Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion

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Abstract

This article examines the impact of parallel importation and the doctrine of patent exhaustion on access to pharmaceutical products in developing nations around the world. Parallel importation is of particular relevance to developing countries given that it is in these countries where medicines are often limited and exorbitant prices can be charged for those drugs that are available. Against this backdrop, this article examines the international legal regulation of patent exhaustion and proposes a solution to the difficulties currently experienced by many developing countries in attempting to use parallel importation to promote public health and improve access to medicines. The solution proposed in this article comprises a regional approach to patent exhaustion, which involves the introduction of complimentary legal and policy measures to the regional framework that currently exists in the developing world. It is argued that this proposal strikes an optimal balance between protecting intellectual property rights and increasing access to medicines that works in the best interests of pharmaceutical patent holders and developing country patent users.

Keywords

International intellectual property; parallel importation; patent exhaustion; patent; exhaustion; public health

IPRs [intellectual property rights] are justified by their societal purpose: they constitute a public policy tool to encourage innovation and creativity. These are the ends, and the patents and copyrights granted to innovators and creators are the means to achieve it. But the hierarchy of ends and means does not end here. Indeed, the encouragement of innovation and creativity is itself serving higher purposes: economic, social and cultural development that should benefit all.

So, international intellectual property policy is a question of striking the right balance between private interests, their public policy objective (access to knowledge) and other public goods. Should this public / private bargain be struck in the same way in all WTO Members? Not necessarily. Here the level of development and the national public policy objectives come into play.¹

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¹) Pascal Lamy, Director-General of the World Trade Organisation, The TRIPS agreement 10 years on: Conclusions by Pascal Lamy, Address Before the International Conference on the 10th Anniversary of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (24 June 2004), 4, available online at http://trade.ec.europa.eu/doclib/docs/2004/june/tradoc_117771.pdf.

1. Introduction

1.1. *The Problem of Access*

On 17 May 2011, the Clinton Health Access Initiative, UNITAID and the United Kingdom (UK) Department for International Development (DFID) announced price reductions on key anti-retroviral (ARV) drug regimens used to treat HIV/AIDS in developing nations.² Preferred first-line treatment options based on Tenofovir and Efavirenz were reduced by 60%, from an average annual cost of US\$400 per patient per year to an annual per patient cost of less than US\$159.³ Whilst these reductions were intended to and will likely 'provide millions of people with increased access to better, cheaper and more convenient first and second-line drug regimens',⁴ there remain significant obstacles to accessing medicines in developing countries. In South Africa, DFID estimates that approximately 43% of South Africans live on less than \$2 a day and 26% live below the international poverty line of \$1.25 a day, so that even reduced price ARV drugs remain beyond the reach of many millions of South African HIV/AIDS patients.⁵ Similarly, it is estimated that only 5% of the one million Thai citizens believed to be infected by HIV/AIDS are able to afford the medicines prescribed to them.⁶

The devastating consequences of high pharmaceutical prices are now well known in many developing countries worldwide. While extreme poverty and grossly inadequate healthcare expenditure by many poor country governments pose significant barriers to access to essential medicines,⁷ the international community has also recognised that this is a complex issue that necessitates a concerted response on a global level.⁸ Ganslandt, Maskus and Wong argue that the

² CHAI, UNITAID and DFID Announce Lower Prices for HIV/AIDS Medicines in Developing Countries: *Partnership to Reduce ARV Prices will Yield Savings of at Least \$600 Million Over 3 Years*, UNITAID, available online at <http://www.unitaid.eu/en/resources/news/331-clinton-health-access-initiative-unitaid-and-dfid-announce-lower-prices-for-hiv-aids-medicines-in-developing-countries.html> (last visited 29 March 2013).

³ *Ibid.*

⁴ William J. Clinton quoted in *Ibid.*

⁵ *Major Challenges: Tackling health and HIV and AIDS*, United Kingdom Department for International Development, available online at <http://www.dfid.gov.uk/Where-we-work/Africa-Eastern-Southern/South-Africa/Major-challenges/> (last visited 29 March 2013).

⁶ A. Sykes, 'Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries and the Doha "Solution"', 3 *Chicago Journal of International Law* (2002), 47–68.

⁷ As noted by T. Jones, 'Commentary', in *Public Health Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* 202 (World Health Organization, Geneva, 2006), in G. Dutfield, 'Delivering Drugs to the Poor: Will the TRIPS Amendment Help?', 34 *American Journal of Law & Medicine* (2008), 107–124, at 108:

Concerning access, patents are not the issue but the overwhelming poverty of individuals, absence of state healthcare financing, lack of medical personnel, transport and distribution infrastructure plus supply chain charges which can make affordable originator or generic products unaffordable. In many countries, medicines are unaffordable from whatever source, price or patent status.

⁸ International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa: A Report Prepared for The World Intellectual Property Organization*, International

task of responding to the problem of access requires the global economy to pursue two distinct yet interrelated goals:

1. Encouraging research aimed at finding treatments for diseases common in developing nations; and
2. Achieving widespread distribution of existing medicines (and any new medicines once they have been developed) at sufficiently low costs.⁹

With respect to the first objective, many proposals have been advanced to increase incentives for the development of new medical treatments. Sachs, Kremer and Hamoudi have put forward an idea for a vaccine-purchase fund,¹⁰ while Barton¹¹ and Subramanian¹² have developed proposals for ensuring tiered pricing of existing HIV/AIDS drugs. Similarly, the Developing Economies' Fund for Essential New Drugs proposal provides for the grant of fixed lump-sum payments for new innovations, with the payments partly subsidised by industrial country governments.¹³ It is hoped that these proposals will encourage further research into new treatments for diseases that primarily affect the poor.

In relation to the second objective, since research and development (R&D) into new medicines is an on-going and lengthy process,¹⁴ it is extremely important that a solution be found to the more immediate problem of distributing existing medicines at affordable prices. This requires urgent and focused attention given that there is clear evidence that existing distribution mechanisms are inadequate and have left many millions of poor patients unable to purchase medical treatments even at decreased prices.¹⁵ Importantly, any improvement to drug distribution will require consideration of the principles underlying the protection of intellectual property rights (IPRs) and will concern, in particular, the varied functions of

Intellectual Property Institute, available online at http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf.

⁹ M. Ganslandt, K.E. Maskus and E.V. Wong, 'Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal', in C. Fink and K.E. Maskus (eds), *Intellectual property and development: lessons from recent economic research* (World Bank, Washington, DC, 2005), p. 207 (hereinafter The DEFEND Proposal).

¹⁰ J. Sachs, M. Kremer and A. Hamoudi, 'The Case for a Vaccine Fund', in The DEFEND Proposal, *supra* note 9, at 210.

¹¹ J. Barton, 'Draft on Tiered Pricing for WG-4', in The DEFEND Proposal, *supra* note 9, at 210.

¹² A. Subramanian, 'Putting Some Numbers on the TRIPS Pharmaceutical Debate', in The DEFEND Proposal, *supra* note 9, at 210.

¹³ The DEFEND Proposal, *supra* note 9, at 217, 218.

¹⁴ According to Gerald Mossinghoff, President of the Pharmaceutical Research and Manufacturers of America, it takes an average of US\$359 million and about 10 to 12 years to bring one new pharmaceutical to the market: J.M. Silberman, 'The North American Free Trade Agreement's Effect on Pharmaceutical Patents: A Bitter Pill to Swallow or a Therapeutic Solution?', in A. Bryan Baer, 'Price Controls through the Back Door: The Parallel Importation of Pharmaceuticals', 9 *Journal of Intellectual Property Law* (2001), 109–136, at 125.

¹⁵ The DEFEND Proposal, *supra* note 9, 209, 212.

patent rights in the development of and access to pharmaceuticals.¹⁶ On the one hand, patents confer extensive market power on rights holders and thereby provide pharmaceutical companies and drug researchers with incentives to bear the high costs and risks of R&D into new drug development.¹⁷ Yet on the other hand, economic studies have shown that the exclusive rights conferred on patent holders can significantly raise the prices of patented pharmaceuticals in developing countries.¹⁸

Against this backdrop, improved drug distribution will need to strike an effective balance between allowing patent holders to use their patents to cover the fixed costs of R&D, and lowering the cost of patented medicines to permit developing countries to respond to public health crises more effectively.¹⁹ Notably, many developing countries have employed or are looking to employ different mechanisms of drug distribution in an attempt to strike this balance. These mechanisms include issuing compulsory licensing and permitting parallel imports of patented medicines from markets where they are sold at lower prices.²⁰ This paper will take the second of these two mechanisms – parallel importation – and will analyse whether this complex and contentious practice can indeed offer a balanced solution to medicine distribution.

1.2. *Parallel Importation*

Parallel importation, often known as grey marketing, refers to the situation where an item validly marketed under the intellectual property (IP) regime in one country is imported into a second country through an unofficial trade channel contrary

¹⁶ M. Buckley, 'Looking Inward: Regional Parallel Trade as a Means of Bringing Affordable Drugs to Africa', 41 *Seton Hall Law Review* (2011), 625–669, at 644.

¹⁷ J.O. Lanjouw, 'The Introduction of Pharmaceutical Patents in India: Heartless Exploitation of the Poor and Suffering?', *National Bureau of Economic Research Working Paper* 6366 (National Bureau of Economic Research, Cambridge, MA, 1998).

