Bioethical Issues of IPRs

Theme 5 – Practical Implications for Healthcare

Access to Essential Medicines and Patents holders

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Since 1977 the World Health Organisation has published a "model" list of "essential medicines". It defines essential medicines as "those which satisfy the priority health care needs of the population". However, it does not give a definition of "priority health care needs", stating that "The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility"[1] The model list reflects WHO's own considered view of medicines which are necessary for the treatment or prevention of the most significant and common diseases worldwide, drawn up with consideration of manufacturing quality, efficacy and safety. The value of the list is both in assisting countries with limited health budget draw up their own list of medicines which will be provided by the state or by insurance programmes, and in specifying medicines which the WHO or other international agencies may assist countries in making available to their populations. Most of the medicines on its list, which is revised regularly, are so-called generic drugs. Generic drugs are drugs whose production and sale are not patent-protected. However some drugs on the list are patent protected.

Recently a number of countries and campaigning organisations (such as Oxfam, War on Want, and Médecins sans Frontières/Doctors without Borders) have argued that the essential medicines concept should be focused more on a principled definition of "essential". That is, whether or not a medicine is regarded as essential as a matter of international law and policy should not depend on whether it is on WHO's model list, nor on the possibly arbitrary decisions of national governments regarding their "priority health care needs", but rather on some objective criteria such as whether they are life-saving. Such organisations argue that

[1] World Health Organisation "Essential Drugs and Medicines Policy" http://www.who.int/medicines/ (homepage; accessed 16th June 2003).

WHO's position illegitimately links an agenda concerning "essential health care" (health care that is essential for preserving life and a certain minimum standard of medical welfare) and "rational medicines use" (which includes an element of cost control). Because this list of criteria is rather hard to draw up, the campaigning organisations have tended to focus instead on a list of diseases. The list most famously includes HIV/AIDS but also includes malaria and tuberculosis, and other "tropical" diseases. Antiretroviral (ARV) treatments for HIV/AIDS are often central in this debate since with ARV treatment someone who is HIV positive may live for many years, while they may die fairly quickly without treatment, especially in situations where health is generally poor and resources are scarce. Hence ARV treatment is argued to be essential in that it is effectively life-saving. Some ARV treatments are on WHO's list, but most are not. Even those which are on the list are not always easily or cheaply available.

The debate over *access* to essential medicines has tended to take the concept of essential medicines broadly, along the lines proposed by the campaigning groups. It has then focussed on what is needed in order to make sure that citizens of poor countries are able to access the medicines defined as essential. Considerable problems exist in many settings in making affordable and effective health care of any kind available, independently of the question of the price of drugs. Nonetheless, it is probably true to say that most of the academic and political debate in this area has focussed on drug pricing and availability. This is for three main reasons: first, it is an area where apparently much could be done to make drugs more cheaply and easily available (even if other health-influencing factors prove much more intractable, such as long term endemic poverty). Second, it is an area where the moral agency and hence moral responsibility appears to be clear (governments and corporations apparently have clear obligations to aid the dying and the seriously ill). Third, this debate is a clear and central example for use in debates over world trade, international law and policy,

"globalisation", and the respective roles and interests of national governments and multinational corporations.[2]

The force of the concept of an "essential" medicine is obviously contested, as the differing positions of the WHO and the campaigning organisations would imply. However, what is clear is that its force has a normative element. A medicine which is essential ought to be available to those who need it, or its unavailability at least given a defence and justification.

The ethical literature on this issue is extensive. Arguments have tended to concentrate on the following issues:

1. The existence of a right to treatment. This debate has covered themes such as the existence or otherwise of a basic human right to health, a derived right to a decent minimum standard of health care, and the contrasting claims of natural rights theories and consequentialist theories which deduce rights from welfare-maximising principles.

2. The scope of property rights. Since patents are a form of intellectual property right, many commentators have focused on whether there can be property rights at all, over whether medicinal products or innovations are "special" in terms of IPR, over whether bearers of rights have moral obligations to use or vary such rights in the face of desperate need (and how desperate does the need have to be?), and over whether intellectual property is merely an intellectual or legal construction which can be varied at the will of a sovereign state, or whether states are subject to the international agreements they have made to protect such rights, or whether intellectual property rights are natural rights which the state has no particular power to alter.

