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Patents for Humanity

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Patents for Humanity

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This article evaluates two policy initiatives by the United States Government to address access to essential medicines—Priority Review vouchers and “Patents for Humanity”. Such proposals are aimed at speeding up the regulatory review of inventions with humanitarian uses and applications by the United States Food and Drug Administration, and the United States Patent and Trademark Office. It is argued that such measures fall short of international standards and norms established by the World Intellectual Property Organization Development Agenda 2007; the World Trade Organization’s Doha Declaration on the TRIPS Agreement and Public Health 2001 and the WTO General Council Decision of August 30, 2003; and the World Health Organization’s declarations on intellectual property and public health. This article concludes that there is a need for broader patent law reform in the United States to address matters of patent law and public health. Moreover, there is a need to experiment with other, more promising alternative models of research and development – such as medical innovation prizes, a Health Impact Fund, the Medicines Patent Pool, and Open Source Drug Discovery.

Introduction

The topic of intellectual property (IP) and access to essential medicines is a large field of jurisprudence, policy-making, and scholarly work.¹ There remain fiercely contested debates over patent law, public health, and access to essential medicines in a number of international fora—such as the World Intellectual Property Organization (WIPO),² the World Trade Organization (WTO)³ and the World Health Organization (WHO).⁴

In 2011, the Delegation of South Africa put forward a submission on behalf of the African Group and the Development Agenda Group to the WIPO Standing Committee on Patents.⁵ The submission emphasized:

“The issue of patents and its impact on public health has been the subject of discussion in many fora. In 2003, the 56th World Health Assembly of the World Health Organization (WHO) had urged Member States ‘to reaffirm that public health interests are paramount in both pharmaceutical and

¹ For an overview of the area, see Frederick Abbott and Graham Dukes, *Global Pharmaceutical Policy: Ensuring Medicines for Tomorrow’s World* (Cheltenham: Edward Elgar, 2009); Thomas Pogge, Matthew Rimmer and Kim Rubenstein, (eds) *Incentives for Global Public Health: Patent Law and Access to Medicines* (Cambridge: Cambridge University Press, 2010); Cynthia Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford: Oxford University Press, 2011); Duncan Matthews, *Intellectual Property, Human Rights and Development* (Cheltenham: Edward Elgar, 2011).

² *World Intellectual Property Organization Development Agenda 2007*, available at <http://www.wipo.int/ip-development/en/agenda/> [Accessed March 25, 2012]. For commentary, see Jeremy de Beer (ed.), *Implementing the World Intellectual Property Organization’s Development Agenda* (Ottawa: Wilfred Laurier University Press, 2009).

³ See World Trade Organization, “Doha Declaration on the TRIPS Agreement and Public Health”, November 14, 2001, WT/MIN(01)/DEC/2; World Trade Organization, “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health”, Sept. 1, 2003, WT/L/540. For commentary, see Sarah Joseph, *Blame It on the WTO? A Human Rights Critique* (Oxford: Oxford University Press, 2011).

⁴ World Health Organization, *Public Health, Innovation and Intellectual Property* (Geneva: 2008); World Health Organization, “Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”, May 24, 2008, WHA61.21.

⁵ “Proposal Submitted by the Delegation of South Africa on Behalf of the African Group and the Development Agenda Group”, May 18, 2011, SCP/16/7, p.16.

health policies,’ and ‘to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).’ Furthermore, the 2001 Doha Ministerial Declaration on the TRIPS Agreement and Public Health affirmed, *inter alia*, that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.

The WHO Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property adopted in 2008 states that while international IP agreements contain flexibilities that could facilitate increased access to pharmaceutical products by developing countries, they may face obstacles in the use of flexibilities. Thus, there is a need to address this problem and remove obstacles faced by developing countries in making full use of the public health related flexibilities.”

The Delegation of South Africa concluded:

“In order to protect public health, the flexibilities and safeguards contained and allowed by the TRIPS Agreement would need to be incorporated in the national legislation”.

The Delegation further insisted: “There is equally the need to ensure that international commitments, including regional and bilateral arrangements, do not restrict these flexibilities and safeguards”. South Africa also emphasized that “these safeguards and flexibilities have to be workable in practice, particularly with respect to ensuring access to medicine”.

In December 2011, the US Government made a submission to the WIPO Standing Committee on Patents on the topic of patents and health.⁶ Espousing a position of intellectual property rights maximalism, the US Government maintained that the patent rights of pharmaceutical drug companies should receive strong and unyielding protection:

“Weakening the patent rights granted to pharmaceutical researchers and manufacturers in certain markets not only removes or reduces the incentive to develop new medicines, but also leads manufacturers to keep already developed medicines out of those markets. It has been shown that more goods become available in developing countries when IP rights are strengthened there. In the particular case of medicines, it has been shown that all else being equal, a new drug is more likely to be launched in a country where patent protection is strong, rather than one where such protection is lacking.

To successfully employ a technology such as manufacturing of medicines, know-how and specialized skills are often required in addition to the detailed disclosure found, for example, in a patent. Resorting to a compulsory license or other non-voluntary mechanism would not gain the cooperation of the patent owner, and the recipient of the compulsory license may not easily be able to successfully manufacture the medicine.”

In this statement, the US Government disparaged access mechanisms—such as compulsory licensing, Crown or government use and acquisition, and technology transfer—even though such measures have long been recognised and accepted as legitimate under international law. The US Government expressed a preference for alternative voluntary licensing and funding mechanisms—such as patent pools, advance market commitments, corporate social responsibility programmes, and philanthropic donations.

⁶ “Patents and Health: A Proposal by the Delegation of the United States of America”, December 7, 2011, SCP 17/11.

At the international level, there has been a concerted push by the United States to impose TRIPs Plus standards in respect of patent protection for pharmaceutical drugs through the means of bilateral and regional free trade agreements.⁷ The United States has been pushing for TRIPs Double Plus agreements in new fora—particularly with the Anti-Counterfeiting Trade Agreement⁸ and the proposed Trans-Pacific Partnership Agreement.⁹

Nonetheless, at the domestic level, the US Government has experimented with measures designed to address access to essential medicines—most notably, priority review vouchers and fast-track mechanisms for humanitarian patents. Such mechanisms are worthy of closer analysis and scrutiny.

This article provides a critical evaluation of two measures promoted by the US Congress and the US Government to address access to essential medicines—priority review vouchers and “Patents for Humanity”. It seeks to assess whether these measures are appropriate and well-adapted to be applied elsewhere in other jurisdictions, or incorporated into international schemes. This article does not seek to survey or cover the large field of access to medicines. It has a narrow scope and a particular focus—namely, the use of vouchers and fast-track mechanisms in the context of access to medicines. I have considered a number of policy issues related to access to essential medicines elsewhere and do not intend to repeat or cover that same ground.¹⁰ Part I looks at the development of priority review vouchers under the US Food and Drug Administration (FDA). Part 2 considers the programme of the US Patent and Trademark Office (USPTO) to provide fast-track mechanisms for “Patents for Humanity”. This article concludes that such measures provide minor incentives for the manufacturers of pharmaceutical drugs and medicines, and do little to provide or ensure access to essential medicines. It is argued that the US Government’s measures fall well short of implementing the WIPO Development Agenda, the WTO’s Doha Declaration on the TRIPs Agreement and Public Health, the WTO General Council Decision of 30 August 2003, and the WHO declarations on intellectual property and public health. The conclusion flags the need for a consideration of alternative mechanisms for research and development in respect of access to essential medicines.

I. Priority review vouchers

The FDA is a key institution in respect of the regulation of pharmaceutical drugs and medicines.¹¹ Under the Orphan Drugs Act 1983, the FDA has traditionally sought to advance the evaluation and development of products for the diagnosis or treatment of rare diseases and conditions. The Drug Price Competition and Patent Term Restoration Act 1984—the Hatch-Waxman Act—establishes a process to allow for generic pharmaceutical drug manufacturers to file for regulatory approval from the FDA. There has been much discussion as to whether the FDA could provide greater incentives for the regulatory review of neglected diseases.

⁷ See e.g. United States-Singapore Free Trade Agreement 2003; United States-Chile Free Trade Agreement 2003; Australia-United States Free Trade Agreement 2004; United States-Dominican Republic-Central America Free Trade Agreement 2005.

⁸ Anti-Counterfeiting Trade Agreement 2011, not yet in force. For commentary on ACTA, see Brook Baker, “ACTA—Risks of Third-Party Enforcement for Access to Medicines” (2011) 26(3) *American University Journal of International Law* 579; Andrew Rens, “Collateral Damage—The Impact of ACTA and the Enforcement Agenda on the World’s Poorest Peoples” (2011) 26(3) *American University Journal of International Law* 784; Peter K. Yu, “Six Secret (and Now Open) Fears of ACTA” (2011) 64 *SMU Law Review* 101.

⁹ Department of Foreign Affairs and Trade, “Trans-Pacific Partnership Agreement Negotiations”, available at <http://www.dfat.gov.au/fta/tpp/> [Accessed March 25, 2012]; Deborah Gleeson, Kyla Tienhaara and Thomas Faunce, “Challenges to Australia’s National Health Policy from Trade and Investment Agreements” (2012) 196(5) *The Medical Journal of Australia* 1.

¹⁰ See Matthew Rimmer, “The Race to Patent the SARS Virus: The TRIPs Agreement and Access to Essential Medicines” (2004) 5(2) *Melbourne Journal of International Law* 335; Matthew Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889; Matthew Rimmer, “Race Against Time: The Export of Essential Medicines to Rwanda” (2008) 1(2) *Public Health Ethics* 89; Matthew Rimmer, “The Lazarus Effect: The (RED) Campaign, and Creative Capitalism” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010); Thomas Pogge, Matthew Rimmer and Kim Rubenstein, “Access to Essential Medicines: Public Health and International Law” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010).

¹¹ See John Braithwaite and Peter Drahos, *Global Business Regulation* (Cambridge: Cambridge University Press, 2000); Marcia Angell, *The Truth about the Drug Companies: How They Deceive Us and What to Do about It* (New York: Random House, 2004); Fran Hawthorne, *Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat* (Hoboken: John Wiley & Sons, 2005).