¹⁸ See K.E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries: Final Report to World Intellectual Property Organisation* (WIPO, 2001); C. Fink, 'Patent Protection, Transnational Corporations, and Market Structure: A Simulation Study of the Indian Pharmaceutical Industry', in C. Fink and K.E. Maskus (eds), *Intellectual property and development: lessons from recent economic research* (World Bank, Washington, DC, 2005), pp. 227–258.

¹⁹ F.M. Abbott, 'First Report (Final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation', 1 *Journal of International Economic Law* (1998), 607–636, at 612.

²⁰ At the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines on 20 June 2001, a number of developing countries submitted a paper opposing any international prohibition on parallel importation: TRIPS Council, Submission by the Africa Group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, *TRIPS and Public Health*, IP/C/W/296 (19 June 2001) (hereinafter Developing Countries Submission). The paper states at paragraph 25:

... adoption of the principle of international exhaustion of rights [allowing parallel trade] can be a useful tool for health policies. Where the prices of pharmaceutical products are lower in a foreign market, for instance, a government may allow importation of such products into the national market, so as to allow offers of drugs at more affordable prices.

to the wishes of the corresponding rights holder in that second country.²¹ Several forms of parallel importation are used around the world. The most common practice is known as ‘passive parallel importation’, which involves importers buying goods in a foreign country and selling them in the domestic market.²² Another form is ‘active parallel importation’, whereby a foreign licensee or distributor of an IPR holder enters the domestic market to compete with the rights holder or an official domestic licensee.²³

Whilst limited empirical research exists with regard to the economic effects of international exhaustion,²⁴ there is evidence that competition from parallel imports exercises a downward effect on prices and thereby enhances consumer welfare through price reductions.²⁵ While few would dispute that increasing access to lower priced medicines in developing countries is a worthy goal, many have criticised the impact of parallel importation on patent rights and questioned its role in incentivising pharmaceutical R&D.²⁶ This paper will analyse this debate.

1.3. *The Exhaustion Doctrine*

Any analysis of parallel importation necessarily involves an examination of the exhaustion of rights doctrine. This is because there is an inextricable link between parallel imports and the exhaustion of IPRs. The exhaustion doctrine defines the point at which an IPR holder (for the purpose of this paper a patent rights holder) ceases to have exclusive rights over the resale of its product.²⁷ In general, a patent owner’s rights are exhausted as soon as a patented product is placed on the

²¹ A.J. Stack, ‘TRIPS, Patent Exhaustion and Parallel Imports’, 1 *Journal of World Intellectual Property* (1998), 657–689, at 666.

²² C. Fink, ‘Entering the Jungle of Intellectual Property Rights: Exhaustion and Parallel Importation’, in C. Fink and K.E. Maskus (eds), *Intellectual property and development: lessons from recent economic research* (2005), pp. 171–188, at 172 (hereinafter *Entering the Jungle*).

²³ *Ibid.*, 172.

²⁴ Tuomas Mylly provides a good overview of the limited but most persuasive studies on the economic effects of parallel importation in T. Mylly, ‘A Silhouette of Fortress Europe? International Exhaustion of Trade Mark Rights in the EU’, 7 *Maastricht Journal* (2000), 51–80, at 56, note 16.

²⁵ See M. Ganslandt and K. Maskus, ‘Intellectual property rights, parallel imports and strategic behavior’, *Research Institute of Industrial Economics Working Paper Series 704* (2007), available online at <http://ifn.se/Wfiles/wp/wp704.pdf>; P. West and J. Mahon, ‘Benefits to Payers and Patients from Parallel Trade’, York Health Economics Consortium Working Paper (York Health Economics Consortium, York, 2003).

²⁶ See Stack, *supra* note 21, at 684, 685; Fink, *supra* note 22, at 172.

²⁷ The 1873 US Supreme Court case of *Adams v Burke*, 84 U.S. (17 Wall) 453 (1873) is often said to be the first decision in which the concept of exhaustion of IPRs was clearly articulated: U.N. Conference on Trade & Dev.-Int’l Ctr. For Trade & Sustainable Dev. (UNCTAD-ICTSD), *Resource Book on TRIPS and Development* (2005), p. 629, 94 (hereinafter *TRIPS Resource Book*). The Court held that the patent holder’s control over an invention was exhausted on its first sale and noted at 456:

In the essential nature of things, when the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use. The article, in the language of the court, passes without the limit of the monopoly. That is to say, the patentee or his assignee having in the act of sale received all the royalty or consideration which he claims for the use of his invention in that particular machine

market for sale, with the result that a purchaser can resell the article without being liable for infringement.²⁸ This doctrine is of greatest significance when patented products are traded internationally and patent rights in the product are held in multiple nations.²⁹ Where this occurs, it is necessary to ascertain which, if any, of the patent rights are exhausted by the sale of the article. If the rights have been exhausted, then parallel imports will be allowed within that particular country.

At present, there are substantial differences between developed and developing nations in relation to the legal treatment of patent exhaustion. In general, many developing countries appear to favour a regime of international patent exhaustion under which parallel importation is permitted, while a large number of developed countries prefer a national or regional exhaustion regime pursuant to which various restraints are placed on parallel imported products.³⁰ These differences derive from the flexible treatment of exhaustion in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).³¹

1.4. *International Legal Regulation of Exhaustion*

As will be outlined in further detail below, Article 6 of the TRIPS Agreement provides discretion to WTO members to adopt their own policies and rules with respect to exhaustion of rights, with the result that members may permit or prohibit parallel importation under national legislation.³² The flexible treatment of exhaustion in Article 6 is reinforced in paragraph 5(d) of the WTO Declaration on the TRIPS Agreement and Public Health (Doha Declaration).³³

Against this backdrop, this paper will analyse whether the flexibilities provided under Article 6 of the TRIPS Agreement can be effectively used by those developing country WTO members that wish to employ parallel importation as a public health policy tool to promote access to medicines. In concluding that they cannot, a proposal will be advanced that will allow developing countries to make better use of the Article 6 flexibilities and that will also sufficiently incentivise pharmaceutical companies to continue R&D into diseases that plague poor nations.

or instrument, it is open to the use of the purchaser without further restriction on account of the monopoly of the patentee.

²⁸ D.E. Donnelly, 'Parallel Trade and International Harmonization of the Exhaustion of Rights Doctrine', 13 *Santa Clara Computer & High Technology Law Journal* (1997), 445–515, at 447.

²⁹ *Ibid.*, at 447.

³⁰ Stack, *supra* note 21, at 657.

³¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (hereinafter TRIPS Agreement).

³² F.M. Abbott, *Parallel importation: Economic and social welfare dimensions* (2007), available online at http://www.iisd.org/pdf/2007/parallel_importation.pdf.

³³ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) (hereinafter Doha Declaration).

While there are several reasons why pharmaceutical companies may be resistant to the solution proposed below, it is essential that a new approach is adopted to resolve the current difficulties so as to equip the poorest nations of the world with effective mechanisms to overcome the burdens of disease.³⁴

1.5. *Structure*

This paper is divided into four parts. Section 1 provides a brief overview of the current international legal regulation of patent exhaustion. This section discusses Article 6 of the TRIPS Agreement and paragraph 5(d) of the Doha Declaration and details the historical inability of the TRIPS negotiators to agree on a uniform doctrine of exhaustion. It then provides a brief explanation of the varied treatment of patent exhaustion around the world by contrasting the exhaustion regimes adopted in many developed and developing nations. Section 3 discusses several practical difficulties currently faced by developing countries in using the flexibilities provided under Article 6 as a public health policy tool. The proposal suggested in Section 4 attempts to remedy these constraints by recommending that certain regional organisations adopt a regime of regional exhaustion coupled with complementary regulatory and policy measures. Section 5 canvasses several theoretical and practical difficulties that may arise from a regional approach and discusses how these issues might best be resolved.

2. Existing Legal Framework

2.1. *International Treaty Provisions*

Prior to the negotiation and implementation of the TRIPS Agreement, national governments maintained different policies of exhaustion, which often varied with the type of IP which was being protected (specifically copyright, trademarks or patents).³⁵ During the Uruguay Round negotiations of the General Agreement on Tariffs and Trade (GATT), which took place from 1986 to 1994, there was extensive discussion regarding the form of exhaustion regulation that was to be included in the TRIPS Agreement.³⁶ In general, developing countries largely favoured a rule of international exhaustion,³⁷ the European Union (EU) wished to preserve its regime of regional exhaustion³⁸ and the United States (US) favoured rules

³⁴) Buckley, *supra* note 16, at 669.

³⁵) Stack, *supra* note 21, at 657; TRIPS Resource Book, *supra* note 27 at 94.

³⁶) E. Alsegard, 'Global pharmaceutical patents after the Doha Declaration – What lies in the future', 1 SCRIPT-ed (2004), 1–34, at 12; TRIPS Resource Book, *supra* note 27 at 97 to 104.

³⁷) See J.S. Chard and C.J. Mellor, 'Intellectual Property Rights and Parallel Importation', in Abbott, *supra* note 19, at 609.

