Medical Knowledge as a Global Public Goods for Health

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(revised June 2002)

I. The issue

Knowledge obviously is, and always has been, central to all development in health. Because knowledge itself is such a wide and general concept, it is encountered in many different manifestations and has many facets. All forms of knowledge tend to be subject to commercial as well as public (that is, government and other non-profit organization) interest. In addition, knowledge relating to health is even more varied because it is often invested in the community in the form of traditional knowledge, which coexists along with various forms of "modern" medical knowledge. Because of its universal applicability, knowledge is often termed the 'archetypal' public good (Stiglitz, 1999). Clearly, therefore, it is important to consider knowledge from the perspective of being a GPGH.

Knowledge and technology relevant for health covers a very wide area, and includes knowledge about the following elements :

- understanding health risks and patient characteristics
- preventive actions, both individual and public
- diagnostic procedures and practices
- curative procedures
- palliative interventions
- delivery systems for all of the above.

It is evident that all of these are potentially subject to commercial exploitation, and therefore can be classified as "commercial knowledge". Much of the technology can be embodied in specific goods (such as pharmaceuticals or vaccines) which can then be marketed. New markets are also emerging in various other areas including forms of diagnostic activity, including genomics, which is covered in Chapter . Given this, all these form of medical knowledge can be potential cross-border "club goods", excludable but non-rivalrous in nature. This also means that the production of knowledge itself can be affected by the clubs that exist with respect to different types of knowledge, as discussed below. Further, the ability to benefit from medical knowledge is not uniform. Even when the best practice is known, such as in preventive actions or treatment of diseases, the effectiveness of such knowledge will depend upon the delivery systems and the nature of the existing health and infrastructure services. These issues are covered in Chapter .

In this chapter, the focus is specifically on medicines, or pharmaceutical technology – both "modern" and "traditional" - rather than on other forms of medical knowledge. This is taken as an example reflecting similar processes for other forms of medical knowledge.

II. Is medical knowledge a global public good ?

A global public good can be defined as one which exhibits a significant cross-border degree of "publicness", that is in terms of being non-rival and non-excludable in consumption. Knowledge in general is a public good, because it is fundamentally non-rivalrous in nature, implying that there is zero marginal cost from an additional person consuming the good. And it is one of the few public goods whose inherently international nature has never been questioned. Clearly, scientific truths or mathematical theorems are universal, and remain true in any part of the world. Also, it is usually difficult if not impossible to set controls specifically on the cross-border transmission of knowledge. The externalities associated with knowledge are also typically international, or not susceptible to limitation by national boundaries.

Nevertheless, the issue is not entirely clear-cut, because knowledge is only partly a public good. It may be embodied in forms that make it excludable to some extent. Indeed, control over some forms of knowledge has been a major source of power in societies throughout history. In the current international context, excludability typically expresses itself in commercial form, creating types of knowledge that may be classified as "club goods" with large externalities. Typically, however, excludability itself does not have geographical dimensions, that is, clubs in the case of knowledge tend to be defined not according to national boundaries but according to other criteria such as purchasing power spanning countries/regions. Such forms of knowledge are still socially underprovided, creating the need for public action to ensure both adequate provision and universal access. [1]

As for all forms of public goods, there are static and dynamic issues in the social provisioning of knowledge. Attempts to increase the development of knowledge by increasing private appropriability in various ways (such as through patents) are said to result in dynamic gains, by encouraging more innovative activity. However, such measures may also result in static losses, because of the fact that the knowledge obtained from such innovative activity may be underutilised because of underproduction, monopolistic pricing or similar behaviour on the part of the patent holder. (Stiglitz 1999). Public action to ensure the adequate provision of medical knowledge needs to balance these static and dynamic considerations.

