

Three Proposals for Rewarding Novel Health Technologies Benefiting People Living in Poverty. A Comparative Analysis of Prize Funds, Health Impact Funds and a Cost-Effectiveness/Competitive Tender Treaty

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This paper sets out to analyse three different academic proposals for addressing the needs of the poor in relation to new, rather than ‘essential’ medicines. It focuses particularly on (1) research and development (R&D) prize funds, (2) a health impact fund (HIF) system and (3) a multilateral treaty on health technology cost-effectiveness evaluation and competitive tender. It compares the extent to which each responds to the ‘market fundamentalist’ philosophy (that we maintain forms a loose theoretical background for the patent-driven approach to pharmaceutical R&D) and begins to analyse their respective strengths and weaknesses.

Summary

The moral and practical problem of how poor people will continue to gain affordable access to medicines is one of the most pressing issues currently confronting humanity. This is not just because of the large numbers of people, in both developed and developing nations who we now have good evidence are dying prematurely for lack of such access (particularly in groups such as children and the elderly). It is also an urgent issue because the regulatory incentives for pharmaceutical research and development (R&D), which particularly include domestic patent regimes and intellectual property provisions in international trade agreements do not favour an output focus directly related to impact on the global burden of disease (GBD).

This paper sets out to analyse three different academic proposals for addressing this situation in relation to new, rather than ‘essential’, medicines. It focuses particularly on (1) research and development prize funds, (2) a health impact fund (HIF) system and (3) a multilateral treaty on health technology cost-effectiveness evaluation and competitive tender. It compares the extent to which each responds to the ‘market fundamentalist’ philosophy (that we maintain forms a loose theoretical background for the

patent-driven approach to pharmaceutical R&D) and begins to analyse their respective strengths and weaknesses.

Introduction

Significant concern now exists that the global system for researching and developing pharmaceuticals is not focused on relieving the global burden of disease and the health needs of the chronically poor. Amongst the main factors responsible are domestic patent regimes and the intellectual property provisions of international trade agreements (Hilary, 2001; Farmer, 2003; Shaffer and Brenner, 2004; Angell, 2005). The term ‘chronically poor’ refers to those people predicted to remain impoverished despite (or because of), the putative effects of corporate globalisation. This is not a definition to which precise numerical data can readily be attached, but serves a useful role in framing the conceptual debate that follows.

In this context, there appears to be a fundamental disagreement amongst government policy-makers between two social philosophies, each of which is often supported before the public on the basis of their respective version of ethical reasoning (this is becoming increasingly synonymous at the global level with international

human rights reasoning). The first philosophy, referred to here as ‘market fundamentalism’ and promoted by lobbyists and apologists for multinational pharmaceutical companies, holds that it is almost an overarching social good that pharmaceutical companies should be legally permitted to enjoy market monopolies over products for which they own patents. This is considered by such industry representatives to be an ethical point of view in that it upholds the ethical principles that an innovator should get a fair reward, that society always benefits whenever investment is promoted regardless of the trade-offs in diminished public goods that sometimes have to be made. Related arguments concern so-called alleged ‘free-riding’ on developed nation R&D (MacDonald, 2006). Attempts by governments to constrain the activities of pharmaceutical corporations in the public interest can be criticised, according to the same canons, as an assault on freedom of action in the market that inhibits competition, innovation, economic growth and employment.

The second competing philosophy holds that the provision of medicines should be organized to serve public health and the global poor. The ethical justification for this is frequently rooted in appeals to the importance of universal valuing of the social virtue of respect for human dignity as increasingly conceptualised in international human rights norms (Sen, 1999; MacDonald, 2006).

One recent example of the first ‘market fundamentalist’ social philosophy in practice in this context concerns certain recent multilateral and bilateral trade agreements that have achieved notoriety in academic circles for including provisions aimed at removing or altering domestic medicines policies that facilitate access to essential medicines by the poor; the rationale being that they are ‘unnecessarily restrictive non-tariff barriers to trade’ (Faunce, 2005; Shaffer *et al.*, 2005).

