generic medicine with the same composition as the already registered orginator medicine of Smith-Kline Beecham's.[19] As noted above, Biotech would have had to comply with the provisions of the Medicines Act and General Regulations.

[16] See Copyright section in the submission of the National Association of Pharmaceutical Manufacturers, available here: http://napm.co.za/legislative-submissions/.
[17] *Biotech Laboratories (Pty) Ltd v Beecham Group Plc and Another* 2002 (4) SA 249 (SCA).
[18] The generic producer unsuccessfully argued that the originator's package insert was not original in terms of section 2(1) of the 1978 Act. The generic producer also unsuccessfully argued that copyright in the orginator's package insert vested in the State. The MCC only approved or disapproved the inserts, but such inserts are not made under the MCC's direction and control (see 5(2) of the 1978 Act).
[19] *Biotech* (n 17) at p256.

24. Although the generic producer was interdicted from copying the orginator's package insert in this case, it must be borne in mind that the limitations of the 1978 Act forced the generic producer to frame legal arguments on very narrow grounds. Interestingly, Harms JA speculated that the generic producer "at the behest of the MCC, … copied Smith-Kline Beecham's package insert".[20]

25. There are several legislative reforms which can be implemented in order to avoid the incongruence between the framework of 1978 Act and the Medicines Act and General Regulations. The need for legislative reform and recommendations will be dealt with in turn.

Why legislative reform is needed

26. The judgment of the United States Court of Appeals for the Second Circuit in *SmithKline Beecham Consumer Healthcare, L.P. v Watson Pharmaceuticals, Inc.*[21] gives definitive guidance on the issue of copying the labelling and user guides of an earlier registered product to meet the requirements of the Federal Food, Drug, and Cosmetic Act ("FFDCA").[22]

27. It was held in this case that generic producers of medicines cannot be liable for copyright infringement because the FFDCA under the enforcement of the Food and Drug Administration ("FDA") "require generic drug producers to use the same labelling as was approved by the FDA for, and is used by, the producer of the pioneer drug."[23]

28. This judgment explains why generic medicine producers cannot be liable for copyright infringement:

[20] *Biotech* (17) at p257.
[21] *SmithKline Beecham Consumer Healthcare, L.P. v Watson Pharmaceuticals, Inc.* 211 F. 3d 21.
[22] Drug Price Competition and Patent Term Restoration Act of 1984 101, 21 U.S.C. 355(j).
[23] *SmithKline* (n 21) at paragraph 2.

28.1. The requirements of the FFDCA "not only permit, but require generic producers" to use the same labelling as the orginator product.[24]

28.2. The FFDCA was designed to "facilitate rather than impede the approval … of generic drugs".[25]

28.3. The purposes of the FFDCA would be severely undermined if copyright concerns were to shape the FDA's application of the "same" labeling requirement"[26] and no "severe undermining of the purpose of the copyright laws would follow from the rejection" of an originator's copyright claim.[27]

29. The reasoning in the United States judgment can be applied to the requirements of the MCC in the following ways:

29.1. The requirements of the General Regulations as enforced by the MCC do not expressly require generic medicine producers to use the same package insert as is the case with the FFDCA in the United States. In practice, however, as noted above, package inserts, in terms of regulation 9(1)(a) – (s), have to contain information in accordance with prescribed particulars. Such particulars in a package insert accompanying a generic medicine inevitably need to be the same (or substantially the same) as an orginator's package insert in order for the medicine to meet the overall requirement of therapeutic equivalence. Therefore, as noted in *Biotech*, the generic producer "at the behest of the MCC, … copied [the originator's] package insert".[28]

29.2. The Medicines Act and General Regulations are designed to facilitate, not impede the market entry of generic medicines. Copyright considerations cannot subvert this objective. Harms JA in *Biotech* reinforced this principle by acknowledging that generic medicine producers are "not subjected to the same stringent registration requirements" as producers of originator medicines.[29]

[24] *SmithKline* (n 21) at paragraph 15.
[25] *SmithKline* (n 21) at paragraph 15.
[26] Ibid at paragraph 26.
[27] Ibid at paragraph 27.
[28] *Biotech* (n 17) at p257.
[29] *Biotech* (n 17) at p256.

