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Access to seeds: lessons from the access to medicines debate

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Cover photo: Cowpea seeds.

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A note about Food & Sustainability at QUNO

The Food & Sustainability programme of the Quaker United Nations Office addresses the complex and intertwined issues of trade and innovation policy and how they relate to poverty, hunger and food insecurity. We look at these issues with a particular focus on small-scale farmers, including fisherfolk, forest dwellers and pastoralists, a critical yet largely unheard voice in trade and innovation policy-making. Our work is collaborative, providing the space where it is safe to think, share and explore creative alternatives to a food system that does not work for the majority of the world's population.

Half of the world's food today is produced by 1.5 billion small-scale farmers. The figure is higher for food produced in the non-industrialized world -- up to 80%. Small-scale farmers are stewards of biodiversity; they maintain, adapt, improve and distribute plant varieties. The agricultural biological diversity they enhance and develop provides a major contribution to health and nutrition. They find ways to deal with new pests and disease. They are also active players in critical ecosystem processes, developing and adapting ideas for nutrient cycling, effective water use and the maintenance of soil fertility, both traditional and from elsewhere. Who could be better placed to help the world cope with global environmental change and feed the world than over a billion small-scale farmers living, working and experimenting on the front lines of change? Our work aims to ensure that trade and innovation policy are supportive of, and do not undermine, the critical role of small-scale farmers in providing local and global food security and the resilience we will need to facing ever-increasing environmental change.

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Summary

The history and dynamics of the access to medicines debate provide a number of reflections for those concerned with protecting farmers' access to seeds. Taking the Doha Declaration on TRIPS[1] and Public Health as its point of departure, this paper explores implications for interested parties at the international and national levels, as well as for multilateral institutions themselves.

Three lessons stand out in particular.

1) The process that led to the Declaration highlights the significance of global public opinion in shaping negotiations, as well as the value of combining this with pragmatic coalition-building amongst states, NGOs and the media.

2) Domestically, national governments should make creative use of TRIPS flexibilities. This has been done to bring down the cost of medicines in numerous countries and should be emulated by governments wishing to protect farmers' seed systems, which rely on experimentation, storage, exchange and re-use of seeds. 'Access' in this paper is taken to encompass these activities, rather than simply referring to the availability of new varieties developed by commercial breeders.

3) There is an urgent need for sustained, productive collaboration between relevant multilateral institutions. Collaboration between the WHO, WTO and WIPO on access to medicines has facilitated a broader consideration of innovation. Similar engagement is necessary between the FAO, WTO, WIPO and others to clarify the complicated governance structure for plant genetic resources and ensure farmers' continued access to seed.

[1] Trade-related aspects of intellectual property rights - the WTO agreement setting out minimum standards for IP, effective as of 1 January 1995.

Introduction

Farmers' freedom to experiment with, save, re-use and sell seed has underpinned thousands of years of agricultural innovation, including the development of locally-adapted varieties and the maintenance of on-farm biodiversity. There is increasing concern among those working on plant genetic resources for food and agriculture (PGRFA) that intellectual property rights (IPRs) and seed certification regimes are having a negative impact on seed saving and exchange, crop diversity and agricultural research and development.[1] This, it is argued, may lead to greater crop vulnerability, loss of genetic resources and increased global food insecurity.[2]

To compound the issue, many farmers are themselves food insecure, with around half of the world's undernourished population involved in small-scale agriculture.[3] Informal systems of exchange are often an important source of income for small-scale farmers: impeding it through tighter regulation can exacerbate food insecurity and limit the development and diffusion of locally-adapted varieties.

Access to genetic resources is therefore a prerequisite for local and global food security.[4] In terms of agriculture, this paper treats 'access' as encompassing the freedom to experiment with, save, re-use and sell seed. Following the *Right to Food Guidelines*[5] and the work of former Special Rapporteur Olivier de Schutter,[6] it also takes as

[1] Van Wijk J. 1996. 'How does stronger protection of intellectual property rights affect seed supply? Early evidence of impact.' *Natural Resource Perspectives* No.13, Overseas Development Institute.

[2] Stannard, C. 2013. 'The multilateral system of access and benefit sharing: could it have been constructed another way?' In: M. Halewood, I.L. Noriega and S. Louafi (eds.) *Crop genetic resources as a global commons: challenges in international law and governance.* Abingdon: Routledge. p.251

[3] Hazell, P. et al. 2007. *The future of small farms for poverty reduction and growth.* 2020 Discussion Paper 42. Washington, DC: IFPRI

[4] Rosendal, F.G.K, 'Regulating the use of genetic resources – between International authorities'. *European Environment*, 16(5), pp. 265-277

[5] FAO, 2005. Voluntary guidelines to support the progressive realization of the right to adequate food in the context of national food security. Adopted by the 127th session of the FAO Council, November 2004.

[6] For instance: De Schutter, O. 2009. 'Seed

Varietal selection of cowpeas. Photo: IITA/Flickr

its premise the notion that ensuring farmers' access to seeds represents an important aspect of fulfilling the right to food.

In a similar way, ensuring access to medicines has long been viewed as a critical part of fulfilling the right to health.[7] Both the access to medicines and access to seeds debates have their own case histories and forums in which discussions take place, but are both significantly affected by developments within intellectual property and the global trading system, as well as trends in multilateralism more generally. This paper draws out a number of relevant lessons from the access to medicines debate and considers how they may be applied to PGRFA as a means of furthering the goal of sustainable global food security.

Three lessons stand out in particular. First, those seeking to create traction in the negotiation of sensitive issues should work to generate sustained public interest in the topic. Second, there is a strong incentive for states to invest in a public sector capable of making use of existing flexibilities within international agreements. Finally, the complex regulatory structure for PGRFA makes it vital that the key multilateral bodies engage in the co-production of knowledge and collaboration that goes beyond formal mutual reporting.

policies and the right to food: enhancing agrobiodiversity and encouraging innovation.' Report presented to the UN General Assembly (64th session) (UN doc. A/64/170).