These trade agreements also restrict government’s capacity to stockpile and compulsorily licence patented and otherwise prohibitively expensive vaccines in public health emergencies (Faunce, 2005). Such emergencies could include those created by pandemic influenza or bioterrorist attack, as well as HIV/AIDS, multidrug-resistant tuberculosis and malaria. While increasing claims to corporate monopoly privileges over intellectual property (including maintaining the latter should be regarded as a species of ‘natural right’ (Parsi & Egan, 2002; Martin, Sorenson & Faunce, 2007), proponents of these types of trade agreements claim that they stimulate investment and research. But they also appear to make new medicines more unaffordable and create significant opportunity costs for governments seeking to develop policies that assist the poor either by facilitating research in or access to new health technologies.

This paper starts with the premise that an ethical approach to the access to innovative health technologies by the poor requires that an international human rights-based, transparent regulatory pathway be developed at the international level. We will examine three alternative models with a view to ascertaining the most effective way of achieving this global regulatory reform. Whilst many such plans are now being promoted, these three have been selected because they involve a focus on varied aspects of the problem and take up different regulatory mechanisms as solutions. This fits well with our interest in reform of global regulatory systems. In considering the relative strengths and weaknesses of three strategies for altering the approach to development of new health technologies for the benefit of the chronically poor, we also keep in mind the practical benefits and difficulties of implementing such plans.

Background: The Global Regulatory Architecture of Health Technology Research

The need for policy change in the area of international trade and intellectual property law so that they promote research that better responds to patients’ needs and ensures equal access to innovations has been well detailed (Carbone, 2003; Faunce, 2005; ‘t Hoen, 2006; Stiglitz, 2006a,b). Our argument is that the dysfunction of the current patent system as a component of global regulatory architecture of health technology policy, is an outcome of corporate decisions based on a simplified economic theory whose dubious ethical status has received insufficient attention. Pharmaceutical companies direct their research where they can make the most profit, regardless of need, sustainability and the relative long-term value of that organisation or its products to society.

The *Doha Declaration on TRIPS and Public Health*, often lauded as a significant step towards equity in the trade and medicines arena, states that ‘trade agreements should be interpreted and implemented to protect public health and promote universal access to medicines.’ Section 2101(b)(4)(C) of the *Trade Promotion Authority Act 2002* (US) (TPA Act) even required US negotiators to ensure that subsequent trade agreements uphold the *Doha Declaration* (Gathii, 2002). Nevertheless, this has largely remained a dead letter and even phrasing the problem in terms of ‘access to medicines’ can be viewed as endorsing a dependency on research in developed nations as a necessary part of the solution.

General ethical and legal criticism can be levelled that a long-term election cycle does not provide effective democratic control over international law-making

at the initiative of corporate-influenced executive governments, particularly in areas such as trade and medicines (Henkin, 1990). The expedited international law-making involved in sealing trade deals by semiautonomous organizations such as the USTR (United States Trade Representative closely associated with private industry), tends to reduce the involvement of democratic legislatures and an independent judiciary in the regulatory process (Anonymous, 1993–1994). The formulation of the US trade policies over the last decade, for example, has involved minimal consultation with health agencies regarding the health impact of the policies. Interviews with USTR officials have revealed that there is little evidence that USTR consulted HHS or OGHA (Health & Human Services Office of Global Health Affairs) about the potential impact on public health of specific pharmaceutical provisions in FTA, although the HHS OGHA's mission includes promoting the health of the world's population. Further, the USTR receives counsel on specific sectors and issues from 14 'trade advisory committees' ('t Hoen, 2006; MacDonald, 2006). Most of the committees have no public health representation; the committees on intellectual property and chemicals each have just one member appointed to represent public health interests, while the intellectual property committee has five representatives from the brand pharmaceutical industry, and the chemicals committee has 10.

This aristocratic nature of international regulatory law-making process led by an emerging transnational capitalist class poses more serious threats to national policy and law-making in developing countries (Allott, 2003; Chimni, 2004). More specifically, the problems created for developing countries by bilateral trade agreements limiting the exceptions to intellectual monopoly privilege protection have been widely noticed (Abbott, 2005).

We now consider three widely differing approaches to remedying such inequities inherent in the global regulatory architecture of health technology policy.