30. In light of the above, there is a clear need to reform the 1978 Act in order to remove any incongruence between the 1978 Act and the Medicines Act and General Regulations. This incongruence can be described as a siutation where there are conflicting sets of legislation which do not necessarily deal with the same topics.

31. In these circumstances, both sets of legislation would have to be read and applied together.[30] In other words, both Acts would need to be read in order to "[preserve] the purposes of both and [foster] harmony between them".[31] Because of the limitations of the 1978 Act as illustrated in the *Biotech* case, the purposes of the Medicines Act and General Regulations have been subverted by copyright considerations.

32. Where two sets of conflicting legislation cannot be reconciled, "the inevitable result is a 'legislative short circuit', since original legislation cannot be invalidated. This means that there could be a gap in the law".[32]

33. In respect of the conflict between the 1978 Act and the Medicines Act and General Regulations, there are two interrelated ways to address the "legislative short circuit":

    33.1. Through the implementation of legislative amendments set out below.

    33.2. In terms of the section 39(2) of the Constitution[33] as interpreted and applied by the Constitutional Court in *South African Police Service v Public Servants Association*, "[a]ll law must conform to the Constitution and be interpreted and applied within its normative framework."[34] Further, in *Holomisa v Argus Newspapers Ltd*, it was held that section 39(2) is "not merely an interpetive directive, but a force that informs all legal institutions and decisions."[35] The purposes of the Medicines Act and General Regulations include the realisation of

[30] *Maccsand (Pty) ltd v City of Cape Town and Others* 2012 (4) SA 181 (CC).
[31] *SmithKline* (n 21) at paragraph 25.
[32] Botha C., *"Statutory Interpretation"* (Juta: 2014), page 137.
[33] Constitution of the Republic of South Africa, 1996.
[34] *South African Police Service v Public Servants Association* 2007 (3) SA 521 (CC) at p529 per Sachs J.
[35] *Holomisa v Argus Newspapers Ltd* 1996 (2) SA 588 (W).

the right of access to health care services in terms of section 27 of the Constitution. Copyright considerations cannot prevail over a legislative framework designed to facilitate access to medicines.

Amendment to section 2 of the 1978 Act

34. One way of addressing the above concerns would be an amendment to section 2 of the 1978 Act.

35. Section 2 of the 1978 Act should be amended by an addition in subsection 2 after subsection (2A). This addition should expressly include the wording of 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." (emphasis added)

36. This would be a codification of what is known as the "idea/expression divide" or "merger effect doctrine".[36] An addition to subsection 2 of the 1978 Act should provide more clarification than the general wording of Article 9.2 of TRIPS, but still within the parameters of the provision:

36.1. It should state that "methods of operation" include the description of the specific use of a product in terms of the requirements of another Act or Regulation.

36.2. Further clarifying the idea/expression divide, an amendment should expressly state that any leaflet accompanying a product which contains factual information (for example, in the case of a medicine: the composition of the product, its scheduling status, indications, interactions, dosages and side-effects) shall not attract copyright protection.

[36] T Endicott and M Spence, "*Vagueness in the Scope of Copyright*" (2005) 121 LQR 657.

37. Legislative clarity on the idea/expression divide related to factual information contained in a leaflet accompanying a product is imperative. Therefore, South Africa, through the Amendment Bill, can achieve such clarity in line with the recommendations above. There are examples of case law aboad where a lack in legislative clarity results in courts failing to provide adequate guidance on the idea/expression divide.

