Journal of African Law (2024), **68**, 19–39
doi:10.1017/S0021855323000323

RESEARCH ARTICLE

Going It Alone or Acting as a Collective? Evaluating the East African Community Policy on Implementing TRIPS Obligations

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(Accepted 22 February 2023; first published online 15 December 2023)

Abstract

The grim realities of the COVID-19 pandemic have resuscitated discussions about the effectiveness of the flexibilities entrenched in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for improving access to medicines. This article revisits this vexed issue by examining whether a regional approach to implementing TRIPS obligations could deliver a better outcome for access, especially in low- and middle-income countries, where manufacturing capacity is almost non-existent. Using the East African Community (EAC) as a case study, the article critiques recommended implementation options under the EAC policy on TRIPS flexibilities, concluding that, if significantly implemented, these recommendations could yield a better outcome for access.

Keywords: COVID-19 and access to medicines; TRIPS Agreement; East African Community; EAC policy on TRIPS flexibilities

Introduction

The East African Community (EAC) is a regional economic bloc comprising Kenya, Uganda, Tanzania, Rwanda, Burundi, South Sudan and the Democratic Republic of the Congo.[1] Apart from South Sudan,[2] all partner states are members of the World Trade Organization (WTO), thus making them subscribers to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[3] As subscribers, each partner state must enact TRIPS minimum standards at national level. However, for optimization purposes, the EAC opted in 2013 for a regional approach to implementation by adopting the Regional Intellectual Property Policy on the Utilization of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation (EAC Policy on Flexibilities / EACPoF).[4] In a nutshell, the EACPoF recommends implementation options for replication at national levels which will promote access to medicines among EAC

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1 EAC "Overview of EAC", available at: <https://www.eac.int/overview-of-eac> (last accessed 1 November 2023).

2 WTO "Accessions: South Sudan", available at: <https://www.wto.org/english/thewto_e/acc_e/ssd_e/a1_south_sudan_e.htm> (last accessed 1 November 2023).

3 The TRIPS Agreement, 1869 UNTS 299, was opened for signature on 15 April 1994 and entered into force on 1 January 1995.

4 EAC Secretariat, 2013, available at: <https://ipaccessmeds.southcentre.int/wp-content/uploads/2019/12/EACTRIPSPolicy.pdf> (last accessed 15 November 2023).

populations. As a policy document, the EACPoF is non-binding, which necessitated the draft of the EAC Health Protocol on Public Health Related WTO-TRIPS Flexibilities (the Protocol);[5] upon ratification by all partner states, this Protocol would confer the force of law on these recommendations. Unfortunately, the Protocol remains unratified at the time of writing.[6]

This article extends the frontiers of existing scholarship on this topic by holistically evaluating the recommendations in both documents. In the next section, the article examines the legal basis for WTO members' adoption of different implementation approaches when incorporating TRIPS minimum standards at national level. The subsequent section is a detailed appraisal of the EACPoF's and the Protocol's recommendations. In an attempt at comparative analysis, this section benchmarks proposed recommendations against prevalent implementation options in the US, the European Patent Convention (EPC) countries and India: reliance on the first two jurisdictions is justified, given that both are heavily referenced throughout the EACPoF, while India is preferred because of its implementation of TRIPS obligations which is in favour of access to medicines. Additionally, for a few TRIPS obligations, examples are drawn from implementation approaches in Canada and Australia, owing to the peculiarities of their interpretations. The concluding section reflects on the potential utility of the EAC approach for access to medicines in the region.

Implementing TRIPS minimum standards amid WTO members' other interests

TRIPS sets minimum standards for substantive intellectual property (IP) rights which WTO members must implement nationally. One principal concern which this somewhat harmonized global approach may raise for members is how it could affect their right to prioritize other equally important national interests over IP protection. A glance through members' implementation practices, however, indicates that this concern has been largely allayed, with members construing TRIPS minimum standards differently and including policy-space provisions which permit disregarding IP rights in national laws. That members could so act seems to contradict the perception of TRIPS as a "minimum standards" agreement. Nevertheless, this practice finds support both under TRIPS and existing Panel / Appellate Body (AB) jurisprudence.

Generally, TRIPS articles 1, 7 and 8 (reaffirmed by the Doha Declaration on the TRIPS Agreement and Public Health)[7] collectively sanction the adoption of state-centred approaches to implementing TRIPS minimum standards. First, article 1(1) provides that "[m]embers *may*, but *shall not* be obliged to, implement … more extensive protection than is required by this Agreement" (emphasis added). This provision signals that willing members could go above TRIPS minimum standards in their implementation. The remainder of that article, which recognizes members' right to freely "determine the appropriate method of implementing" TRIPS, is further attestation to the implementation choice that members have.

TRIPS article 7 is an important balancing provision: it requires that the "protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge", should be "in a manner conducive to social and economic welfare", and should achieve "a balance of rights and obligations". None of these objectives is defined in TRIPS – which is a clear indication of the multiple implementation options open to members. Thus, some members have invoked the "promotion of technological innovation" objective to justify a "TRIPS-plus" regime because of their belief that this would incentivize more innovation, whereas other members have invoked the same objective to exclude TRIPS-plus provisions, believing that

5 Ibid.

6 CB Ncube "Three centuries and counting: The emergence and development of intellectual property law in Africa" in R Dreyfuss and J Pila (eds) *The Oxford Handbook of Intellectual Property Law* (2018, Oxford University Press) 409 at 424.

7 14 November 2001 (WT/MIN(01)/DEC/2).

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

too much protection may reduce depth in the public domain and stifle innovation.[8] Similarly, a member may implement "the transfer and dissemination of technology" objective by establishing a punitive local regime intended to compel domestic exploitation of patented inventions;[9] meanwhile, other members have justified the establishment of a stronger IP regime using the same objective, contending that such a regime promotes technology transfer.[10]

Additional support is found in TRIPS article 8(1), which recognizes members' right to "adopt measures *necessary* to protect public health and nutrition, and to promote public interest in sectors of vital importance to their socio-economic and technological development" (emphasis added). Any such measures designed to "protect public health and nutrition" will vary from country to country, as will the definition of "sectors of vital importance". Article 8(2) then concedes to members the freedom to adopt measures necessary "to prevent the abuse of intellectual property rights by rights holders or the resort to practices" which may restrain trade or disadvantage technology transfer. The Doha Declaration subsequently emerged to reaffirm the extent of this concession.[11]

While these provisions indisputably confirm deference to members vis-à-vis a national implementation approach, this deference is not absolute. For instance, members must show that an adopted approach meets a "consistency test"[12] and arguably a "necessity test" (based on article 8 (2)), especially when such an approach seeks to derogate from TRIPS-protected rights. The WTO Panel / AB enjoys absolute jurisdiction regarding the rightness or otherwise of a challenged implementation approach.[13] This body also decides which test will apply to its analysis, although a perusal of earlier disputes decided under TRIPS indicates a preference for the "consistency test", which is applied in a holistic manner. This involves an application of articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT):[14] interpretation of the treaty "in good faith in accordance with the ordinary meaning" of contextual use of terms and in the light of the treaty's object and purpose. In determining context, the text, preamble, annexes, subsequent agreements, etc of a treaty are all relevant.[15] Applied to the consistency question, the Panel / AB analysis often proceeds from engaging not only the text and preamble of TRIPS, but also its object and purpose as expressed in TRIPS articles 7 and 8. The relevant provisions of the Doha Declaration are also considered.[16]

For instance, the Panel in *Canada – Patent Protection of Pharmaceutical Products* concluded that the Canadian regulatory review exception, which permits competitors to use patented pharmaceutical inventions prior to patent expiry for the purpose of obtaining marketing approval, is consistent with TRIPS.[17] According to the Panel, this option, which would otherwise have contravened TRIPS

8 These contrasting approaches were reflected in the debate on a TRIPS waiver between developed and developing countries; see generally B Mercurio "The IP waiver for COVID-19: Bad policy, bad precedent" (2021) 52 *International Review of Intellectual Property and Competition Law* 983; T Chaudhary and A Chaudhary "TRIPS waiver of COVID-19 vaccines: Impact on pharmaceutical industry and what it means to developing countries" (2021) *Journal of World Intellectual Property* 1.

9 Brazil and India are leading examples: see Industrial Property Law (Brazil) Law 1996, art 68(1)(I); Patents Act (India) 1970, sec 83; M Trimble "Patent working requirements: Historical and comparative perspectives" (2016) 6/3 *UC Irvine Law Review* 483.

10 Tanzania, Uganda and Kenya are examples: see OA Olatunji "Historical account of dwindling national flexibilities from the Paris Convention to post-TRIPS era: What implications for access-to-medicines in low-and-middle-income-countries?" (2022) 25/2 *Journal of World Intellectual Property* 391.