A. A new incentive

Some academics have suggested reforms to drug marketing and regulatory review mechanisms. In 2006, David Ridley, Henry Grabowski and Jeffrey Moe from Duke University proposed a system to give pharmaceutical companies incentives for developing drugs for neglected diseases.¹² The authors noted the scale of the problem, which they sought to address:

“Infectious and parasitic diseases accounted for more than half of healthy years lost in Africa in 2002, but only 3 per cent of healthy years lost in developed countries. Communicable diseases that disproportionately affect people in developing countries include malaria, leishmaniasis, Chagas disease, tuberculosis, dengue fever, and African trypanosomiasis. Lack of scientific knowledge is not the major barrier to drug development for many of these diseases. Scientists know more about the biology, immunology, and genetics of leishmania and trypanosomes than any other parasites. Rather, successful compounds often do not enter costly clinical development. The barrier is a lack of financial incentive. Because most people suffering from these neglected diseases live in low-income countries, there is little financial incentive for private pharmaceutical companies to invest in research and development (R&D) for new treatments.”

Under the proposal, a drug developer with a treatment for a neglected disease would receive a “priority review voucher” from the FDA for an expedited review of a second treatment of its choice. The voucher could be sold to another company or acquired as part of a buyout of its owner. Summarizing the proposal, the authors argued:

“We propose a novel pull mechanism in which a voucher is awarded for creating and licensing a drug that treats neglected diseases in the developing world. The transferable voucher would give the bearer priority-review status at the FDA for another drug. If the voucher speeds FDA approval by a year, it could increase the present value of sales of a blockbuster drug by more than US\$300 million. The developer also would be eligible for orphan drug tax credits. In a well-functioning voucher market, drugs that consumers and payers value more would reach the market sooner. We estimate that the additional cost of faster FDA review would be US\$1 million and could be passed on to the manufacturer. The cost to the government would be the additional cost associated with any drug for a neglected disease (that is, orphan drug tax credits).”

The authors conclude that the priority review voucher could provide benefits in developing countries and the United States at relatively low cost:

“The voucher would appeal to pharmaceutical manufacturers, consumers (who appreciate faster access to blockbuster drugs), the military (whose personnel operate in developing countries and might be exposed to neglected diseases), and advocates for health in developing countries.”

The lead author, David Ridley, observed:

“Tropical and infectious diseases cause enormous suffering, but because the victims are in poor countries there is little or no profit for pharmaceutical manufacturers. Our plan makes it commercially viable to develop new therapies for neglected diseases.”¹³

¹² David Ridley, Henry Grabowski and Jeffrey Moe, “Developing Drugs for Developing Countries” (2006) 25(2) *Health Affairs* 313.

¹³ Duke University, “Duke Faculty Propose Incentives for Developing Drugs for Neglected Diseases”, March 7, 2006, available at http://today.duke.edu/2006/03/developing_drugs.html [Accessed March 25, 2012].

Moe commented: “Our concept has benefits for U.S. consumers, discovery-driven companies and neglected disease sufferers”. The researcher added: “Those of us who have benefited so greatly from the fruits of innovative research and development shouldn’t accept ‘market failure’ as insurmountable when so many suffer globally.”

This work has undoubtedly had a high impact, and tapped into the zeitgeist. Not only has it been widely cited amongst researchers and scholars,¹⁴ the notion of priority review vouchers have been picked up by legislators. No doubt part of the appeal and attraction of the proposal was that it transcended the deadlocked debates over patent law, public health, and access to essential medicines.

In 2007, the US Congress adopted this proposal as part of the Food and Drug Administration Amendments Act 2007.¹⁵ Section 1102 of the amendments introduces a new s.524 to the Federal Food, Drug, and Cosmetic Act 1938. Section 524(a)(1) defines “priority review” as

“review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007”.

Section 524(a)(2) defines a “priority review voucher” as

“a voucher issued by the Secretary to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) or section 351 of the Public Health Service Act after the date of approval of the tropical disease product application.”

Section 524(a)(3) provides that the term “tropical disease” can include tuberculosis, malaria, blinding trachoma, buruli ulcer, cholera, dengue, dracunculiasis (guinea-worm disease), fascioliasis, Human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, yaws, and “any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations, designated by regulation by the Secretary”.

Section 524(b)(1) provides that “the Secretary shall award a priority review voucher to the sponsor of a tropical disease product application upon approval by the Secretary of such tropical disease product application”. Section 524(b)(2) states:

“The sponsor of a tropical disease product that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under s.505(b)(1) or s.351 of the Public Health Service Act will be submitted after the date of the approval of the tropical disease product application.”

Section 524(c) contains a limitation—providing that priority review vouchers cannot be granted in respect of tropical disease product applications made prior to the date of the enactment of the legislation. Section 524(c) address priority review user fees.

In April 2011, Senator Robert Casey, a Democrat from Pennsylvania, introduced a bill called the Creating Hope Act 2011.¹⁶ The legislation was designed to expand the priority review voucher scheme to apply to tropical and rare paediatric diseases. Senator Casey said of the initiative:

¹⁴ Google Scholar identifies 72 citations of the paper, and the Web of Knowledge notes 34 citations of the paper, as of March 15, 2012.

¹⁵ Food and Drug Administration Amendments Act of 2007 s.1102, 15 U.S.C. s.301 (2006).

¹⁶ For a discussion of the legislative proposal, see Edward Connor and Pablo Cure, “‘Creating Hope’ and Other Incentives for Drug Development in Children” (2011) 3(66) *Science Translational Medicine* 66. There have also been earlier initiatives like this—for example, Senators Sam Brownback (R-Kan.) and Sherrod Brown (D-Ohio) put forward the Creating Hope Act of 2010, s.3697.

“Millions of Americans are affected by rare diseases and neglected conditions for which there is currently no hope because there is no treatment. The Creating Hope Act brings light where there is now only darkness by providing an incentive, at no cost to taxpayers, to develop treatments for these illnesses. The broad support for this legislation speaks to the need to solve this problem.”¹⁷

Casey’s press release noted:

“Despite this significant unmet medical need, private companies seldom pursue new therapies for tropical illnesses or rare diseases because it requires making an investment in products that will likely not recoup the high costs associated with their research, development, marketing and distribution.”

It also elaborated: “Developing products for children is particularly challenging because of the difficulties associated with conducting clinical trials on this population.”

The legislation contained a number of measures to reform and revise the priority review voucher scheme. First, the scheme would expand priority review vouchers to include treatments for paediatric rare diseases. Secondly, the Bill would prevent companies from receiving a voucher for products that they already market in other countries. Thirdly, the Bill would allow for vouchers to be transferable and tradable (which is controversial). Fourthly, the Bill would allow sponsors to seek a designation from the FDA before they submit their new drug application that the drug, if approved, will qualify for a voucher. Fifthly, the Bill would strength reporting and marketing requirements. Sixthly, the Bill would add the Chagas disease to the FDA’s list of neglected tropical diseases.

The legislative proposal was supported by advocates for children’s health. Nancy Goodman, Executive Director of Kids v. Cancer, observed:

“I want to ensure that one day, children like my son, Jacob, who are diagnosed with brain cancer and other serious and rare diseases, will have drugs available for safe and effective treatments.”

Dr. Peter C. Adamson, Chair of the Children’s Oncology Group at the Children’s Hospital of Philadelphia, commented:

“As a pediatric oncologist who leads the Children’s Oncology Group, a nationwide team of physicians, scientists, nurses and others dedicated to treating children with cancer, I know that improving the outcome for children with cancer will require development of new, more effective anti-cancer drugs. With cancer remaining the leading cause of disease related death in children in the United States, the Creating Hope Act of 2011 will provide a critically important new way to help engage scientists in the biopharmaceutical industry to help develop better medicines for the children we care for.”

Peter Saltonstall, President and CEO of the National Organization for Rare Disorders (NORD), commented: “By expanding priority review vouchers to include pediatric rare diseases, this legislation would encourage the development of treatments for children with serious rare diseases.” The legislation has been referred to the Senate Committee on Health, Education, Labor, and Pensions for consideration.

In September 2011, Representative Michael McCaul, a Republican from Texas, introduced legislation (H.R. 3059) to amend the Federal Food, Drug, and Cosmetic Act to “improve the priority review voucher incentive program relating to tropical and rare pediatric diseases”. The Bill has 24 co-sponsors. The legislation was referred to the House Energy and Commerce Committee.

¹⁷ Robert Casey, “Casey Introduces Bipartisan Bill to Help Develop Treatments for Rare Diseases”, March 17, 2011, available at <http://www.casey.senate.gov/newsroom/press/release/?id=a8deb1ac-6ffd-424b-84b9-c166b4d6ff7> [Accessed March 25, 2012].

The issue of antibiotic resistance is a particular issue for pharmaceutical innovation.¹⁸ There has been some discussion as to whether a priority review voucher scheme would be effective in encouraging the development of drugs with antibacterial resistance. Ramanan Laxminarayan and John Powers comment that

“without clear eligibility criteria related to novelty and ability to address public health needs, application of a similar scheme for antibacterials might encourage manufacturers to develop ‘me-too’ antibacterials solely to earn the vouchers, which are economically valuable”.¹⁹

There has also been consideration of whether priority review vouchers could be adapted to the field of biosecurity and promote the clinical development of medical countermeasures—including drugs and vaccines—effective against chemical, biological, radiological and nuclear threats to the United States.²⁰

David Ridley and Alfonso Calles Sánchez have also argued that a priority review voucher scheme should be established in the European Union to be awarded by the European Medicines Agency or the European Commission.²¹ The authors contend: “For each new neglected-disease therapy approved, the developer would be awarded a voucher for priority marketing authorisation and accelerated pricing and reimbursement procedures for a medicine of the developer’s choice.” Ridley and Sánchez comment:

“The pricing and reimbursement feature differs from the US version of the programme, which only accelerates FDA scientific review; the US Government plays a small part in negotiating prices with manufacturers, whereas pricing and reimbursement negotiations in Europe are important and time-consuming features of government involvement.”