[7] See: http://www.who.int/medicines/areas/human_rights/en/

Common themes: seeds, medicines and IP

The realisation of access to medicines in fulfilling the right to health is heavily dependent on the legal framework governing their production and distribution.[8] Similarly, farmers' access to seeds is increasingly contingent on laws governing the procurement and use of genetic resources.[9] With medicines and foodstuffs being simultaneously fundamental to sustaining human life and enormously valuable economically, it is perhaps unsurprising that they are two of the most controversial issues under negotiation at the World Trade Organization (WTO).

The economic value of controlling access to these resources has been reflected in the expansion and strengthening of intellectual property regimes, for which purpose the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) has, until recently,[10] been IP proponents' most important tool. Being a member of the WTO is beneficial for states wishing to gain access to foreign markets, but it comes with a cost: countries must become Parties to all WTO Agreements. Aside from TRIPS, this includes the Technical Barriers to Trade (TBT) Agreement, Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Agriculture (AoA). States must therefore assume obligations that they might not otherwise choose – for instance having to grant patents in all fields of technology, where previously they may have chosen to grant either limited protection or none at all.[11]

The extension of IPRs in this respect has had significant impacts within both the public health and agricultural sectors. For farmers, predictable

[8] UNDP, 2011. *The Doha Declaration ten years on and its impact on access to medicines and the right to health.*

[9] It should be noted that at present many small scale farmers continue to access seeds through informal systems. The concern is that they are increasingly at risk of being incorporated into a system that limits their ability to access seed in this way.

[10] Arguably, pursuing multi- and pluri-lateral free trade agreements is proving a more productive strategy. See for instance Fink and Reichenmiller, 2006. 'Tightening TRIPS: intellectual property provisions of U.S. free trade agreements.' In: Newfarmer, R (ed.) *Trade, Doha and Development: a window into the issues.* Washington, DC: World Bank. 289-303

[11] UNDP, 2011. p.6

effects have included reduced rates of saving seeds, increased prices of purchased seeds and the required purchase of additional proprietary inputs at greater expense.[12] For health systems, the TRIPS Agreement's setting of a minimum IP standard for WTO Members has restricted the right to reject product or process patents. This limits states' ability to provide medicines at lower cost through production of generic drugs.[13] Consequently, much of the work of those advocating for access to medicines has involved clarifying and promoting 'flexibilities' that were design features of TRIPS, thereby helping developing countries in particular to provide medicines more affordably.[14]

It should be noted of course that while plant genetic resources and pharmaceuticals have both come under increasing regulation through the extension of intellectual property rights, there are some key differences in context.

Probably the most fundamental is the fact that the issues are approached from two different angles: access to medicines generally concerns how to get inexpensive medicines *into* countries that currently have no capacity to produce them domestically, while from a food security perspective the onus for many – the FAO included[15] – is on protecting and maintaining the agrobiodiversity that already exists *within* many farming systems, especially in the Global South. This aside however, the similarities in context are considerable: the inability of the market alone to deliver medicines and ensure food security for the world's poor; the urgency of strengthening national capacity to implement TRIPS flexibilities;[16]

[12] Howard, P.H. 2015. 'Intellectual property and consolidation in the seed industry.' *Crop Science* 55:1-7

[13] Helfer, L.R. 2014. 'Pharmaceutical patents and the human right to health: the contested evolution of the transnational legal order on access to medicines.' In: T. Halliday and G. Shaffer (eds.) T*ransnational Legal Orders.* Cambridge: Cambridge University Press. pp.311-339

[14] See for instance Nicol, D. and Owoeye, O. 2013. 'Using TRIPS flexibilities to facilitate access to medicines.' *Bulletin of the World Health Organisation* 91. pp.533-539

[15] See for instance FAO, 2010. *Biodiversity for food and agriculture: contributing to food security and sustainability in a changing world.* http://www.fao.org/fileadmin/templates/biodiversity_paia/PAR-FAO-book_lr.pdf

[16] See also: Bragdon, S.H., forthcoming. Reinvigorating the public sector: the case of food security, small-scale farmers, trade and intellectual property rules. Geneva: QUNO

the value of publicity in generating political capital to deal with sensitive negotiating topics; and the potential benefits of enhanced collaboration between relevant agencies. These are important themes and therefore form the backbone of the following analysis.

The Doha Declaration

For many, the Doha Declaration on the TRIPS Agreement and Public Health was seen as a significant victory, in which it was affirmed that TRIPS "does not and should not prevent members from taking measures to protect public health."[17] It also reaffirmed "the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose."[18] This was widely regarded as a confirmation of the validity of governments' decisions to issue compulsory licenses[19] to drive down the cost of medicines. However, this flexibility only extended as far as production of generic medicines for the *domestic* market, presenting a problem to countries that didn't have the capacity to manufacture generic pharmaceuticals themselves. Paragraph 6 of the Declaration required the TRIPS Council to find an 'expeditious' solution to this problem. The subsequent process led to a measure being agreed on 30 August 2003, which permitted the granting of compulsory licences for the production of pharmaceuticals for export, as well as changes in legislation to facilitate import to those countries without manufacturing capacity. At face value this appears a desirable outcome; regrettably however the stringent conditions placed on implementing such legislation drew criticism for being effectively unworkable.[20] Médecins Sans Frontières (MSF) for instance, bluntly declared it "neither expeditious, nor a solution."[21] Indeed, some critics have argued that the Paragraph 6 solution effectively nullified the gains made by developing countries in the Doha Declaration, making it very unlikely that new drugs will be effectively incorporated into treatments in southern countries.[22]

[17] WTO Ministerial Declaration on the TRIPS agreement and public health, WT/MIN(01)/DEC/2, 20 November 2001. Paragraph 4.

[18] Ibid. Paragraph 4

[19] When a government allows someone else to produce the patented product or process, compensating but without the consent of the patent owner.

[20] Nicol and Owoeye, 2013.

[21] MSF, 2006. *Neither expeditious, nor a solution: the WTO August 30th decision is unworkable.* Prepared for the XVI International AIDS Conference, Toronto, August 2006.