3. The nature of corporations and economic incentives. Here it has been argued that corporations exist to serve particular economic and welfare ends, that their function

[2] For a useful recent discussion of this last point see S.K. Sell *Private Power, Public Law: The Globalization of Intellectual Property Rights* Cambridge: Cambridge University Press, 2003. For a useful over-view of trade policy in the health context, see K Lee, K Buse, S Fustukian (Eds.) *Health Policy in a Globalising World* Cambridge: Cambridge University Press, 2002.

is either non-moral or only minimally moral, and that in order for corporations to flourish they need to be able to take fairly earned profits. Contrary to this position, arguments have been levelled which contest the idea of "fair" profit, the empirical economics of return on pharmaceutical investment and incentives to pursue research, the nature of corporate social responsibility, and the political power and influence of multinational companies as quasi-state entities from a geopolitical perspective.

4. The nature and scope of duties to aid and rescue. Analogous to long-standing debates over our duties to those starving, there have been a number of consequentialist (particularly utilitarian) authors who have argued that we have a powerful duty derived from welfare maximisation or harm minimisation principles to aid the sick and disaster-stricken, independently of whether such people have a right to such assistance. Such arguments have also been advanced from a Kantian perspective. Typically proponents of this view have little time for corporate arguments about limited social responsibility, but it is possible to construct arguments which contend that what counts is efficiency and economic liberty and competition is a more efficient and effective mechanism for promoting welfare than voluntary assistance.

Udo Schüklenk and I set out a suite of arguments in a recent paper which give a consequentialist argument for the existence of an obligation lying with states to make treatment for life-threatening diseases available as cheaply as possible to those in need of such treatment.[3] In particular we argued that states can have an obligation to take out compulsory licenses for patented medicinal products which would otherwise be unavailable or unaffordable due to the patent-holder's licensing or pricing practices.

Our argument aimed to establish this through a number of steps. First, we assumed the standard consequentialist position, to the effect that there is no morally relevant difference between consequences of actions and consequences of failure to act. Second, we assumed

[3] Schüklenk U, Ashcroft RE "Affordable Access to Essential Medication in Developing Countries: Conflicts Between Ethical and Economic Incentives" *Journal of Medicine and Philosophy* 2002; 27: 179-195

the common version of consequentialism popular within bioethics, to the effect that one should act so as to prevent preventable deaths. This leaves aside difficult questions such as the nature of utility, welfare, harm and suffering. It has some analytical difficulties, concerning the comparative evils of death and suffering, and the meaning of "preventability", but it makes for considerable simplification in the argument. It should be possible to preserve the main conclusions of the argument through replacing this theory with a more sophisticated utilitarianism, if desired. We then reviewed the available options for improving access to essential medicines in poor countries: charitable donation, public-private partnership, parallel pricing by suppliers, and compulsory licensing.

Our arguments, briefly summarised, were that charitable giving is too unpredictable, too voluntary, and too dependence-inducing to be a central plank of policy in this area, however commendable it might be. We also argued that charitable donation gave the appearance that saving life was optional, whereas we argued that it was the central human duty to others. Parallel pricing, while commonplace in fact, is neither binding on firms, nor acceptable to most pharmaceutical industry companies as a matter of policy. Public-private partnerships share similar difficulties to charitable giving, in that corporations take part in them only if they see a clear interest in doing so. While not all companies are strict profit-maximisers, they certainly avoid activities which would certainly lose them money. So this approach may merely lead to government aid by other means, and a substantial diversion of funds away from frontline aid and toward the pharmaceutical companies. Moreover, such partnerships give companies some explicit leverage over governments, and as has been argued concerning the involvement of private sector companies in other development projects, may lead the development of health care more to serve industrial interests than the interests of those in the countries requiring assistance. Our argument was therefore that none of the alternatives to compulsory licensing were entirely satisfactory, in that none could guarantee either the appropriate level of long-term supply of drugs, nor the appropriate price structure, and all could lead to a strengthening of company interests and a weakening of state sovereignty. On the other hand, compulsory licensing could – at the very least – strengthen

the bargaining power of states, and allow them the capacity to seek drugs from a broader competitive marketplace.