Ridley and Sánchez conclude that “European governments have made substantial contributions to research and development of medicines for orphan and neglected diseases” and that “the introduction of a priority review voucher scheme in the EU similar to that in the USA would be a useful additional contribution”. The authors maintain: “The use of similar systems in the two regions could help to expand incentives for developing new treatments for neglected diseases.” However, this proposal has found little favour with the European Union—especially at a time when it has been grappling with the global financial crisis, and austerity measures in various Member States of the European Union.

There has also been a push to include priority review vouchers at the international level. In 2010, the WHO Expert Working Group on Research and Development Financing considered whether the concept of the priority review voucher should be implemented.²² Rightly in my opinion, the Group was of the view that the proposal was flawed:

“This proposal offers ‘priority regulatory review’ of a commercial product in return for registration of a drug for a neglected disease in the United States. Priority review allows a company to bring a product to the market faster, resulting in many hundreds of millions of dollars of additional sales if the product is successful. It has been estimated that a reduction in the review time from 19.4 to 6.4 months for a drug receiving priority review could be worth US\$322 million to developers. The vouchers can be traded. The design of the priority review voucher has, however, major flaws and it could be of substantially greater value if these were addressed. A neglected disease product need not

¹⁸ Kevin Outterson, “The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation” (2010) 31(3) *Cardozo Law Review* 613.

¹⁹ Ramanan Laxminarayan and John Powers, “From the Analyst’s Couch: Antibacterial R&D Incentives” (2011) 10 *Nature Reviews Drug Discovery* 727.

²⁰ Jason Matheny, Michael Mair and Bradley Smith, “Cost/Success Projections for US Biodefense Countermeasure Development” (2008) 26 *Nature Biotechnology* 981.

²¹ David Ridley and Alfonso Calles Sánchez, “Introduction of European Priority Review Vouchers to Encourage Development of New Medicines for Neglected Diseases” (2010) 376(9744) *The Lancet* 922.

²² World Health Organization, *The Report of the World Health Organization Expert Working Group on Research and Development Financing* (Geneva: 2010), p.75.

be suitable for use in developing countries, and developers need only to register the product in the United States. Thus, firms can register products in the United States that have already been used in other countries for many years (as was the case with the first product to receive a priority review voucher); and there is no link between award of the voucher and actual uptake of the product in developing countries, i.e. the firm does not have to register or sell the product in developing countries in order to receive the voucher.”

The report observed:

“The priority review voucher may be worth further consideration because of its attraction for small-to-medium enterprises; it may be one of the more potent ‘pulls’ to bring these firms into the field, including firms in innovative developing countries.”

However, it noted:

“This would only be the case, however, if the priority review voucher was redesigned to address the flaws described above in order to deliver far better value for money for both the funders and the recipients (patients in developing countries).”

A 2011 meeting of the WHO Expert Working Group on Research and Development Financing rated priority review vouchers as a middling policy option amongst the wide spectrum of choices.²³ Higher priorities included patent pools, open source strategies, prizes, and direct grants to small-to-medium enterprises.

B. Advocates of priority review vouchers

Republican Senator Sam Brownback was one of the supporters of priority review vouchers, which create a market-based approach to eliminating neglected diseases by encouraging pharmaceutical companies to invest in developing treatments for such diseases. Brownback commented:

“In the developing world, millions of people suffer from curable diseases that many of us think no longer exist. The biggest challenge to finding cures for these diseases is the lack of a market. The lack of interest in finding treatments for neglected diseases has led to only a few new drugs in the market. Between 1975 and 1997, only 13 new drugs were developed for neglected diseases. Because pharmaceuticals are expensive to develop, companies have fewer incentives to pursue [sic] therapies when the purchases are primarily poor people. We can encourage pharmaceutical companies by granting a patent extension for a lifestyle drug or a neglected disease product if they make the investment to develop a treatment for a neglected disease. A drug company can recoup costs incurred by developing drugs for a neglected disease by securing these new patent rights.”²⁴

The Senator observed that “too many people in the developing world suffer and die from diseases that for the most part are both preventable and curable”. In his view, “the main obstacle to responding to the needs of those suffering is insufficient incentive for companies to produce drugs that treat and prevent neglected tropical diseases”.

Senator Joseph Lieberman also supported the introduction of priority review vouchers:

²³ World Health Organization, “Report of the Second Meeting of the Consultative Expert Working Group on Research and Development: Financing and Coordination”, July 2011, available at http://www.who.int/phi/news/cewg_rd_2nd_meeting_report.pdf [Accessed March 25, 2012].

²⁴ “Lieberman Calls for Incentives for Research on Disease Treatment: Senator Joins Colleague in Introducing Neglected Diseases Act”, May 2, 2006, available at <http://votesmart.org/public-statement/169327/lieberman-calls-for-incentives-for-research-on-disease-treatment> [Accessed March 25, 2012].

“We have the technology and brain power to bring about cures for these damaging diseases, but what’s lacking is a market incentive to tackle them. This bill will help bring relief to thousands of people suffering from ancient diseases in a world with contemporary medical capabilities. The technology and brain power behind cures should not be limited to the privileged and our bill aims to remove the barriers that have too long prevented these cures from reaching the nation’s underprivileged. The financial benefit companies would receive from the patent incentives in our bill can help offset the cost of crucial R&D investments needed to combat these neglected diseases, which can be as high as US\$1 billion dollars per drug.”

The amendment provides a significant financial incentive for pharmaceutical companies to produce neglected tropical disease treatments by awarding them with a FDA priority review voucher for bringing to market such products. The priority review vouchers could be applied to any drug in a company’s production pipeline and would reduce the FDA review time from roughly 18 months to 6 months. The 12 month shorter review process would be worth more than US\$300 million if applied to the top 10 per cent grossing drugs.

Bill Gates has enthused about the priority review vouchers at the 2008 World Economic Forum:

“Some of the highest-leverage work that government can do is to set policy and disburse funds in ways that create market incentives for business activity that improves the lives of the poor. Under a law signed by President Bush last year, any drug company that develops a new treatment for a neglected disease like malaria or [tuberculosis] can get priority review from the Food and Drug Administration for another product they’ve made. If you develop a new drug for malaria, your profitable cholesterol-lowering drug could go on the market a year earlier. This priority review could be worth hundreds of millions of dollars.”²⁵

He lauds the initiative as an instance of “creative capitalism”:

“Of course, governments do a great deal to help the poor in ways that go far beyond nurturing markets: they fund research, subsidize health care, build schools and hospitals. But some of the highest-leverage work that government can do is to set policy and disburse funds in ways that create market incentives for business activity that improves the lives of the poor.”

Tim Wells of the Medicines Malaria Venture in Geneva was optimistic about the value of the priority review voucher:

“Even if only one in ten of the vouchers were deployed successfully, it would still have a book value of tens of millions of dollars. This is enough to help drive innovative clinical development.”²⁶

BIO Ventures for Public Health recommended that the WHO should consider the virtues of this US legislative measure at the international level:

“By taking advantage of existing market forces, patients in the developing world can have faster access to lifesaving products that may not otherwise be developed. And sponsors of neglected disease drugs can be rewarded for their innovations. This new financial incentive complements other market-based incentives to stimulate investment in global health R&D. Donor countries have recently committed to other new initiatives. Earlier this year, for example, five leading industrialized countries along with the Bill & Melinda Gates Foundation committed US\$1.5 billion to a pilot Advance Market Commitment that guarantees a developing world market for pneumococcal vaccines. To create the

²⁵ Bill Gates, “Creative Capitalism”, delivered at the World Economic Forum, January 24, 2008, available at <http://www.gatesfoundation.org/speeches-commentary/Pages/bill-gates-2008-world-economic-forum-creative-capitalism.aspx> [Accessed March 25, 2012].

²⁶ Bethan Hughes, “Priority Voucher Flops” (2011) 29 *Nature Biotechnology* 958.

next generation of medicines for the developing world, we need to continue to develop and support these types of market incentives. And we need to ensure that we have appropriate tools in place to measure and improve their impact.”²⁷

The organisation emphasized that “new market-based solutions are needed to leverage industry expertise and encourage greater investment in innovation for these neglected diseases”.

The economist Nicola Dimitri contended that priority review vouchers “tend to increase R&D efforts, notably if a firm obtaining a voucher has in its portfolio a particularly valuable compound to prioritize”.²⁸ Dimitri maintained:

“When this is so the bearer is, in some sense, outperforming the market because the value it can create internally, by prioritizing a drug, is higher than what it could obtain by selling the voucher.”

C. A critique of priority review vouchers

The priority review voucher mechanism can be criticised on a number of theoretical grounds.

First, there have been concerns expressed as to whether the incentive provided by a priority review voucher is an efficient means of encouraging R&D in respect of neglected diseases. Aaron Kesselheim argued that “priority-review vouchers represent an inefficient and potentially dangerous way of encouraging research into tropical diseases”.²⁹ He maintained: “It is inefficient because the program does not directly connect the incentive with the innovation”. Kesselheim maintained:

“Relying on these sorts of transactions to spur innovation is speculative as well, and the deals between small and large pharmaceutical companies affecting agents of great importance to global health will lack transparency.”

He wondered whether access to essential medicines would be inhibited by side deals within the pharmaceutical industry: “Such deals may include other payments or exchanges of intellectual property that raise the cost or restrict the future availability of the products.”

Secondly, there is some uncertainty as to the value of an expedited review. Ian Spatz of the pharmaceutical company Merck has commented that the benefits were overstated:

“Unfortunately, their particular prescription—a transferable voucher for an expedited review within the U.S.—is built on faulty assumptions that make the success of their plan questionable. The authors base their estimates of the value of an expedited review on an estimate of standard FDA review of 18.4 months compared to 6.4 months for priority review. According to the FDA, in fiscal year 2003, the actual difference was 13.8 months compared to 6.4 months. Perhaps more importantly, under the Prescription Drug User Fee Act (PDUFA) program, the FDA has committed to delivering action on 90 percent of applications within a time frame of 10 months for standard reviews and 6 months for priority reviews. For companies like Merck, these are the review periods that we count on for planning purposes.”³⁰

²⁷ BIO Ventures for Public Health, “New Market Incentive to Encourage Innovation for Global Health FDA Bill Creates Priority Review Voucher for Neglected Tropical Diseases”, available at http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_BVGH_Full_Contribution.pdf [March 25, 2012].