Knowledge relevant for health can be considered as a GPGH for several reasons. The extent of spread of medical knowledge affects not just the global incidence of disease, but also the possibility of cross-border transmission of disease and conditions of ill-health. In addition, there are significant global externalities emerging from knowledge of different systems of preventive and curative medical systems, which in turn aids the process of production of such knowledge at a global level. Consequently, certain forms of public intervention to assist more provision of and wider access to medical knowledge, can also be considered as GPGH, as will be discussed below. There are significant differences between modern commercial medical knowledge and traditional knowledge. Typically, most traditional knowledge is by definition

[1] It must be admitted that the very notion of "underprovision" of knowledge production is problematic since it assumes that there is an "optimal" level, which is certainly not the case. The basic idea is that market functioning alone would imply lower levels of knowledge production than systems with public intervention.

unpatented and not present in codified or standardised form, which alters the static and dynamic issues with respect to both assessment and intervention.

Three aspects of medical knowledge are relevant. These are production, dissemination and consumption (or end use) of such knowledge. Some examples of various types of medical knowledge and their characteristics are provided in the table below. (Obviously, the list is not exhaustive.) The types of knowledge described are all club goods, that is, excludable but non-rivalrous in consumption. This means that such knowledge will be underprovided - in terms of production, dissemination and consumption – by private agents alone in social systems in which profit motives dominate, unless public action intervenes.

Table 1 : Examples of some types of medical knowledge and their features as GPGH

Category of knowledge	Embodied in goods/services such as	Excludable?	Rival in consumption?	Level and type of possible intervention
Production:				**National :** Increased public research funding; Fiscal incentives; Patent rights; Coercive rules **Global** : Global research funds; global public purchase funds; rules regarding patent regimes or fiscal incentives
Diagnostic	Scanning machines	Yes	No	
Preventive	Vaccines	Yes	No	
Curative/Palliative	Drugs	Yes	No	
Delivery	Clinics/ hospitals	Yes	No	
Dissemination:				**National:** Public provision; fiscal benefits **Global:** Increasing space/coverage through incentives and rules; increasing access through public spending
Specialised to practitioners and health providers	Educational and training institutions	Yes	Sometimes	
General and universal	Print media Radio/TV Internet	Only sometimes across borders	No	
Consumption: Access to knowledge about prevention, diagnosis, treatment	Marketing and provisioning systems	Yes	No	Public funds, Regulations
Access to knowledge about goods and services (such as drugs)	Accessible information	Yes	No	

III. The production of medical knowledge

The development and production of medical knowledge requires investment by society – of time, resources, skills. Because of the non-excludability of such knowledge, there is a danger that levels of investment would be socially sub-optimal, in both static and dynamic senses. In addition, because of the *global* public good characteristics, there are dangers that public intervention in individual countries

would still be inadequate from a global perspective. There are broadly five ways in which societies can choose to promote socially desired medical research. These are :

- the assignment of private rights for the commercial use of research, as in patent regimes and other systems of recognising private intellectual property rights;
- the direct public funding and organisation of medical research;
- ensuring private profitability of investment and production through various means such as public pre-purchase agreements, ensuring monopolies, or providing fiscal incentives;
- reliance upon (or encouraging through fiscal and other means) private donor or charitable funds;
- statutorily requiring those involved in medical businesses such as pharmaceutical companies and other health care providers to reinvest a proportion of revenues into health research.

Each of these strategies has both positive potential and associated difficulties. None of them need be adopted in isolation; rather, they can be combined to varying degrees.

III. (i) Patent regimes

The currently dominant means of dealing with the public good-related problems of social underproduction of medical knowledge is the assignment of private rights through patent regimes. The advantage of this is that, by allowing benefits to be channelled to private agents in the form of monopoly or licensing rights, it encourages more private investment in medical knowledge production than would otherwise have occurred. The basic problem of this method is that the research and investment agenda then tends to be set by private industry, which is influenced by interests of commercial profitability rather than social need. Further, once such research and development is completed and placed under the control of private agents, there is the further problem of the possibility of monopolistic behaviour and high prices of the results of such research. In addition, private drug markets typically suffer from various forms of market failure. These include informational imbalances - thus, for example, consumers are not in a position to judge the quality and efficacy of drugs, which creates the need for a social monitoring and surveillance system; lack of competition created by patent protection, brand loyalty and market segmentation; besides the obvious externalities in the form of substantial social benefits of drug consumption.