[22] Orsi, F. et al. 2007. 'TRIPS post-2005 and

Tellingly perhaps, the system has been used only once since the solution was concluded – for a supply of an anti-retroviral from Canada to Rwanda.[23]

Nonetheless, as Peter Drahos notes, the initial Declaration represented the unusual outcome of "a weak coalition making a gain that an observer would not have predicted."[24] Many advocates welcomed the Declaration because they saw it as giving primacy to public health over private intellectual property rights.[25] Given the significance of this acknowledgement and the fact that there have been similar dynamics present in WTO negotiations regarding agriculture, the following sections examine some of the implications for ensuring access to seeds. A similar recognition that states should prioritise protecting biodiversity and realising the right to food over private IP rights would be valuable indeed.

Public opinion, political capital

In considering the factors that led to the Declaration, Drahos has noted that the "networking of networks by the weak…created a form of sanction that cast its shadow over Doha, that of the court of global public opinion."[26] Analyses of the events leading up to the Declaration consistently cite a legal case initiated in 1997 by pharmaceutical companies against the South African government as significant in drawing public attention to the access to medicines problem.[27] In filing against a domestic law that was aimed, through various mechanisms, at lowering the cost of drugs to South Africans,[28] pharmaceutical companies opened themselves up to media criticism[29] for ostensibly placing patents and profits before lives.[30] As media attention intensified

access to new antiretroviral treatments in southern countries: issues and challenges.' *AIDS* 21. 1-7

[23] UNDP, 2011. p.22

[24] Drahos, P. 2007. 'Four lessons for developing countries from trade negotiations over access to medicines.' *Liverpool Law Review* 28. p.19

[25] T'Hoen, E.F.M. 2003. 'TRIPS, pharmaceutical patents, and access to essential medicines: a long way from Seattle to Doha' *Chicago Journal of International Law* 27(3)

[26] Drahos, 2007, p.19

[27] See for instance Murthy, 2002; Barton, 2004; Haakonsson and Richey, 2007.

[28] Sidley, P. 2001. 'Drug companies withdraw law suit against South Africa.' *British Medical Journal* 322(7293) p.1011

[29] See 'South Africa fights Aids drug apartheid.' *The Observer,* 14 January 2001. http://www.theguardian.com/business/2001/jan/14/aids.theobserver1

[30] Murthy, 2002, p.1313

in early 2001, supporting strong patent regimes quickly became equivalent to blocking HIV/AIDS sufferers' access to critical medication.[31] Faced with a public relations catastrophe, the 39 pharmaceutical companies eventually withdrew the lawsuit in April 2001, with MSF noting that the case had "caused public outrage worldwide."[32]

Importantly however, the global sentiment carried through to the WTO Doha Ministerial in November of the same year. Politically isolated and subject to intense public scrutiny, the U.S. abandoned the interests of its pharmaceutical sector and supported a declaration that "unambiguously helped to prevent millions of needless deaths"[33] by asserting the primacy of public health and clarifying the flexibilities within TRIPS.

Concerns over farmers' access to seeds and the impact of multinational corporate activity on informal, localised seed systems have yet to attract the same kind of mainstream publicity. Significantly, during the Doha negotiations, NGOs succeeding in reducing the complexities of patent law and HIV/AIDS to a simple choice comprehensible to the public: profits or lives.[34] Farmers need access to a diversity of seeds – to respond to environmental change and provide nutritious food to their families. Breeders' profits should not preclude this – in the same way that profit should not compromise an HIV/AIDS sufferer's access to treatment.

Unfortunately this link remains absent from the popular consciousness. As yet there has been no truly defining headline story that would provide an example for the mass media to frame the issue around, as there was with the South African drug controversy. Public concern about the current food system does appear to be growing on the back of court cases such as *Monsanto Canada Inc. v Schmeiser*[35] and documentaries such as *Food, Inc.* or *King Corn*,[36] but the continuing complexity and scale of these issues and the lack of a 'simple' solution has not yet generated the kind of political

[31] Ibid.

[32] See C. Schwetz, MSF. 'South Africa: public opinion forces 'Big Pharma' to back down.' http://www.msf.org/article/south-africa-public-opinion-forces-big-pharma-back-down

[33] Drahos, 2007, p.20

[34] Ibid.

[35] 2004 S.C.C.D.J. LEXIS 31, *Monsanto Canada Inc. v. Schmeiser*, summary available online URL: http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1507&context=btlj

[36] See: http://www.pbs.org/pov/foodinc/ ; http://www.kingcorn.net/

capital that compelled negotiators to excavate the sensitive subject of pharmaceuticals in the lead-up to the Doha Declaration. Going forward, it would be prudent for those state actors, NGOs and others seeking to positively influence law-making around seeds and IP to bear in mind the utility of public opinion as a catalyst: the attention and scrutiny around the South African case, consolidated by the Declaration, has effectively cemented access to medicines as a priority concern for multilateral processes relating to public health.

"It would be prudent for those seeking to positively influence law-making around seeds and IP to bear in mind the utility of public opinion as a catalyst."

Yet public scrutiny alone is insufficient to guarantee progress in multilateral negotiations on access issues. Networking and strategy were also critical in the process that led to the Doha Declaration. As Drahos describes in his useful review of the negotiations:

"*…an Africa Group that joined with a large coalition of developing countries that included Brazil and India, that drew on the power of Northern NGOs to work the Northern mass media, that gained the quiet support of some European states, that gained resources from Geneva-based NGOs was a group strengthened by many ties.*"[37]

Such are the dynamics at the multilateral level. Given the similarities in power relations, political divisions and subject matter, the Doha Declaration negotiations may represent a useful point of reference for those working to protect access to plant genetic resources through the WTO.

As important a lesson as this may be, any successes in that arena will be rendered moot if states do not have (or choose not to use) the ability to translate political momentum into effective use of policy space. The increasing tension between the WTO, bi- or pluri-lateral free-trade negotiations and other overlapping commitments brings domestic regulatory capacity into even sharper focus. The following section explores this in greater detail.