11 Doha Declaration, para 5.

12 TRIPS, arts 1(1), 7 and 8 and Doha Declaration, para 4.

13 Id, part V.

14 1155 UNTS 331, opened for signature on 23 May 1969 and entered into force on 27 January 1980.

15 VCLT, arts 31 and 32.

16 See *Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, Reports of the Panel (28 June 2018), WT/DS435/R (*Australia – Tobacco Plain Packaging*), para 7.2410.

17 *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000.

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

article 28, constitutes a limited exception to that article[18] and aligns with TRIPS' overall object and purpose.[19] Similarly the Panel in *Australia – Tobacco Plain Packaging* found Australia's Tobacco Plain Packaging Act to be compliant with TRIPS.[20] The Panel agreed that public health is a recognized societal interest under TRIPS article 8(1), which may justify an otherwise prohibited encumbrance on the use of a trademark, contrary to the obligation under TRIPS article 20 against this.[21] The Panel's analysis preceding this conclusion followed the same holistic pattern.

On the other hand, it remains inconclusive whether a WTO member taking exceptional measures must also comply with a "necessity test". In *Australia – Tobacco Plain Packaging*, Honduras and the Dominican Republic asked the AB to overrule the Panel's decision that Australia did not need to meet a necessity test.[22] In agreeing with the Panel, the AB ruled that a measure need not be necessary in the sense of there being no alternatives which are less encumbering – a yardstick used when applying this test within a context of the General Agreement on Tariffs and Trade.[23] The AB explained further that the question of whether a necessity test applies should be determined on a case-by-case basis, and held in this case that such application was not required considering that TRIPS' drafters had used the word "unjustifiably", not "unnecessarily", in article 20.[24] Therefore the circumstances in which the Panel will apply a "necessity test" to analysing the TRIPS compliance of a national implementation approach remain to be seen.

The proposed EAC approach for TRIPS implementation

This section is a comparative critique of the implementation options recommended under the EACPoF. A comparative approach allows for the EAC recommendations to be benchmarked against prevalent implementation approaches elsewhere.

Transition period

Section 2(1) EACPoF provides that "all Partner States qualified … as Least-Developed Countries shall exclude from patent protection pharmaceutical products and processes until January 1, 2016 or until the expiry of such later period of extension". This provision implements TRIPS article 66(1), which exempts least-developed countries (LDCs) from applying the provisions of TRIPS, "other than Articles 3, 4 and 5", for a period of ten years and for such other period as may be approved by the Council for TRIPS (I will refer to this as the "general exemption"). The provision is also based on the Doha Declaration, paragraph 7, which proposes the institutionalization of a parallel exemption regime for LDCs on pharmaceutical products until 1 January 2016 (I will refer to this as the "pharmaceutical exemption"). The pharmaceutical exemption exempts LDCs from the obligations to protect pharmaceutical patents under section 5 and undisclosed information under section 7 of TRIPS.[25] Finally, the EACPoF provision implements the Decision of the Council for TRIPS of 27 June 2002 which formalizes the pharmaceutical exemption.[26]

18 See TRIPS, art 30.

19 *Canada – Patent Protection*, above at note 17 at 151–69.

20 *Australia – Tobacco Plain Packaging*, above at note 16; Tobacco Plain Packaging Act 2011 (Cth).

21 *Australia – Tobacco Plain Packaging*, above at note 16, paras 7.2402–7.2405.

22 See Appellate Body Report (9 June 2020), WT/DS/435/AB/AR, WT/DS/441/AB/R, paras 6.653–6.655.

23 Ibid; see generally General Agreement on Tariffs and Trade (GATT) 1994, art XX(d); C Henckels "The ostensible 'flexibilities' in TRIPS: Can essential pharmaceuticals be excluded from patentability in public health crises?" (2006) 32/2 *Monash University Law Review* 335; D Mitchell and T Samlidis "The implications of WTO plain packaging disputes for public health measures" (2021) 70 *International and Comparative Law Quarterly* 1011; G Wilkinson "Tobacco plain packaging, human rights and the object and purpose of international trade mark protection" in S Frankel (ed) *The Object and Purpose of Intellectual Property* (2019, Edward Elgar Publishing) 182.

24 Appellate Body Report, above at note 22, para 6.653.

25 Doha Declaration, para 7.

26 Extension of the transition period under article 66.1 of the TRIPS Agreement for least-developed country members for certain obligations with respect to pharmaceutical products, Decision of the Council for TRIPS of 27 June 2002 (IP/C/25).

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

Based on this provision, Uganda, Rwanda, Tanzania and Burundi, all LDCs, could rely on the pharmaceutical exemption to exclude patent protection for pharmaceutical products and processes until 2016 and to include provisions which would allow them to benefit from future extensions.[27] The latter part of this recommendation is particularly pertinent given that the Council for TRIPS has so far extended the general exemption three times: from 1 January 2006 to 1 July 2013, from 2013 to 1 July 2021, and from 2021 to 1 July 2034.[28] The pharmaceutical exemption has also been extended once, from 1 January 2016 to 1 January 2033.[29]

The EACPoF also recommends the exclusion of patent protection for pharmaceutical processes. The authors of the *Resource Book on TRIPS and Development* have contended that this approach is inconsistent with TRIPS, a suggestion based on the premise that the Doha Declaration only refers to "pharmaceutical products".[30] Rejecting this view, Abbott argues that the term "pharmaceutical product" as used in these documents should be construed as covering process patents issued in respect of pharmaceutical products.[31] Abbott's view is logical, especially when considered against the background that produced the Doha Declaration, which became necessary to clarify the role of TRIPS and the extent to which WTO members could use flexibilities related to public health. This being the case, it is probable that members were more concerned with measures that would increase access to medical products – the final outputs of patented pharmaceutical inventions – than a nuanced distinction between pharmaceutical products and processes.

Section 2 EACPoF also recommends that LDC partner states who had earlier enacted a "mailbox" system should abolish it.[32] TRIPS article 70(8)(a) creates the obligation to accept "mailbox" applications – an obligation imposed on members whose laws did not offer patent protection to pharmaceutical and agricultural chemical products when TRIPS entered into force. This recommendation raises two questions: Are LDCs exempted from the mailbox obligations? And is it consistent with TRIPS to roll back obligations which are already implemented? On the first question, one view is that LDCs are not exempted from the mailbox obligation.[33] In this view, the pharmaceutical exemption recognized under the Doha Declaration, and subsequently affirmed in Council decisions, only applies to pharmaceutical products and undisclosed information.[34] If it were intended to exempt the mailbox obligation, proponents argue, it would have been clearly so worded.[35] It is further argued that when the Council intended to temporarily exempt LDCs from providing five years' exclusive marketing rights to owners of mailbox applications, a decision was expressly adopted, in July 2002.[36]

A counterargument favouring the EAC approach is that the general exemption under TRIPS article 66(1) is broad enough to accommodate an exemption from the mailbox obligation, since LDCs

27 Protocol, sec 2(1).

28 Extension of the transition period under article 66.1 for least-developed country members, Decision of 29 November 2005 (IP/C/40); Extension of the transition period under article 66.1 for least-developed country members, Decision of 11 June 2013 (IP/C/64); World Trade Organization "WTO members agree to extend TRIPS transition period for LDCs until 1 July 2034", available at: <https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm> (last accessed 15 November 2023).

29 Extension of the transition period under article 66.1 of the TRIPS Agreement for least-developed country members for certain obligations with respect to pharmaceutical products, Decision of 6 November 2015 (IP/C/73).

30 Decision of 27 June 2002, above at note 26; see also United Nations Conference on Trade and Development and International Centre for Trade and Sustainable Development (UNCTAD), *Resource Book on TRIPS and Development* (2005, Cambridge University Press) at 720.

31 FM Abbott "The Doha Declaration on the TRIPS Agreement and public health: Lighting a dark corner at the WTO" (2002) 5/2 *Journal of International Economic Law* 469 at 504.

32 Protocol, sec 2(2).

33 UNCTAD, *Resource Book*, above at note 30 at 723.

34 Decision of 27 June 2002, above at note 26; see also Abbott "The Doha Declaration", above at note 31 at 502.

35 UNCTAD, *Resource Book*, above at note 30 at 719.

36 Least-Developed Country Members – Obligations under Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products, Decision of 8 July 2002 (WT/L/478).

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

are only obligated to comply with articles 3, 4 and 5. A further rebuttal could be that the continuing nature of the exemptions to which LDCs are entitled is such that requiring them to fulfil a mailbox obligation is practically untenable. For instance, since TRIPS entered into force for LDCs in 2006, both the general and pharmaceutical exemptions have been extended and are open to further extensions. This being the case, patent applications "deposited" in mailboxes in LDCs since 2006, when that obligation first arose, may remain in the imaginary mailbox for as long as extensions are requested and granted.