38. One such case is the English case of *Elanco v Mandops*.[37] The defendant in an action for copyright infringement changed the first version of its leaflet for a weed-killer at the claimaint's insistence to avoid infringement of the claimant's copyright. However, the defendant was successfully sued for infringement for having reproduced the wording in its second leaflet even though it had been carefully redrafted to avoid taking the wording of the claimant's instructions. The leaflet consisted mainly of factual information.

39. Package inserts for medicines contain numerous pieces of factual information as required by the MCC in terms of regulation 9 of the General Regulations. In order to show therapeutic equivalence, the package insert accompanying a generic medicine would inevitably have to include such factual information. The above recommendations for an amendment to section 2 of the 1978 Act provide a viable way to address this problem and a clear boundary of protected subject matter.[38]

40. A further amendment to section 2 of the 1978 Act after subsection (3) could also make provision for potential or actual conflicts with other legislation.[39]

<u>Amendment of section 12 of the 1978 Act</u>

41. If a package insert accompanying a medicine is eligible for copyright protection in terms of section 2 of the 1978 Act (although this is would be highly unlikely if the above recommended amendments to section 2 are in place), there should be an

[37] *Elanco v Mandops* [1980] RPC 213.
[38] T Endicott and M Spence, "*Vagueness in the Scope of Copyright*" (2005) 121 LQR 657.
[39] For example, see section 2(8) of the Consumer Protection Act 68 of 2008.

amendment to section 12 of the 1978 Act. Section 12 of the 1978 Act sets out general exceptions from protection of literary and musical works. Package inserts are literary works as stated above.

42. An amendment to section 12 of the 1978 Act should include an addition after subsection (13). This addition should state that copyright in a literary work shall not be infringed by the use thereof in satisfaction of the legal requirements in terms of another Act or Regulation.

43. There is a clear precedent for this type of a provision. In the United Kingdom, the Copyright, Designs and Patents Act 1998 ("UK Copyright Act") contains a provision, section 171, dealing with "rights … under other enactments". Section 171 of the UK Copyright Act then goes on to list when rights under other enactments cannot be affected by copyright enforcement under the provisions of the UK Copyright Act. One such circumstance is under section 171(3) which prevents or restricts the "enforcement of copyright, on grounds of public interest."[40]

44. This is another way to ensure that copyright considerations do not stifle the registration process of generic medicines.[41]

Insertion of section 13A in the 1978 Act

45. The Bill provides for an expansion on the rights of reproduction.[42] An insertion after section 13 of the 1978 Act should provide for the right of reproduction aimed at meeting the requirements of another Act or Regulation.

46. This would facilitate the process of registration of generic medicines.[43] Generic medicine producers, if such a right of reproduction were to be implemented, would be able to reproduce parts of the originator's package insert in order to satisify the

[40] This provision has been applied on numerous occasions by appellate courts in the United Kingdom. See: *Hyde Park Residence Ltd. v. Yelland* [2000] R.P.C. 604; and *Lion Laboratories Ltd. v. Evans* [1985] Q.B. 526.
[41] See *SmithKline* (n 21) at paragraph 15 explained above.
[42] Government Gazette Notice No. 39028 at pages 20-21.
[43] *Biotech* (n 17) at p256.

requirement of prescribed particulars set out in regulation 9 of the General Regulations.

47. This new type of right of reproduction can also be reconciled with the general exceptions in respect of the reproduction of works set out in section 13 of the 1978 Act. The reproduction by the generic medicine producer of parts of the originator's package insert would be considered as the "normal exploitation of the work and is not unreasonably prejudicial to the legitimate interests of the owner of the copyright."[44] Under these circumstances, however, this new type of right of reproduction should not be restricted to reproduction of one copy only as currently stipulated in regulation 2(a) of the Regulations in terms of the 1978 Act.[45]

Amendment of section 23 of the 1978 Act

48. Section 23 of the 1978 Act deals with the infringement of copyright. Another way to avoid copyright considerations stifling the registration of generic medicines is through an amendment to section 23 of the 1978 Act which should include an addition after subsection (2).