There are, no doubt, many weaknesses in this paper. However, we think that we set out the structure of the argument reasonably clearly, and although the article was written before the Doha WTO meeting and published after it, we think that our position is broadly consistent with the Doha Declaration and its support of states' rights to issue compulsory licenses in health emergencies.

An important feature of the consequentialist argument – indeed any consequentialist argument – is that it is not agent relative. In other words, while our argument is targeted at policy-makers and corporate officers since they have the power to make a considerable difference here, nothing in the argument really addresses the specific structure of states and companies, as these have no intrinsic moral status. They are purely ad hoc arrangements, and are morally defensible to the extent that they are the most efficient means of social organisation to achieve their ends, which are merely derivative ends from the overarching end of preventing preventable deaths. Hence, our argument is essentially an argument about welfare-interests and derived rights, with welfare-interests understood as being natural and derived rights being artificial. Secondly, it is an essentially moral argument, with little interest in political expediency or political interests. To some extent consequentialist arguments are influenced by "what works" and by social processes understood as quasi-stable features of the environment in which one acts. But some social processes and institutions are more stable or deep-rooted than others. Intellectual property rights are rather self-evidently constructed, since they vary so much from place to place, time to time, and modes and extent of enforcement.

The analytical weaknesses of consequentialism, and these considerations about the constructed nature of states, markets and social institutions have lead me to consider an alternative tack. This is an approach directly taken from political theory, which eschews a moral approach to the issue of obligations to citizens in need. The argument starts by considering the function of a state. It can be argued that all political theories aside from

arguments for simple despotism argue that states exist to protect the interests of their subjects as a collective group. Most political theories in the modern period argue that groups are constituted in some way through the coming together of individuals or families to combine in order to derive benefits from such combination. The dominant theory in contemporary political thought conceives of this coming together and combination in terms of some version of social contract theory. However such theories are justified, the central idea is plausible: viz., that we do better together under some central authority which makes rules and commands effective assent to such rules from all citizens, than we would do without such an authority. Considerable disagreements exist within political theory about the scope of such rules, about whether natural rights exist prior to social combination and how far these can be modified or overridden by "political" (social, non-natural, artificial) rules or rights. However, the central idea of the constitution of a rule-making and rule-enforcing authority, justified to the extent that it is able to protect citizens better than they would be protected in the absence of such an authority, is widely accepted.

The most influential account of this theory of combination and authority is perhaps that of John Locke, in his *Two Treatises of Government*. Locke's influence can be traced perhaps to his fusing of natural rights theory (in particular the natural right of property) with a social contract theory. However, for a number of reasons I prefer to work from Thomas Hobbes's earlier theory, in his *Leviathan*. Hobbes argues that states come into being through the vesting of authority in a sovereign power, much as in Locke, but unlike Locke Hobbes holds that there are no natural rights (including no rights to property). All rights are creations of the sovereign, and variable at the will of the sovereign. Prior to the creation of a sovereign power, men and women are in the state of nature, which Hobbes famously held to be a state of War. War, for Hobbes, was not merely the condition of violence, but the condition of living under the ever-present threat of imminent violence. Moreover, although Hobbes has sometimes been accused of implying that violence was an essential tendency in humans, it is probably fairer to say that the threat of violence derived as much from conditions of natural scarcity of the means of survival rather than from human nature alone. The chief problem for humans was that the state of War tends to be self-perpetuating, since in that state no

one can plan, there is no reason to invest, invent or improve, since all can come to nothing in a moment. Hence the chief advantage of a sovereign power was that it creates a condition of order in which planning, ingenuity and investment all become worthwhile and stable possibilities.