²⁸ Nicola Dimitri, “The Economics of Priority Review Vouchers” (2010) 15(21–22) *Drug Discovery Today* 887.

²⁹ Aaron Kesselheim, “Drug Development for Neglected Diseases—The Trouble with FDA Review Vouchers”, (2008) 359 *The New England Journal of Medicine* 1981.

³⁰ Ian Spatz, “Benefits of Expedited Review Likely Overstated”, *Health Affairs*, March 13, 2006, available at <http://content.healthaffairs.org/cgi/eletters/25/2/313> [Accessed March 25, 2012].

There has also been criticism that priority review vouchers will be an additional windfall for pharmaceutical drug manufacturers, in addition to the benefits of patent rights. Aidan Hollis of the University of Calgary notes that “firms which are developing very profitable products will be rewarded even more”.³¹

Thirdly, the priority review vouchers mainly target certain neglected diseases—including tuberculosis and malaria, but not HIV/AIDS. As Kevin Outterson has noted, developing countries would benefit from essential medicines related to Type I diseases, as well as Type II and Type III diseases.³²

Fourthly, there is a concern that priority review vouchers do nothing to enhance access to essential medicines. Hollis has commented that the proposal does not address “the access problem, but helps to increase incentives through creating distortions in markets in developed countries”.³³ He notes that such an approach “would encourage research investment, but the net impact on consumers is uncertain, as they would benefit from more innovation, but at greater cost”.

Finally, there has been criticism that the priority review voucher scheme is open to strategic behaviour and gaming by self-interested applicants. In 2009, the FDA approved Coartem tablets for the treatment of malaria infections in adults and children.³⁴ Dr. Murray Lumpkin, deputy commissioner for International and Special Programs of the FDA, commented: “Malaria is a global life-threatening disease. It is encouraging to have new treatment available, particularly for children.” The FDA awarded Novartis—the manufacturer of Coartem—a one-time priority review voucher to use towards a future new drug application. It noted that the voucher could be transferred by the company to another manufacturer, if need be.

Bethan Hughes recounts the tribulations of Novartis, the first company to deploy a priority review voucher.³⁵ Novartis of Basel recently used the only priority review voucher to have a “priority” review of their supplemental biologics license application to the FDA for Ilaris (canakinumab). Eric Althoff, head of global media relations, commented: “We decided to utilize our PRV for ACZ885 (canakinumab) in gouty arthritis because of the significant unmet need that exists despite standard treatment options.” Bethan Hughes observes of the Novartis application:

“Unfortunately, Novartis received a complete response letter from the FDA requesting additional clinical data to evaluate the benefit-risk profile for use of Ilaris in refractory patients. As Novartis used their PRV (which cost an additional fee of US\$5,280,000 on top of the sBLA fee) but did not achieve approval of the supplementary indication for Ilaris, industry observers have been quick to suggest that use of this first PRV has been a failure. This is because the potential value of the PRV has been predicted based on additional sales revenue that a company would theoretically receive if approval was achieved at an earlier date.”

Novartis is a controversial applicant—especially given its litigation against provisions of India’s unique patent regime and its treatment of pharmaceutical drugs.³⁶ Médecins Sans Frontières (MSF), in alliance with patient groups and affected communities, has appealed to Novartis to drop its case against the “pharmacy of the developing world”.³⁷

James Love of the Knowledge Ecology International commented that this application was an abuse of the system:

³¹ Aidan Hollis, “Optional Rewards for New Drugs for Developing Countries”, February 23, 2005, available at http://www.who.int/intellectualproperty/submissions/en/Optional_rewards.pdf [Accessed March 25, 2012].

³² Kevin Outterson, “Should Access to Medicines and TRIPS Flexibilities Be Limited to Particular Diseases?” (2008) 34 *American Journal of Law and Medicine* 279.

³³ Hollis, “Optional Rewards for New Drugs for Developing Countries”, 2005, available at http://www.who.int/intellectualproperty/submissions/en/Optional_rewards.pdf [Accessed March 25, 2012].

³⁴ Food and Drug Administration, “FDA Approves Coartem Tablets to Treat Malaria”, April 8, 2009, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149559.htm> [Accessed March 25, 2012].

³⁵ Bethan Hughes, “Priority Voucher Flops” (2011) 29 *Nature Biotechnology* 958.

³⁶ See *Novartis AG v Union of India* (2007) 4 Madras Law Journal 1153; see also Hafiz Aziz ur Rehman, *The Pharmacy of the Developing World: Indian Patent Law and Access to Essential Medicines*, Ph.D. thesis, ANU College of Law, 2012.

³⁷ Médecins Sans Frontières, “Novartis’s Day in Court Set for 28 March, Campaign to Drop the Case Continues”, March 1, 2012, available at <http://www.msfaccess.org/content/novartis%E2%80%99s-day-court-set-28-march-campaign-drop-case-continues> [Accessed March 25, 2012].

“While the [priority review voucher] was designed as an incentive to develop new drugs, Coartem was developed and put on the market outside the United States years before the PRV legislation was proposed.”³⁸

II. “Patents for Humanity”: A fast-track for humanitarian patents

The US President Barack Obama appointed David Kappos—previously, an intellectual property expert with IBM—as the head of the USPTO. Kappos has certainly sought to experiment with new policy models—within the constraints of his role. He has been interested in improving the quality of patent examination and the time taken for patent examination. He has, for instance, trialled fast-track examination,³⁹ the Peer-to-Patent project,⁴⁰ a scheme for clean technologies,⁴¹ and a project for humanitarian inventions, entitled “Patents for Humanity”.⁴²

In September 2010, Kappos announced that the USPTO would introduce a new fast-track pilot program for patents, with humanitarian applications.⁴³ Under the proposal, patent holders who made their technology available for humanitarian purposes would be eligible for a voucher entitling them to an accelerated re-examination of a patent. This proposal was in part inspired by the priority review voucher scheme.

Kappos commented: “A voucher for fast-track re-examination of a patent is a valuable incentive for entities to distribute humanitarian technologies through licensing or other means.” It was envisaged that the range of subject matter covered by the new fast-track pilot program would be broad:

“Among the technologies which address humanitarian needs that would be eligible for the program are treatments for tropical diseases, diagnostic medical tools, crops with higher yields or better nutritional value, and treatments for sanitation or clean water.”

A fraction of such technologies—such as, for instance, climate-ready crops and water purification—would include clean technologies. The scheme was designed “to increase the diffusion of technologies that address humanitarian needs through market forces” through creating “an incentive to provide patented technologies for humanitarian research, which in turn may spur the development of new technologies to address humanitarian needs”.

In the *Federal Register*, the USPTO sought public comments on proposals to incentivise the creation and wider distribution of technologies that address humanitarian needs.⁴⁴ Promoting the scheme in Geneva, Kappos maintained:

“We feel the right to a fast-track re-examination could be a very valuable right, allowing a patent owner to affirm the validity of his or her patent more quickly and less expensively.”⁴⁵

³⁸ James Love, “Novartis Games the FDA Priority Review Voucher”, Knowledge Ecology International, April 10, 2009, available at <http://keionline.org/blogs/2009/04/10/novartis-games-the-fda-priority-review-voucher> [Accessed March 25, 2012].

³⁹ Kristen Osenga, “The Patent Office’s Fast Track Will Not Take Us in the Right Direction”, *Patently-O Patent Law Journal*, June 3, 2010, available at <http://www.patentlyo.com/osenga.pdf>; see also Kristen Osenga, “Entrance Ramps, Tolls, and Express Lanes—Proposals for Decreasing Traffic Congestion in the Patent Office” (2005) 33 *Florida State University Law Review* 119.

⁴⁰ Peer to Patent project, available at <http://peertopatent.org/> [Accessed March 25, 2012].

⁴¹ For an analysis, see Matthew Rimmer, *Intellectual Property and Climate Change: Inventing Clean Technologies* (Cheltenham: Edward Elgar, 2011), pp.163–169.

⁴² “Patents for Humanity”, available at http://www.uspto.gov/blog/director/entry/patents_for_humanity [Accessed March 25, 2012].

⁴³ USPTO, “USPTO Launches Effort to Incentivize Humanitarian Technologies: New Initiative Encourages Businesses to Develop and Disseminate Technologies that Address Humanitarian Needs”, September 20, 2010, available at http://www.uspto.gov/news/pr/2010/10_41.jsp [Accessed March 25, 2012].

⁴⁴ USPTO, “Request for Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System” (2010) 75(181) *Federal Register* 57261.

⁴⁵ David Kappos, “Press Conference on Intellectual Property”, United States Mission to the United Nations and Other International Organizations in Geneva, September 23, 2010, available at <http://geneva.usmission.gov/2010/09/23/press-conference-on-intellectual-property-protection/> [Accessed March 25, 2012].

However, in my view, such a scheme would appear to only offer a minor incentive to patent holders to disseminate technologies to address humanitarian concerns.

A. Comments

The proposal from the USPTO received a somewhat mixed reaction from key stakeholders in the field of patent law and access to essential medicines. A range of comments were received from governments and international agencies; non-profit and aid organisations; academic and research institutions; industry groups; law firms and associations.

i. Non-profits and aid organizations

A joint submission was made by Knowledge Ecology International, Doctors without Borders, Oxfam, and Public Citizen.⁴⁶ The civil society groups congratulated the “USPTO for considering new mechanisms to encourage innovation and licensing of technologies for humanitarian purposes”. The joint submission made the point:

“The USPTO’s proposal recognizes implicitly that the patent system as presently implemented fails to adequately serve the needs of neglected populations around the world.”

Indeed, the civil society groups emphasize that

“new mechanisms are needed to incentivize technological advances responsive to the needs of developing countries, and to ensure that these technological advances can provide meaningful benefits to disadvantaged populations”.

The civil society groups warned: “The voucher program must be carefully designed if it is to deliver real humanitarian benefits, and avoid becoming a public giveaway of valuable rewards for little in return.” Moreover, the organisations worried that, “if the mechanism is improperly designed or implemented it could have unintended, harmful consequences that would undermine its purported benefits”.