On the roll-back question, an LDC rolls back its TRIPS obligations when it lowers the level of IP protection already enacted owing to an extension to the transition period. Relying on a paragraph from the 2005 extension of the general exemption, Abbott has mooted the possibility that allowing a roll back of obligations may breach TRIPS.[37] This paragraph states that LDCs "*will ensure* that any changes in their laws, regulations and practice made during the additional transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement" (emphasis added).[38] It is, however, arguable that by not using the modal verb "shall", which is associated with legal compulsoriness,[39] this provision is simply persuasive. More importantly, given that TRIPS clearly recognizes the rights of LDCs to use flexibilities to the extent legally permissible, it does not seem likely that the Council would derogate from these rights, using a decision. It is therefore not surprising that the 2013 Decision affirmed the rights of LDCs to use flexibilities in unmistakable terms.[40] For instance, while this Decision recognizes the progress LDC members had already made, "including in accordance with paragraph 5 of IP/C/40" and "their *determination* to preserve and continue the progress towards implementation of the TRIPS Agreement" (emphasis added), it equally acknowledges their right to make "full use of the flexibilities provided" under TRIPS.[41] This being the case, abolishing the mailbox obligation as recommended in the EACPoF will undoubtedly be consistent with TRIPS.

Patentability criteria

TRIPS article 27(1) establishes members' obligation to offer patent protection to inventions which meet the tripartite requirements of novelty, inventiveness and industrial application. TRIPS also concedes to its signatories the discretion to determine what inventions should be deemed "patentable subject matters". Because both the criteria and scope of patentable subject matters are not defined, WTO members have commonly invoked them as flexibilities whenever necessary.

Another noticeable practice is how members have responded differently when approximating the "patentable subject matter" obligation. An examination of existing responses reveals two broad approaches. Under the first approach, members proceed from the assumption that a subject matter is eligible for a patent if it complies with the tripartite test (novelty, inventiveness and industrial applicability), does not fall under TRIPS-type exclusions, and / or is not expressly excluded by national patent laws.[42] The EPC countries and India are examples of members using this approach.[43] Under the second approach, members adopt a broad definition of patent eligibility, leaving it to the judiciary to determine the specific question of whether the subject matter of a challenged patent or patent application satisfies this definition. The US uses this approach: an invention is only patentable if it is one of process, machine, manufacture or composition of matter, or if it falls

37 FM Abbott "Technical Note: The LDC TRIPS transition extension and the question of rollback" (International Centre for Trade and Sustainable Development policy brief no 15/2013, 2013).

38 Decision of 29 November 2005, above at note 28, para 5.

39 See D Pearce, *Statutory Interpretation in Australia* (9th ed, 2019, Lexis Nexis Australia).

40 Decision of 11 June 2013, above at note 28.

41 Ibid.

42 See TRIPS, art 27(2)–(3).

43 See the Convention on the Grant of European Patents 1977, arts 52–53; Patents Act (India), secs 2–3.

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

within the judicial exceptions.[44] The EACPoF recommends the first approach: patent eligibility depends on whether a proposed subject matter satisfies the tripartite criteria and is not expressly excluded from patentability.[45] This, according to the EAC, is to ensure "that EAC Partner States have enough policy space for public health purposes".[46] Specific recommendations on each criterion are fully explored below.

Novelty

The EAC Protocol provides that:

> "All Partner States shall provide for and apply a strict novelty requirement through considering a wide concept of prior art, including everything disclosed to the public whether by use, in written or oral form … which are published anywhere in the world and which can be accessed by the general public."[47]

This proposition is undoubtedly pro-access, as it enriches the public domain and ensures that only quality inventions are rewarded by patent monopoly. The proposed construction also aligns with the prevalent construction in leading WTO members. For instance, under the EPC, "novelty" is assessed against worldwide prior arts, including written publications, oral descriptions, uses and contents of yet-to-be-published patent applications.[48] The United Kingdom, Japan, Canada and India are other examples.[49] Until recently, the US used to be an outlier in this area because it limited novelty to US prior arts.[50] This, however, is no longer the case, as the America Invents Act now requires that inventions be assessed against worldwide prior arts.[51]

Inventive step

Inventive step – also known as non-obviousness – is used to assess whether an improvement asserted in a patent application is substantial enough to justify granting the patent.[52] It plays an important role by filtering out low-quality inventions, thereby reducing the number of granted monopolies. Assessing an invention for inventiveness involves a highly technical and difficult process; hence Cornish's observation that determining the inventiveness criterion is "the largest single cause of uncertainty about the validity of patents".[53]

There seems to be substantial unanimity among WTO members – the majority of whom favour a high standard – on the construction of the inventiveness requirement. The EPC, for instance, favours a problem–solution approach. This requires, first, that an examiner determines the prior

44 See Patent Act 1952, 35 USC, sec 101. For US judicial application of this provision, see *Diamond v Chakrabarty* [1980] 447 US 303; *Mayo Collaborative Services v Prometheus Laboratories, Inc* [2012] 566 US 66; *Bilski v Kappos* [2010] 561 US 593; *Association for Molecular Pathology v Myriad Genetics, Inc* [2013] 569 US 576; R Dreyfuss, J Nielsen and D Nicol "Patenting nature: A comparative perspective" (2018) *Journal of Law and the Biosciences* 1; J Cockbain and S Sterckx "Are natural products and medical diagnostic tests still eligible for patents in the USA?" (2012) 1/4 *Pharmaceutical Patent Analyst* 365 at 367.

45 EACPoF at 12–14.

46 Id at 13.

47 Protocol, sec 5(1).

48 EPC, art 64.

49 See Patents Act (UK) 1977, sec 2; Patent Act (Japan) 1959, art 29(1); Patent Act (Canada), RSC 1985, c P-4, sec 28(2); Patents Act (India), sec 2(1)(l).

50 "Novelty" used to be assessed against public knowledge or use of the invention in the US; the offer for sale or sale of the invention in the US; a description of the invention in another patent application with earlier priority date in the US; and a description of the invention in a printed publication or patent anywhere in the world.

51 35 USC, sec 102(a).

52 See generally AL Landers "A comparative approach to the inventive step" in T Takenaka (ed) *Research Handbook on Patent Law and Theory* (2019, Edward Elgar Publishing) 454.

53 WR Cornish *Intellectual Property* (3rd ed, 1996, Sweet & Maxwell) 163.

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

art(s) closest to the claimed invention; second, they objectively frame a technical problem from the closest prior art(s); and finally, they determine whether, provided with the ascertained prior arts and the framed technical problem, the claimed invention would be obvious to a person ordinarily skilled in the art.[54] An examiner must also ascertain the common general knowledge (CGK), that is, the average knowledge of a skilled person in the field of the technology.[55] The scope of prior art for this purpose is worldwide, and CGK is assessed internationally. The "person skilled in the art" is defined as a person of "average knowledge and ability" who can do "routine work and experimentation".[56] Finally, the EPC strictly applies other secondary indicia, such as unexpected technical effect, long-felt need and commercial success, to ensure that only quality patents are granted.

However, while the EPC has been rightly dubbed "tougher on inventive step",[57] other WTO members have recently also increased their inventiveness standard. In the US, for example, the traditional test for obviousness was outlined in *Graham v John Deere*, where the overall question was whether a claimed invention would be obvious to an averagely skilled person in light of the teaching, suggestions and motivations (TSM) disclosed in prior arts before the filing date.[58] Cotter opines that this standard was so low that many of the patents granted by the United States Patent and Trademarks Office (USPTO) and the courts were of low quality.[59] This, however, changed in *KSR International Co v Teleflex Inc* (a case dealing with a combination patent, where each element of the combination was available in prior arts), where the Court of Appeal for the Federal Circuit (CAFC) held that "the art did not teach, suggest, or motivate the combination because none of it was intended to solve the precise problem the inventor had attempted to solve".[60] The US Supreme Court overturned this decision, holding, among other things, that the USPTO and the CAFC should avoid an overly rigid and formalistic approach to applying the TSM test to the obviousness enquiry.[61] The Court then raised the level of CGK expected of a person skilled in the art: s/he was not to be seen as an "automation", but as a person of "ordinary creativity" with the capacity to try to solve problems by combining multiple prior art documents.[62] *KSR* has therefore raised the US obviousness standard to that of inventive step in Europe.

The foregoing discussion reveals that any inventiveness enquiry will not be complete without providing for important elements such as the scope of prior arts, CGK, a person skilled in the art, combination of prior art references and other relevant secondary indices. Members are also free to define each of these elements in accordance with their national interests. To return to the EAC, the Protocol provides that "[i]n the context of the inventive step requirement, all Partner States shall provide that the non-obviousness of an invention shall be determined on the basis of a person who is highly skilled in the art".[63] While this recommendation seems broad, it is, however, silent on salient elements, including how prior arts or CGK should be defined or how combination patents should be handled. One probable explanation may be that the EAC prefers this approach because it allows partner states to fill in requisite details in national inventive step guidelines. The danger in this, though, is that it may defeat the rationale behind having a regional approach

54 Guidelines for Examination in the European Patent Office, November 2019, part G, chap VII.

55 Ibid.

56 Ibid.

57 J Brunner et al "The patentability criteria for inventive step / non-obviousness" (International Association for the Protection of Intellectual Property (UK National Group) working guidelines Q217, 2011) 3.