49. This addition should stipulate that the "exclusive rights" of the copyright owner in section 23(1) of the 1978 Act do not extend to anything done by an alleged infringer in order to fulfill the requirements of another Act or Regulation. As stated above, the UK Copyright Act provides for a qualification to the exclusive rights of a copyright owner. The effect of section 171 of the UK Copyright Act is that rights under other enactments cannot be affected by the exclusive rights of copyright enforcement under a copyright legislative framework. Copyright enforcement is, therefore, restricted or prevented.

THE DEFINITION OF PARALLEL IMPORTATION OF GOODS

50. The Amendment Bill suggests the following definition for parallel importation of goods:

[44] Section 13 of the Copyright Act 1978.
[45] Published under Government Notice R2530 in *Government Gazette* 6252 of 22 December 1978.

" … 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."[46]

51. There are two concerns with this definition:

51.1. Copyright protection and trade mark protection is conflated.

51.2. Further explanation of parallel importation including exhaustion of rights is later provided for in the Amendment Bill, and also speaks exclusively of trade marked goods.[47]

52. The definition above should be removed. The section dealing with a full explanation of parallel importation and exhaustion of rights should be expanded to include reference to the 1978 Act.[48]

53. Given that there is a conflation with trade mark protection in the Amendment Bill, we would like to ensure that there is no conflation with patent protection in this regard. We urge the DTI to consider in terms of the draft NNIP and subsequent patent law reform, separately from the 1978 Act, our specific joint recommendations dealing with parallel importation[49] in respect of international, branded and generics medicines as well as those manufactured under compulsory license.

THE INTELLECTUAL PROPERTY TRIBUNAL

54. The Amendment Bill establishes an Intellectual Property Tribunal ("IP Tribunal")[50] to replace the existing Copyright Tribunal established under section 29 of the 1978 Act.

[46] Section 1(g) of the Copyright Amendment Bill.
[47] Government Gazette Notice No. 39028 at 20.
[48] See the recommendations contained in the Joint Submission on the Copyright Amendment Bill by an international team of academics from South Africa and the USA, pages 3 and 21.
[49] See SECTION27, Treatment Action Campaign and Doctors Without Borders (MSF Southern Africa) Joint Comment Submission on the Draft National Intellectual Property Policy, 2013, available here: http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf.
[50] Government Gazette Notice No. 39028 at 36.

While it is desirable to create an accessible form of dispute resolution for authors, owners and users of copyright,[51] several issues arise out of the proposed establishment of the IP Tribunal.

The breadth of the IP Tribunal's jurisdiction

55. The breadth of the IP Tribunal's jurisdiction is potentially too wide. In its current form in the Amendment Bill, it –

    55.1. "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";

    55.2. "may adjudicate any application or referral made to it in terms of [the 1978] Act, Companies Act, 2008 or any legislation…"; and

    55.3. "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".

56. The proposed IP Tribunal's jurisdiction is very wide in scope compared with the Companies Tribunal established in terms of section 180 of the Companies Act 2008.[52] The DTI stated at the recent Copyright Amendment Bill Conference that the IP Tribunal is based on the Companies Tribunal.

57. If this is so, the IP Tribunal's functions should be limited to applications and referrals in terms of the 1978 Act or legislation relevant to the enforcement and protection of copyright only. There should be no reference to "any legislation" or broadly "intellectual property rights". Reference to these should also be removed from section 29N of the Amendment Bill dealing with orders of the IP Tribunal.

58. It is imperative that there are specific forums for each category of intellectual property right ("IPR") given the specific objectives and requirements of each piece of legislation

[51] Comments made by the Department of Trade and Industry at the Copyright Amendment Bill Conference, 27 August 2015.
[52] Companies Act 71 of 2008.

governing each IPR. With regard to patents, we have recommended that the Patents Act 1978[53] should provide for meaningful pre- and post-grant opposition mechanisms, which are administrative in nature, that recognise broad standing requirements inclusive of civil society and adequate access to information to facilitate such interventions.[54]

The IP Tribunal as a forum of first instance in copyright matters

59. The proposed IP Tribunal in its current form would act as a forum of first instance unlike the Companies Act which provides for investigation, alternative dispute resolution and complaints mechanisms in terms of sections 166 – 175 before a referral to the Companies Tribunal.