This is why there have been concerns relating to strict implementation of the TRIPS regime with respect to drug patents in particular, and growing recognition that such a regime may not in fact be a Global Public Good as supposed by its protagonists, but rather a regime which needs substantial revision before it can meet public health concerns. These concerns about the enforcement of the TRIPS agreement emerge particularly with reference to health conditions in developing countries, since the agreement is seen as increasing the power of large corporations who may be in a position to capture patents, vis-à-vis state regulatory authorities. Some of the most frequently expressed concerns include the following :

- Increased patent protection leads to higher drug prices and other monopolistic practices, even as while the number of patented drugs of importance from a public health perspective is likely to increase in the coming years.

- The access gap between developed and developing countries, and between rich and poor in all countries, will continue to increase, especially as producers in developing countries would have to wait for 20 years before they can have access to innovations.
- The shift from process to product patents in certain developing countries will have adverse effects on local manufacturing capacity and remove a source of generic innovative quality drugs on which the poorer countries depend.

Growing public concern about the effects of TRIPs prompted the WTO Doha Declaration on TRIPs and Public Health, of December 2001. While this did not go far enough in terms of providing legally binding commitments and is a political document rather than a legal one, it still provides a framework for dealing with the use of the TRIPs agreement by large companies in the developed world, especially in matters relating to public health. Similarly, while it is still vague about the possibilities for export of cheaper drugs produced using compulsory licensing, it leaves open the chance that this can be decided positively by the TRIPs Council eventually. Thus, it emphasised that (a) each member country has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; and (b) each member country has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

However, there are still many other possibilities in terms of changing the TRIPs agreement to render it more open to meeting global public health concerns and avoiding the monopoly and exclusion aspects that it currently provides to producers of medicines as GPGH. Within such an approach, several articles may require revision, for instance, Article 27.1 in order to exclude the patentability of "essential medicines" listed by WHO; Article 30 so as to incorporate an explicit recognition of an "early working" exception for the approval of generic products before the expiration of a patent; and, Article 31 in order to clarify the right to grant and the scope of compulsory licenses for public health reasons; decreasing the life of patents from the currently proposed 20 years; etc.

III. (ii) Private and public investment in knowledge production for health

Over the past two decades, there has been an important shift in the responsibility for knowledge production for health, with greater reliance on private activity in this area. This has been associated with a change in research patterns themselves, moving at the margin away from areas of greater social importance to those of currently higher profitability. Disease research has been increasingly oriented towards the curative aspects of disease rather than prevention, and has dealt more with diseases that are more common or more potentially dangerous in the rich societies. By contrast, the diseases common among the poor in developing countries are not the focus of private research and investment. Only 4 out of 1223 new drugs developed by private industry between 1975 and 1997 were relevant for tropical diseases. (Pecoul et al 1999, page 361.)

Similarly, even within diseases or treatment of more general relevance, there is a disproportionate emphasis on non-essential treatment such as cosmetic surgery or drugs like Viagra. Private pharmaceutical investments tend to focus R&D on products that may be attractive from a commercial point of view but which add little to therapeutic innovation. Many "new" formulations tend to be "me-too" products that imitate existing drugs and do not provide significant therapeutic improvement. This amounts to a global public "bad", because of the associated waste of resources.

Privatisation of much medical research may give rise to conflicts of interest, which may become significant enough to affect the quality of the research and certainly of the results of the clinical trials of certain drugs or investigative methods. This affects not just the direction of research but even the very quality and efficacy of the research, which can have extremely adverse health implications in the medium and long term. The growing commercialisation of medical research done in US universities has raised fears – and provided several instances – of private corporations funding medically relevant research, trying to influence the results or determine the nature of publication. Often, researchers themselves are encouraged to have a financial stake in the process, because they have taken shares in the companies concerned.