The submission expressed concern about the strategic gaming behaviour which had taken place in respect of priority review vouchers:

“The voucher program should be designed as a pure incentive program to incentivize the development of both meaningful technological innovations and significant humanitarian dissemination practices. In order to achieve this goal, the mechanism should try to eliminate abuses that may arise.

For instance, patent holders should not be able to apply for a humanitarian voucher if the invention has already been used or licensed for the humanitarian purpose that the applicant is seeking under a new application and does not offer additional and important humanitarian benefits. Improvements to existing technologies that do not confer a new purpose should not be eligible for vouchers.

Also, the USPTO should ensure that companies with many patents do not merely donate low-value patents in order to accelerate the re-examination of high-value ones. The proposed competitive prize mechanism plus minimum standards for voucher awards can help prevent such a giveaway.”

⁴⁶ Knowledge Ecology International, Doctors without Borders, Oxfam, and Public Citizen, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_sanjuan2010nov19.pdf [Accessed March 25, 2012].

Citing the example of Novartis obtaining a priority review voucher for Coartem, the submission emphasizes that “the USPTO program must eliminate these and similar efforts to ‘game’ this new initiative”. The submission emphasizes that a prize-based approach, an independent review mechanism, and an opportunity for public comment may help limit the risks of “gaming the system”. The submission recommends that the USPTO’s scheme should embrace open licensing and technology transfer to developing countries.

AVAC, which engages in global advocacy for HIV prevention, commented on the USPTO proposal.⁴⁷ The group discussed its particular interest in the topic:

“AVAC has advocated for responsible IP practice and policy in the service of facilitating HIV prevention biomedical research and development for a number of years. In 2005 and in 2010, AVAC published results of its IP evaluations and policy recommendations affecting large molecule HIV vaccine biologics. We assembled the first significant database of the underlying HIV vaccine patent landscape—a field characterized by issues of a patent thicket, uncertainty with regard to research tools, and complexity in sharing voluminous data sets and biological samples that are necessary for discovery and which underpin the application for many new patents. Copies of these reports are cited here with request that USPTO focus its development of humanitarian purposes policies on the AVAC recommended principles for collaboration, sharing and harmonization directed at the public good.”

This group was uncertain as to whether a re-examination voucher program would have a material effect or include a sufficient range of “humanitarian purposes”. It was also concerned that the definition of “humanitarian purposes” was too limited. The group worried that there was insufficient incentives for public researchers and institutions, especially given their involvement in the area of HIV/AIDS research.

The group, Incentives for Global Health, led by Professor Thomas Pogge, was supportive of the proposal:

“We share the USPTO’s view that incentives can help to stimulate more useful and more accessible innovation, and we strongly support the USPTO’s effort to creatively advance innovation using IP system incentives.”⁴⁸

It emphasizes the need for a simple, reliable method of assessing humanitarian impact; the importance of the “last mile” problem; and the need for technological, financial and geographic neutrality.

The Medicines Patent Pool was mildly hopeful that the “Patents for Humanity” project would encourage patent holders to participate in patent pools and share essential medicines:

“The Medicines Patent Pool welcomes the initiative of the USPTO to improve access to important technologies, such as pharmaceuticals, in developing countries. If designed well, we believe the Voucher could have an important impact on the willingness of patent-holders to generate innovation with potential benefits for populations in low- and middle-income countries, and contribute to ensuring that the fruits of scientific progress are accessible to those who need them. We hope the Voucher initiative will encourage pharmaceutical patent-holders to share their patents with the Medicines Patent Pool.”⁴⁹

Nonetheless, the Medicines Patent Pool was concerned about threats to the integrity of the regime. The group makes the sensible point that there is a need to ensure that the quality of patent examination is not adversely impacted by an accelerated process:

⁴⁷ AVAC, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_fisher2010nov23.pdf [Accessed March 25, 2012].

⁴⁸ Incentives for Global Health, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_lipkus2010nov19.pdf [Accessed March 25, 2012].

⁴⁹ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, p.8, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_moon2010nov19.pdf [Accessed March 25, 2012].

“In general, it will be important to avoid creating perverse outcomes, such as the reinforcement of weak patents through hurried re-examinations or encouraging more widespread patenting in developing countries.”⁵⁰

Indeed, it noted “two key risks have been identified with the analogous US FDA priority review voucher program that bear mentioning here: first, a priority review obligation may put additional burden on the agency and thereby extend the waiting time for other applicants; secondly, the accelerated deadline may negatively affect the quality of regulatory decisions”.⁵¹

ii. Industry

In its submission, PhRMA—the peak industry body for pharmaceutical drug manufacturers—questioned whether such a scheme was appropriate.⁵² First, it emphasized that “PhRMA members devote substantial resources to humanitarian endeavors”. Secondly, it maintained that patent rights are essential to pharmaceutical innovation. Thirdly, PhRMA contended that it was not the function of the USPTO to run humanitarian programmes:

“The PTO’s goal of incentivizing humanitarian invention is laudable; however, PhRMA questions whether the proposed initiative is the best way to achieve the goal. This proposal may present challenges to the fundamental principle of non-discrimination and the smooth functioning of the patent process. Other incentive programs, such as those undertaken by other government agencies with different core missions, may be better suited to incentivizing R&D or other activities in this area.”

PhRMA raises the questions about eligibility criteria, the use of vouchers and decision-making.

The Biotechnology Industry Organization (BIO) also supported strong patent rights protection: “In order to provide innovative technology to the marketplace, strong intellectual property rights are the key to a successful business model.”⁵³ Bio

“commends the USPTO for likewise exploring creative and market-oriented ways to incentivize the development and distribution of humanitarian technologies, a goal that BIO and its members have long shared and are working hard to achieve.”⁵⁴

BIO maintained that any regime should be technology-neutral:

“The United States Government is free to create technology-specific or problem-specific incentive and reward programs to address developing-country needs in the particular areas of, for example, education, medical care, nutrition, pollution, animal health, transportation, communication, and the like. Such programs would be developed and implemented by agencies with specific technology expertise and legal and policy mandates in these areas. In contrast, the patent system is primarily concerned with furthering the progress of technological innovation, without regard to the applicability of inventions in specific policy areas. Maintaining the strict technology-neutrality of the patent system

⁵⁰ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.2.

⁵¹ Medicines Patent Pool, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, pp.2–3.

⁵² PhRMA, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_korn2010nov19.pdf [Accessed March 25, 2012].

⁵³ Biotechnology Industry Organization, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_sauer2010nov19.pdf [Accessed March 25, 2012].

⁵⁴ Biotechnology Industry Organization, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.1.

is critically important to BIO's member companies from an international comparative, trade, and treaty obligation perspective as well. Accordingly, BIO members still have many open questions about the inclusiveness of the proposed program and how its technology-neutrality can be ensured."⁵⁵

There seemed to be a lack of consensus amongst the stakeholders of BIO about the relative merits and disadvantages of the scheme proposed by the USPTO.

AdvaMed, a medical technology association, was roundly hostile to the proposal, maintaining that the USPTO straying from its right and proper institutional role:

"The role of the USPTO, with regard to medical technology, is to determine the patentability of what is often a limited aspect of a medical device. Although obtaining patent protection directly impacts the ability to command investment capital to further a medical technology's development, the proposed voucher program's potential to consistently bring new medical technologies to patients sooner would be tenuous, as obtaining patent protection is an early step in developing a medical technology and bringing it to market. Accordingly, the proposed program would not directly benefit patients. More importantly, AdvaMed is concerned that adding additional complexities and workload to an already-overburdened USPTO staff will have an adverse impact on all technologies."⁵⁶

The Association maintained:

"While the voucher program is a noble idea, it will not lead to any increase in humanitarian technology and could actually impede such technology along with other technologies by diverting scarce resources within the PTO from handling the normal application work load."⁵⁷

Gilead Sciences is a pharmaceutical drugs company, with a strong emphasis upon the development of therapeutics for the treatment of HIV/AIDS.⁵⁸ The company observes that "Gilead believes in a system of strong intellectual property protection" and "Gilead also believes that along with intellectual property comes responsibility to vulnerable populations". Gilead Sciences "strongly supports the creation of a fast-track ex parte re-examination voucher pilot program to incentivize technology creation or licensing to address humanitarian needs". Interestingly, the company thought that there would be diplomatic benefits arising from the programme:

"In addition, we endorse this program because it strengthens the diplomatic hand of the United States Government. This program provides the United States with strengthened credibility in the developing world to show that the intellectual property policies of the United States encourage responsible use of intellectual property rather than merely protecting the monopoly of patent holders having no regard to broader humanitarian implications. Importantly, a commitment to humanitarian use helps to protect the underlying innovation."

The company stressed that "award recipients would ideally be those innovators that make strides in reducing the prevalence of a disease or reducing the impact of diseases".

The company Novartis put in a short submission, stating its belief that "the USPTO's proposal is a meritorious and worthwhile endeavour", and that it hoped that "a robust conversation between the healthcare industry and the USPTO will ensue to establish specific parameters to further define this new initiative".⁵⁹

⁵⁵ Biotechnology Industry Organization, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", 2010, p.3.

⁵⁶ AdvaMed, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, p.2, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_chang2010nov19.pdf [Accessed March 25, 2012].

⁵⁷ AdvaMed, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", 2010, p.1.

⁵⁸ Gilead Sciences, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_lis2010nov19.pdf [Accessed March 25, 2012].

⁵⁹ Novartis, "Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System", November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_ryberg2010nov19.pdf [Accessed March 25, 2012].