In the Hobbesian argument, property rights, including rights of monopoly (which include our patent rights) are derived from sovereign authority, and are created through such authority to the specific end of improving social welfare and moving us further away from the state of War. To the extent that they achieve this end, they are legitimate, and to the extent that they fail to achieve this end, they can contribute to the weakening of the state. Finally, a state can be so weakened that it collapses either through internal decay into the state of War, or through external invasion or military defeat. Hence the sovereign authority has a duty to create conditions which make this decay or vulnerability to external threat less, rather than more likely. Thus it would be a mistake to read the Leviathan as merely an autocratic, self-interested power, against which revolt is never legitimate. Rather, its legitimacy derives from its functional efficacy in averting the state of War. Amongst other things, this can require rule through the law, with the requirements of liberal law (non-arbitrariness, transparency and disinterestedness in adjudication, for instance) adhered to. But it can also require refusing to treat legal provisions as irreversible and invariable, where these cease to be functional. Hence in conditions of dire need, such as in public health disaster, it may be necessary to vary property rights.

In another place, I show how this Hobbesian account can be inserted into a moral argument which creates a perfect duty on states, derived from the legitimacy conditions I sketch here, to provide medical assistance in public health disasters.[4] Here I conclude by relating this argument to another argument frequently invoked, concerning the "public interest" justification for maintaining IP rights over essential medicines.

The World Trade Organisation's meeting in Doha affirmed the acceptance of the international community that compulsory licensing of patented medicines was acceptable, in the case of

[4] RE Ashcroft "Access to Essential Medicines: A Hobbesian Social Contract Approach" *Developing World Bioethics* (Forthcoming, 2004) – manuscript available from the author.

public health emergencies. Moreover, it accepted that it was in the end each individual country's right to decide when an emergency obtains.[5] This is consistent with my Hobbesian reading of state sovereignty. Nonetheless, the interpretation of this statement has been under considerable pressure from various countries and industry associations, who argue that "emergency" should be interpreted narrowly (for instance, an anthrax bioterror attack might be an emergency, but long term endemic tuberculosis would not be). The principal argument here is that there is a strong public interest in creating IP rights, and in sticking to the law relating to IP. This hinges both on the need to secure the commercial conditions necessary to ensure that investments can be recovered and a level of profitability maintained, and on the need to ensure that the law is regarded as stable and largely independent of political will and expediency.

What would a Hobbesian say to this? Largely speaking, a Hobbesian would agree with the need for stable and non-arbitrary law, but would also hold that in a sense the state of emergency is always present, merely being held at bay by the construction of a sovereign authority (amongst other things). Hence the "emergency" condition refers not only to actual emergency, but also to the imminence of possible emergency. This is what should shape public policy. In the light of this, the necessity here is to examine the public interest argument on its merits and to see which policy would better protect that public interest. Hence, the Hobbesian would insist on demonstration that the public interest is actually better maintained by strong IP protection for the pharmaceutical industry, and this demonstration would largely be empirical, rather than logical. Hence, the Hobbesian would need to be assured that the industry's own claims about its needs for special economic and legal status, through strong IP protection in law and public policy, were actually borne out by the facts. Does innovation actually respond to IP protection? Does industry actually grow faster or produce more new treatments where IP protection is stronger? Are treatments more readily available? Are more tax revenues or higher disposable incomes available in a society where

[5] WTO Ministerial meeting, Doha November 2001, "Declaration on the TRIPS agreement and public health", WT/MIN (01)/DEC/2, http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed 16th June 2003)

this IP is enforced? And so on. If, on the other hand, strong IP protection has the consequence that people are unable to provide for their own medical care, states are unable to meet that need, and this can be ascribed wholly or in part to the IP regime itself, then the Hobbesian would incline to the view that the IP regime should be changed. The central point is that IP – like other political artifices – must be tested against what it is designed, in the last instance, to achieve: protection of citizens against disaster. Indeed, on a Hobbesian view of the state, the state must select the policy which best averts the state of War. If the argument I sketch here is plausible, then this may mean that the state has a political obligation to issue compulsory licenses if that is the best means available to provide treatment at low cost (perhaps in addition to the moral obligation we discuss in our earlier paper).

As with our earlier consequentialist argument, this position has many holes.[6] But again, it does suggest a line of approach to IP and medicines which provides a strong challenge to the standard liberal view. On that basis, I commend it to you as an approach worth developing.

[6] Many of which I discuss in my concluding remarks to the "long" version of this paper; op. cit. n.4