60. The Amendment Bill, therefore, fails to provide for investigation, alternative dispute resolution and complaints mechanisms.[55] The incorporation of these would ensure that authors, owners and users of copyright have adequate access to an efficient dispute resolution mechanism.

Appointment of members of the IP Tribunal

61. There is no clear rationale for the appointment of members to the IP Tribunal with diverse qualifications (such as commerce, economics and public affairs) as proposed in section 29B of the Amendment Bill.

62. Any of these members can be appointed as Chairperson and also preside over proceedings. A tribunal established in terms of the 1978 Act should be akin to the Tribunal established in terms of section 45 of the Trade Marks Act 1993.[56] The Amendment Bill, section 29J, states that any member presiding over an application

[53] Patents Act 57 of 1978.
[54] See SECTION27, Treatment Action Campaign and Doctors Without Borders (MSF Southern Africa) Joint Comment Submission on the Draft National Intellectual Property Policy, 2013, available here: http://www.fixthepatentlaws.org/wp-content/uploads/2013/10/S27-TAC-MSF-Submission_on_IP_Policy.pdf.
[55] See sections 168 – 169 of the Companies Act 2008.
[56] Trade Marks Act 194 of 1993.

would have powers of subpoena. The Registrar in the Tribunal of the Registrar of Trade Marks is a legally qualified person with the powers "possessed by a single judge in a civil action before the [Gauteng] Division of the [High Court of South Africa]" in terms of section 45(1) of the Trade Marks Act.

63. In order for the IP Tribunal to function adequately as a forum directly below the High Court within a copyright-specific jurisidiction, its proceedings need to be administered and overseen by a legally qualified member. Even the Companies Tribunal requires its members to have legal training and experience.[57]

64. Parties in proceedings before the IP Tribunal can then adduce the evidence of experts qualified in economics, commerce and public affairs and also have the opportunity to call experts to testify in proceedings. Therefore, the involvement of these experts should be under the auspices of the IP Tribunal's rules regarding the hearings of proceedings[58] and calling of witnesses.[59]

DISABILITY AND ACCESS TO READING AND LEARNING MATERIAL PROTECTED BY COPYRIGHT

65. SECTION27 applauds the inclusion within the Amendment Bill of the accommodation of the particular needs of persons with disabilities in gaining access to copyrighted material in the form of section 19D of the Bill. We urge that section 19D be enacted and implemented as it is currently drafted and that this is used as a starting point from which to ensure meaningful access to reading and learning materials for people with print disabilities in South Africa.

66. Though section 19D, unlike the definitions section of the Amendment Bill, rightfully covers necessary accommodations within copyright law of all disabilities,[60]

[57] Section 195(3)(a) of the Companies Act 2008.
[58] See section 182 – 183 of the Companies Act 2008.
[59] See section 184 of the Companies Act 2008.
[60] The definition of disability in the definitions section of the Amendment Bill should, SECTION27 submits, be amended to include *all* persons with disabilities, as it appears section 19D is intended to do.

SECTION27's submissions here pertain specifically to access to copyrighted works for visually impaired persons. SECTION27 has extensive experience working with all 22 special schools for visually impaired learners in South Africa, the South African National Council for the Blind ("SANCB"), Blind SA, the South African Braille Authority ("SABA"), the Orientation and Mobility Action Group and the Visually Impaired Educators Forum.

67. Many visually impaired people, whether totally blind or partially sighted, form the core of a large group of people in our country that can be described as having a "print disability".[61] This means that they cannot, for reason of their disability, read ordinary print text. In order to meet the needs of visually impaired persons, text may for example, require adaptation and production in Braille, large print, or various accessible electronic formats.