The health-care company Sanofi-Aventis commented:

“Although, such a voucher could be valuable under the right circumstances, we believe that alternatives to the fast-track ex parte re-examination voucher could provide greater incentives and thereby better incent humanitarian efforts and would help us justify continuing and increasing our humanitarian efforts in the face of the disparate needs of the company’s stakeholders.”⁶⁰

Although not united in their opinions, the industry groups suggest that regulatory institutions should not concern themselves with matters of humanitarian aid and that such matters are better left to other agencies. I would dispute this. It is entirely proper and appropriate that patent offices such as the USPTO consider the implications of the examination and grant of patents for access to essential medicines. Professor Brad Sherman has observed that the patent system is not a system of regulation purely designed for instrumental economic ends:

“While there is no denying the important role that patents play in macro-economic policy, there is no reason why the patent system, as a regulatory tool, should only be used in the pursuit of economic ends, nor any reason why “external” factors such as the impact of technology on the environment or health should not fall within the core remit of the patent system. That is, there is no compelling reason why the various practices, rules and concepts that have been developed and fine-tuned over the last couple of centuries or so should only be used for economic ends. Given that modern patent law already performs a number of, sometimes surprising, non-economic roles, this is not as alien a proposal it might first appear.”⁶¹

Indeed, patent offices would be justly criticised for failing to properly engage with public policy concerns—such as access to health-care and essential medicines.⁶² The patent system is not hermetically sealed off from larger questions about development, access to knowledge, and access to essential medicines.

iii. Academic and research institutions

Professor Susan Sell considers the role of academic and research institutions in the development and licensing of humanitarian intellectual property:

“Universities may feel caught between the conflicting imperatives of attracting private sector funding and generating revenue through patenting activity on the one hand, and promoting public goods through ‘humanitarian intellectual property’ policies on the other. It is clear that universities have an important role to play in preserving the balance between exclusion and access as well as paving the way to more informed, effective, and socially responsible agricultural intellectual property policies.”⁶³

It is notable that a number of academic and research institutions commented on the USPTO’s proposal for “Patents for Humanity”.

The Association of American Universities and the Council on Governmental Relations emphasized that

⁶⁰ Sanofi-Aventis, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_c_farquharson2010nov19.pdf [Accessed March 25, 2012].

⁶¹ Brad Sherman, “Regulating Access and Use of Genetic Resources: Intellectual Property Law and Biodiscovery” (2003) 25(7) *European Intellectual Property Review* 301.

⁶² Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge: Cambridge University Press, 2010).

⁶³ Susan Sell, “What Role for Humanitarian Intellectual Property?: The Globalization of Intellectual Property Rights” (2004) 6(1) *Minnesota Journal of Law, Technology, and Science* 191, 211.

“the university community strongly supports the goal of USPTO to explore strategies that would use the patent system to incentivize activity addressing humanitarian needs, and encourages USPTO to pursue a pilot program as proposed in the Federal Register notice”.⁶⁴

The submission provided a qualified endorsement of the scheme:

“While we support the goals of the USPTO proposal, we are concerned that some aspects may need to be carefully considered to avoid unintended consequences and potential exploitation. We believe that USPTO should consider instituting a competitive review process for voucher issuance to assure quality and effectiveness. We also suggest that the number of vouchers issued on an annual basis be substantially limited, at least until the results of the pilot program are known. While possible transferability of the re-examination vouchers on the open market would substantially enhance their value, auctioning the vouchers off to the highest bidder could lead to negative public perceptions and questions about public vs. private benefit. We urge USPTO to consider whether the enhanced value offsets these possible negative consequences.”

The submission noted a number of US universities had endorsed the declaration on *Nine Points to Consider in Licensing University Technology* and a *Statement of Principles and Strategies for the Equitable Dissemination of Medical Technologies*. The Association of University Technology Managers had also launched a Global Health Initiative.⁶⁵

That University of California has long been a pioneer and path-finder in respect of licensing of patents related to humanitarian inventions.⁶⁶ That university was a driving force behind the statement *Nine Points to Consider in Licensing University Technology*. The ninth point focuses attention on

“unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improve therapeutics, diagnostics and agricultural technologies for the developing world”.⁶⁷

The University of California Berkeley’s Socially Responsible Licensing Initiative seeks to promote the widespread availability of technologies and healthcare products in developing countries.⁶⁸ The University of California provided:

“We feel that it is important for the PTO to carefully consider how best to identify innovative patents that actually address compelling humanitarian needs. Administratively, the challenge the PTO faces is that documenting actual humanitarian use is difficult at patent filing since the data needed is available only after the product is on the market. On the other hand, providing a fast-track voucher only after product introduction acts as a reward rather than an incentive to invest in technologies that address humanitarian need. In addition, the PTO will need avoid rewarding patents that purport to address humanitarian needs but never result in actual humanitarian benefit. The University encourages the PTO to consider a broad view of humanitarian needs that can be met with technologies that extend beyond the pharmaceutical industry.”⁶⁹

⁶⁴ The Association of American Universities and the Council on Governmental Relations, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_norton2010nov19.pdf [Accessed March 25, 2012].

⁶⁵ Association of University Technology Managers, “Global Health Initiative”, available at <http://www.autm.net/home.htm> [Accessed March 25, 2012].

⁶⁶ University of California, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 22, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_foote2010nov22.pdf [Accessed March 25, 2012].

⁶⁷ Association of University Research Managers, “In the Public Interest: Nine Points to Consider in Licensing University Technology”, available at http://www.autm.net/Nine_Points_to_Consider.htm [Accessed March 25, 2012].

⁶⁸ University of California, Berkeley, Office of Intellectual Property and Industry Research Alliances, “Socially Responsible Licensing and Intellectual Property Management”, available at <http://ipira.berkeley.edu/socially-responsible-licensing-ip-management> [Accessed March 25, 2012].

⁶⁹ University of California, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, 2010, p.3.

The University of California continued:

“The PTO proposes vouchers for fast-track *ex parte* re-examination, but having a voucher for fast track initial examination might possess greater value for some patent applicants, such as universities.”

Emory University noted in its submission:

“Many universities have given considerable thought to encouraging humanitarian activities through licensing and have come up with certain requirements as part of their licensing practices and in our opinion the USPTO’s proposal can provide additional leverage in securing licensing terms with humanitarian goals.”⁷⁰

The research institution was conscious, though, that the incentive fell well short of the costs involved in developing new humanitarian technologies:

“Although the financial requirements of developing new technologies to address humanitarian needs likely far outweighs the incentive of the USPTO’s proposed voucher, we believe the voucher should be viewed within the context of global efforts within the administration to encourage development of such technologies.”

The University of Mississippi noted that it had a major research program in the National Center for Natural Products Research in the School of Pharmacy to develop pharmaceutical drugs for neglected diseases.⁷¹ The University of Mississippi argued:

“Since it is easier for a university to license the patent rights of an issued patent than of a pending patent application, an accelerated initial review would enhance our chances of commercializing technologies for humanitarian needs.”

Universities Allied for Essential Medicines is a coalition of students from top research institutions from around the world. The organisation

“plays a distinct role in the access to medicines movement because of its unique position in promoting the use of socially responsible patenting and licensing practices, including global access license terms at universities and public research institutions”.⁷²

The organisation urged the USPTO not to repeat the mistakes of the priority review voucher scheme:

“If USPTO issues automatic awards to FDA priority review recipients, the USPTO re-examination award process will inherit the flaws of the FDA priority review. One such flaw was shown with the very first FDA priority review voucher, awarded to Novartis for its antimalarial drug Coartem. Novartis developed Coartem over a decade before the FDA implemented the priority review award. Therefore, contrary to the goal of the FDA program, Novartis was not incentivized to research and develop treatments for neglected tropical diseases. Automatic awards granted to recipients of the FDA voucher would allow these same exploitations to occur with USPTO re-examination vouchers.”

⁷⁰ Emory University, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, p.1, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_hollinger2010nov19.pdf [Accessed March 25, 2012].

⁷¹ University of Mississippi, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, October 27, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_chambliss2010oct27.pdf [Accessed March 25, 2012].

⁷² Universities Allied for Essential Medicines, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, November 19, 2010, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_guillen2010nov19.pdf [Accessed March 25, 2012].

Universities Allied for Essential Medicines maintained: “Many examples of global access policies and various innovative mechanisms can provide a solid basis for implementing the proposed USPTO program”. It argued: “Building upon current positive practices while continuing to augment them and learning from potentials for gaming of the system will create the most humanitarian value from the program.”

The Wisconsin Alumni Research Foundation has, traditionally, been supportive of strong protection of intellectual property rights. The Foundation agreed

“that a fast-track re-examination proceeding could allow patent owners to less expensively affirm the validity of their patents, and applauds the USPTO for its leadership and vision on this proposal”.⁷³

The Foundation argued “that the greatest opportunity to facilitate humanitarian efforts related to patented technologies is not in the re-examination stage, but in the initial examination stage”.

iv. Law firms and legal associations

The American Intellectual Property Law Association—led by Q. Todd Dickinson, a former director of the USPTO—was unenthusiastic about the scheme, arguing:

“The current proposal ... is unlikely to achieve the desired results, and may create the undesirable impression that re-examination is a necessity because issued patents are inherently unreliable or defective.”⁷⁴

The Intellectual Property Owners Association (IPO) was also rather dour in its assessment of the regime:

“Although the proposed voucher program may provide a mechanism to gather information about ongoing humanitarian uses of technology, IPO believes other, more efficient ways of gaining this information can be developed which could offer viable alternatives to incentivizing additional development or patenting of such technologies.”⁷⁵

IPO complained that “the proposed program raises significant concerns regarding access to and availability of re-examinations for all patent applicants and risks unintended consequences”. IPO also worried:

“By creating a market for vouchers, the Notice might also incentivize parties to obtain marginal or low-quality patents, or could encourage the filing for patents on inventions that would otherwise be made available to the public.”

Thomas Kowalski of the law firm Vedder Price questioned the design of the scheme:

“What will the USPTO do to ensure that those in the developing world as well as the poor in the developed world can gain access to the technology? Also, the voucher should be tied specifically to the technology with the humanitarian use instead of being independent and transferable.”⁷⁶

Howard University School of Law suggested that there was a need for the USPTO to obtain assistance from humanitarian agencies and institutions in assessing the credentials of applications:

⁷³ Wisconsin Alumni Research Foundation, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, Department of Commerce, available at http://www.uspto.gov/patents/law/comments/humanitarian_b_sullivan2010nov19.pdf [Accessed March 25, 2012].

⁷⁴ American Intellectual Property Law Association, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_g_garlock2010nov19.pdf [Accessed March 25, 2012].