Alternative 1: Medical R&D Treaty

The model of a global Medical Research and Development Treaty (Medical R&D Treaty) Treaty requires signatory countries to commit to spending a predetermined proportion of gross domestic product on medical R&D, as set by the WHO. This model was first proposed by Love and Hubbard and a broad group of influential academics as an alternative framework to address neglected diseases. Under the treaty, the aim is that R&D health technology financing becomes a globally shared responsibility, thus at least outwardly addressing the issue of free-riding by nations that spend little on health technology R&D

(Hubbard and Love, 2004). By rewarding health technology innovation from the prize fund at the R&D phase, the treaty encourages the price of the drug to immediately fall to the marginal cost of production (Hollis, 2006; WHO, 2006). This creates different markets for pharmaceutical R&D and for pharmaceutical production and distribution, each potentially subject to different regulatory arrangements.

The treaty includes minimum national financial obligations for supporting medical R&D. But each country would be free to fund its required R&D contribution with varying business models, including strong IP rights and high prices, public funding or tax credits. Further, the treaty would reward innovation directly with a system whereby contributions to R&D on neglected diseases receive payments from a prize fund (Presma, 2005). The size of the prize would be proportionate to the innovator's performance against evaluative criteria.

At the core of the proposed Medical R&D Treaty is an obligation to finance Qualified Medical Research and Development (QMRD). This obligation is tied to a country's GDP, either using different rates for each of four income groups (high, high medium, low medium and low), or a graduated rate. QMRD would include (1) basic biomedical research, including development of biomedical databases and research tools; (2) development of pharmaceutical drugs, vaccines and medical diagnostic tools; (3) medical evaluations of these products; and (4) preservation and dissemination of traditional medical knowledge. There is a separate obligation to finance Priority Medical Research and Development (PMRD) and two alternative methods of setting benchmarks for PMRD. In the current draft at least half of PMRD investments must be targeted for neglected diseases.

Like Love, Nobel Prize-winning economist Joseph Stiglitz advocates the use of a medical prize fund as an alternative to the patent system (Stiglitz, 2006b, p. 1280). In this case, the fund is even more specifically targeted at spurring research and development into the so-called 'neglected diseases' that afflict people in the developing world, such as AIDS and malaria. Nonetheless, the medical prize funded by advanced industrial nations, he suggests, would ensure the best possible way of using whatever knowledge we acquire, allowing for the power of competitive markets to ensure a wide distribution at the lowest possible price (Stiglitz, 2006b, p. 1280). The benefit of the prize system developed by Stiglitz is that it reduces the desire of pharmaceutical companies to focus on incremental innovation, such as 'me-too' drugs (where innovation resides more in technological changes and advertising than provable health benefits), and to push for real R&D breakthroughs in pursuit of a cash prize (Wei, 2007). Once a prize has been awarded, it

would allow for the production of generic medication at cost prices.

Although this model relies on a quantifiable contribution based on GDP, the Medical R&D Treaty model does not implement protection measures against the influence of the pharmaceutical industry with regard to the discretionary allocation of prizes. Although Love has highlighted the benefit of flexibility when determining the value of a medicine, the greater the discretion of the rewards authority, the greater is the opportunity for the industry to undermine the intended function of the treaty.

This problem could perhaps be addressed through implementing evaluative criteria based on objective principles set out in the treaty. Yet implementation of this model will require considerable amounts of information to allocate prizes correctly, possibly in the form of an international health information network. Although it is unlikely that the significant developments in health systems that would enable reporting on this scale will be available in the shorter term, prize models are problematic in any case as they do not provide a financial reward for a pharmaceutical company until the risk associated with R&D has already been taken. Prize models may also be inefficient because they award prizes that are sometimes substantially greater than the cost of the R&D.

The prize fund model shares similar elements with the Advance Purchase Commitment (APC) model under which governments agree to purchase fixed quantities of drugs at predetermined prices if a company's R&D is successful, thereby creating markets for products, which would otherwise be too uncertain to attract sufficient investment (Noehrenberg, 2006, p. 419). But the R&D prize system, with its basis in government funding carries considerable risks. Marlynn Wei expresses a primary objection: 'the administration would give rise to partiality, arbitrariness, or even corruption—the dangers of all institutions giving discretionary power to the administrators' (Wei, 2007). This leads many detractors to believe that the devil is indeed in the details for the R&D prize system, with much necessary components still unclear, such as determining prize spending and the value of prize payments.