³⁸) Frederick M. Abbott notes that the EU proposal for the TRIPS Agreement included a nation waiver for customs unions and free trade area IP rights measures. Abbott writes that the EU proposal was

restricting parallel importation for reasons including existing US legislation and legal policy.³⁹ However, despite the efforts of negotiators to reach a consensus on a uniform set of exhaustion rules, these differing viewpoints could not be reconciled.⁴⁰ As a result, when the Uruguay Round negotiations concluded and the Marrakesh Agreement Establishing the World Trade Organisation⁴¹ was signed on 15 April 1994, it was decided to agree to disagree and the current text of Article 6 of the TRIPS Agreement was adopted:

For the purposes of dispute settlement under this Agreement, subject to the provisions of Article 3 and 4 (national and most favoured nation (MFN) treatment) nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.⁴²

Following implementation, many WTO developing country members expressed concern regarding the impact of the TRIPS Agreement on access to medicines.⁴³ At a meeting of the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines on 20 June 2001, a WTO member delegation comprised of a number of developing countries submitted papers for consideration by the Council.⁴⁴ In these papers, the delegation highlighted the difficulties created for developing members by various provisions of the TRIPS Agreement and called for the right for members to establish and maintain health systems without restriction by the TRIPS Agreement.⁴⁵

After protracted negotiations, the Fourth WTO Ministerial Conference adopted the Doha Declaration on 14 November 2001, which provides guidance for the implementation of relevant rights and obligations laid down in the TRIPS Agreement.⁴⁶ The Doha Declaration confirms that public health considerations can and

subsequently explained as an attempt to prevent an attack on the intra-EU exhaustion rule: F.M. Abbott, 'GATT and the European Community: A Formula for Peaceful Coexistence', in Abbott, *supra* note 19, at 609, note 3.

³⁹ In his position as Co-Rapporteur for the Committee on International Trade Law of the International Law Association and Special Rapporteur for the TRIPS Agreement in 1998, Frederick M. Abbott discussed the US standpoint on exhaustion with members of the US Trade Representative's Office with responsibility for the TRIPS Agreement during the Uruguay Round of TRIPS Agreement negotiations: Abbott, *supra* note 19, at 609.

⁴⁰ See TRIPS Resource Book, *supra* note 27, for a detailed analysis of the TRIPS Agreement negotiations concerning the exhaustion of IPRs and parallel importation.

⁴¹ Marrakesh Agreement Establishing the World Trade Organization, 15 April 1994, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) (hereinafter WTO Agreement).

⁴² TRIPS Agreement, Article 6.

⁴³ F.M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: lighting a dark corner at the WTO', 5 *Journal of International Economic Law* (2002) 469–505, at 481, 482.

⁴⁴ *Ibid.*, at 481, 482.

⁴⁵ *Ibid.*, at 483, 484.

⁴⁶ E.F.M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond', in J.P. Moatti, T. Barnett, B. Coriat, Y. Souteyrand, J. Dumoulin and Y.A. Flori (eds), *Economics of AIDS and Access to HIV/AIDS care in Developing Countries: Issues and Challenges* (2003), pp. 39–67, at 41.

should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in the TRIPS Agreement may be used to improve access to medicines.⁴⁷ Importantly, paragraph 5(d) of the Doha Declaration clarifies the meaning of Article 6 of the TRIPS Agreement:

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.⁴⁸

The combined effect of Article 6 of the TRIPS Agreement and paragraph 5(d) of the Doha Declaration is that if a country wishes to adopt international exhaustion to allow the parallel importation of lower-priced medicines for public health purposes then this will be permitted and the decision will not be subject to challenge under the WTO dispute settlement system.⁴⁹

2.2. National Legislative Responses to Exhaustion

As a result of the flexible treatment of patent exhaustion in the TRIPS Agreement and the Doha Declaration, a variety of exhaustion doctrines have been adopted around the world.

2.2.1. National Exhaustion

Under a regime of national exhaustion, the first sale of a patented good only ‘exhausts’ the patent holder’s right to control subsequent sales within the country where the patented product was sold.⁵⁰ The practical effect of national exhaustion is that once a patentee sells a patented product, the purchaser holds title free and clear of the patent, including the right to resell the product to third parties. Notably, national exhaustion does not affect any patent rights in parallel patents in foreign countries. Thus, while the patentee may not control commerce in his patented product after it has been first sold within the jurisdiction, the patentee may exclude parallel imports of the same product entering from other countries.⁵¹

⁴⁷ Joint United Nations Programme on HIV/AIDS (UNAIDS), *Doha+10: TRIPS flexibilities and access to antiretroviral therapy: lessons from the past, opportunities for the future* (Technical Brief), UNAIDS, available online at http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2260_DOHA+10TRIPS_en.pdf.

⁴⁸ Doha Declaration, para. 5(d).

⁴⁹ J. Reinbothe and A. Howard, ‘The state of play in the negotiations on TRIPS (GATT/Uruguay Round’, in S.K. Verma, ‘Exhaustion of Intellectual Property Rights and Free Trade – Article 6 of the TRIPS Agreement’, 29 *International Review of Industrial Property and Copyright Law* (1998), 534–, at 535–536.

⁵⁰ Donnelly, *supra* note 28, at 497.

⁵¹ V. Chiappetta, ‘The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion And A Few Other Things’, 21 *Michigan Journal of International Law* (2000), 333–392, at 341–342

A number of developed countries support national exhaustion of patent rights, including the US and Australia.⁵²

2.2.2. *Regional Exhaustion*

Under a system of regional exhaustion, patent rights are exhausted only if a product is placed on the market within that region.⁵³ Where this approach is adopted, the patent holder may not prohibit parallel imports within the region but may restrict parallel goods that derive from outside the region.

A regional exhaustion approach is applied in the EU and the European Economic Area (together the EC) with respect to patents. In Case 187/80 *Merck v Stephar* [1981] ECR 2063, the European Court of Justice (CJEU) confirmed that patent holders cannot restrict intra-EC parallel trade in pharmaceuticals.⁵⁴ The decision was based upon provisions in the Treaty Establishing the European Community to protect the free movement of goods.⁵⁵ In contrast, for those patented goods initially sold outside the EC, the EC appears to support a policy proscribing parallel importation.⁵⁶ While there is limited CJEU case law on this point, it is generally accepted that the policy goal of free trade within the EC necessitates this approach to regional exhaustion.⁵⁷

As will be discussed in Section 3.1 below, the 16 member states of the African Intellectual Property Organisation (OAPI) are also subject to regional exhaustion within the OAPI region.⁵⁸

⁵² Maskus, *supra* note 18, at 5, 6.

⁵³ Christopher Stothers, Visiting Lecturer in Intellectual Property Law University College of London, Patent exhaustion: the UK perspective, Address before the 16th Annual Conference on Intellectual Property Law and Policy, Fordham University School of Law (27–28 March 2008).

⁵⁴ The decision in *Merck v Stephar* was expressly confirmed by the CJEU in December 1996 in Joined Cases C-267/95 and C-268/95 *Merck & Co. Inc and ors v Primecrown Ltd and ors, Beecham Group plc and ors v Europharm of Worthing Ltd* [1996] ECR I-6285.

⁵⁵ Treaty of Rome establishing the European Economic Community, 25 March 1957, 298 U.N.T.S. 11; 163 B.F.S.P. 206.

⁵⁶ In C-355/96 *Silhouette International Schmied GmbH & Co. KG v Harlauer Handelsgesellschaft mbH* [1998] ECR I-04799, the CJEU confirmed that trade mark holders can restrict the parallel importation of trade marked goods initially sold outside the EC. While it is uncertain whether this principle extends to patents, the English High Court in *Zino Davidoff SA v A&G Imports Ltd.* [2000] EWHC 127 (Ch), [1999] 3 All ER 711, at para 11 made several obiter dicta comments in support of proscribing parallel importing of patented goods initially sold outside the EC.

⁵⁷ C-355/96 *Silhouette International Schmied GmbH & Co. KG v Harlauer Handelsgesellschaft mbH* [1998] ECR I-04799.

⁵⁸ P.L. Osewe, Y.K. Nkrumah and E.K. Sackey, *Improving Access to HIV/AIDS Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities* (The World Bank, 2008), available online at <http://apps.who.int/medicinedocs/documents/s17514en/s17514en.pdf>; E.S. Nwauche, Associate Professor of Law at Rivers State University of Science and Technology, A development oriented intellectual property regime for Africa, Address Before the 11th General Assembly of Council for the Development of Social Science Research for Africa (Dec. 6–10, 2005), available online at <http://ebookbrowse.com/nwauche-pdf-d43302270>.

2.2.3. *International Exhaustion*

Under a doctrine of international exhaustion, the first sale of a patented good in any jurisdiction worldwide terminates the patent holder's rights in any parallel patents held in any other jurisdiction.⁵⁹ The theoretical basis of international exhaustion is that the patentee has received a reward by means of the first sale in a particular country and so should not be able to control the resale of that same product in any other country.⁶⁰ Following this approach, a patented product may move freely anywhere in the international market following first sale in any jurisdiction.

At present, a large number of developing countries support international exhaustion, including India, Kenya, Ghana, Argentina, Thailand, Malaysia and South Africa.⁶¹

3. Effectiveness of the Current Legal Regulation of Exhaustion

While Article 6 of the TRIPS Agreement explicitly allows developing countries to adopt an exhaustion regime tailored to specific national needs, in reality it remains difficult for many of these countries to make effective use of Article 6 as a public health policy tool.