[37] Drahos, 2007. p.19

TRIPS flexibilities and a robust public sector

Occuring six years after Doha, the food price crisis of 2007-08 was an important catalyst for reversing the long-standing neglect of agriculture as a vital economic sector. Governments began to reassert the important role of the state in leading agricultural development programmes and the critical role of public investment generally.[38] As Wise and Murphy note: "the debates over how countries and international institutions should manage our food system are more open than they have been in decades."[39]

While the price crisis reflected broader underlying problems with the global food system, the push for a reassertion of public governance is pertinent to plant genetic resources specifically. This renewed space must be used to discuss and implement inclusive seed policies that can form the bedrock of sustainable food security.

QUNO's work focusing on small-scale farmers has, among other things, highlighted their lack of representation at the national and international levels, explored the effects of different approaches to IP protection of seeds on 'informal' seed and innovation systems and discussed what a more appropriate regulatory system might look like.[40]

In terms of TRIPS and access to medicines, the Doha Declaration made a necessary attempt to clarify some of the flexibilities relating to compulsory licensing for public health purposes and the restrictions on them. Flexibilities are present for plants too. Article 27.3(b) of the TRIPS Agreement, while obliging WTO Members to provide some form of plant variety protection (PVP), allows them to choose between providing patent protection or implementing an 'effective' *sui generis*[41] system. On the face of it, WTO members in meeting their TRIPS obligations have significant scope for designing their own nationally-appropriate

[38] Wise, T.A. and Murphy, S. 2012. *Resolving the food crisis: assessing global policy reforms since 2007.* Global Development and Environment Institute and Institute for Agriculture and Trade Policy. http://www.ase.tufts.edu/gdae/Pubs/rp/ResolvingFoodCrisis.pdf

[39] Ibid.p.6

[40] See for instance Bragdon, S.H. and Smith, C. 2015. *Small-scale farmer innovation.* Geneva: Quaker United Nations Office. http://quno.org/sites/default/files/resources/SSF%20Innovation%20WEB.pdf

[41] A system tailored to the country's national context.

regimes. Some argue however that the interpretation of an 'effective' *sui generis* system remains problematic, since the UPOV[42] Convention is the only agreed-upon example of such a system. The complexities and potential impacts of a UPOV-type regime on small-scale farmers is discussed in more detail later in this paper. At this point however it should suffice to note de Jonge's assertion that:

"*Given that saving and exchanging seed is the main source of seed for smallholder farmers in Sub-Saharan Africa, it seems only logical to conclude that any PVP system* [i.e. UPOV '91] *that would effectively ban such practices is likely to have a strong negative impact on smallholder farmers' livelihoods and on national food security…*"[43]

Bearing this in mind, it is troubling that joining UPOV '91 is often a demand made of developing countries during the negotiation of bi- and pluri-lateral free trade agreements,[44] either in exchange for other concessions or as a result of a weaker overall bargaining position.

This use of pluri-lateral agreements to circumvent multilateral deadlock and further national objectives is an example of what has been termed 'forum-shifting'[45] – undertaken in this case as a result of developed countries' frustration with WTO processes (particularly developing countries' increasing assertiveness and the scrutiny of civil society). The UPOV '91 example is just one within a suite of stricter, more specific criteria for IPRs than those outlined in TRIPS.[46] This trend has raised serious concerns among civil society, policy-makers and developing country negotiators who fear that governments' space to implement systems that support food security and livelihood objectives is rapidly being constricted.[47]

[42] Union Internationale pour la Protection des Obtentions Végétales

[43] De Jonge, B. 2014. 'Plant variety protection in sub-Saharan Africa: balancing commercial and smallholder farmers' interests.' *Journal of Politics and Law* 7(3) p.105

[44] See for instance FTAs concluded between the US and Lebanon, Jordan, Peru and Tunisia (Rajotte, 2006)

[45] See for instance Sell, S.K. 2009. 'Cat and mouse: industries', states' and NGOs' forum-shifting in the battle over intellectual property enforcement.' Available at SSRN: http://ssrn.com/abstract=1466156

[46] El Said, M.K. 2010. *Public health related TRIPS-plus provisions in bilateral trade agreements: a policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region*. WHO: Regional Office for the Eastern Mediterranean. p.227

[47] Rajotte, T. 2006. 'The negotiations web:

That these fears are well-founded is symptomatic of a broader truism: economic circumstances and political dynamics at the national level have an obvious and significant bearing on TRIPS implementation. Predictably, the countries that participated most in TRIPS negotiations had the greatest technical expertise on the agreement and made the most targeted efforts to use its inherent IP flexibilities.[48] While capacity building initiatives have been undertaken for countries without expertise in IP, concerns have been raised about the nature of this assistance and whether they truly encourage use of flexibilities rather than reproducing a specific set of norms not necessarily appropriate to the variations in national contexts.[49]

Though the Doha Declaration touches on the subject of technical cooperation and capacity-building throughout, fifteen years on, similar questions remain about the lack of attention to broader social or economic priorities within the programmes offered.[50]

The need for stronger domestic governance is therefore urgent if national IP systems are to be made context-appropriate whilst policy space still permits it. In this respect we see a significant contrast between public health and agriculture.

"The need for stronger domestic governance is urgent if national IP systems are to be made context-appropriate whilst policy space still permits it."

A variety of measures have been debated and adopted nationally in

complex connections.' In: : G. Tansey and T. Rajotte (eds.) *The future control of food: a guide to international negotiations and rules on intellectual property, biodiversity and food security.* London: Earthscan.

[48] Deere, C. 2009. *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries.* Oxford: Oxford University Press. Chapter 1

[49] Oliva, M.J. 2006. 'Promoting and extending the reach of intellectual property: the World Intellectual Property Organization (WIPO)' In: G. Tansey and T. Rajotte (eds.) *The future control of food: a guide to international negotiations and rules on intellectual property, biodiversity and food security.* London: Earthscan.