58 The test for obviousness is summarized thus: first, determine the scope and content of the prior art; second, ascertain the differences between the claimed invention and the prior arts; and third, resolve the level of ordinary skill in the pertinent arts. *Graham v John Deere* [1966] 383 US 1, 148.

59 See TF Cotter *Patent Wars: How Patents Impact Our Daily Lives* (2018, Oxford University Press) at 31–32.

60 Id at 33; see also *KSR International Co v Teleflex Inc* [2007] 228 F App'x 988 (Fed Cir Jun 20, 2007).

61 *KSR International Co v Teleflex Inc* [2007] 550 US 398, 404.

62 Id at 420–21; see generally Manual of Patent Examining Procedure: 2141 Examination Guidelines for Determining Obviousness under 35 USC 103 [R-10 2019].

63 Protocol, sec 5(2).

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in the first instance. According to the EAC, a regional approach is intended to create sufficient policy space for public health purposes.[64] Such a goal can only be achieved when all partner states subscribe to a high standard of inventive step. Without these essential details, there will be nothing to compel partner states to, for instance, assess inventive step against worldwide prior arts, apply what is worldwide CGK for testing what a person skilled in the art should know, or rightly define a person skilled in the art.

More importantly, the EAC recommends that inventiveness should "be determined on the basis of a person … *highly skilled* in the art".[65] Although the section is silent on who this imaginary person is, one can surmise that it is intended to set a high standard, which will invariably make granting of patents difficult. The problem with this standard, though, is that it is unrealistic. As indicated in the jurisdictions considered above, particularly in India, a skilled person has always been defined as a person of "ordinary" skill who is devoid of extraordinary inventive capacity.[66] This approach is recommended because it mirrors the reality that persons with inventive capacity in any field are not the rule but the exception. This being the case, it is more realistic to assess the obviousness of an invention using the standard of an averagely skilled person. Moreover, experience from other jurisdictions shows that the requirement of inventiveness is a peculiar one because its interpretation is significantly influenced by judicial subjectivity. Hence, a standard is not high simply because a statute provides so; it is high because the court interprets it as such.[67] The EAC should avoid complicating this test and should simply follow the common practice of using a notional person of average skill.

Industrial application

TRIPS also requires that an invention be capable of industrial application; some national laws (e.g. the US) adopt the term "usefulness" or "utility". As the practices in some jurisdictions show, the rationale for this requirement is to distinguish between useful arts used within industry, and fine or aesthetic arts.[68] The relevant EAC provision states: "All Partner States shall strictly apply the industrial application requirement."[69] The EAC specifically recommends that partner states could draw inspiration from either the USPTO Guidelines or European Patent Office (EPO) jurisprudence.[70]

Generally, three implementation approaches are discernible. The first approach adopts TRIPS' language of "industrial application", providing, for instance, that the requirement is met if an invention can be "made or used in any kind of industry, including agriculture".[71] "Industry" is broadly construed and encapsulates physical activity of a "technical character".[72] However, an invention need not involve the use of a machine or lead to the actual manufacture of a product to fulfil "technical character" and, by extension, the industrial application requirement.[73] This approach, which is adopted under the EPC Guidelines, has been adopted by other WTO members, including India,[74] and is claimed to be the strictest.[75]

64 EACPoF at 13.
65 Protocol, sec 5(2).
66 In India, such a person is presumed to have average skill and be capable of completing routine work and experimentation: see Guidelines for Examination of Patent Application in the Field of Pharmaceuticals, October 2014, para 8.6.
67 Lai demonstrates the subjective role of the court in interpreting and applying the inventive step principle; see J Lai "Validity of obviousness in the patent process: A case study of *Aktiebolaget* (LOSEC)" (2007) 38 *Victoria University of Wellington Law Review* 603.
68 See EPC Guidelines, para G.III.1; India Guidelines for Patent Examination, para 9.1.
69 Protocol, sec 5(3).
70 EACPoF at 13.
71 TRIPS, art 27(1).
72 EPC Guidelines, para G.III.1.
73 Ibid.
74 India Guidelines, above at note 68, para 9.1.
75 UNCTAD, *Resource Book*, above at note 30 at 361.

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The US represents a second approach, which simply requires that an invention be useful.[76] Until recently, this approach had been criticized for its low threshold, resulting in the patentability "of purely experimental inventions that cannot be made or used in an industry, or that do not produce a so-called technical effect".[77] However, similar to its recent responses to enquiries on novelty and obviousness, the US has raised the bar of its "usefulness" requirement to the equivalent of what is obtainable under the EPC.[78] As its latest guidelines show, to be patentable, an invention must assert specific and substantial utility which is credible: specific in the sense that it is not generic, and substantial in the sense that adequate information has been disclosed at the filing date to allow an ordinarily skilled person to use the invention in its expressed form.[79] Furthermore, where several utilities are asserted, it is sufficient that only one of them is specific, substantial and credible. As such, the "usefulness" requirement in the US is now construed as "practical utility", "substantial utility", "specific utility" or "real world use", failing which an invention will be deemed unpatentable.[80]

Last is the utility-linked "promise of the patent" or "the promise doctrine" approach, formerly in use in Canada. To be patentable in Canada, an invention must have utility, a requirement assessed by examining the whole patent document to ascertain if the applicant has made a promise of what the invention could do.[81] Where an applicant has not expressly made a promise of utility, a patent will be issued if a scintilla of utility, that is, any use at all, can be established from reading the patent document. This accords with the practice in other jurisdictions, including the US, the EPC countries and India.[82] However, where promise(s) is / are expressly made or could be deduced from a holistic reading of the patent documents, a patent will only have utility if this / these promise(s) is / are fulfilled or can be soundly predicted at the filing date.[83] The problem here is that where an application asserts multiple uses or makes multiple promises, a patent will not be issued unless all asserted promises are fulfilled or soundly predicted.[84] This latter test led to the refusal and invalidation of several patents in the past and was extolled by advocates for access to medicines as the best.[85] The Canadian Supreme Court, however, axed the "promise of the patent" doctrine in *AstraZeneca Canada Inc v Apotex Inc*, where it held that showing a scintilla of utility is all that is needed to satisfy the utility requirement.[86] This decision brings the Canadian approach in line with the predominant approach of requiring practical or real-world utility.

The EACPoF recommends that "industrial application" be construed with guidance from the USPTO or the EPO Guidelines.[87] As the discussion above shows, the construction of "industrial

76 35 USC, sec 101.

77 UNCTAD, *Resource Book*, above at note 30 at 361.

78 See Manual of Patent Examining Procedure: 2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement [R-11 2013].

79 Ibid.

80 Ibid.

81 Canadian patent law requires that an invention be "useful": see Patent Act (Canada), above at note 49, sec 2; the "promise of the patent" doctrine is a creation of the courts, through construction over the years. See generally ER Gold and M Shortt "The promise of the patent in Canada and around the world" (2014) 30 *Canadian Intellectual Property Review* 35; C Ho "Should all drugs be patentable? A comparative perspective" (2015) 17/2 *Vanderbilt Journal of Entertainment and Technology Law* 295 at 327.

82 In these jurisdictions, proving any use will suffice, even if more uses were asserted.

83 See Gold and Shortt "The promise of the patent", above at note 81; Ho "Should all drugs", above at note 81.

84 Ibid.

85 See J Lechleiter "How lax patent rules in Canada are suffocating life-saving innovation", *Forbes*, available at: <https://www.forbes.com/sites/johnlechleiter/2013/08/26/how-lax-patent-rules-in-canada-are-suffocating-life-saving-innovation/> (last accessed 1 November 2023).

86 *AstraZeneca Canada Inc v Apotex Inc* [2017] SCC 36; see also E Crowne "Promises not kept: Supreme Court of Canada abandons promise doctrine" (2017) 12/10 *Journal of Intellectual Property Law and Practice* 816.

87 EACPoF at 13.

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applications" under these guidelines (as well as in Canada) now favours "practical utility"; hence, EAC partner states can model their interpretation on any of the three options.