68. Scarce access to reading materials for people with disabilities is a big problem worldwide which has historically been exacerbated by inflexible national and international approaches to copyright law. The problem created is so severe that it has been described by the World Blind Union as a "book famine" for people with print disabilities.[62]

69. Though there are over 129 million book titles in the world, persons with print disabilities can only presently obtain access to roughly 7% of these titles as a best case scenario in some developed countries. The famine is more acute in developing countries where approximately 1% of book titles are available to people with print disabilities. This is despite the fact that 90% of people with print disabilities are located in developing countries.[63] As Marcus Low has noted, this book famine impacts on learners at schools and students in universities particularly acutely:

[61] P Harpur& N Suzor "Copyright Protections and Disability Rights: Turning the Page to a New International Paradigm" *University of New South Wales Law Journal*, 36(3), pp. 745-778.
[62] World Blind Union "Press Release WIPO Negotiations Treaty for Blind people" (20 April 2013) available at http://www.worldblindunion.org/english/news/pages/press-release-wipo-negotiations-treaty-for-blind-people.aspx.
[63] P Harpur& N Suzor "Copyright Protections and Disability Rights: Turning the Page to a New International Paradigm"*University of New South Wales Law Journal*, 36(3), pp. 745-778.

"Most books today exist somewhere in an electronic format. Yet, blind students often struggle to get hold of accessible format books required for study – which makes an already hard educational experience even more difficult.

Apart from its impact on education and work, the book famine also limits the ability of blind people to be included in the cultural life of the societies they live in."[64]

70. In late 2014 and early 2015, SECTION27 visited 20 of the 22 special schools for learners with visual impairments in South Africa on behalf of the SANCB, Blind SA and SABA. These visits, which will be detailed in a comprehensive report to be presented to the Portfolio Committee for Basic Education later this year, reveal that the book famine in South Africa severely affects learners with disabilities in particular.[65] Copyright law, and South Africa's intellectual property regime more generally, therefore have an important role to play in the realisation of the "immediately realisable" and "unqualified" right to basic education entrenched in South Africa's Constitution.[66] In this regard, SECTION27 would like to draw the attention of the DTI to the following findings of the SECTION27's report:

70.1. Due to a failed tender process in 2012, the Department of Basic Education ("DBE") is yet to fund, publish or print a single Braille textbook for learners with visual impairments;

70.2. Though adaptation, production and distribution of Braille workbooks has begun, some schools still indicate that they are yet to receive full and equal access to their full complement of each volume of the required workbooks;

[64] Marcus Low "Copyright bill will empower blind people" (26 August 2015) available at http://groundup.org.za/article/copyright-bill-will-empower-blind-people_3245

[65] SECTION27, "Left in the Dark: Failure to Provide Access to Quality Education to Blind and Partially Sighted Learners in South Africa" (2015, forthcoming) on file with SECTION27 until publication, available on request.

[66] *Juma Masjid Primary School and Others v Ahmed Essay N.O. and Others* CCT 29/10 [2011] ZACC 13 at para 37; *KwaZulu-Natal Joint Liaison Committee v MEC Department of Education, Kwazulu-Natal and Others* (CCT 60/12) [2013] ZACC 10; 2013 (6) BCLR 615 (CC); 2013 (4) SA 262 (CC) (25 April 2013) at para 38.

70.3. The Visually Impaired Educators Forum, comprising approximately 40 visually impaired educators, indicates that there are as yet no Braille teachers' guides for the CAPS curriculum available to educators with visual impairments;

70.4. Many schools have limited capacity to adapt print content and produce Braille due to inadequate staffing, insufficient technical expertise and limited access to and poor maintenance of appropriate brailing equipment;

70.5. Publishers often refuse schools and Braille printing works access to electronic copies of textbooks and other necessary materials for learning in accessible formats. This refusal appears often to be based on the publishers' possession of copyright over these materials;