[50] See for instance Saana Consulting, 2011. *Analysing the impact of IP technical assistance.* Report commissioned for the UK Intellectual Property Office. p.74 Available online: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/311736/ipresearch-impactofip-201106.pdf

Saving sorghum seed, Maharashtra. Photo credit: ICRISAT/Flickr

numerous domestic public health systems – Malaysia, Indonesia and Thailand's effective use of compulsory licensing, for instance.[51] In Africa, Ghana, Guinea, Eritrea and Zambia, among others, have either issued compulsory licenses or undertaken parallel importing[52] to increase access to medicines.[53] In other cases, most notably in Brazil, the mere proposal of using compulsory licenses has proved useful for obtaining price discounts on drugs.[54] TRIPS flexibilities relating to food and agriculture have received comparatively little attention however, and many WTO Members have not used them or have only done so to a limited extent.[55] India, Thailand, Malaysia and Ethiopia stand out in a sparsely populated field of states

[51] Gupta, R. 2010. 'Compulsory licensing under TRIPS: how far it addresses public health concerns in developing nations.' *Journal of Intellectual Property Rights* 15. pp.357-363

[52] [2] Imports of a patented or trademarked product from a country where it is already marketed more cheaply. This cannot be challenged under the WTO dispute settlement system. See: http://www.who.int/trade/glossary/story070/en/

[53] For these examples and others, see: Love, J.P. 2007. *Recent examples of the use of compulsory licenses on patents.* KEI Research Note 2. Available online: http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf

[54] Ibid.

[55] Correa, C.M. 2012. *TRIPS-related patent flexibilities and food security: options for developing countries.* Geneva: QUNO / ICTSD.

implementing a *sui generis* system for PVP.[56] Ethiopia's system is designed to accommodate the interests of subsistence farmers, who are the major food producers and suppliers in the country.[57] The Thai PVP Act almost directly echoes work on access to medicines by providing for compulsory licensing: the Director-General of the Thai Department of Agriculture may at his discretion authorise third parties to use protected varieties without the authorisation of the breeder.[58] This, it is argued, provides essential stability to national welfare by strengthening food security.

Though such systems might be few in number, they demonstrate that the *sui generis* approach is more than simply aspirational. It is this kind of positive, ground-up policy-making tailored to the national context that many have argued, as Taubman does, is "of a piece with the logic and content of the [TRIPS] Agreement as a legal text, and with the decisions taken about its place within the legal and institutional framework."[59] Indeed, some maintain that states have been guilty of *over*compliance – that is, failing to implement the treaty in ways consistent with local needs and values in spite of deliberate ambiguity in its terms built-in to allow this.[60] This may be partly due to fear surrounding the politically-charged nature of negotiations at the WTO translating into hesitant policy-making at the domestic level.

"Taking advantage of current flexibilities in international law is not only valuable: it is essential for food security, biodiversity and farmer livelihoods."

[56] See QUNO: http://www.quno.org/resource/2014/1/developing-country-sui-generis-options-plant-variety-protection

[57] Hindeya, T.W. 2014. 'TRIPS, Plant Varieties and the Right to Food: A Case Study of Ethiopia's Legal Regime on Protection of Plant Varieties' (July 23, 2014). Available at SSRN: http://ssrn.com/abstract=2470877

[58] Lertdhamtewe, P. 2014. *Developing country sui generis options: Thailand's sui generis system of plant variety protection.* QUNO Briefing Paper No.3: Food, biological diversity and intellectual property. Available online: http://www.quno.org/sites/default/files/resources/QUNO%20Thailand%20-%20plant%20variety%20protection%20-%202014%20(1).pdf

[59] Taubman, A. 2015. 'Thematic review: negotiating "trade-related aspects" of intellectual property rights.' In: J. Watal and A. Taubman (eds.) *The making of the TRIPS Agreement: personal insights from the Uruguay Round negotiations.* WTO: Geneva

[60] Land, M. 2012. 'Rebalancing TRIPS' *Michigan Journal of International Law* 33(3) p.435

Ultimately then, while the ratcheting-up of IPR regimes is certainly troubling, there remains scope for creative, contextually relevant policy-making. For countries with significant numbers of small-scale farmers, investing in a more robust public sector capable of designing and administering a context-appropriate PVP system and taking advantage of current flexibilities in international law is not only valuable: it is essential for food security, biodiversity and farmer livelihoods in the long-term. Hindeya, for instance, notes that Ethiopia's system "strikes the necessary balance between the interests of right holders... the public interest in general and farmers' rights in particular."[61] Such a balance, he argues, allows Ethiopia's PVP regime to play a positive role in the country's realisation of the right to food.

This invocation of the right to food is an important one, reflecting the growing attention paid to the intersection of human rights and intellectual property law.[62] As became evident in the access to medicines debate, the human rights approach can be a useful entry point for those seeking to make trade and intellectual property regimes more equitable. But balancing TRIPS obligations and those enshrined in human rights treaties is just one challenge within a complex governance regime. This complexity both shapes and constrains implementation politics,[63] which affects both public health and plant genetic resource governance in turn. Noting the inter-agency work undertaken on the subject of access to medicines, the remainder of this paper explores the need for interagency engagement in order to ensure farmers' access to seed.

Better collaboration between multilateral institutions

The importance of collaboration among agencies to help improve access to medicine is widely acknowledged within the relevant institutions. Since 2005, the WTO has been convening annual workshops on intellectual property and public health; the most recent being a five-day Workshop on Trade and Public Health in October

[61] Hindeya, 2014. p.109

[62] See for instance Helfer, L.R. and Austin, G.W. 2011. Human rights and intellectual property: mapping the global interface. Cambridge: Cambridge University Press

[63] Helfer, L. 2009. 'Regime shifting in the international intellectual property system.' *Perspectives on politics* 7(1) 39-44

2015. Trilateral cooperation between the WHO, WTO and WIPO has led to a number of technical symposiums which, in their own words, seek to foster "a better understanding of the linkage between public health and intellectual property policies and to enhance a mutually supportive implementation of those policies."[64] A detailed study – *Promoting access to medical technologies and innovation* – was published in 2013 as a capacity-building resource for policy-makers.[65] While undoubtedly there remains a lot of work to ensure that policies are indeed "mutually supportive,"[66] the fact that the need for cooperation has been recognised, formalised and realised (in some form) is an important step.