3.1. *International Pressure and the Threat of Trade Sanctions*

In several instances, multinational pharmaceutical companies and developed country governments have placed substantial trade pressure on particular developing countries that have attempted to introduce parallel importation as a means of lowering drug prices.⁶² This has left low and middle income countries particularly vulnerable to the 'marked ascendancy' of power of global corporations and dominant developed country governments.⁶³ Perhaps the most salient example of such pressure occurred in 1997 when the South African government introduced the Medicines and Related Substances Control Amendment Act 1997 (SA), pursuant to which the South African Health Minister was given the power to issue compulsory licences and to prescribe parallel imports on patented medicines.⁶⁴ In 1998, the Pharmaceutical Manufacturers' Association of South Africa and 39 pharmaceutical companies initiated proceedings against the South African government

⁵⁹ See Donnelly, *supra* note 28, at 498.

⁶⁰ *Ibid.*, at 509.

⁶¹ Maskus, *supra* note 18, at 6.

⁶² Dutfield, *supra* note 7, at 116.

⁶³ K. Buse, N. Drager, S. Fustukian and K. Lee, 'Globalisation and health policy: trends and opportunities', in K. Lee, Buse, K; Fustukian, S, (eds.), *Health Policy in a Globalising World* (2002), p. 256, in S.K. Sell, 'The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive and Institutional Dimensions', 77 *Temple Law Review* (2004) 363–399, at 365.

⁶⁴ Dutfield, *supra* note 7, at 116.

seeking a declaration that the legislation was unconstitutional.⁶⁵ The pharmaceutical companies claimed that the legislation abrogated a number of their rights under the South African Bill of Rights, in particular their freedom from arbitrary deprivation of property.⁶⁶ In addition, US development aid to South Africa was made conditional on the withdrawal of the provisions.⁶⁷ While the legal action was eventually withdrawn in April 2001,⁶⁸ this example demonstrates the power imbalances that are prevalent in the international IP arena. The US government may have bowed to international pressure in South Africa, but there is no guarantee that the US or other developed country governments will not exert similar pressures in the future on those developing countries that decide to implement international exhaustion.⁶⁹

Indeed, another example of heavy-handed pressure occurred in March 2006 when Pfizer brought a patent infringement action against the government-owned Philippine International Trading Corporation (PITC) and the Bureau of Food and Drugs (BFAD) in the Philippine Regional Trial Court of Makati Branch.⁷⁰ Pfizer alleged that PITC and BFAD had infringed Pfizer's Philippine patent for its anti-hypertension drug Norvasc.⁷¹ In particular, Pfizer claimed that PITC had imported samples of Norvasc from India where the drug was protected under an Indian patent and available at a much lower price.⁷² PITC and BFAD defended their actions by claiming that they had granted approval to the Indian product in the form of a parallel import drug registration but had not intended to sell the drug until after Pfizer's Philippine patent had expired in 2007. PITC referred to a 'Bolar provision' in Philippine regulatory practice and argued that this provision allowed it to import samples of a product and develop and test it while the product was still

⁶⁵ Case No. 4183/98 *The Pharmaceutical Manufacturers' Association of South Africa & Ors v The President of the Republic of South Africa & Ors & Treatment Action Campaign* (2001) (Transvaal Provincial Division); see W.W. Fisher III and C.P. Rigamonti, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy*, *Harvard Law School: The Law and Business of Patents* (10 February 2005), available online at <http://cyber.law.harvard.edu/people/ffisher/South%20Africa.pdf>.

⁶⁶ See South Africa. Constitution of the Republic of South Africa, Act No. 108 of 1996, Article 25(1).

⁶⁷ C.M. Correa, 'Public Health and Intellectual Property Rights', 2 *Global Social Policy* (2002) 261–278, at 271.

⁶⁸ Sarah Joseph notes that the pharmaceutical companies dropped the suit for several reasons, including the extraordinary wave of public protest that had been provoked by the case and the possibility of failure: S. Joseph, 'Pharmaceutical Corporations and Access to Drugs: The 'Fourth Wave' of Corporate Human Rights Scrutiny', 25 *Human Rights Quarterly* (2003), 425–452, at 443.

⁶⁹ James Love, Director of Ralph Nader's Washington-based Consumer Project on Technology quoted in S. Barber, 'End of AIDS Drugs Case Sees Spotlight Fall on New Arenas', *Business Day* (25 April 2001), available online at <http://www.bday.co.za/bday/content/direct/1,3523,836777-6078-0,00.html>.

⁷⁰ *Pfizer Limited (United Kingdom) and Pfizer Inc. (Philippines) v The Philippine International Trading Corporation, BFAD Director Leticia Barbara B. Gutierrez, BFAD LICD Officer-in-Charge Emilio L. Polig, Jr. and the Bureau of Food and Drugs* (2006) Civil Case No 06–172, Republic of The Philippines Regional Trial Court – National Capital Judicial Region Makati City Branch.

⁷¹ J. Yu, 'The Front: Pfizer v The Philippines', 27 *Multinational Monitor* (Jul–Aug 2006), 4, available online at <http://www.multinationalmonitor.org/mm2006/072006/front.html>.

⁷² *Ibid.*

under Philippine patent in order to prepare for an early registration upon patent expiry.⁷³ Notably, PTIC claimed that without early registration obtained under the Bolar provision, it would take at least 18 months after the Pfizer patent had expired before a cheaper version could be marketed.⁷⁴ However, despite the public health benefits that PITC argued would result from its actions, Pfizer pursued its action and eventually reached a settlement with PITC pursuant to which PITC agreed not to import the drug until after its patent had expired in The Philippines.⁷⁵

These examples illustrate the aggressive course that many global firms and developed country governments are pursuing with respect to patent exhaustion regimes adopted by developing countries. Despite the flexibilities in Article 6, coercion is increasingly being used to force developing countries to abandon parallel importation and submit to high levels of protectionism.⁷⁶ It is in this context that the current operation of Article 6 fails to properly provide developing nations with the means to decrease drug prices, to promote patent rights 'in a manner conducive to social and economic welfare'⁷⁷ or to adopt measures 'necessary to protect public health and nutrition'.⁷⁸

3.2. *Difficulties with Allowing Unrestricted International Exhaustion for Pharmaceuticals*

Even in the absence of international pressure, it is extremely problematic that Article 6 allows a developing nation to adopt international exhaustion without placing any restrictions on exports of parallel traded pharmaceuticals. The strongest arguments against international exhaustion are made by drug manufacturers who claim that exports of drugs from lower-priced markets into higher-priced markets detrimentally affect price differentiation. This is a practice that occurs when a manufacturer charges different prices in countries where consumers have different preferences.⁷⁹ For instance, the HIV/AIDS treatment drug Tenofovir may carry a high price in the UK due to high UK purchasing power, health insurance and taxes, but the same drug may be priced much lower in Kenya as a reflection of

⁷³ *Ibid.*

⁷⁴ T.I.S. Gerhardsen, 'Pfizer fights IP flexibilities in the Philippines', *Intellectual Property Watch* (30 April 2006), available online at <http://www.ip-watch.org/2006/04/30/pfizer-fights-ip-flexibilities-in-the-philippines/>.

⁷⁵ Yu, *supra* note 71.

⁷⁶ G.E. Evans, 'Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries', 34 *American Journal of Law and Medicine* (2008), 175–223, at 184–185; Sell, *supra* note 63.

⁷⁷ TRIPS Agreement, Article 7.

⁷⁸ TRIPS Agreement, Article 8.

⁷⁹ N. Gallus, 'The Mystery of Pharmaceutical Parallel Trade and Developing Countries', 7 *Journal of World Intellectual Property* (2004), 169–183, at 171.

the decreased ability of Kenyan consumers to pay.⁸⁰ From an economic perspective, as long as production costs are covered, differential pricing can be beneficial because it allows firms to serve those markets where consumers' ability to pay is limited and which may not have been served if producers were required to set a uniform global price.⁸¹

Schemes of price differentiation are threatened when international exhaustion is introduced without restricting parallel exports from low price to high price countries.⁸² Many commentators argue that an international exhaustion regime that does not restrict such exports can in fact increase prices in the lower priced markets.⁸³ This is because manufacturers may increase the prices of drugs in developing markets if they fear that exports of those goods (that might ordinarily be sold at a cheaper price) will undercut higher prices in developed markets.⁸⁴ In order to prevent cheaper goods entering high price markets, firms may also choose to sell at a single price across all markets and may also leave some markets un-served.⁸⁵ Pharmaceutical companies may even decide to discontinue distribution activities in developing markets altogether.⁸⁶

There is also evidence that the threat of parallel exports from developing countries may discourage firms from investing in R&D for medicines to treat diseases common in those countries.⁸⁷ Ganslandt and Maskus argue that it is reasonable to assume that producers take the legal regime of IPRs into account when devising their R&D programs.⁸⁸ Therefore, the risk that parallel exports may undercut higher prices in developed markets may reduce producers' incentives to invest

⁸⁰) Notably, several developing countries appear to reject the findings in the economic literature that drug companies price-discriminate in their favor. The Developing Countries Submission submitted during the TRIPS Council Special Discussion on Intellectual Property and Access to Medicines on 20 June 2001 argued that drug prices are often more expensive in developing countries than in richer countries: *supra* note 20. However, a review of a large number of economic surveys indicates that while there may be some drugs that are more expensive in developing countries than in developed countries, in general, most drugs will be more expensive in developed country markets: see Gallus, *supra* note 79, at 171. These findings are supported by increased international enthusiasm to provide cheaper drugs to developing nations, as exemplified by the price reductions on HIV/AIDS drugs announced by the Clinton Health Access Initiative, UNITAID and DFID: UNITAID, *supra* note 2.