Exclusion from patentability

TRIPS defers to members on excludable subject matters while listing examples of what could be excluded.[88] In implementing this obligation, members seem to favour one of two approaches: a statutory approach or a judicial approach. A statutory approach exhaustively outlines excluded subject matters in patent statutes, compared to a judicial approach where the judiciary controls which subject matters are excludable. The EPC provides an example of a statutory approach, listing excluded subject matters as including discoveries, scientific theories, mathematical methods, aesthetic creations and presentation of information.[89] It then complements these with TRIPS-type exclusions.[90] The US, on the other hand, exemplifies a judicial approach, meaning the authority over what subject matter fails the "process, machine, manufacture, or composition of matter, or any improvement thereof" test of patentability is ceded to the judiciary.[91] In fact, while the US Supreme Court construed the patentability test in *Diamond v Chakrabarty* as meaning that "anything under the sun that is made by man" is patentable, it balanced this by underscoring its power to invoke judicial exceptions based on the laws of nature, natural phenomena and abstract ideas.[92]

Of course, both approaches have their pros and cons: the statutory approach may promote certainty, although being rigid may be its main bane; whereas the judicial approach may promote simplicity and flexibility, but inventors may frown at not knowing beforehand which subject matters are excluded. This notwithstanding, evidence from jurisdictions where the two approaches are used shows that less confusion is associated with a statutory approach – the EPC countries, for example.[93] In contrast, applying the judicial approach could be more problematic, as experience from the US reveals.[94]

At the EAC level, the region has indicated preference for a statutory approach; partner states are advised to exclude from patentability natural substances (even if purified or isolated), new medical uses of known substances, and derivatives of known medical substances.[95] It further recommends that the processes for isolating or purifying natural substances remain patentable, that where new medical uses are considered for protection as processes, patentability requirements should be strictly applied to them, and that derivatives of known medical substances should only be patentable if "they show a significantly enhanced therapeutic efficacy or other significant superior properties".[96] Scholars have rightly cautioned against a total exclusion of nature-based inventions from patentability (as the EAC has done here), citing its potential effects on innovation in life sciences and related fields.[97] However, the EAC approach is better understood against the background of its R&D

88 TRIPS, art 27(2)–(3).
89 EPC, art 52(2).
90 Id, art 53. India excludes 16 subject matters: see Patents Act (India), sec 3.
91 35 USC, sec 101.
92 *Diamond*, above at note 44 at 309.
93 The German apex court held that a product of nature is patentable in Europe once it is isolated or purified; this is unlike the confusing approach adopted in the US. See *Receptor Tyrosine Kinase*, X ZR 141/13 (Bundesgerichtshof 2016); D Nicol et al "International divergence in gene patenting" (2019) 20 *Annual Review of Genomics and Human Genetics* 519; Cockbain and Sterckx "Are natural products", above at note 44 at 367.
94 In the US, this uncertainty has led to calls for the revision of patent eligibility requirements; see generally DO Taylor "The crisis of patent eligibility in America" (2019) 4 *Criterion Journal on Innovation* 733; A Mossoff "Congress should reform patent eligibility doctrine to preserve the US innovation economy" (Edwin Meese Center for Legal & Judicial Studies legal memorandum no 257, 8 January 2020).
95 Protocol, sec 4.
96 Ibid.
97 See Dreyfus, Nielsen and Nicol "Patenting nature", above at note 44 at 3.

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capability and its quest to bridge the technology gap using recognized flexibilities.[98] To this end, excluding product patents for natural substances may be adjudged a step in the right direction. Nevertheless, the EAC recommendations could improve. Given that the essence of adopting a regional approach is to facilitate harmonized incorporation and use of flexibilities, it is surprising that this recommendation fails to bear this rationale out. For instance, section 4 of the Protocol provides that "[a]ll Partner States shall, *in addition to the subject matter already excluded under their national intellectual property laws*, exclude from patentability" (emphasis added). The emphasized provision suggests that partner states are permitted to adopt different approaches to excluded subject matters, thereby creating flexibilities within flexibilities. To promote a common front, partner states should consider incorporating the same set of exclusions, preferably including TRIPS-type exclusions.

The research exception

This exception derives legal imprimatur from TRIPS article 30 and could be implemented to strike the much-needed balance between incentivizing innovations and ensuring public access to patented technologies. To successfully deploy the exception, the three-steps test must be met, as extensively discussed in the Canadian case.[99] The EAC research exception has the following components: first, a patentee's right "shall not extend … to acts done relating to uses on the patented invention for technological or scientific research", whether such uses are intended for commercial purposes or not; second, commercial research uses are only exempted if their purpose is "the generation of new knowledge on the patented substance"; third, patents should only be granted to research tools for which specific uses have been identified; and fourth, a non-exclusive licensing system "shall" be established for patented research tools so that researchers who intend to use them are not prevented by patent rights.[100]

The EAC recommendations, though a limited exception on the right of a patentee, represent a broad interpretation of the research exception, considering that it exempts uses of patented articles for further research regardless of whether such uses have a commercial proclivity or not. This is similar to the prevalent approach among EPC countries, where a distinction is drawn between research activities carried out *on* and those carried out *with* patented subject matters: activities relating to the former are exempted, while those relating to the latter are not.[101] A researcher will *research on* a patented invention if the purpose of their research is to resolve questions or obtain further information about the invention with the intention of improving it.[102] Conversely, this exception will not apply if a researcher simply uses patented subject matter (research tools such as laboratory equipment, antibodies and chemical reagents) in the process of furthering their own research. In this case, once the aim of the research is not to improve the research tools, it does not matter that the researcher is using the tools to achieve novel outcomes in other fields. The EPC approach (which is the same as the EAC recommendations) also considers the economic or commercial background of the research immaterial.

The EAC and EPC approach can be contrasted with the very narrow approach in the US, as established in Justice Story's pronouncement that research on patented articles would only be

98 EACPoF.

99 *Canada – Patent Protection*, above at note 17.

100 Protocol, sec 7(1).

101 See Patent Act 1980 (Germany), sec 11(2); Patents Act (UK), above at note 49, sec 60(5)(b); Intellectual Property Code (France), art L 613-5; Law No 24/2015 on Patents (Spain), art 61(1)(b); Code of Industrial Property Decree No 30 of 2005 (Italy), art 68; Kingdom Act of 15 December 1994 (Netherlands), art 53(3): see generally H Jaenichen and J Pitz "Research exemption / experimental use in the European Union: Patents do not block progress of science" (2015) 5/2 *Cold Spring Harbor Perspectives in Medicine* a020941.

102 Ibid.

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exempted if done "merely for philosophical experiments, or for the purpose of ascertaining the sufficiency" of the patented article to "produce its described effects".[103] Other cases have elucidated on this narrow scope, making it clear that any claim to research exception will fail if the most minute commercial intention may be ascribed to the research.[104] *Madey v Duke University* underscores the narrow scope of this exception: it involved an academic institution which used a former employee's patented laboratory equipment.[105] In response to an infringement action, the university pleaded the research exception, contending that it did not engage in research for primarily commercial purposes. In its decision, the CAFC held that:

> "regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and *is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry*, the act does not qualify for the very narrow and strictly limited experimental use defense."[106]

Given how restrictive the US approach is, the EAC has opted for the right approach, fashioned mainly on that of the EPC, in addition to a requirement that a non-exclusive licensing regime be instituted for patented research tools.

The Bolar exception

The Bolar exception is another exception based on TRIPS article 30 which excuses otherwise infringing acts exerted on a patented invention insofar as such acts are in connection with obtaining marketing approval for patented pharmaceutical products.[107] The name "Bolar" derives from a US case, *Roche Products Inc v Bolar Pharmaceutical Co, Inc*, unsuccessfully argued on the basis of a research exception,[108] but which later propelled the enactment of the Drug Price Competition and Patent Term Restoration Act (the Hatch-Waxman Act).[109] This Act exempts infringing acts carried out on patented articles either within the US or imported into the US, provided that the article is "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products".[110] Unlike the research exception, the Bolar exception has been broadly construed by the US courts to exempt infringement of patents on pharmaceuticals, medical devices and products from patented processes and methods.[111] This exception has also been found to comply with TRIPS.[112]

Broader construction of this exception can also be found among other WTO members – e.g. Germany, the UK, France, Italy and Spain do not limit the scope of the exception to generics alone (it applies to pharmaceuticals generally),[113] and the exception applies to cover uses within

103 *Whittemore v Cutter* [1813] 29 Fed Cas 1120 (CCD Mass).

104 *Sawin v Guild* [1913] 21 Fed Cas 554 (CCD Mass); *Roche Products, Inc v Bolar Pharmaceutical Co, Inc* [1984] 221 USPQ 937 (Fed Cir); *Pfizer Inc v International Rectifier Corps* [1982] 217 USPQ (CD Cal); *Embrex, Inc v Service Engineering Corp* [2000] 216 F 3d 1343 (Fed Cir).

105 *Madey v Duke University* [2002] 307 F 3d 1351 (Fed Cir).

106 Id at 1362, emphasis added.

107 CM Correa "The Bolar exception: Legislative models and drafting options" (South Centre Research Paper No 66, March 2016); Jaenichen and Pitz "Research exemption", above at note 101.