It is also a necessary, but as yet unrealised, step that needs taking to address governance of plant genetic resources, since a number of features of the governance architecture remain mutually *un*supportive in this area – particularly in the way they affect small-scale farmers.[67]

One difference between the two areas of work is that access to medicines concerns fewer agencies: most significantly the WHO, WTO and WIPO. By contrast, bodies concerned with plant genetic resources include the WTO, the FAO (through its technical departments, the Commission on Genetic Resources and the World Committee on Food Security (CFS)), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the Convention on Biological Diversity (CBD) and its protocols (in particular the Nagoya Protocol) as well as both UPOV and WIPO (through the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and the Committee on Development and Intellectual Property).

Such an arrangement renders the landscape one of dispaate constituencies, regulatory complexity and grey areas. While attempting collaborative interagency work under these circumstances may be

[64] See WTO website: https://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm Last accessed 8th February 2016

[65] WHO, WIPO and WTO, 2012. *Promoting access to medical technologies and innovation: intersections between public health, intellectual property and trade.* Geneva: WHO.

[66] See for instance Lee, K. et al. 2009. 'Bridging the divide: global governance of trade and health.' *The Lancet* 373(9661) 416-422

[67] The TRIPS Agreement and the ITPGRFA, for example.

technically and politically daunting, it is critical if the multilateral system is to support the development of a more sustainable, just food system.

"Collaborative interagency work is critical if the multilateral system is to support the development of a more sustainable, just food system."

FAO, WIPO and the CBD

Small-scale farmers typically rely on so-called 'informal' seed systems, which interact with some aspects of 'formal' systems – that is, deliberately constructed and bounded systems involving a chain of activities, usually characterising farmers as the users of a certified end product.[68] 'Informal' seed systems on the other hand tend to be locally organized and therefore locally appropriate, flexibly embracing farmers' practices such as exchange and barter among friends and neighbours, acquisition through local markets and development of seed varieties from their own harvests.[69] Formal seed marketing can bring new varieties into the informal seed system, where they may be crossed with local materials to produce varieties adapted to the environmental context.[70] This process is important for maintaining and developing agrobiodiversity, improving productivity and by extension, enhancing the resilience of agricultural systems to shocks such as extreme weather events or new pests or diseases.

While there is recognition that climate change and greater food demand will increase interdependence between seed systems for the purposes of accessing a wider range of plant genetic diversity,[71] this awareness has not translated into policy at the international level. Intellectual property regimes, ostensibly designed to promote innovation, frame innovation in very narrow terms. Within agriculture it is typically conceptualised as a

[68] Sperling, L. and Cooper, H.D. 2003. 'Understanding seed systems and strengthening seed security.' In: *Improving the effectiveness and sustainability of seed relief. Proceedings of a stakeholders' workshop, Rome, 26-28 May 2003*. Rome: FAO

[69] Ibid.

[70] Louwaars, N. 2007. *Seeds of confusion: the impact of policies on seed systems.* PhD dissertation, Wageningen, The Netherlands. p.36 http://edepot.wur.nl/121915

[71] GIZ. 2014. *Farmers' seed systems: the challenge of linking formal and informal seed systems.* Documentation of the Expert Talk, 4th June 2014, Bonn.

process of development and transfer of technologies *to*, or sometimes *with* farmers, meaning that the complex and valuable innovative work done *by* farmers goes largely unrecognised.[72] Increasing awareness of the value of small-scale farmers' practices within multilateral IP discourse may therefore represent a step towards a more broadly appropriate IP system, assuming that is a common objective.

Under the auspices of the FAO, the International Treaty (ITPGRFA) – adopted in 2001, recognises the importance of traditional knowledge in protecting biodiversity, as well as the need for increased participation of farmers in decision making processes related to the use of such resources.[73] The Treaty establishes a multilateral system of sharing genetic resources, a process WIPO was involved in through work on terms of access.[74] Broader collaboration has been officially proposed before, with the FAO approving a draft memorandum of understanding in 2005, only for it to be repeatedly opposed in the WIPO General Assembly by countries concerned that WIPO's perspective on IP would negatively impact the FAO's mission and policies.[75]

Elsewhere, similar fears have stymied collaboration between WIPO and the CBD. Rajotte has noted the benefits that could arise from negotiators in each institution having a better understanding of the pertinent issues at the other, whilst describing a "schizophrenic" relationship: invitations to collaborate are matched by a deep anxiety that WIPO will have a detrimental influence on CBD discussions.[76] Perhaps because of this, WIPO's contributions have been largely restricted to technical documents that avoid taking a stance on IP issues.

Regardless of the validity of these concerns, they should not invalidate a broader consideration of the potentials of joint working, in particular the value that might accrue from a more even exchange with experts from the FAO sharing technical knowledge with WIPO, rather than being simply recipients of advice. Small-scale

[72] For a comprehensive review of small-scale farmer innovation, see QUNO, 2015. *Small-scale farmer innovation systems: a review of the current literature.* Geneva: QUNO

[73] International treaty on plant genetic resources for food and agriculture, Article 9. ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf

[74] Rajotte, T. 2006.

[75] Ibid.p.157

[76] Rajotte, 2006. p.154

farmers' importance and contribution to food security are increasingly highlighted within outputs associated with the FAO,[77] as is the importance of combining the strengths of both formal and informal seed systems to conserve a broad base of genetic diversity - a fundamenal aim of the CBD.[78] The 2015 release of FAO's Voluntary Guide for National Seed Policy Formation,[79] with the approval of the Commission on Genetic Resources for Food and Agriculture is a good example of this, indicating the ripeness of this subject for meaningful collaboration.