70.6. Technological assistive devices such as the BrailleNote Apex, a portable computer which allows the user to read contents loaded onto it in electronic format on a Braille display, which have been distributed by the provincial departments of education in at least three provinces, are severely limited in their impact by copyright restrictions and publishers' refusal to compromise;

70.7. The CAPS curriculum, implemented by the DBE for several years now, is widely regarded as "too visual" and appears to not have been proactively formulated and planned with the particular needs of visually impaired learners in mind;

70.8. There is generally a severe shortage of reading materials available to visually impaired learners and students in South Africa. This includes access to prescribed curricula and also additional leisure reading material that should be made available to learners at school libraries; and

70.9. All of these problems are even more pronounced with regard to access to reading materials in South Africa's national languages other than English and Afrikaans. The majority of visually impaired learners, who speak the nine indigenous African languages recognised as official languages by South Africa's Constitution, therefore have little electronic or Braille access to reading materials in their home languages.

71. Section 19D of the Amendment Bill, in its current formulation, will solve some, but not all, of the problems detailed above.

72. Firstly, it will remove a common barrier to access by allowing the making of accessible format copies of books for use by print handicapped persons without the consent of the copyright holder. This will allow educational institutions to, much more effectively and timeously, provide some materials for learners with print disabilities.

73. Secondly, it will allow people with print disabilities and those acting on their behalf to access accessible format books already available in electronic libraries in other countries that have ratified the Marrakesh Treaty. This will decrease the need to rescan books or have books read on tape – both labour-intensive factors contributing to the limited access to accessible format books in South Africa at present.

74. However, even with books more easily available in accessible formats, people with print disabilities will still need access to the electronic reading devices, refreshable braille displays and braille printers that would allow for the actual reading of such books. Moreover, electronic access supplements rather than replaces the need for Braille materials, particularly in the context of the general dearth of available reading materials for persons with print disabilities worldwide and in South Africa in particular. The need for Braille and large print materials in South Africa, is presently perhaps even more important than elsewhere, given the wide range of indigenous South African languages that existing global electronic archives and modern assistive devices do not yet cater for.

75. Furthermore, whilst applauding acknowledgment in the Preamble of the Amendment Bill that it aims to "provide for access to copyright works for a person with disabilities" and acknowledging the groundbreaking inclusion of section 19D to accommodate for access to reading materials for visually impaired learners, SECTION27 submits that much more will need to be done in order to ensure that visually impaired learners have equal access to and enjoyment of their right to basic education. The DTI and

other governmental stakeholders, including the DBE and Department of Arts and Culture, should therefore take cognisance of these acute problems in the finalisation, enactment and implementation of the Amendment Bill.

76. In order to realise the rights to basic education,[67] access to information[68] and equality[69] of children with visual impairments and to fulfil the state's obligation to "promote" and "fulfil" their rights,[70] SECTION27 therefore submits that, in addition to the enactment of section 19D of the Amendment Bill in its current form, the following are necessary steps:

76.1. **Ratification of the Marrakesh Treaty:**

76.1.1. The urgent ratification of the Marrakesh Treaty must prioritised by the South African government and actively promoted by the DTI. The Marrakesh Treaty specifies state parties' obligations in ensuring access to published works for persons with visual impairments. Its content, though more detailed, is entirely consistent with section 19D of the Amendment Bill. Though the South African government and civil society were intricately involved in the production of the treaty which was concluded in June 2013, South Africa has yet to sign or ratify the treaty. This despite public indications from senior government officials that "South Africa is enforcing the Marrakesh Treaty".[71] The reason for the delay in the ratification of the Marrakesh Treaty remains unclear.[72] SECTION27 submits that there is a constitutional obligation on the state in terms of the rights to basic education, access to information and equality to ratify the Marrakesh Treaty as soon as is practicable. The