108 *Roche Products Inc*, above at note 104; see G Fox "*Integra v Merck:* Limiting the scope of the S 271(E)(1) exception to patent infringement" (2004) 19/1 *Berkeley Technology Law Journal* 193.

109 See 21 USC, sec 355 and 35 USC, sec 156.

110 35 USC, sec 271(e)(1).

111 *Eli Lilly & Co v Medtronic, Inc* [1990] 496 US 661; *Amgen, Inc v International Trade Commission* [2008] 519 F 3d 1343 (Fed Cir).

112 *Canada – Patent Protection*, above at note 17.

113 Patent Act (Germany), above at note 101, sec 11(2)(b); Patents Act (UK), above at note 49, sec 60(5)(i); Intellectual Property Code (France), art L 613-5(b), above at note 101 (it is unclear if this exception applies outside the EU); Italian Code of Industrial Property, art 68; Spanish Law on Patents, above at note 101, art 61(1)(c).

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the EU and abroad.[114] The construction favoured by the EAC is broader than those adopted in these jurisdictions. According to the Protocol:

> "All Partner States shall provide that it is not an infringement … to make, use, construct, sell or offer to sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of the particular Partner State or any other country that regulates the manufacture, construction, use or sale of *any product*."[115]

As this provision shows, the EAC approach additionally exempts from infringement cases where patented products are exported from the EAC to another country for the purpose of obtaining regulatory approval in that country. A combined decision of the Delhi High Court illustrates how this may apply in practice. In one of two cases, Bayer sought a mandamus against Natco, a generic firm, to restrain it from exporting its product sorafenib tosylate to China; in the second case, Bayer requested that the court stop Alembic, another generic firm, from exporting its product rivaroxaban to Europe.[116] Both firms raised the Bolar exception under section 107A of Indian patent law, arguing that the recipient (importing) firms needed the drugs for testing related to obtaining marketing approval. Bayer counterargued that the exception did not apply, because, among other things, neither Natco nor Alembic required the exported drugs for marketing approval. The High Court, however, applied the exception.[117]

This broad construction will particularly benefit the EAC, as obtaining marketing approval before the expiry of a patent will be easier not only among EAC partner states, but also between individual partner states and countries outside the region.

Test-data protection

Though test data are not conventional IP, TRIPS enjoins WTO members to protect them against "unfair commercial use" if they are "undisclosed"; if it takes "considerable effort" to generate them; if their submission is mandatorily required to obtain marketing approval; and if marketing approval applications relate to pharmaceutical and agricultural chemical products which "utilize new chemical entities".[118] Disclosure of test data is, however, permissible where it is "necessary to protect the public" or where other measures to protect the data against unfair commercial use have been instituted. Members can find additional flexibility in this provision because of the non-definition of terms like "unfair commercial use" and "new chemical entities".[119] The two common implementation options are the misappropriation and data-exclusivity regimes. A misappropriation regime prohibits regulatory agencies from disclosing originators' test-data information, which is submitted to them as a requirement for obtaining marketing approval for pharmaceutical products,

114 See Jaenichen and Pitz "Research exemption", above at note 101.

115 Protocol, sec 7(2), emphasis added.

116 See *Bayer Corporation v Union of India and Others*, LPA no 359/2017, and *Bayer Intellectual Property GmbH and Another v Alembic Pharmaceuticals Ltd* [2019] RFA(OS) (COMM) 6/2017 (22 March).

117 See SK Rathod "The curious case of India's Bolar provision" (2018) 14/1 *Journal of Generic Medicines* 16.

118 TRIPS, art 39(3).

119 For instance, Andanda and Correa advocate for a strict construction of "new" which excludes mere modifications to known chemical entities and that "unfair commercial use" be construed to allow reliance on test data; see P Andanda "Managing intellectual property rights over clinical trial data to promote access and benefit sharing in public health" (2013) 44 *International Review of Intellectual Property & Competition Law* 140; Correa "The Bolar exception", above at note 107 at 17, 25–28. Skillington and Solovy, along with Gervais, advocate for the other option: G Skillington and E Solovy "The protection of test and other data required by article 39.3 of the TRIPS Agreement" (2003) 24 *Northwestern Journal of International Law & Business* 1 at 26; D Gervais *The TRIPS Agreement: Drafting History and Analysis* (4th ed, 2012, Sweet & Maxwell) at 544–55.

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to generic competitors.[120] This approach, however, does not preclude regulatory agencies from *relying* on submitted data to affirm generic competitors' claims to bioequivalence.[121] Skillington and Solovy, along with Gervais, have contended that this approach is inconsistent with TRIPS because it constitutes "unfair commercial practice" against originators of test data who invested heavily in generating these data.[122] But since TRIPS does not define the phrase "unfair commercial use", TRIPS compliance may be argued based on the fact that the approach permits regulatory agencies to rely on submitted data for verification purposes only, so that where a generic application fails the verification process, approval is denied and the test data with the regulatory agencies remain undisclosed, as TRIPS requires.[123] India adopts a misappropriation regime.[124]

A data-exclusivity regime, on the other hand, confers a monopoly right on an originator of test data to control whether, and how, the data may be accessed during the monopoly period.[125] Two variants are identifiable: one totally precludes reliance on the test data until after the expiration of the exclusivity period, while the other allows reliance throughout this period subject to payment of licensing fees.[126] The US and EPC countries enact a data-exclusivity regime. In the US, test data relating to new chemical entities are protected for five years, while those relating to new clinical information are only protected for three years.[127] Among the EPC countries, test data relating to new medicinal products enjoy ten years' exclusivity.[128] Though applications for generic approval may be submitted after the eighth year, the products thereafter can only be marketed after an additional two years of market exclusivity; in case a new use is later found, another one year of exclusivity is granted.[129] This is known as the 8+2+1 rule.[130]

The EAC opts for the misappropriation regime: partner states are to protect test data against "unfair commercial use and disclosure".[131] Even though the Protocol does not define this, it clearly permits regulatory agencies in the region to rely on submitted test data to verify bioequivalence claims in generic applications.[132] Going a step further, the EAC provides that partner states shall not consider the patent status of a drug in respect of which marketing approval is sought.[133] It is especially laudable that the EACPoF expressly recommends that partner states exclude patent linkage.

120 See W Armouti and M Nsour "Test data protection: Different approaches and implementation in pharmaceuticals" (2016) 20/2 *Marquette Intellectual Property Law Review* 267 at 269–70; J Reichman "Rethinking the role of clinical trial data in international intellectual property law: The case for a public goods approach" (2009) 13/1 *Marquette Intellectual Property Law Review* 1 at 10–13.

121 Ibid.

122 Skillington and Solovy "The protection of test and other data", above at note 119; Gervais, *The TRIPS Agreement*, above at note 119.

123 Ibid.

124 A Sharma "Data exclusivity with regard to clinical data" (2007) 3 *The Indian Journal of Law and Technology* 82 at 96–97.

125 Armouti and Nsour "Test data protection", above at note 120 at 276–83; Reichman "Rethinking the role", above at note 120.

126 Ibid.

127 See the Hatch-Waxman Act, 35 USC, sec 156, above at note 109.

128 Council Directive 2001/83/EC on the Community Code relating to medicinal products for human use [2002] OJ L 311/67; Council Regulation (EC) 726/2004 laying down Community procedure for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European medicines Agency [2004] OJ L 136, art 14(11).

129 Ibid.

130 See Armouti and Nsour "Test data protection", above at note 120 at 287–89.

131 Protocol, sec 12(1).

132 Id, sec 12(2).

133 Id, sec 12(3).

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Disclosure requirement

Disclosure requirement distinguishes between patented inventions and inventions protected as trade secrets: secrecy is the hallmark of the latter, full disclosure that of the former.[134] WTO members also have the option of requiring that a patent applicant indicates the best mode known to them at filing or priority date.[135] To implement this obligation, the EAC Protocol provides that "[a]ll Partner States shall require patent applicants to disclose *all modes* and *expressly indicate the best mode* for carrying out an invention" (emphasis added).[136] On the extent of disclosure required, the Protocol continues: "Partner States shall determine the level of required disclosure on the basis of the relevant expertise" in their domain. Two observations may be made here. First, neither the first part ("all modes") nor the latter ("best mode") directly addresses the core obligation of "sufficient and clear" disclosure required under TRIPS. Second, the EAC approach appears to muddle up the nuanced difference between a "sufficiently clear and complete" disclosure and the optional requirement to indicate a "best mode". The former focuses on the crucial question of whether the information disclosed in the patent specification is elaborate enough to allow a person skilled in the particular art to make a product from the proposed invention. Meanwhile, in the latter case, there is a presumption that the promised invention will work and that there is more than one method of working it. Thus "sufficient and clear" disclosure is not synonymous with "best mode" as the EAC approach seems to suggest.