One cross-border implication of the commercialisation of research is the attempt by private companies to find least cost methods of clinical testing, which is typically one of the more expensive aspects of drug development. There is growing evidence of companies moving to undertake such tests on poorer populations in developing countries, especially in Africa and India, where regulation and surveillance standards are lower, the patents involved do not have full knowledge of the risks involved, etc. Not only is this ethically problematic, it also can reduce the quality of the results provided, and affect populations in other countries who then take the drug so tested.

Finally, there are concerns that when medical research is left to private agents, the costs, especially of drug development, can be greatly exaggerated. While information about the costs of developing new drugs vary widely, and tend to be shrouded in secrecy, these unreliable estimates form the basis of important public policy decisions. James Love (2000, 2001) points out that there can be confusion surrounding the actual costs of drug research and development because of (a) the extent of allowance for risk and the opportunity cost of capital (b) varying definitions of what is a new drug and the description of "me-too" products as completely new innovations (c) private agents taking credit for research and expenses not actually borne by them, such as when they purchase rights to or otherwise appropriate the fruits of publicly funded research or traditional knowledge (d) skewed samples and therefore misleading averages of costs and expenses incurred. Some estimates suggest that even according to the drug companies' own data, the level of R&D expenditure is not enough to warrant high monopoly prices being charged. [2]

[2] One study of the nine top pharmaceutical companies in the US found that eight of them spent twice as much on marketing, advertising and administration as on R&D, and all of them made more profits than their total R&D spending. (Families USA Foundation 2001)

All this suggests that, if most medical research is to be in the private domain, there is need for much stronger regulatory mechanisms than currently exist, to control and monitor private research. These mechanisms need to be international in scope, so WHO can play a useful role in ensuring the adoption and enforcement of universal standards in this regard. Indeed, global regulation and incentive creation for such research is clearly a GPGH, given the inability of many individual governments to undertake it, and the cross-border implications of such research.

So there is a strong case for changing the overall orientation of medical research, towards much greater public involvement. It is important to remember that even in the United States, until the mid to late 1980s, most such research was actually funded by governmental and quasi-governmental agencies, other public bodies and universities, rather than by corporations. Even today, much of the final research on medicines done (and patented) by private companies, remains based on the research carried out by public agencies or under public funding. Indeed, there are increasing concerns that public funds have been substantially used to develop drugs or therapeutic techniques, which have subsequently been allowed to be patented privately. [3] With increased public activity in the funding and direction of medical research, the control over such technologies would also need to remain in the public domain. For many drugs, it is important that this domain be a global]public domain with open access.

The problem with public funding of research that is most widely discussed is that it can lead to some misdirection of resources given the possibilities of mistakes (another example of "government failure"). There are questions relating to the efficient functioning of government-run labs and research institutions, to which types of research and development activities to fund, whom to fund, and so on. While these may be problems, usually the losses associated with some possibly wasted resources are far outweighed by the benefits in terms of increased production and access to medical knowledge. Further, when global funding for medical knowledge is considered, these problems are less apparent.

III. (iii) Incentives for private investment and development

The use of fiscal incentives (tax breaks, subsidies, and so on) to promote medical research and development is an established practice in many countries. But there are cross-border issues here, which make public intervention at the international level desirable. To begin with, many developing country governments do not have the fiscal means to provide the necessary incentives for desired medical investment. This is associated with the type of problem mentioned earlier, of inadequate investment in knowledge which relates to diseases of the poor. Secondly, because of the global or cross-border effects of some research, even individual country governments which can afford to, are unlikely to spend as much in the form of subsidies or other incentives for private investors, to enable investment in knowledge production to the

[3] Thus, for example, most work in gene isolation has been undertaken by public institutions using funds provided by governments and charities. However, most gene patents are in the hands of private companies who use the fruits of public research to complete the final stages of work and are more rapid in applying for patents. (Sexton, 2001) This is covered in more detail in the chapter on genomics.

extent that is socially desirable. Thirdly, many developing countries do not have the infrastructure or resources to enable adequate testing of drugs to ensure safety and public knowledge of effects and side-effects, and therefore can be at a disadvantage when confronted with the superior lobbying and advertising power of multinational drug companies. There is therefore clearly a case for international or joint action in this regard, which should be led by the UN, WHO and other organisations with contributions from national governments.