[67] Constitution of the Republic of South Africa 1996, section 29(1)(a).
[68] Ibid, section 32.
[69] Ibid, section 9.
[70] Ibid, section 7(2).
[71] "Treat our disabled people with dignity" (December 2013) available at http://www.gov.za/blog/treat-our-disabled-people-dignity.
[72] M Low "Blind sidelined by Department of Trade and Industry" (2 October 2013) available at http://groundup.org.za/content/blind-sidelined-department-trade-and-industry#sthash.MQEfbY6h.dpuf.

government is required to fulfil all of its constitutional obligations in terms of section 238 of the Constitution "diligently and without delay".[73]

76.2. **Bill of Rights framing:**

76.2.1. The extension of the acknowledgment in the Preamble of the Amendment Bill that it aims to "provide for access to copyright works for a person with disabilities" to acknowledge that it also aims to contribute towards the realisation of the rights of persons with disabilities. Indeed the Preamble makes no reference to human rights at all, despite the clear relevance of many human rights to various sections of the Amendment Bill and the Constitution's requirement that all law is interpreted, construed and developed in line with the Bill of Rights.[74] The important context detailed in this submission on the effects of the Amendment Bill on the rights to access to information, basic education and equality of learners are but one example of the human rights impact of the Bill.

76.3. **Proactive measures to increase access to reading and learning materials:**

76.3.1. Creating exceptions to copyright law to allow for access for persons with disabilities is an essential and enormous step in the right direction which will no doubt contribute to the alleviation of the book famine in South Africa. However, if the provisions of section 19D are going to make meaningful changes to the majority of visually impaired persons in South Africa who live in poor and under-resourced communities, proactive and coordinated state action will be required to expand the pool of accessible materials. Member states of the UNCRPD are under an obligation to "take all appropriate measures to ensure that persons with disabilities ... [e]njoy access to cultural materials in accessible formats".[75] The Constitutional Court has recently

[73] Constitution of the Republic of South Africa 1996, section 238.
[74] Ibid, section 39(2).
[75] Convention on the Rights of Persons with Disabilities, Article 30(1).

decided that the rights in the Bill of Rights must be interpreted in light of provisions of the UNCRPD, which has been ratified by South Africa.[76] The Court has also previously concluded that the government must take "reasonable and effective" positive steps to realise all of the rights in the Bill of Rights.[77] This is particularly urgent with regard to provision of materials for school learners and students in tertiary education institutes in South Africa. It is also of increased importance in relation to the need to make accessible materials in South Africa's nine official indigenous African languages available to their home language speakers. This will require South Africa to invest heavily, urgently and consistently in "digitising the wealth of written human knowledge" and to "take steps to ensure that new works are made accessible from the outset".[78] The inaccessibility of curricula in school, is a stark reminder of how *ad hoc* processes and copyright exceptions created by section 19D of the Amendment Bill and included with the contents of the Marrakesh Treaty are, alone, insufficient to combat the severity of the book famine.[79]

CONCLUSION

77. This submission is endorsed by the Treatment Action Campaign.

78. We remain available to the DTI and Standing Advisory Committee on Intellectual Property to answer any questions or participate in individual consultations.

79. SECTION27 thanks the DTI for the opportunity to make this submission.

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[76] *De Vos N.O and Others v Minister of Justice And Constitutional Development and Others* (CCT 150/14) [2015] ZACC 21 (26 June 2015) at para 58.

[77] *Glenister v President of the Republic of South Africa and Others* (CCT 48/10) [2011] ZACC 6; 2011 (3) SA 347 (CC) ; 2011 (7) BCLR 651 (CC) (17 March 2011) at para 189.

[78] P Harpur& N Suzor "Copyright Protections and Disability Rights: Turning the Page to a New International Paradigm" *University of New South Wales Law Journal*, 36(3), pp. 745-778.

[79] For more detail on this argument as it applies to the Marrakesh Treaty see P Harpur& N Suzor "Copyright Protections and Disability Rights: Turning the Page to a New International Paradigm" *University of New South Wales Law Journal*, 36(3), pp. 745-778.

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