A strength of the R&D prize treaty is that industry will always be attracted to a large pool of government money. In this sense the model represents a continuation of the carrot-on-a-stick approach to encouraging pharmaceutical companies, which they have grown accustomed to 'gaming' for their own advantage. Proponents can point to historical examples of such prizes as alternatives to patents. They can highlight how a prize system (unlike the patent approach) can be directed to valuable global goals

concerning reduction in the burden of disease (making it more congruent with human rights norms). This proposal has certainly attracted the most attention amongst policy makers and scholars, which is a testimony to the support it is receiving from well-connected activist individuals and organizations. Preventing corruption of the processes by which the R&D goals are set and funds allocated will be one of the biggest challenges for this proposal if it is established. Which existing international organization, if any, should act as administrator will also be a possible source of controversy.

Alternative 2: Alternative to Patents Health Impact Fund

Under this model, pharmaceutical innovators would have the option to forego a conventional patent on a new discovery and claim instead an alternative patent (Pogge, 2005) (or in later formulations a nonpatent claim (Hollis, 2008) upon a Health Impact Fund (HIF) that would reward them, out of public funds, in proportion to the health impact or therapeutic value of their product. Like the Medical R&D Treaty, this HIF model reorients the direction of pharmaceutical companies towards neglected diseases through the implementation of a prize fund (Hollis, 2008). There are, however, many differences from the first proposal discussed here. The first and possibly the most significant is that pharmaceutical patents are not directly threatened while pharmaceutical companies are offered a new source of revenue from the development of drugs for neglected diseases. This may make the proposal at least initially more acceptable to multinational corporate executives involved in this area.

Under the HIF model, in order to increase the value obtained, innovators would seek to ensure their medicine had maximum health impact through promoting the construction or improvement of healthcare systems to ensure that patients have the knowledge and motivation to use the medicines to optimal effect (Pogge, 2005; Pogge, 2008). Further, generic brands would be encouraged and supported as this would further increase the number of users with favourable impact on the global disease burden. Rewarding pharmaceutical companies for a product's actual clinical effectiveness entrusts them with flexibility in choosing the best therapeutic approach and encourages them to ensure appropriate use and distribution. The HIF model aims to remove a crucial obstacle to a dramatic reduction in the global disease burden by giving medical innovators stable and reliable financial incentives to address the medical conditions prevalent in the developing countries (Pogge, 2006; Hollis, 2008).

The first principle here is that the results of any successful effort to develop (research, test and obtain regulatory approval for) a new essential drug are to be provided as a public good that all pharmaceutical manufacturers may use free of charge. This reform is argued to eliminate the second market failure (associated with monopoly pricing powers) by allowing competition to bring the prices of new essential drugs down close to their marginal cost of production. The second principle (at least in initial formulations) appears to be that, similar to the current regime, inventor firms should be entitled to take out a multiyear patent on any essential medicines they invent but, during the life of the patent, should be rewarded out of public funds in proportion to the impact of their invention on the global disease burden (Pogge, 2005). The third component is to develop a fair, feasible and politically realistic allocation of these costs, as well as compelling arguments in support of this allocation (Pogge, 2008; Hollis, 2008).

A problem with the practical efficiency of this model will be that of designing and implementing a robust means of assessing the comparative cost-effectiveness of a newly developed pharmaceutical. It seems to have been envisaged that the pharmaceutical industry would retain control over the direction of research. Like the Medical R&D Treaty proposal, the discretionary nature of the HIF model requires an international health information network to avoid gaming by pharmaceutical companies who may attempt to exaggerate the health impact of a new drug (Hollis, 2008; Ravvin, 2008).

The international dimension of this model could also be called into question. The public funds to cover the reward for invention come from taxpayers in developed countries, while most of the benefits from the invention could well be consumed by the people in developing countries. It is arguable that some of the contributions might be made up by lower health care and pharmaceutical costs (Hollis, 2008). Despite the moral support that it may attract, the idea may confront difficulties with obtaining enough political support unless there is a wider international cooperation. In this respect, it is worth examining the synergies of the HIF model with the Health Technology Cost-Effectiveness and Competitive Tender Treaty, to which we turn our attention in the next section.