⁸¹) Entering the Jungle, *supra* note 22, at 177.

⁸²) D.A. Malueg and M. Schwartz, 'Parallel Imports, Demand Dispersion and International Price Discrimination', 37 *Journal of International Economy* (1994), 167–195, at 185.

⁸³) See Gallus, *supra* note 79, at 171; Malueg and Schwartz, *supra* note 82; Entering the Jungle, *supra* note 22, at 177.

⁸⁴) See Baer, *supra* note 14.

⁸⁵) See *Ibid.*; Gallus, *supra* note 79.

⁸⁶) Baer, *supra* note 14.

⁸⁷) *Ibid.*, at 129.

⁸⁸) Ganslandt and Maskus, *supra* note 25, at 29.

in costly R&D⁸⁹ or product-quality improvement programs.⁹⁰ While several commentators have questioned whether developing country parallel importation regimes actually affect drug R&D,⁹¹ there is persuasive evidence that the parallel importation regime adopted by a particular country is an important factor considered by pharmaceutical companies.⁹² The former Director-General of the International Federation of Pharmaceutical Manufacturers Associations, Harvey Bale Jr., argues that patent holders will be less likely to transfer technology and production capacity to those low-priced developing countries that allow international exhaustion but do not prohibit parallel exports.⁹³ Bale also notes:

The threat of parallel trade takes away any incentive of vaccine and pharmaceutical patent holders to make significant concessions to poorer countries.⁹⁴

This is clear evidence that the existing flexibilities in Article 6 of the TRIPS Agreement fail to strike an appropriate balance between lowering the cost of drugs and allowing pharmaceutical patent holders to use their patent rights to recover the costs of drug R&D.

The considerations outlined above clearly illustrate that the current regulation of patent exhaustion impedes developing countries from adopting exhaustion regimes for public health policy reasons and fails to provide adequate incentives for firms to engage in the distribution of reasonably priced medicines.⁹⁵ On a positive note, there is evidence that pharmaceutical companies are beginning to consider lowering prices for drugs sold in the developing world.⁹⁶ However, companies still harbour serious concerns over the impact of parallel importation on price differentiation models and drug R&D.⁹⁷ As trade in IP grows and as the deadline draws nearer for least-developed countries to implement the TRIPS

⁸⁹) C. Li and K.E. Maskus, 'The impact of parallel imports on investments in cost-reducing research and development', 68 *Journal of International Economy* (2006) 443–455.

⁹⁰) T. Valletti and S. Szymanski, 'Parallel trade, International Exhaustion and Intellectual Property Rights: A Welfare Analysis', 54 *Journal of Industrial Economics* (2006) 499–526; The DEFEND Proposal, *supra* note 9, at 209.

⁹¹) For example, Correa notes that the contribution to R&D that could be made by some developing countries or regions is negligible in global terms. He points to an IMS Health market report which found that Africa only accounts for 1.3% of world pharmaceutical sales: IMS Health Market Report, in Correa, *supra* note 67, at 270).

⁹²) H.E. Bale Jr., 'The Conflicts between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals', 1 *Journal of International Economic Law* (1998), 637–653, at 648.

⁹³) *Ibid.*, at 648.

⁹⁴) *Ibid.*, at 648.

⁹⁵) The DEFEND Proposal, *supra* note 9, at 208, 209.

⁹⁶) See for example, S. Boseley, 'Drug giant GlaxoSmithKline pledges cheap medicine for world's poor', *The Guardian* (13 February 2009), available online at <http://www.guardian.co.uk/business/2009/feb/13/glaxo-smith-kline-cheap-medicine>.

⁹⁷) Bale, *supra* note 92, at 648.

Agreement provisions with respect to pharmaceutical patents,⁹⁸ it is critical that improvements are made to the current regulation of patent exhaustion in order to remedy the difficulties outlined above.

4. Suggested Reform to the International Regulation of Patent Exhaustion

Despite the difficulties outlined in Section 2 above, it is important that the flexibilities provided under Article 6 of the TRIPS Agreement continue to be employed by developing countries in order to address and appropriately manage the critical problem of access to medicines. There is evidence that many developing countries are attempting to use the exhaustion flexibilities in Article 6 of the TRIPS Agreement to improve access to ARV medications.⁹⁹ In Africa, at least 22 of the 54 African countries have adopted an international or regional exhaustion regime to allow parallel imports of medicines.¹⁰⁰ One such example is in Kenya, where section 58(2) of the Industrial Property Act 2001 provides for international exhaustion:

The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.¹⁰¹

UNAIDS notes that since May 2002, organisations such as Médecins San Frontières (MSF), the Mission for Essential Drugs and Supplies and Action Aid have imported generic ARV medications into Kenya under these parallel import provisions.¹⁰²

Examples such as Kenya appear to contrast with the difficulties experienced in South Africa and The Philippines when both of those governments attempted to introduce international exhaustion regimes (see Section 3.1 above). However, there is limited information available regarding the international response to the parallel importation regimes presently in force in Africa and so it is unclear whether trade or diplomatic pressures were in fact placed on any of those African governments. Moreover, even if those countries were not subjected to international pressure, they must still contend with the reluctance of drug companies to discount prices in markets that allow parallel imports without export restrictions and must also face the risk that these companies may cease supplying their national markets altogether.¹⁰³

⁹⁸) Under Article 66.1 of the TRIPS Agreement, least-developed countries were given until 1 January 2006 to implement the provisions of the TRIPS Agreement. On 30 November 2005, this deadline was extended to 1 July 2013 or to the date a country was no longer 'least developed' if that was earlier. For pharmaceutical products, paragraph 7 of the Doha Declaration extended the deadline for least-developed countries to 1 January 2016.

⁹⁹) UNAIDS, *supra* note 47.

¹⁰⁰) *Ibid.*

¹⁰¹) Industrial Property Act 2001 No.3 (27 July 2001), Section 58(2).

¹⁰²) UNAIDS, *supra* note 47.

¹⁰³) Bale, *supra* note 92, at 648.

Against this backdrop, it is necessary to adopt an even more effective approach to the flexibilities in Article 6 in order to further improve affordability of medicines in the developing world and provide safeguards for pharmaceutical companies on returns from investments in drug R&D.¹⁰⁴ The proposal outlined below represents such an approach.

4.1. *A Regional Framework for the Harmonisation of Patent Exhaustion*

At present, a number of regional economic communities (RECs) have been established in Africa, Latin America and Asia, many of which strive to achieve economic cooperation and the harmonisation of macro-economic policies.¹⁰⁵ Independently of these RECs, a number of regional IP organisations have been founded to harmonise IP legislation for the member states of each region.¹⁰⁶ There are currently four such organisations in the developing world, namely, the Eurasian Patent Office in Eastern Europe and Central Asia, the OAPI and the African Regional Intellectual Property Office in the African region and the Andean Pact in Latin America.¹⁰⁷

The OAPI is a particularly good example of an efficient regional IP organisation in the developing world in that it implements a common procedure for granting IP rights and promotes economic development by effective protection of such rights.¹⁰⁸ The OAPI operates under the Revised Bangui Agreement of February 1999, which serves as the national patent law for all OAPI member countries and provides for a single OAPI patent that covers all 16 OAPI member states.¹⁰⁹ Importantly, under Article 8(1)(a) of the Revised Bangui Agreement, the 16 OAPI member states are

¹⁰⁴) See Buckley, *supra* note 16, at 644.

¹⁰⁵) In Africa, there are over 10 RECs, the largest being the Common Market for Eastern and South Africa, the Southern African Development Community, the Economic Community of West Africa States and the East African Community. In Latin America, the largest RECs are the Common Southern Market (MERCOSUR), the Andean Community, the Caribbean Community (CARICOM) and Central American Common Market. In Asia, regional organisations are more loosely institutionalised and have not yet involved the creation of separate *supranational* institutions. The relevant regional groupings are the Association of South East Asian Nations and the South Asian Association for Regional Cooperation: Sisule F. Musungu, Susan Villanueva and Roxana Blasetti, *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks*, World Health Organization, Part IV.1 (April 2004), available online at <http://ipronline.org/resources/docs/trips-health-southcetnre2004.pdf>.

¹⁰⁶) *Ibid.*, at Part IV.1.

¹⁰⁷) Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy: Report of the Commission on Intellectual Property Rights*, Commission on Intellectual Property Rights, available online at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

¹⁰⁸) *Ibid.*

¹⁰⁹) See Revised Bangui Agreement Relating to the Creation of an African Intellectual Property Organization, Constituting a Revision of the Agreement Relating to the Creation of an African and Malagasy Office of Industrial Property tit.1, para. 1, Article 2, 24 February 1999, available online at http://www.wipo.int/wipolex/en/other_treaties/details.jsp?treaty_id=227 (select 'Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization') (hereinafter Revised Bangui Agreement); see Nwauche, *supra* note 58, at V.1(a).

subject to a regional exhaustion regime such that parallel imports are permitted between OAPI member countries.¹¹⁰ In essence, the OAPI has created a microcosm of a regional parallel trade system in Francophone Africa.¹¹¹

Building upon this existing regional framework, it is recommended that regional IP organisations be established in each of the existing RECs and in any new regional communities created in the future. These organisations would operate in a similar manner to the OAPI in that they would facilitate the harmonisation of IP law within each designated region.¹¹² Whilst the function of each REC does and will invariably differ, agreements similar to the Revised Bangui Agreement ought to be introduced for each regional IP organisation so as to clearly articulate the legal requirements for IP rights in each respective region.