Another challenge with this approach is that it emphasizes the disclosure of "all modes" and the indication of the "best mode" on the assumption that doing so will provide an additional ground for invalidating patents or for challenging pending applications.[137] While this approach could be seen as aligning with the overall EAC objective of broadening the public domain, the uncertainty surrounding the implementation of the "best mode" requirement calls for caution in practice. This is because determining what an applicant knew at a particular point in time will require a subjective analysis.[138] As such, even where an applicant has more than one mode of working an invention but chooses to disclose just one mode, which is not the best mode, the subjective nature of this test means that the court will be heavily reliant on how much of the information subjectively known to an applicant comes to light during discoveries.[139] Additionally, scholars such as Jacobs, Walmsley, Adamo and Robinson have rightly criticized the best mode requirement as it currently stands for not requiring disclosure of any better mode of working the invention which a patent applicant may discover after the patent filing date.[140]

The US and Australia are two jurisdictions exemplifying the probable uselessness of a "best mode" requirement. In the US, prior to the enactment of the America Invents Act, a patent could be invalidated for failure to disclose a best mode. However, the uncertainty surrounding this led to the removal of the requirement as a ground for invalidation under the Act.[141] The experience in Australia is no better; Gregg, for instance, decries how the practical application of

134 TRIPS, arts 29(1) and 39(2).

135 Ibid.

136 Protocol, sec 6(1).

137 See K Adamo "The best mode requirement in United States patent practice in 1993" (1993) 12 *John Marshall Journal of Computer & Information Law* 353; A Robinson "The American Invents Act and the best mode requirement: Where do we go from here?" (2012) 20/1 *Journal of Intellectual Property Law* 179; C Gregg "Making sense of the 'best method' mess" (2019) 117 *Intellectual Property Forum: Journal of the Intellectual and Industrial Property Society of Australia and New Zealand* 31.

138 Ibid.

139 Ibid.

140 A Jacobs "Best mode requirement: What the law is and what it should be" (1994) 16 *Houston Journal of International Law* 533, 537; S Walmsley "Best mode: A plea to repair or sacrifice this broken requirement of United States patent law" (2002) 9/1 *Michigan Telecommunications and Technology Law Review* 125; Adamo "The best mode requirement", above at note 137 at 356–57; Robinson "The American Invents Act", above at note 137 at 191–95.

141 Ibid.

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the best-method requirement in Australia has become a "mess", noting in particular that "the inherent difficulty in establishing the state of mind of the applicant … is undoubtedly why the APO [Australian Patent Office] rarely raises best method objections during examination".[142]

Based on the foregoing, the EAC should consider substituting this rather unworkable "best mode" approach with the simple option recommended by TRIPS, which is hinged on an applicant disclosing their invention in a sufficiently clear and complete manner as to enable a person skilled in the art to work it.

Opposition procedure

Opposition procedure is useful for bolstering patent quality and avoiding or reducing evergreening. It derives legitimacy from TRIPS article 62(4), which authorizes members to decide if an administrative *inter partes* procedure (e.g. opposition) is necessary. Countries have implemented this obligation using either or both of pre-grant and post-grant opposition procedures.[143] The US and EPC countries are examples of a post-grant approach, while both options are enacted in India. Like other flexibilities, how this is implemented is a function of national policy priorities. For instance, countries with vibrant R&D capability often deem a post-grant approach more appropriate for striking a balance between incentivizing innovation and sustaining public access to patented inventions. This option arguably favours patentees, as it allows them to immediately acquire the legal right required to bar generic competitors from unauthorized exploitation of their inventions.[144] It is further preferred because it avoids unnecessary delays, encourages inventors to innovate more and boosts economic development. In the US, opposition procedure takes the form of a post-grant review, which is available within nine months of a patent grant, and an *inter partes* review, which is available from nine months post-grant or after the conclusion of a post-grant review application.[145]

On the other hand, countries may adopt a pre-grant approach as a policy tool for broadening the public domain and weeding out low-quality patents. Unlike a post-grant approach, a pre-grant approach has the peculiar advantage of depriving patent applicants of the legal right to bar generic competitors from imitating or copying the contents of their patent applications. Thus, technically speaking, generic competitors may not be liable for infringement if they produce and stockpile articles using the inventions claimed in pending applications.[146] India has both pre-grant and post-grant oppositions: the former becomes available after publication of a patent application, while the latter must take place within 12 months after the grant.[147] The EAC recommends the Indian approach, suggesting that partner states make opposition procedure available "before and after" the patent grant.[148] It is, however, silent on the grounds for opposing applications.[149] The EAC approach may be criticized for several reasons. First, while partner states may be allowed to flesh out provisions on procedural matters, the failure to aggregate grounds on which patent applications may be opposed is a missed opportunity. It is suggested that, like the Indian approach, a list of

142 Gregg "Making sense", above at note 137 at 34.

143 J Levin and R Levin "Patent oppositions" (John M Olin Center for Studies in Law, Economics and Public Policy working paper no 283, 2002).

144 A Soobert "Breaking new grounds in administrative revocation of US patents: A proposition for opposition – and beyond" (1998) 14 *Santa Clara High Technology Law Journal* 63 at 160.

145 The main difference between the two is the grounds upon which an application may be brought: wider grounds are available under post-grant reviews, as against the limited grounds available under *inter partes* reviews. See 35 USC, secs 311–319 and 321–329.

146 But note that if the application is successful, infringement action may lie against generic competitors, since patent rights accrue from filing; see TRIPS, art 33. See A Kapczynski "Harmonization and its discontents: A case study of TRIPS implementation in India's pharmaceutical sector" (2009) 97/6 *California Law Review* 1571 at 1599.

147 Patents Act (India), sec 25.

148 Protocol, sec 3(1).

149 Id, sec 3(1)–(2).

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possible grounds for opposition be included.[150] Second, adopting both pre-grant and post-grant methods will certainly cause inordinate delay in the process of granting patents; this is inadvisable for a region which is heavily dependent on foreign patent applicants for patenting activity and economic development, since it may result in those applicants becoming discouraged from filing applications in the region. Third, because the current approach allows applicants to challenge applications before and after grant, poorly drafted pre-grant opposition applications may be filed as placeholders for the subsequent submission of well-researched post-grant applications. A pre-grant opposition will therefore be better aligned with the overarching objective of the EAC.

Parallel importation

TRIPS leaves the choice of exhaustion regime to WTO members.[151] The doctrine of exhaustion is closely linked to a patentee's exclusive rights to "offer for sale", "sell" or "import" his / her patented articles.[152] These rights are deemed "exhausted" after they are first exercised (directly or indirectly) by patentees who then lose control over the subsequent sales of the articles manufactured from the patented inventions, the so-called "first sale" doctrine. The geographical coverage of exhaustion, however, depends on the type of exhaustion regime adopted by members: for a national regime, patentees lose the right to control subsequent sales in a single country, although their right of import in that country remains unaffected; for a regional regime, the right of subsequent sales and import right in the defined region is exhausted; while for an international regime, both the rights of subsequent sale and import are extinguished worldwide, provided in all cases that the original placement of the patented articles on the relevant market is by or with the patentees' approval.[153] The availability of parallel importation as a flexibility is therefore dependent on the exhaustion regime adopted by a country.[154]

Parallel importation could be particularly beneficial for broadening market access for implementing members as it allows them to shop around for cheaper drug prices.[155] It is in view of this perceived benefit that the EAC suggests that partner states adopt the international exhaustion regime.[156] However, this is yet another recommendation which appears apt theoretically but which lacks practical utility. One reason, according to McKeith and du Plessis, is that while the implementation of parallel importation may lead to moderate price reduction, evidence indicates that middlemen benefit more from it.[157] Moreover, over-reliance on parallel importation, especially for finished medical products, may conflict with the overall aim of the EAC to improve access to medicines through enhanced pharmaceutical production capacity.[158] Furthermore, reciprocal implementation may sometimes be required for parallel importation to work. Thus simply providing for an international exhaustion regime does not guarantee the useability of this flexibility abroad, because the regime of exhaustion adopted in the destination markets often matters – a reality beyond the

150 Patents Act (India), sec 25(1)(a)–(k).

151 TRIPS, art 6; Doha Declaration, para 5(d).

152 TRIPS, art 28.

153 See S McKeith "Pharmaceutical patents in developing nations: Parallel importation and the doctrine of exhaustion" (2013) 6 *African Journal of Legal Studies* 287; R Rai and S Jagannathan "Parallel imports and unparallel laws: An examination of the exhaustion doctrine through the lens of pharmaceutical products" (2012) 21 *Information & Communications Technology Law* 53; V Pathak "Intellectual property rights and parallel trade: Debate on national versus international exhaustion of rights" in B Nirmal and R Singh (eds) *Contemporary Issues in International Law: Environment, International Trade, Information Technology and Legal Education* (2018, Springer).