⁷⁵ Intellectual Property Owners Association, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, http://www.uspto.gov/patents/law/comments/humanitarian_g_muthig2010nov19.pdf [Accessed March 25, 2012].

⁷⁶ Michael Francisco, “USPTO’s Do-Good Vouchers” (2010) 28 *Nature Biotechnology* 1226.

“To ensure that the USPTO is not overburdened by researching these issues, it should elicit the assistance of humanitarian aid organizations, such as the World Health Organization (WHO), that are likely to have on hand information and data on the various humanitarian issues outlined.”⁷⁷

B. Pilot programme

In 2012, after much consultation, the USPTO launched a 12-month pilot program entitled “Patents for Humanity”.⁷⁸ In his blog, Director David Kappos discusses his ambitions for the scheme:

“Sweeping revolutions in technology continue to fundamentally redefine the way we connect with one another and interact with the world. Today, an entrepreneur can do business with a remote village across an ocean just as quickly as a student in Boston can video-conference with a professor in Beijing. Political rallies can be organized by the click of a button, while gripping images of that rally can be shared across continents with a cell phone.

And while an ever-shrinking and increasingly interconnected world allows technologies and information to spread in unprecedented ways, it also reminds us of the unique challenges we face as a planet. That’s why the United States Patent and Trademark Office, during a global development event today at the White House, announced the *Patents for Humanity* pilot program. Because while 21st century challenges are global in scope, so too are their solutions.”⁷⁹

Kappos contends:

“By building smarter irrigation systems in towns plagued by drought, by delivering cost-effective medicinal vaccines to communities without hospitals, and by engineering weather-resistant crop strains to farms ravaged by natural disasters, patented inventions have the power to create lasting solutions for some of the most serious issues confronting the world’s poorest and underserved regions.

He maintains:

“By offering strong incentives for businesses of all sizes to engage in these humanitarian efforts, *Patents for Humanity* encourages up to 1,000 applicants to demonstrate how their patented, or patent-pending technologies, are advancing research and results in four categories: Medical Technology, Food and Nutrition, Clean Technology, and Information Technology.”

He observes:

“Not only will the faster processing help technologists move solutions to the marketplace faster; it will also demonstrate that humanitarian endeavors and smart economic growth can work hand in hand.”

Kappos concludes: “By harnessing the power of science and technology with research and development, *Patents for Humanity* plays a key role in advancing President Obama’s global development agenda.” He observes:

“By collaborating with parts of the world in ways unimaginable just a few years ago, and by unleashing broader prosperity in emerging economies, this important new USPTO initiative demonstrates that the power to innovate is the power to lead, by design and by solution.”

⁷⁷ Howard University School of Law, “Comments on Incentivizing Humanitarian Technologies and Licensing through the Intellectual Property System”, available at http://www.uspto.gov/patents/law/comments/humanitarian_f_jamar2010nov18.pdf [Accessed March 25, 2012].

⁷⁸ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544; see also USPTO, “‘Patents for Humanity’ Pilot Programme, Awards Challenge 2012”, available at <http://www.youtube.com/watch?v=35WV6IyeUTw&feature=youtu.be> [Accessed March 25, 2012]; USPTO, “Patents for Humanity”, available at <http://patentsforhumanity.challenge.gov/rules> [Accessed March 25, 2012].

⁷⁹ David Kappos, “Patents for Humanity”, February 8, 2012, available at http://www.uspto.gov/blog/director/entry/patents_for_humanity [Accessed March 25, 2012].

The purpose of the scheme is “to incentivize the distribution of patented technologies to address humanitarian needs”.⁸⁰ The *Federal Register* explains the rules of the competition:

“The pilot program will be run as an awards competition. Participating patent applicants, patent owners, and licensees will submit program applications describing what actions they have taken with their patented technology to address humanitarian needs among an impoverished population or further research by others on humanitarian technologies.

Applications will be considered in four categories: Medical Technology, Food & Nutrition, Clean Technology, and Information Technology. Independent judges will review the program applications, and a selection committee will recommend awardees based on these reviews. Awardees will receive a certificate redeemable to accelerate select matters before the USPTO and public recognition for their efforts, including an award ceremony at the USPTO.

The certificate can be redeemed to accelerate one of the following matters: an *ex parte* re-examination proceeding, including one appeal to the Board of Patent Appeals and Interferences (BPAI) from that proceeding; a patent application, including one appeal to the BPAI from that application; or an appeal to the BPAI of a claim twice rejected in a patent application or reissue application or finally rejected in an *ex parte* re-examination, without accelerating the underlying matter which generated the appeal. *Inter partes* re-examinations and interference proceedings are not eligible for acceleration, nor are the forthcoming post grant reviews, *inter partes* reviews, derivation proceedings, or supplemental examinations.

Certificates awarded in the pilot are not transferable to other parties.”

Such a scheme seems a somewhat impure and eclectic hybrid among a priority review voucher, a patent fast-track system, and a prize regime.

The criteria of the competition focuses, quite strictly, upon humanitarian issues. There are two pathways—“humanitarian use” or “humanitarian research”.

Rules published in the *Federal Register* note that “the *humanitarian use* criteria recognize applying eligible technologies to positively impact a humanitarian issue”.⁸¹ It observed:

“Examples of technologies with potential humanitarian uses include treatments for disease, medical diagnostics, water purification, more nutritious or higher-yield crops, pollution reduction, and education or literacy devices, among others.”

The applicants must address subject matter, targeted population, and demonstrated impact.

The *Federal Register* notes that “the *humanitarian research* criteria recognize making patented technologies available to others for conducting research on a humanitarian issue”.⁸² It suggests:

“Examples of technologies with potential humanitarian research benefits include patented molecules, drug discovery tools, gene sequencing or splicing devices, special-purpose seed strains, or other patented research material.”

This category focuses on contributing needed tools to areas of humanitarian research lacking commercial application. The applicants will have to address the research impact of the technology, whether the area is a neglected field, and whether they took action to share the invention with others.

The White House Office of Science and Technology Policy emphasized that the “Patents for Humanity” project is intended to work in concert with a number of other initiatives.⁸³ In particular, it noted that:

⁸⁰ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6544.

⁸¹ USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6545.

⁸² USPTO, “Humanitarian Awards Pilot Program” (2012) 77(26) *Federal Register* 6544, 6546.

⁸³ Quentin Palfrey and Hillary Chen, “Rewarding Inventors Who Work to Solve Global Challenges”, February 8, 2012, available at <http://www.whitehouse.gov/blog/2012/02/08/rewarding-inventors-who-work-solve-global-challenges> [Accessed March 25, 2012].

“Global Access in Action, in partnership with Baker & McKenzie, announced plans to develop and implement a program to educate patent holders and their lawyers about humanitarian use licenses for life-saving intellectual property.”

Moreover, the American Bar Association has agreed to encourage its members to help with the “Patents for Humanity” project. The National Institutes of Health and the US Department of Energy have implemented new programs to expedite and facilitate transfers of global health and clean energy technologies. Such initiatives are intended to be part of the Global Development Policy of the US Government.⁸⁴

In March 2012, David Kappos enthused to the US Congress about the scheme:

“This 12-month pilot advances the President’s global development agenda by rewarding companies who bring life-saving technologies to underserved regions of the world, and by highlighting positive examples of humanitarian actions that are compatible with business interests and strong patent rights.”⁸⁵

Kappos, I fear, overstates his case here. It is indeed hard to reconcile intellectual property maximalism with humanitarian objectives. At the time of writing, the USPTO has extended the deadline for applications to the Humanitarian Awards Pilot Program until the October 31, 2012.

There is a gap between the grandiloquent claims made for the “Patents for Humanity” project, and the decidedly modest scale and nature of the programme. A patent fast-track seems a minor incentive. The “Patents for Humanity” project falls well short of implementing international agreements and declarations such as the WIPO Development Agenda, the WTO’s Doha Declaration on the TRIPS Agreement and Public Health, the WTO General Council Decision of 30 August 2003, and the WHO declarations on intellectual property and public health.

Conclusion

There were high hopes that, under President Barack Obama, the US Government would adopt a constructive approach to intellectual property and access to essential medicines. However, there has been little in the way of progress in terms of the US Government’s stance on patent law and public health. In some respects, there has been backsliding and regression from the position of the Bush Administration. Sean Flynn notes that the United States replaced “the May 2007 access to medicine policies included in the Peru Free Trade Agreement with its new ‘access window’ (aka ‘team’) approach requiring TRIPS-plus data exclusivity, linkage and patent extensions”.⁸⁶ Hans Lofgren despairs that in some respects the Obama administration has gone backwards, with its support of the Anti-Counterfeiting Trade Agreement and the Trans-Pacific Partnership Agreement:

⁸⁴ White House, Office of the Press Secretary, “U.S. Global Development Policy”, September 22, 2010, available at <http://www.whitehouse.gov/the-press-office/2010/09/22/fact-sheet-us-global-development-policy> [Accessed March 25, 2012].

⁸⁵ David Kappos, “USPTO FY 2012 Budget Request”, testimony before the Subcommittee on Commerce, Justice, Science, and Related Agencies, Committee on Appropriations, United States House of Representatives, March 1, 2012, p.4, available at http://www.uspto.gov/news/speeches/2012/KapposTestimony120301_FINAL.pdf [Accessed March 25, 2012].

⁸⁶ Sean Flynn, “Intellectual Property Trans-Pacific Partnership Agreement Talks Stall in Melbourne”, March 12, 2012, available at <http://infojustice.org/archives/8847> [Accessed March 25, 2012]. Zach Carter and Sabrina Siddiqui, “Obama’s Global Health Policy Undercuts Reform at Home”, The Huffington Post, 10 July 2012, available at http://www.huffingtonpost.com/2012/07/10/obamas-health-policy-global-health-reform_n_1659742.html [accessed August 17, 2012]; and *Global Commission on HIV and the Law, Risks, Rights and Health* (New York: UNDP and HIV/AIDS Group, 2012) available at <http://www.hivlawcommission.org/> [accessed August 17, 2012].