A regional approach to IP regulation will enable developing countries to identify common interests and formulate unified policies and standpoints.¹¹³ The success of the developing country delegation in the discussions prior to the introduction of the Doha Declaration (see Section 2.1 above) illustrates the benefits of coordination amongst developing countries.¹¹⁴ The establishment of IP organisations within each REC will enable developing countries to respond to trade pressures more effectively so as to avoid situations such as those experienced in South Africa and The Philippines.

4.2. *Regional Exhaustion within Each REC*

Using the Revised Bangui Agreement as a guide, it is proposed that a regime of regional exhaustion be introduced in each REC so as to permit parallel imports between the member states of each region. The proposal uses the Revised Bangui Agreement and the OAPI as a source of guidance rather than the regional exhaustion regime that operates in the EC. While it is important to appreciate the EC's experience in establishing and maintaining regional patent exhaustion, the specific EC policy objectives of a single market and free trade and the unique role of EC governments in fixing national drug prices indicate that it is far more useful to use the activities of the OAPI as a guideline for the introduction of regional exhaustion in the developing world.¹¹⁵

¹¹⁰ Revised Bangui Agreement, Article 8(1)(a); see T. Kongolo, *The New OAPI Agreement as Revised in February 1999: Complying with TRIPS*, 3 *Journal of World Intellectual Property* (2000), 717–736.

¹¹¹ Buckley, *supra* note 16, at 668.

¹¹² Musungu et al., *supra* note 105, at 35.

¹¹³ Buckley, *supra* note 16, at 668.

¹¹⁴ Abbott, *supra* note 43, at 480.

¹¹⁵ Buckley, *supra* note 16, at 668. Nonetheless, the importance of regional exhaustion in the EC was articulated by the CJEU in Case C-44/01 *Pippig Augenoptik v Hartlauer Handelsgesellschaft* [2003] ECR I-3095. The Court noted at 63, '... in completing the internal market as an area without internal frontiers in which free competition is to be ensured, parallel imports play an important role in preventing the compartmentalization of national markets.'

The proposed regional exhaustion model has three important features. The first two features operate in a similar manner to the regional exhaustion scheme under the Revised Bangui Agreement, while the third element introduces additional protection for pharmaceutical companies that will provide extra incentives for continued drug R&D and further encourage those companies to supply drugs to REC member states at a reduced price. The model will:

1. Permit parallel importation between the countries that form part of each REC;
2. Restrict the import of products originating from outside each REC; and
3. Prohibit those products that have been parallel imported into REC member states from being exported out of each REC.

Firstly, by allowing parallel trade between the countries within each REC, it is likely that lower drug prices will result for REC consumers.¹¹⁶ Malueg and Schwartz have shown that parallel importation can be beneficial among countries with similar demand structures (for example, within a regional trade agreement).¹¹⁷ Given that RECs are integrated markets structured according to their geographical location and the economic development levels of their members, the countries within each REC are likely to have similar demand patterns.¹¹⁸ Therefore, a high demand for ARV drugs in the Common Market for Eastern and South Africa may decrease ARV drug prices in that REC, while a high demand for anti-malarial drugs in the CARICOM may reduce the prices of those drugs in CARICOM member states. Musungu, Villanueva and Blasetti support these findings by noting that where regional groupings reflect similar geography, climatic conditions and cultural practices, then this will result in lower consumer drug prices due to increased economies of scale in procurement and distribution.¹¹⁹ Moreover, drug prices may also decrease given that regional exhaustion may reduce transportation costs typically incurred with parallel trade on an international level.¹²⁰

The second element involves restricting imports into each REC of patented products that originate in non-REC countries. This means that patent owners in REC member states will be able to enforce their rights to block parallel imports of any products patented outside each REC. In doing so, in each REC the source of imports of cheaper drugs will become the REC countries where medicines are priced at the lowest level. Importantly, parallel importation will only occur if there are differences in drug prices between the countries within each REC.¹²¹

¹¹⁶) Malueg and Schwartz, *supra* note 82; Entering the Jungle, *supra* note 22, at 177, 178.

¹¹⁷) *Ibid.*; Entering the Jungle, *supra* note 22, at 177, 178.

¹¹⁸) Musungu et al., *supra* note 105, at Part IV.

¹¹⁹) *Ibid.*, at Part IV.

¹²⁰) Maskus, *supra* note 18, at 21.

¹²¹) Buckley, *supra* note 16, at 632.

At present, there is ample evidence that drug prices differ significantly between countries in Africa.¹²² Therefore, by using the price differences between REC member states, cheaper medicines may be imported into those countries within each REC where drugs are sold at a higher price.

It is important to note that the Revised Bangui Agreement has been criticized by a number of different organizations given that it does not allow parallel imports to enter the OAPI from non-OAPI member countries.¹²³ The Agreement has been characterized as being more restrictive than necessary under the TRIPS Agreement¹²⁴ and several advocacy groups have warned that preventing imports from outside the OAPI ‘means that Francophone countries in Africa will no longer be able to shop around for the cheapest medicines’.¹²⁵ However, the proposed model will not depart from the Revised Bangui Agreement in respect of the treatment of non-REC patented products given that this would, in effect, implement a regime of international exhaustion for the countries in each REC. As discussed in Section 3.2 above, there is substantial opposition from pharmaceutical companies to developing country regimes of international exhaustion, particularly where parallel exports are not restricted.¹²⁶ Therefore, by limiting parallel imports to the countries within designated RECs, drug companies will be able to structure their pricing models more effectively and may be more inclined to provide lower-priced medicines in the knowledge that these drugs will only be parallel traded within each REC.¹²⁷

For those countries that currently employ international exhaustion, a move to regional exhaustion will necessarily restrict the markets from which those countries can source parallel imports. However, it is argued that there will likely be some, if not multiple, markets within each REC that will have lower-priced drugs available for the purposes of parallel importation.¹²⁸ Moreover, a regional

¹²²) A. Cameron, M. Ewen, D. Ross-Degnan, D. Ball and R. Laing, ‘Medicine Prices, Availability, and Affordability in 36 Developing and Middle-Income Countries: A Secondary Analysis’, 373 *Lancet* (2009), 240–249; Buckley, *supra* note 16 at 628, 656. Buckley notes that drug prices differ significantly between OAPI countries and also between countries in Africa more generally. For example, Buckley cites a study that found that the price of the drug ceftriaxone sold in Uganda was 124% higher than the price of the same drug sold in Ethiopia: K. Myhr, ‘Comparing Prices of Essential Drugs Between Four Countries in East Africa and with International Prices’, *Médecins Sans Frontières MedlinePlus* (2000), available online at <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a685032.html>, in Buckley, *supra* note 16, 628.

¹²³) See in particular Médecins Sans Frontières, ‘New Agreement on Patents for Medicines in Francophone Africa Threatens Health of Populations, MSF: Doctors Without Borders Press Release’ (11 May 2000), available online at <http://doctorswithoutborders.org/press/release.cfm?id=597&cat=press-release>; World Health Organization, ‘Fears over new regional patent agreement’, 28/29 *Essential Drugs Monitor* (2000) 35, available online at <http://apps.who.int/medicinedocs/pdf/s2248e/s2248e.pdf>.

¹²⁴) Sell, *supra* note 63, at 385.

¹²⁵) Bernard Pécoul, M.D., Director of the MSF Access to Essential Medicines Campaign in Médecins Sans Frontières, quoted in *supra* note 123.

¹²⁶) See Bale, *supra* note 92, at 648.

¹²⁷) *Ibid.*, at 648.

¹²⁸) Buckley, *supra* note 16, at 657, 658.

approach to patent exhaustion will allow all REC member states to benefit from enhanced coordination, better utilization of scarce resources and greater bargaining power.¹²⁹ Thus, those countries currently employing international exhaustion will be in a far better position under a regional exhaustion scheme than if they were to insist on maintaining international exhaustion.

The third feature of the proposed model is the prohibition of parallel exports from each REC so as to prevent slippage of low-cost drugs into industrialized nations. As discussed in Section 3.2 above, drug manufacturers are only able to maintain effective international price discrimination when parallel exports from low-priced markets are prevented from reaching high income -countries.¹³⁰ Therefore, this proposal recommends that those goods that are parallel imported within each REC be prohibited from leaving each region.¹³¹ One mechanism that might be used to prohibit parallel exports involves the use of private contracts to establish exclusive sales territories for authorized sellers.¹³² These contracts might be entered into between parallel importers and REC procurement authorities and might specify that products are only to be used within the territory of the REC and not exported outside.¹³³ For the sake of clarity, the IP laws created by the relevant REC IP organization might expressly provide that such contractual export restrictions are to be enforceable.¹³⁴

4.2. *Regulation and Enforcement of Regional Exhaustion*

Regional exhaustion will only be effective if strong regulatory and enforcement mechanisms are implemented in each REC.¹³⁵ In terms of regulation, it is important that developing countries within each REC investigate the development of appropriate competition policies.¹³⁶ National institutions should also be introduced to oversee and enforce those policies and undertake regular, periodic

¹²⁹) Buckley, *supra* note 16, at 659.

¹³⁰) Gallus, *supra* note 79, at 172; see D. Matthews and V. Munoz-Tellez, 'Parallel Trade: A User's Guide', in A. Krattiger, R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satyanarayana, G.D. Graff, C. Fernandez and S.P. Kowalski (eds), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (MIHR, Oxford, 2007), pp. 1429–1434.