Alternative 3: A Multilateral Treaty on Health Technology Cost-Effectiveness Assessment and Competitive Tender

The first two proposals examined here have sought to overcome ethical problems with the direction of health technology R&D outlined at the beginning of the paper,

by either providing a replacement of the existing patent system (the Medical R&D Treaty) or an alternative to it for a limited set of conditions related to health needs of underprivileged populations (the HIF model). Both involve the creation of new administrative infrastructure and its insertion into the global regulatory system for health technologies.

A different approach involves aggregating and formalising at the global level the existing networks of national assessors scrutinising the safety and cost-effectiveness of new health technologies, while supporting and expanding domestic legislative arrangements whereby governments subsidise to citizens the cost of new health technologies through centralised public-funded price negotiation schemes involving closed-bid competitive tender for therapies urgently required to meet identified public health needs. This Cost-Effectiveness Assessment and Competitive Tender model involves a multilateral treaty establishing basic principles and procedures for price negotiations between governments (or UN agencies) and manufacturers of new health technologies based on expert assessment of safety and cost effectiveness (Faunce, 2006).

Unlike the Medical R&D Treaty (Alternative 1 discussed above) it leaves the existing patent system intact and does not require nations to allocate a large proportion of their GDP to a system several steps removed from their direct control. Unlike the HIF system (Alternative 2 discussed above) it does not require any alteration of patent law (on early formulations of HIF) or require the creation of international public funds largely contributed by developed countries. In this latter sense also it has advantages over the Advance Market Commitment (APC) model where calculating in advance the amount of R&D reimbursement is a major issue (Hollis, 2008).

What the Cost-Effectiveness Assessment and Competitive Tender Treaty requires instead is a combination of (1) formalisation in a multinational treaty of the basic principles by which urgently required, new health technologies are assessed for safety and cost-effectiveness and then (2) linkage through the same mechanism with domestic regulatory processes in which public funds are allocated to subsidise expenditure by citizens on new health technologies, for example by closed-bid competitive tender.

One value of a Cost-Effectiveness Assessment and Competitive Tender Treaty is that states are more likely to commit themselves to facilitating a public goods agenda in the area of medicines policy if they can convince themselves that it is financially responsible and does not cut across existing intellectual property protections, or strongly protected areas of state sovereignty. In effect,

there is a chance they could be persuaded that such a treaty merely moves to a global stage successful science-based systems of equitably allocating public funds for health technology purchase such as the Australian Pharmaceutical Benefits Scheme (PBS) and New Zealand's PHARMAC system (Faunce, 2007, Ch. 7). It is designed to ensure that markets operate most competitively to deliver the best community value on criteria of objectively demonstrated therapeutic significance. A political advantage of the Global Cost-Effectiveness Assessment and Tender Treaty is that central government price negotiation on evidence-based criteria with the relevant patent holder/manufacturer can be strategically presented as a form of expenditure minimisation, or a fiscally responsible way of obtaining community health value for public expenditure. Increased tendering for active pharmaceutical ingredients and generic medicines will create significant savings in developing nation health budgets. Post-tender, the winning company will have a new, larger, market share, be able to buy chemicals in bulk and exploit economies of scale in production (OXERA, 2001).

Multinational pharmaceutical manufacturers may well view any process of using expert assessment of published cost-effectiveness evidence about their products, particularly if linked with a competitive tender process, as challenging the role of advertising and monopolistic practices to control the marketplace to their advantage under the 'market fundamentalist' philosophy outlined earlier. One of their major counterarguments is likely to be that such mechanisms (whatever their apparent value in terms of distributive justice, global ethics and international human rights) would allow foreign nations to free ride on US research and development and so promote high domestic US drug prices (Faunce, 2007b; Koltich, 2006). As a 'pull' mechanism, they could claim it will not be specific enough (unless globally endorsed through a Treaty) to encourage their R&D to flow in directions required by the global burden of disease.