The key institutions must now move beyond simply reporting to each other in formal statements. Better communication and the co-production of knowledge in areas of intersection could feasibly lead to a broader understanding of appropriate seed governance and contribute in the long term to the development of more flexible technical assistance programmes and inclusive policy advice.

FAO and UPOV

First signed in 1961 by a group of Western European countries, the UPOV Convention is increasingly diverse in its membership, with new signatories in the last five years including Peru, Macedonia, Montenegro and Tanzania.[80] In light of this diversity, the relationship between UPOV and its members may deserve some new attention. In 1991, when UPOV's most recent iteration was adopted, many features of the international landscape were different. Concerns about loss of biological diversity were just emerging and being voiced during the CBD negotiations; the seed industry was only in the earliest stages of substantial consolidation; and there was less awareness of the need for agricultural systems to be resilient to a rapidly changing climate.[81]

Some of these concerns were made explicit in The State of the World's Plant Genetic Resources for Food and

[77] For example Wolfenson, K.D.M. 2013.

[78] FAO, 2010. *The second report on the state of the world's plant genetic resources for food and agriculture.* Rome: FAO

[79] FAO, 2015. *Voluntary guidelines to support the progressive realization of the right to adequate food in the context of national food security.* Adopted by the 127th session of the FAO Council, November 2004.

[80] See: http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf

[81] Dutfield, G. 2011. *Food, biological diversity and intellectual property: the role of the International Union for the Protection of New Varieties of Plants (UPOV).* Intellectual Property Issue Paper Number 9. Geneva: QUNO

Quinoa varieties, Peru. Photo: Bioversity International/Alfredo Camacho

Agriculture, published by FAO in 1997 and followed by an updated assessment in 2010. Chapter 8 of the second report addresses the contribution of PGRFA to food security and sustainable agricultural development, explaining the importance of local and indigenous varieties and the importance of this genetic diversity, while acknowledging that improved, careful linkages to formal seed systems would be advantageous.[82] Trilateral collaboration between the WHO, WTO and WIPO facilitated a joint reconsideration of innovation and access issues in medicine.[83] If undertaken appropriately, inter-agency discussion can make a similar contribution to a broader understanding of different, viable approaches to plant breeding and conservation. Whether the resulting body of information would be considered sufficiently important to merit further discussions among members about a revision (or at least a re-opening of the less restrictive UPOV 1978) would remain to be seen, but the fact remains: communication is important and more of it is needed to reduce the occurrence of agencies working at cross-purposes.

The importance of informal seed systems and small-scale farmers' *in-situ* conservation and innovation work is closely bound up in the

[82] FAO. 2010. *The second report on the state of the world's plant genetic resources for food and agriculture.* Rome: FAO http://www.fao.org/docrep/013/i1500e/i1500e.pdf

[83] WHO, WTO and WIPO, 2012.

politically challenging concept of Farmers' Rights. Recognised but not defined in the International Treaty,[84] the text emphasises the responsibility of national governments to protect and promote farmers' participation in decision-making, benefit sharing and preservation of traditional knowledge, as well as rights farmers have under national law to save, re-use, exchange and sell farm-saved seed.

Fundamentally, the International Treaty seeks to re-establish a form of collective pooling and management of genetic resources.[85] By contrast, a UPOV '91-based PVP system places ownership of certain genetic resources in the hands of individual breeders. There is concern that small-scale farmers will suffer twofold from such a system: first, because PVP does not encourage breeding related to the types of minor crops that enable farmers to meet communities' nutritional needs, and second, because although the UPOV system may allow on-farm replanting, its rules restrict farmers' freedom to buy seed from sources other than the original breeders or their licensees. This can limit their access since traditional varieties are likely to be excluded from government-approved seed lists.[86] The interaction between formal and informal systems – so important for the reasons described previously – may be substantially reduced by these rules.

Clearly, the relationships are not simple. For instance, while UPOV '91 reduces farmers' exemption from restrictions on protected varieties, countries that ratify it may restore a version of the exemption through national legislation.[87] At present however, the use of this mechanism by states is poorly understood. Indeed, the fundamental discussion around a UPOV-based PVP system suffers from a dearth of empirical data about

[84] Article 9.2, International Treaty on Plant Genetic Resources for Food and Agriculture.

[85] See Halewood, M. et al. 2013. 'The global crop commons and access and benefit-sharing laws: examining the limits of policy support for the collective pooling and management of plant genetic resources.' In: M. Halewood, I.L. Noriega and S. Louafi (eds.) *Crop genetic resources as a global commons: challenges in international law and governance*. London: Routledge

[86] Dutfield, 2006. p.42

[87] UPOV 1991, Article 15(2) notes that: 'each Contracting Party may…restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety…'

the impacts of the 1991 agreement on small-scale farmers.[88] A trilateral study could begin to address this gap, and within the International Treaty at least, there is some appetite for engagement. At its fifth session in September 2013, the Governing Body, through Resolution 8/2013, requested the Secretary "to invite UPOV and WIPO to jointly identify possible areas of interrelations among their respective international instruments."[89] This sentiment was echoed by many states during the sixth session in October 2016. Norway for example suggested joint symposiums with WIPO and UPOV and, supported by others, commissioning a study on the interrelations between them.[90] The actualisation of such activities could be a significant and valuable step forward and deserves encouragement for this reason.

FAO, WTO and WIPO

Collaborative work already takes place between the FAO and WTO, but does so in silos related to different WTO agreements. The WTO did take part in the preparatory work on the FAO's flagship publication, *The State of Agricultural Commodity Markets 2015-16*, which focused on trade and food security, specifically drawing on the WTO Agreement on Agriculture. Separately, the FAO and WTO have a formal relationship relating to sanitary and phytosanitary standards – the subject of another specific agreement. The same collaborative attention must be given to the TRIPS Agreement.