¹³¹) Notably, the European Commission also endorses a model based on tiered pricing, noting that '[e]xperience with vaccines and contraceptives demonstrates that significant price differentials can be achieved between prices in developed and developing countries'. However, as a reflection of the need to curb parallel exports, the Commission warns that '[s]uch initiatives should be carefully monitored to ensure that scarce public finances that target prevention and services for the poorest and the many are not diverted to non-curative treatment for the few': International Intellectual Property Institute, *supra* note 8, at 18.

¹³²) Entering the Jungle, *supra* note 22, at 181.

¹³³) Health Research for Action, Regional Assessment of Patent and Related Issues and Access to Medicines: Final draft report for CARICOM member states and the Dominican Republic Version 1.14 (2009), available online at http://www.pancap.org/docs/World_Bank_Studies/Regional_Assessment_of_Patent_and_Related_Issues_and_Access_to_Medicines.pdf.

¹³⁴) *Ibid.*

¹³⁵) Commission on Intellectual Property Rights, *supra* note 107, at 144, 163, 164.

¹³⁶) *Ibid.*, at 147.

reviews of all aspects of the particular country's national IP regime to ensure that the laws and regulations are relevant and appropriate.¹³⁷ In relation to enforcement, this should involve a system of border controls by customs authorities in each REC member state to block all parallel exports from leaving the REC and to act as an efficient means of fighting counterfeits and other unlawful reproductions.¹³⁸ Effective enforcement might also include the establishment or strengthening of commercial courts or other specialised courts that would hear IP-related matters.¹³⁹ These courts would improve developing countries' capacity for national enforcement and provide enhanced access to justice for the business sector as a whole.¹⁴⁰ Whilst this is necessarily a brief overview, it is fundamental that regulatory and enforcement mechanisms similar to the above recommendations be adopted in order to ensure the efficiency of a regional exhaustion regime.

Ultimately, there are elements of this proposal that are likely to generate opposition from pharmaceutical companies intent on maintaining systems of price differentiation and maximizing company profits. As is likely with any proposal that attempts to lower drug prices to improve access to medicines, it may well be that company profits decrease as a result of this model. Yet the gravity of the problem of access to affordable medicines faced by so many developing nations requires that effective remedies be adopted and swiftly. As discussed above, a regional approach will enhance the international bargaining power of developing nations and will provide greater incentives for pharmaceutical companies to distribute medicines at decreased prices. Drug companies will be particularly encouraged by the fact that the proposal prohibits parallel imported goods from leaving each REC and requires that border controls are strengthened and enforcement mechanisms maintained in each REC. These factors provide strong reason as to why this approach should be adopted as an effective distribution solution.

5. Theoretical and Practical Implications of REC Regional Exhaustion

This Section addresses a number of theoretical and practical implications that might arise if the proposed regime of regional exhaustion were adopted. Firstly, a regional approach to IP regulation will need to comply with the MFN principle set out in Article 4 of the TRIPS Agreement. Secondly, the proposed model will need

¹³⁷ *Ibid.*, at 147.

¹³⁸ M. Wathelet, 'Trademark Protection', in A. Bychkov (ed.), *Customs Unions', in Trademark Protection in the New Customs Union between Russia, Kazakhstan and Belarus: A Right Holder's Perspective* (Baker & McKenzie, Moscow, 2010), available online at <http://www.iccwbo.org/uploadedFiles/BASCAP/Pages/Part%202.pdf>.

¹³⁹ Commission on Intellectual Property Rights, *supra* note 107, at 147.

¹⁴⁰ *Ibid.*

to comply with the provisions of the General Agreement on Tariffs and Trade 1994 (GATT 1994 Agreement).¹⁴¹

5.1. *The MFN Principle in Article 4 of the TRIPS Agreement*

It is important to analyse the relationship between the proposed regional exhaustion model and the MFN principle in Article 4 of the TRIPS Agreement. As expressly provided in Article 6 of the TRIPS Agreement, all exhaustion regimes implemented by WTO members must operate subject to the MFN principle in Article 4.¹⁴² A comparable MFN principle also exists in Article I of the GATT 1994 Agreement.¹⁴³ The relationship between the TRIPS Agreement and the GATT 1994 Agreement was considered by the WTO Appellate Body in the *US–Havana Club* decision.¹⁴⁴ In that case, the Appellate Body determined that the interpretation of the national treatment and MFN principles in the TRIPS Agreement is informed by the interpretation of comparable provisions in other WTO agreements.¹⁴⁵ Therefore, it is necessary to consider how regional exhaustion regimes affect the MFN principle in Article 4 of the TRIPS Agreement and the equivalent MFN provision in Article I of the GATT 1994 Agreement.

The MFN principle in the TRIPS Agreement provides for the immediate and unconditional extension to nationals of all WTO members ‘any advantage, favour, privilege or immunity’ granted with respect to the protection of IPRs to nationals of any country.¹⁴⁶ Under the proposed model, patent holders within each REC will not be permitted to invoke their patent rights to prevent parallel imports of goods placed on a market within the REC region but will be allowed to invoke their rights to prevent imports from outside the REC. Therefore, it might be argued that REC patent owners possess a particular ‘advantage’ over patent owners in countries outside of the REC that are subject to international exhaustion and cannot object

¹⁴¹) General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) (hereinafter GATT 1994 Agreement). Note that Frederick M. Abbott argues that Article 6 of the TRIPS Agreement does not exclude the application of the GATT 1994 Agreement provisions to the rules regarding exhaustion: Abbott, *supra* note 19, at 633. A contrary view has been presented by Marco Bronckers who asserts that only the TRIPS Agreement applies to exhaustion issues given that it is a *lex specialis* agreement that has absolute precedence over the GATT 1994 Agreement in intellectual property issues: M. Bronckers, ‘The Exhaustion of Patent Rights under WTO Law’, 32 *Journal of World Trade* (1998), 137–159, at 157. However, a large number of commentators reject Broncker’s views and argue that alongside the national treatment and MFN principle, the basic principles of the GATT 1994 Agreement are also applicable to the issue of exhaustion: see Mylly, *supra* note 24, at 6.

¹⁴²) TRIPS Agreement Article 6.

¹⁴³) GATT 1994 Agreement Article I.

¹⁴⁴) *United States – Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, Report of the Appellate Body, 2 January 2002 (US–Havana Club).

¹⁴⁵) *Ibid.*; see TRIPS Resource Book, *supra* note 27, at 249.

¹⁴⁶) TRIPS Agreement, Article 4.

to parallel imports once the product has been sold in any international market. This suggests that the proposed model may infringe the MFN principle unless a relevant exception can be relied upon.

Several regional trade agreements have relied on the exception to the MFN principle in Article 4(d) of the TRIPS Agreement.¹⁴⁷ However, given that Article 4(d) is limited to agreements that entered into force before the TRIPS Agreement, it cannot be used to exempt this model.¹⁴⁸ Where Article 4(d) does not apply, there is limited precedent and much uncertainty as to whether regional exhaustion models will be otherwise exempted from complying with the MFN principle.¹⁴⁹ Importantly, UNCTAD and ICTSD note that caution must be taken not to 'oversell the benefits of national treatment and MFN from the standpoint of developing WTO Members'.¹⁵⁰ UNCTAD and ICTSD suggest that Doha agenda discussions on improving the treatment of developing countries within the WTO framework indicated that WTO members felt that the national treatment and MFN principles may need to be adjusted in order to promote development.¹⁵¹ With this in mind, it is necessary to question whether a regional exhaustion model could in fact be overturned by invoking the MFN principle in the TRIPS Agreement if the final result is that developing countries remain at a distinct disadvantage in relation to more globally competitive foreign operators.¹⁵² The answer to this question is unclear but it may well have serious implications for the operation of the WTO and GATT.¹⁵³

Despite this uncertainty, if the proposed model is objected to on the basis of the MFN principle in Article I of the GATT 1994 Agreement, it may be possible for

¹⁴⁷ The EC, the Andean Community, the North American Free Trade Agreement and the MERCOSUR have all relied on Article 4(d) to avoid the MFN principle: D. Vivas-Eugui, 'Regional and bilateral agreements and a TRIPS-plus world: The Free Trade Area of the Americas (FTAA) Quaker International Affairs Programme and ICTSD', *TRIPS Issues Paper* 1 (2003), available online at <http://www.quno.org/geneva/pdf/economic/Issues/FTAs-TRIPS-plus-English.pdf>.

¹⁴⁸ TRIPS Agreement Article 4(d).

¹⁴⁹ TRIPS Resource Book, *supra* note 27, at 108. It is also interesting to note that when the EC was questioned about its reliance on Article 4(d) of the TRIPS Agreement at the TRIPS Council review of EC legislation in October 1997, the EC responded as follows:

The principle of national treatment in Article 3 of the TRIPS Agreement, and most-favoured-nation treatment in Article 4 of the TRIPS Agreement shall not apply to the principle of Communities exhaustion of patent rights, since the latter principle cannot be considered as an 'advantage, favour, privilege or immunity' but is rather a limitation or restriction to the rights conferred by the patent. The principle of Communities exhaustion is applicable to all persons and companies (EC or otherwise) holding a patent within the European Communities.