“Remarkably, the US position under Obama represents a step back from the 2001 Doha Declaration on TRIPS and Public Health, the 2008 WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and even the policy adopted by the Bush Administration in 2007.”⁸⁷

This article has considered two key initiatives deployed by the US Government: priority review vouchers and “Patents for Humanity”. The proposals are both designed to accelerate the regulatory review of patents with humanitarian purposes. It is certainly pleasing that the FDA and the USPTO have shown initiative in crafting policy solutions to address access to essential medicines. It is right and proper that such institutions play a leadership role in addressing innovation in respect of matters of public health and access to medicines—such as infectious diseases, neglected diseases, and pediatric diseases. Credit should be especially given to the innovative leadership of David Kappos, who has been willing to overcome resistance from certain stakeholders in order to pursue such development goals.

It is the contention of this article that, for all their grand intentions and humanitarian ambitions, the use of vouchers are shadow solutions, because they are not an effective means of addressing the magnitude of the problems associated with access to essential medicines. For its noble ambitions, the priority review voucher scheme has been a disappointment, especially given that it has been the subject of strategic gaming behaviour by pharmaceutical drug manufacturers. I am somewhat more positive about the “Patents for Humanity” project—partly because it had a stronger deliberative process and partly because it displayed a greater awareness of the complexities of crafting a policy instrument. At best, such regimes could serve as a minor or incidental incentive for public research institutions, not-for-profit entities, and pharmaceutical drug manufacturers, given both the costs involved in R&D, and the sheer scale of the problem in respect of access to essential medicines. At worst, such mechanisms are vulnerable to gaming and strategic behaviour. Fast-tracking regulatory approval may also have an adverse impact upon the quality of granted patents. Vouchers could well be hoarded by intellectual property owners, and stacked on top of a variety of intellectual property rights, such as patent, trade mark, and data exclusivity rights. It is of concern that the schemes are influenced by a larger ideology that strong intellectual property rights protection, coupled with other incentives, are the best means of promoting health-care and development. There is little engagement with the view that nation states should be able to make use of flexibilities within the intellectual property regime to address matters of development, access to medicines, and access to knowledge.

No doubt some commentators might consider such a verdict harsh or tough. Nonetheless, it is argued that there are more flexible and effective measures of promoting the research, development, and deployment of medicines for humanitarian uses and purposes. As Aaron Kesselheim comments:

“Though Congress should reconsider the usefulness of the voucher program, there are more direct ways to encourage drug development for medical conditions for which current incentives have proven inadequate.”⁸⁸

There is well-founded criticism that priority review vouchers and the “Patents for Humanity” project are a poor substitute for substantive patent law reform. The US patent system has been the subject of recent revision. Campaigning to become the US President, Barack Obama vowed to “Reform the Patent System”.⁸⁹ He pledged: “A system that produces timely, high-quality patents is essential for global competitiveness in the 21st century.”

In September 2011, President Obama signed the America Invents Act 2011 commenting:

⁸⁷ Hans Lofgren, “The Trans-Pacific Partnership Agreement: A Threat to Affordable Medicines and Public Health” (2011) 4(2) *Southern Med Review* 2.

⁸⁸ Kesselheim, “Drug Development for Neglected Diseases” (2008) 359 *New England Journal of Medicine* 1981.

⁸⁹ The Obama Campaign website has since been archived. Quoted in Matthew Rimmer, “Reform the Patent System” *Australian R&D Review*, October 2009, p.10.

“I am pleased to sign the America Invents Act. This much-needed reform will speed up the patent process so that innovators and entrepreneurs can turn a new invention into a business as quickly as possible. I’m also announcing even more steps today that will help bring these inventions to market faster and create jobs. Here in America, our creativity has always set us apart, and in order to continue to grow our economy, we need to encourage that spirit wherever we find it.”⁹⁰

However, the reforms contained in the America Invents Act 2011 did not address the question of patent law and access to essential medicines. The US regime has a weak defence of experimental use.⁹¹ The safe harbour for research leading to the approval of pharmaceutical drugs has been interpreted by the United States Supreme Court somewhat more broadly.⁹² The MSF Intellectual Property Expert Group has argued that there should be exceptions to patent rights for humanitarian uses.⁹³ The patent regime has not facilitated public sector licensing in respect of essential medicines. The US regime lacks effective mechanisms for compulsory licensing, government use and state acquisition for domestic use.⁹⁴ The US Congress and the Obama administration still have not implemented the WTO General Council Decision 2003 to allow for the export of pharmaceutical drugs to developing countries. There is not a strong record of technology transfer in respect of essential medicines. The US Government could do more to aid the UNITAID patent pool programme. There needs to be a better system of public sector licensing. The next generation of patent law reform in the United States needs to consider such outstanding matters.

Furthermore, it is worthwhile to consider a number of other alternative proposals in respect of encouraging R&D in medical innovation. The economist Joseph Stiglitz and the civil society group Knowledge Ecology International have recommended the use of monetary prizes as an alternative mechanism to stimulate private investment in R&D.⁹⁵ The civil society group suggests that donors and governments should consider prizes as an alternative to marketing monopolies as a reward for successful R&D investments. The US Government has been quite enthusiastic about the use of prizes in other technological contexts, such as promoting innovation in respect of clean technologies.⁹⁶ It is mysterious why the US Congress thus far have not embraced proposals such as Senator Bernie Sanders’ The Medical Innovation Prize Fund Act 2011 and The Prize Fund for HIV/AIDS Act 2011.⁹⁷ There have also been proposals for a Health Impact Fund, which links rewards to the impact of a pharmaceutical drug.⁹⁸ Such a project is worth trialling. The Medicines Patent Pool established by UNITAID has sought to encourage the sharing of patented inventions related to essential medicines.⁹⁹ The US Government could do more to

⁹⁰ White House, “President Obama Signs America Invents Act, Overhauling the Patent System to Stimulate Economic Growth, and Announces New Steps to Help Entrepreneurs Create Jobs”, September 16, 2011, available at <http://www.whitehouse.gov/the-press-office/2011/09/16/president-obama-signs-america-invents-act-overhauling-patent-system-stim> [Accessed March 25, 2012].

⁹¹ *Madey v Duke University* 307 F.3d 1351 (2002).

⁹² *Merck KGaA v Integra Lifesciences I, Ltd.* 545 U.S. 193 (2005).

⁹³ Knowledge Ecology International, “Humanitarian Uses of Patented Inventions”, available at <http://keionline.org/patents/humanitarian> [Accessed March 25, 2012].

⁹⁴ Rimmer, “The Jean Chretien Pledge to Africa Act: Patent Law and Humanitarian Aid” (2005) 15(7) *Expert Opinion on Therapeutic Patents* 889; Rimmer, “Race against Time: The Export of Essential Medicines to Rwanda” (2008) 1(2) *Public Health Ethics* 89; Ellen t’ Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health* (Diemen: AMB Publishers, 2009); Abbott and Dukes, *Global Pharmaceutical Policy* (2009); Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010); William Fisher and Talha Syed, “Global Justice in Healthcare: Developing Drugs for the Developing World” (2007) 40 *University of California Davis Law Review* 581.

⁹⁵ Joseph Stiglitz, “Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations” (2006) 333 *British Medical Journal* 1279; James Love and Tim Hubbard, “Make Drugs Affordable: Replace TRIPS-Plus with R&D-plus” (2004) 6 *Bridges* 3, available at <http://www.cptech.org/ip/health/rndtf/bridges042004.pdf>; Knowledge Ecology International, Selected Innovation Prizes and Reward Programs, *KEI Research Note 1*, March 7, 2008, http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf [Accessed March 25, 2012].

⁹⁶ For an analysis of environmental patents, see Rimmer, *Intellectual Property and Climate Change* (2011), p.343.

⁹⁷ James Love, “Senator Sanders Introduces Two Medical Innovation Prize Bills in U.S. Senate to De-link R&D Costs from Drug Prices”, May 27, 2011, available at <http://keionline.org/node/1147> [Accessed March 25, 2012].

⁹⁸ Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Available for All* (New Haven: Yale University, 2008).

⁹⁹ Medicines Patent Pool, <http://www.medicinespatentpool.org/> [Accessed March 25, 2012]; Geertrui Van Overwalle, *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (Cambridge: Cambridge University Press, 2009); Dianne Nicol and Jane Nielsen, “Opening the Dam: Patent Pools, Innovation and Access to Essential Medicines” in Pogge, Rimmer and Rubenstein (eds), *Incentives for Global Public Health* (2010).

support this important initiative. Finally, groups based at Yale University, Duke University, and elsewhere have proposed an “open source” gift approach to drug development.¹⁰⁰ They have envisaged a decentralised, web-based community wide effort where scientists from both the public and private sectors can work together for a common cause.

Generally, there is a need to avoid “shadow solutions” in respect of intellectual property and global issues. The philosopher Stephen M. Gardiner has commented:

“In a perfect moral storm, we should expect 'shadow solutions' to the problem at hand that reflect only the limited concerns of those with the power to act. Such 'solutions' are morally problematic. Not only are they typically inadequate as a matter of substance, but they also create the dangerous illusion of real action, and this serves as a distraction through which continued buck-passing can be perpetrated.”¹⁰¹

In dealing with Patents for Humanity, we need real solutions, and not merely shadow solutions.

¹⁰⁰ Stephen Maurer, Arti Rai and Andrej Sali, “Finding Cures for Tropical Diseases: Is Open Source an Answer?” (2004) 1(3) *PLOS Medicine* 183; Amy Kapczynski, Samantha Chaifetz, Zachary Katz and Yochai Benkler, “Addressing Global Health Inequities: An Open Licensing Approach for University Innovations” (2005) 20 *Berkeley Technology Law Journal* 1031; Stephen Maurer, “Open Source Drug Discovery: Finding a Niche (or Maybe Several)” (2007) 76(2) *University of Missouri—Kansas City Law Review* 405; Yann Joly, “Open Biotechnology: Licenses Needed” (2010) 28 *Nature Biotechnology*, p.417.

¹⁰¹ Stephen M. Gardiner, *A Perfect Moral Storm: The Ethical Tragedy of Climate Change* (Oxford: Oxford University Press, 2011), 76.