154 Ibid.

155 Ibid.

156 Protocol, secs 7(3), 10–11.

157 McKeith "Pharmaceutical patents", above at note 153 at 291; E du Plessis "The TRIPS Agreement and South African legislation: The case of the parallel importation of medicines" (1999) 3 *Law, Democracy & Development* 55 at 58.

158 See EACPoF.

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control of EAC partner states. Finally, the practical working of this flexibility implies that the recommended approach may be inappropriate for the EAC. For example, parallel importation is built on the notion that big pharmaceutical firms will price-discriminate in favour of poor countries, hoping to recoup R&D investment from higher prices in developed countries.[159] With EAC partner states falling in the category of "poor countries", it will be difficult to identify other markets where patented drugs will be available at prices cheaper than they are sold into the EAC.

Going forward, the EAC may adopt and adapt the approach recommended by Drexl, who notes that big pharmaceutical firms hardly engage in significant price discrimination between developed and less-developed countries because of the fear that cheaper drugs sold into the latter might find their way into the former.[160] Drexl suggests that to benefit from price reduction, poor countries should encourage their trading partners to implement a national exhaustion regime and to do the same themselves. The EAC may adapt this approach and adopt a regional exhaustion regime: this is expected to ease free movement of pharmaceutical products across the region. This can be complemented by the EAC entrenching a framework that will prohibit re-exportation outside the region. With these adjustments, big pharmaceutical firms may feel more comfortable price-discriminating in the region.

Compulsory licensing

Unarguably the most discussed flexibility, compulsory licensing finds legality in TRIPS article 31, which outlines the conditions for granting patents.[161] Article 31bis was later introduced to redress the shortcoming of article 31(f) – that products manufactured from such a licence be used "predominantly for the supply of the domestic market" – and its potential impacts on countries with little or no manufacturing capacity.[162] Following the COVID-19 pandemic, the Ministerial Decision of June 2022 offers further clarifications of the cumbersome provisions of TRIPS articles 31 and 31bis.[163] The EACPoF / Protocol offer copious guides to partner states on how best to incorporate compulsory licensing.[164] Specific areas covered include broad grounds for grant, the need for prior negotiations which may be waived in deserving circumstances, adequate compensation of patent holders, the importance of excluding injunctive relief, and designation of a competent authority.[165] More importantly, the amended TRIPS provision on using compulsory licensing for export is included as an additional ground.[166] Even though compulsory licensing is seldom used even in countries with manufacturing capacity, its inclusion in the EACPoF / Protocol is justified given that the mere threat of its use has been sufficient in the past to compel multinational drug companies to reduce drug prices.[167]

159 Rai and Jagannathan "Parallel imports", above at note 153 at 58–60.

160 J Drexl "EU competition law and parallel trade in pharmaceuticals: Lessons to be learned for WTO/TRIPS?" in J Rosén (ed) *Intellectual Property at the Crossroads of Trade* (2012, Edward Elgar) at 17–19.

161 See paras (a)–(l); R Bird "Developing nations and the compulsory license: Maximizing access to essential medicines while minimizing side effects" (2009) 37 *Journal of Law, Medicine & Ethics* 209; C Ho "Complicated compulsory licenses: The waiver/article 31bis 'solution'" in C Ho (ed) *Access to Medicines in the Global Economy: International Agreements on Patents and Related Rights* (2011, Oxford University Press).

162 See Doha Declaration, para 6; see generally J Reichman "Compulsory licensing of patented pharmaceutical inventions: Evaluating the options" (2009) *Journal of Law, Medicine and Ethics* 247 at 248.

163 WTO, Ministerial Decision on the TRIPS Agreement, adopted 17 June 2022 (WT/MIN(22)/30, WT/L/1141). Using existing compulsory licensing provisions in Nigeria, Adewopo discusses options for optimizing the newly clarified procedure on compulsory licensing for exports to improve access to COVID-19 vaccines in Nigeria; A Adewopo "Access to pharmaceutical patents in the COVID-19 emergency: A case for government use in Nigeria" (2021) 65/S2, *Journal of African Law* 259.

164 Protocol, sec 8.

165 Id, sec 8(1)–(5).

166 Id, sec 8(2)(g)–(h) and sec 8(3).

167 Brazil and the US, for example, have improved access in the past by simply threatening to issue compulsory licensing: see D Harris "TRIPS after fifteen years: Success or failure, as measured by compulsory licensing" (2011) 18/2 *Journal of*

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

Conclusion: The EAC approach and access to medicines

The EACPoF, with its accompanying though yet to be ratified Protocol, charts a harmonized approach for implementing TRIPS obligations in EAC partner states. The contents of these instruments have been critiqued above using a comparative lens. Specific suggestions have also been made about how some of the EAC-preferred implementation options could be improved. This concluding section therefore briefly reflects on the potential utility of the proposed approach for access to medicines in the region.

For ease of discussion, the EAC recommendations are grouped into three. In the first group are obligations on patentability criteria, excluded subject matters, the research exception and opposition procedure. If properly implemented, these obligations could broaden the public domain in ways beneficial for access. Take patentability criteria, for example: the use of worldwide prior arts as the basis for assessing novelty and inventiveness will ensure that EAC applicants are not reinventing the wheel. This should provide EAC researchers with enough room to experiment without worrying about potential infringement claims.

The second group encompasses obligations on the transition period, the Bolar exception, test-data protection, parallel importation and compulsory licensing. If collectively enacted per EAC recommendations, these could potentially facilitate the early entry of generic pharmaceutical products into the region. For instance, the pharmaceutical exemption created under the transition period provides a legitimate basis for excluding otherwise patent-eligible pharmaceutical inventions from patentability. In the absence of patent protection, EAC partner states could either locally manufacture or import pharmaceutical products patented elsewhere but not in the region. The Bolar exception also promotes early entry by permitting early working of patented inventions so that generic producers can obtain the data needed to enter the market immediately after patent expiry. Similarly, the EAC-favoured test-data misappropriation regime allows regional regulatory authorities to rely on originator test data when considering claims to bioequivalence made by generic producers applying for marketing approval. This will no doubt save the time and resources which would have been expended in generating a new set of data from scratch. Given the little manufacturing capacity in the region, parallel importation could in principle be used to import generic drugs from cheaper markets. Partner states could leverage economies of scale to bulk-procure generic drugs or active pharmaceutical ingredients for distribution among themselves. Compulsory licensing can be used in a similar way: EAC partner states can pool manufacturing capacity together to deploy compulsory licensing to manufacture generic drugs within the region or can use compulsory licensing for export to import needed drugs or active pharmaceutical ingredients from available overseas markets.

TRIPS obligations on disclosure and opposition are in the last category. A clear and complete disclosure of how a proposed pharmaceutical invention will work could help define the boundaries of patentees' exclusive rights. This clear demarcation may guide generic producers in making decisions on where to focus their reverse-engineering investments. A pre-grant opposition procedure could also play a crucial role by allowing patent applications to be opposed before an applicant obtains an enforceable legal right.

Overall, within the context of the COVID-19 pandemic, now under control, EAC partner states could leverage EACPoF / Protocol recommendations to improve access to COVID-19 vaccines and therapeutics: pharmaceutical exemption could be deployed by EAC LDCs to exempt COVID-19 technologies from patentability. For LDCs and Kenya, where COVID-19 technologies are already patentable, the disclosure requirements in conjunction with the pre-grant opposition procedure could be useful in weeding out low-quality applications. Similarly, a combined use of the Bolar exception and the test-data misappropriation regime could fast-track the obtainment of marketing

Intellectual Property 367; G Ooms and J Hanefeld "Threat of compulsory licences could increase access to essential medicines" (2019) *British Medical Journal* 365:l2098.

https://doi.org/10.1017/S0021855323000323 Published online by Cambridge University Press

approval for importers of COVID-19 treatments. Lastly, partner states could pool resources to use parallel importation and compulsory licensing (including compulsory licence for export) to either import COVID-19 treatments from abroad or manufacture them in the region.

It is, however, important to note that the effectiveness of the EAC approach is largely dependent on collective implementation among partner states, which may be problematic given that the states are at different stages of economic and technological development. This fact is clearly borne out by the findings of a separate study into the extent to which actual implementation of TRIPS obligations among partner states reflects these regional recommendations.[168] This study finds that, even though partner states have adopted most of the regional recommendations, coherence in implementation remains a big challenge.

Competing interests. None

168 OA Olatunji "Between regional recommendations and national implementation: An analysis of the East African Community partner states' legislative responses to TRIPS obligations" (2023) 54 *IIC – International Review of Intellectual Property and Competition Law* 673.

Cite this article: Olatunji OA (2024). Going It Alone or Acting as a Collective? Evaluating the East African Community Policy on Implementing TRIPS Obligations. *Journal of African Law* **68**, 19–39. https://doi.org/10.1017/S0021855323000323