TRIPS Council Review IP/Q3/EEC/1 (Oct. 22, 1997) in C. Garrison, 'Exceptions to Patent Rights in Developing Countries', *UNCTAD-ICTSD Project on IPRs and Sustainable Development Issue Paper No. 17* (2006), available online at http://unctad.org/en/docs/iteipc200612_en.pdf. It is possible that a similar interpretation could be relied upon with respect to the proposed model.

¹⁵⁰ TRIPS Resource Book, *supra* note 27, at 89.

¹⁵¹ *Ibid.*, at 89.

¹⁵² *Ibid.*, at 89.

¹⁵³ *Ibid.*, at 89.

each REC to rely on Article XXIV of that Agreement to exempt the application of the MFN principle.¹⁵⁴ Article XXIV of the GATT 1994 Agreement provides for the possibility for WTO members to establish free trade areas and customs unions and allows derogation from the MFN principle.¹⁵⁵ In many ways, the proposed model will embody multiple free trade areas in that it will allow parallel imports within each REC and will also allow customs authorities to prevent certain goods in each REC market from leaving the respective region. UNCTAD and ICTSD note that the long history of GATT jurisprudence regarding the operation of regional arrangements within the multilateral trading system suggests that these arrangements use Article XXIV to excuse -derogation from MFN obligations.¹⁵⁶ These authors also note that similar assertions may be made in relation to the MFN principle in the TRIPS Agreement even though there is no express reference to such derogations in the text of the TRIPS Agreement itself.¹⁵⁷

5.2. *Provisions of the GATT 1994 Agreement*

The proposed regional approach must also comply with certain other provisions of the GATT 1994 Agreement. While there are a number of Articles in the GATT 1994 Agreement that may affect a regional exhaustion regime, for reasons of brevity this paper will address one of the most significant provisions, namely Article XI(1) of the GATT 1994 Agreement.

It is possible that the model's proposed proscription of parallel exporting may be contrary to Article XI(1) of the GATT 1994 Agreement.¹⁵⁸ Article XI(1) provides:

No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or *export licences* or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party ... [emphasis added]¹⁵⁹

¹⁵⁴) *Ibid.*, at 86.

¹⁵⁵) GATT 1994 Agreement Article XXIV. See in particular Mylly, *supra* note 24, at 11.

¹⁵⁶) TRIPS Resource Book, *supra* note 27 at 86. While Article XXIV may allow free trade areas to derogate from the MFN principle, Mylly questions whether Article XXIV permits regional exhaustion models that require member states to change from an international exhaustion regime to a regional exhaustion regime: Mylly, *supra* note 24 at 11. Stucki argues that Article XXIV would not allow a mandatory regional exhaustion regime to be introduced into a customs union or a free trade agreement since that would deprive individual member states from introducing or re-introducing international exhaustion: M. Stucki, 'Trademarks and Free Trade. An Analysis in Light of the Principle of Free Movement of Goods, the Exhaustion Doctrine in the EC Law and of the WTO Agreements', in Mylly, *supra* note 24, at 31. Under the proposed model, those developing country members of current RECs that allow international exhaustion will be required to move to a regime of regional exhaustion. Therefore, the views of commentators such as Stucki will need to be clarified before the proposed model can be implemented.

¹⁵⁷) TRIPS Resource Book, *supra* note 27, at 86.

¹⁵⁸) Gallus, *supra* note 79, at 172.

¹⁵⁹) GATT 1994 Agreement Article XI.

The effect of Article XI(1) is that all quantitative export restrictions on products destined for other WTO member state territories will be prohibited.¹⁶⁰ As discussed in Part 3.2 above, the proposed model will restrict parallel exports from leaving each REC. Thus, it is probable that the model will infringe Article XI(1) unless an exception can be relied upon.

In this respect, it may be possible to fit the proposed model within the exceptions to Article XI(1) set out in Article XI(2)(a). Article XI(2)(a) permits temporary export prohibitions or restrictions that ‘prevent or relieve critical shortages of foodstuffs or other products essential to the exporting contracting party’.¹⁶¹ It is arguable that this exception would apply to the proposed model to the extent that the proposed export restrictions relate to pharmaceutical products intended to improve the shortage of medicines in particular REC developing countries.¹⁶² Notably, the exception will only apply if there is a ‘critical’ shortage of medicines and must only be used temporarily. This exception has not yet been considered by a GATT or a WTO panel and so it is difficult to predict with certainty whether and to what extent it would apply to the proposed model.¹⁶³

The proposed export restrictions may also fit under the general exceptions in Article XX of the GATT 1994 Agreement.¹⁶⁴ Article XX(b) provides that export restrictions will be allowed if ‘necessary to protect human, animal or plant life or health’.¹⁶⁵ It may be possible for each REC to justify restrictions on exports of pharmaceuticals from each region on the grounds that these medicines are necessary to promote public health in each REC developing country. Under Article XX(j), export restrictions are allowed if they are ‘essential to the acquisition or distribution of products in general or local short supply’.¹⁶⁶ While Article XX has not been considered by a GATT or WTO panel, it may be easier to apply than Article XI(2)(a) given that it does not require that the shortage be ‘critical’ nor does it place any other qualification on the definition of ‘shortage’.¹⁶⁷ Given that a regime of regional exhaustion absent export restrictions is likely to increase drug prices in the developing countries within the region (see Section 3.2 above), it is suggested that the proposed export restrictions will fall within this exception.¹⁶⁸ Importantly, to fall under Article XX, the proposed parallel export restrictions would need to be constructed in such a manner so as to satisfy the requirements of the Article XX chapeau. Thus, the restrictions should not arbitrarily discriminate between export destination countries and ought not to constitute a disguised restriction

¹⁶⁰ GATT 1994 Agreement, Article XI.

¹⁶¹ GATT 1994 Agreement, Article XI(2)(a).

¹⁶² Gallus, *supra* note 79, at 172.

¹⁶³ *Ibid.*, at 172.

¹⁶⁴ *Ibid.*, at 173.

¹⁶⁵ GATT 1994 Agreement, Article XX(b).

¹⁶⁶ GATT 1994 Agreement, Article XX(j).

¹⁶⁷ Gallus, *supra* note 79, at 173.

¹⁶⁸ *Ibid.*, at 173.

on international trade.¹⁶⁹ It is arguable that these requirements will be met if the restrictions are drafted appropriately.¹⁷⁰

6. Conclusion

The relationship between parallel importation and access to pharmaceutical products has been a central issue in the debate surrounding IP rights and public policy objectives for many years. Recently, the HIV/AIDS crisis faced by developing countries worldwide has focused increasing attention on the role that parallel importation may play in the field of public health. Many poor countries are confronted with chronic ARV drug shortages and must contend with exorbitant prices for those medicines that are available. As a result, millions of people in developing countries cannot gain access to ARV therapy or other essential medicines for diseases prevalent in the developing world.

Ostensibly, the flexibilities provided in Article 6 of the TRIPS Agreement and reinforced in paragraph 5(d) of the Doha Declaration allow developing countries to adopt particular regimes of exhaustion to protect public health and promote access to medicines. There is evidence that many developing countries wish to rely on international exhaustion in order to permit parallel imports of cheaper medicines and help alleviate the national disease burden.¹⁷¹ However, these countries face serious difficulties in doing so. Several developing nations have been subjected to intense diplomatic and trade pressure to overturn international exhaustion regimes and eliminate parallel imports. As a result of such pressure, both the South African and the Philippine governments were forced to halt or abandon public health policies centred upon parallel importation. In this context, it appears that global governance in IP is often obtained through the mechanism of coercion.¹⁷² Even in the absence of international pressure, there is evidence that pharmaceutical companies increase the price of drugs and may even cease to supply or distribute medicines in those developing countries that have adopted international exhaustion without export restriction. Worryingly, pharmaceutical companies may also be less inclined to invest in R&D for medicines to cure diseases common in the developing world if developing countries allow international exhaustion.¹⁷³ Given the dire public health crises currently faced by developing countries, these constraints must be alleviated and a more effective solution to the distribution of medicines discovered. Now is the time to strike a

¹⁶⁹) GATT 1994 Agreement, Article XX.

¹⁷⁰) Gallus, *supra* note 79, at 173.

¹⁷¹) UNAIDS, *supra* note 47, at 13.

¹⁷²) See Sell, *supra* note 63, at 366, 367, 396; Abbott, *supra* note 43, at 471, 472.

¹⁷³) Bale, *supra* note 92, at 648.

better balance between IP and health policy that works in the best interests of developing nations.

The regional exhaustion model outlined in this paper attempts to resolve many of these difficulties by introducing complimentary legal and policy measures to the existing regional framework in the developing world. The model balances the many salient interests at stake: it promotes the interests of developing country governments and associated organisations in providing access to essential drugs, it protects the interests of pharmaceutical companies and their shareholders in maintaining profitability and fostering an optimum of level of pharmaceutical R&D and it ensures adequate protection for patent rights holders by reducing the risk of substandard and counterfeit medicines. While there are reasons why pharmaceutical companies may be resistant to this approach, it is pressing that the difficulties faced by developing nations under the current system are ameliorated and a more effective solution to medicine distribution adopted. The proposed model will play an important role in increasing access to pharmaceutical drugs so that, in the words of Bill Clinton, ‘people in the poorest countries will not have to go without medicine they so desperately need’.¹⁷⁴

¹⁷⁴) W.J. Clinton, Remarks at a World Trade Organization Luncheon in Seattle, in ‘t Hoen, *supra* note 46, at 47.