As discussed in this paper, there is a need to further explore some of the flexibilities available to states wishing to pursue *sui generis* PVP systems in fulfilment of their TRIPS obligations – in particular, moving beyond the limited conclusion that UPOV represents a suitable system. Engagement between the FAO, the WTO's TRIPS Secretariat and WIPO has potential for doing so. As Chistinck and Tvedt note: "if countries took the multiple commitments made under the different treaties into account, and tried to address them in an integrated manner, other options would probably appear as

[88] In 2005, UPOV conducted a study examining the impacts of PVP, but this did not take into account informal seed systems. See: http://www.upov.int/export/sites/upov/about/en/pdf/353_upov_report.pdf

[89] ITPGRFA, 2015. Report and review of submissions on the implementation of Article 9, Farmers' Rights. IT/GB-6/15/13 http://www.planttreaty.org/sites/default/files/gb6w13e.pdf

[90] IISD. 2015. 'Summary of the Sixth Session of the Governing Body of the International Treat on Plant Genetic Resources for Food and Agriculture: 5-9 October 2015.' Earth Negotiations Bulletin 9(656). http://www.iisd.ca/download/pdf/enb09656e.pdf

more promising than adopting the UPOV system."[91] Obviously it is to some extent incumbent upon national governments to pursue such enquiries themselves – as this paper has noted. If done effectively however, collaborative work between the multilateral institutions has the potential to benefit those countries whose limited institutional capacity makes it difficult to prioritise this examination of PVP over apparently more pressing concerns.

The trilateral study between WTO, WHO and WIPO explains that "from an initial focus…on access to medicines for infectious epidemics, debate has broadened to consider innovation policy and a wider range of diseases and medical technologies."[92] Insofar as current trends in intellectual property are based on a limited definition of what counts as 'innovation', a similar study - perhaps undertaken by FAO, the WTO and WIPO – might be useful in the same way. A greater appreciation of small-scale farmers' innovative activities and technologies, which go largely unrecognised within international legislation, might be one positive outcome. For instance, Rosendal notes that because WIPO's staff and are mostly comprised of patent lawyers, negotiations become very technical and lack inclusion of socioeconomic and environmental concerns.[93] If pursued effectively, cooperation with FAO could help foster a more holistic perspective and facilitate more inclusive international policy-making.

Another way of broadening the parameters of discussion might be to bring the issue of farmers' access to seeds to the WTO's TRIPS Council. There is precedent for bringing topics here that have become too controversial in other forums. Ecuador, for instance, with the support of a number of other states, first brought the issue of climate change (in particular facilitating green technology transfer) to the Council after climate negotiations at Cancún failed to settle on the inclusion of intellectual property provisions in the agreements.[94] Since then, the Council

[91] Chistinck, A. and Tvedt, M.W. 2015. *The UPOV Convention, Farmers' Rights and Human Rights: an integrated assessment of potentially conflicting legal networks.* Bonn: GIZ p.75

[92] WHO, WTO and WIPO, 2012. p.9

[93] Rosendal, 2009.

[94] WTO TRIPS Council document IP/C/W/585, 'Contribution of intellectual property to facilitating the transfer of environmentally rational technology: communication from Ecuador.' 27 February 2013. See: https://www.wto.org/english/tratop_e/trips_e/cchange_e.htm

has discussed the issue substantively in a number of meetings.[95] Were states to bring to the Council the issue of farmers' access to seeds, the relative absence of negotiating pressure in this space could generate similarly substantive discussion.

Paragraph 19 of the Doha Declaration mandated that the TRIPS Council look at the relationship between TRIPS and the CBD, as well as the protection of traditional knowledge and folklore, but discussions have not yielded any reports or decisions since 2011.[96] Given small-scale farmers' relevance to these subjects, introducing them as a specific topic may help to bring a sharper focus and generate a more productive exchange of evidence-based perspectives on the subject.

As observers, WIPO, FAO and other interested bodies would be able to contribute evidence and knowledge. In an ideal scenario, such discussion would raise the profile of small-scale farmers as innovators, develop a more nuanced understanding of innovation and lay the foundations of a more holistic approach to its incentivisation.

Prospects

This section has highlighted prospects for collaboration between some of the key institutions whose work increasingly influences farmers' access to seeds. Trilateral cooperation between the WHO, WTO and WIPO was intended to expand debate regarding (pharmaceutical) innovation and sought to reconcile the rights of intellectual property owners with the objective of making medicine globally accessible.

Judging the success of the initiative is not within the remit of this paper: rather, it is taken as an example of the possible informational benefits of such work. The intersection between TRIPS and public health is now well-established: achieving the same awareness of the intersection of international agreements and small-scale farmers would likely necessitate similar collaboration. Given FAO's ever-increasing expertise on the subject of small-scale farmers, agroecology and plant genetic resources for food and agriculture, its greater presence and role at the Geneva-based institutions would be beneficial and should be encouraged.

[95] Extract from minutes of meeting of the Council for Trade-related Aspects of Intellectual Property Rights, 11 June 2014. Available online: www.wto.org/english/tratop_e/trips_e/june2014_on_climate_e.pdf

[96] See: https://www.wto.org/english/tratop_e/trips_e/art27_3b_e.htm

Conclusion

The history and dynamics of the access to medicines debate provide some pertinent reflections for those concerned with protecting farmers' access to seeds. This paper has examined these, exploring implications for stakeholders at the national, international and multilateral levels.

The Doha Declaration highlighted the utility of global public opinion in shaping negotiation processes and the value of combining this with pragmatic coalition-building. Though the future of the Doha round of negotiations is in doubt following the 2015 WTO Nairobi Ministerial Conference, the process that led to the initial Declaration remains instructive.

Domestically, national governments' use of TRIPS flexibilities to bring down the cost of medicines should be emulated by governments wishing to protect farmers' seed systems and accommodate local contextual variations and requirements. States are entitled to develop *sui generis* systems of plant variety protection that would achieve this purpose. However, the limited capacity of many states to effectively implement these remains a concern, as do the nature of technical assistance programmes and the negotiation of bi- and pluri-lateral agreements that may result in countries implementing PVP systems that do not suit their contexts.

Given these realities, balanced collaboration and engagement between its constituent institutions is required if the multilateral system is to function effectively and retain its relevance. Farmer livelihoods, future food security and global biodiversity depend on it.

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