It could likewise be argued that repetition of tendering rounds may increase the likelihood of market concentration if the same suppliers win contracts, so that competitors let their expensive product licence expire. Tendering may not only drive the price down rapidly once a drug comes off patent, but also facilitate the exit of unsuccessful generic suppliers from the market and stall further price increases. While securing supply has been a problem in isolated cases in New Zealand (where the tender system is utilised widely), this problem tends to have been exaggerated by multinational pharmaceutical interests (Faunce *et al.*, 2006). Concerns that tendering may cause difficulties in planning production for generic manufacturers, would be minimised if the process in-

involved an open tender for generics below a government set price, especially if it was linked to tax incentives for companies to create head-to-head clinical trials of their generic products against brand name and other generic competitors, and a systematic program of physician education.

For tendering contracts to function properly as a 'pull' mechanism for health technology R&D, enforceable penalty clauses for failure to deliver or other contract default are crucial. The simplest of such clauses would specify that a defaulting contractor should reimburse the relevant government positive list for the extra cost of obtaining supplies from elsewhere. The contract between the supplier and the relevant government should allow, however, for some flexibility in the agreed volume if demand turns out lower than forecast, or a supplier fails to deliver (Faunce *et al.*, 2006).

This Cost-Effectiveness Assessment and Competitive Tender Treaty model further differs from the prize fund and HIF ideas previously discussed in that it aims to enhance the global scope of fully mature regulatory processes already existent in many jurisdictions (few nations currently have domestic prize fund or patent prize systems in place). It can provide a clear incentive system for pharmaceutical manufacturers to seek to develop innovative medicines for developing world populations, by providing a transparent pathway to a large pool of mixed charitable, United Nations and domestic government funds allocated to being spent, under a competitive tender process, upon pharmaceuticals for otherwise 'research-neglected' diseases in the developing world.

Another advantage of the Cost-Effectiveness Assessment and Competitive Tender Treaty model is that its requisite involvement of experts in the regulatory process will ensure that the whole process is less likely to be captured by the multinational health technology industry to its own advantage. The goal of a global framework treaty on the principles and procedures to guide safety and cost-effectiveness evaluation of new health technologies could also be a more politically achievable one than the earlier discussed proposals if all the different interests are taken into account and weighed in a balanced manner. Working out a road map toward such a treaty would involve discussions about principles on assessor reimbursement (possibly a tax on global financial transactions) and liability protection, rationalisation of commercial-in-confidence protections, post-marketing surveillance and performance indicators for conditional approvals and strategies to obtain information on marginal cost of production and price setting.

Once sufficient ratifications of such a treaty have been achieved, the course of pharmaceutical R&D would be

shaped over time as firms compete to make large profits by having their products placed on the treaty list (Faunce, 2006, p. 8). Its carrot is to provide manufacturers and patent holders with potential access to a level playing field of large and reliable sources of domestic funding once they have met the requisite evidence-based standards. Although the democratic deficit inherent in the international law-making will not be perfectly rectified under this model, the involvement of experts in the regulatory process will assist the likelihood that the whole process will be more transparent and accountable to global health needs.

Conclusion

This paper has attempted to examine three different approaches to driving a more positive agenda on access to both essential and health innovative medicines for the chronically poor. These range from an Medical R&D Treaty, an entirely new patent prize track and a health technologies safety and cost-effectiveness assessment treaty incorporating a closed-bid competitive tender process for funds made available for neglected diseases. The first model seeks to replace the existing patent-driven R&D model for health technology. The second model seeks to establish a prize fund mechanism whereby unique patents can encourage R&D for neglected diseases. The third model leaves patent law alone and seeks to formalise at the global level mechanisms of cost-effectiveness assessment and closed-bid competitive tender for neglected diseases.

If previous trends continue, corporate interests and the state bureaucracies beholden to them will strongly oppose all three of the models discussed above. All three proposals are now part of the published literature in this field. Which of such reforms is likely to be more in the public benefit, or more achievable, will be a matter to be debated by academics, activists and policy makers. Yet a sustainable world of more uniformly healthy people is a vision of respect for humanity and human dignity found in the international human rights system, but not yet in global health technology regulation. In time it is to be hoped it will start to more thoroughly and systematically infuse the international trade and patent systems. It is hoped that the proposals discussed here will be viewed in time as significant contributors to this valuable end.

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