Some possible international measures include

- pre-purchase agreements which would ensure markets and therefore profitability for investment into and subsequent manufacture of particular drugs or diagnostic and therapeutic techniques. (see WHO Bulletin,)
- international organisation-led funding for medical research, bringing together research teams in universities and other private labs based in different countries
- international level surveillance and regulation, with internationally organised testing institutions; recognised criteria for drug acceptance and wide publication/dissemination of knowledge relating to the drugs.

Obviously, public intervention is required even at the national level. For example, the clinical trials necessary to allow the wider use of drugs may not be undertaken if sufficient commercial profitability is not anticipated. This is the case not only for drugs of those resident in poor developing countries, but even for drugs with only a limited expected market in developed or high per capita income countries. This explains the provision of incentives for the development and production of such drugs, such as in the form of tax credits for clinical trial expenditure and/or exclusive marketing rights to the product. While these are seen as national measures, a GPGH perspective shows that in fact they can have significant cross-border implications.

The US Orphan Drug Act is one such attempt. Designed to encourage the private development of drugs for which the market may otherwise be too small for profitable commercial exploitation, it provides for tax credits and exclusive marketing for a period, as recompense for testing expenses for drugs, vaccines, diagnostic drugs, or preventive drugs, used to treat rare diseases or conditions. The right to patents and data exclusivity becomes especially significant in cases when the company cannot claim a patentable invention. The infamous case of the drug paclitaxel (Taxol), for which the company Bristol Myers Squibb has received tax benefits and exclusive marketing rights even though it contributed very little to the actual development of the drug, has added to the controversy surrounding the Orphan Drug Act. It has been criticised for creating undesirable monopolies and rewarding private agents for what they have not done. (Love, 2000) It has also led to the company attempting to establish exclusive marketing control even in other countries. Thus, such legislation can lead to global monopolistic practices with respect to essential or important drugs, and can even operate to inhibit further innovation in other countries as well. The Taxol case has shown that national level incentives can have cross-border effects, suggesting the need to consider even such intervention from a GPGH perspective, and allow for international co-ordination and monitoring of such practices.

III. (iv) Traditional knowledge

Because traditional knowledge has evolved historically over many centuries in varying ways across different societies and does not constitute a homogenous mass, it has been extremely difficult to define it precisely. Following Rahman (2000, page 2) traditional knowledge can be defined as "a tacit type of knowledge that has evolved within the local (grassroots) community and has been passed on from one generation to another, encompasses not only local or indigenous knowledge, but also scientific and other knowledge gained from outsiders." It should be remembered that a significant section of the population in many developing countries (which could be as many as several hundred million people) still relies mainly on traditional practitioners, including traditional birth attendants, herbalists and bonesetters, as well as local medicinal plants, to satisfy their primary health care needs. Therefore it is very much a currently living tradition in many respects, and in some instances the boundaries between it and modern medicinal practice may be hard to draw precisely.

Such knowledge is typically tacit, non-codified and not clearly articulated along modern scientific lines, even though it may be very "scientific" in reasoning otherwise. It tends to be embedded in the experiences of communities, being handed down across generations, and often involves intangible factors including beliefs, perspectives and value systems. Many traditional medicine systems, including those widely prevalent in Asia (such as the acupuncture and acupressure based systems of China, the ayurveda and siddha systems of India, and so on) are holistic in orientation, that is they treat the entire patient rather addressing a symptom or disease alone, as is common in modern allopathic medical practice.

It is often supposed that commercialisation or demand-orientation are "new" features which have been recently sought to be imposed on traditional medical knowledge. However, traditional systems have always relied on some degree of commercial viability. Of course, there are significant differences in cultural attitudes to the commercialising of such medical systems or their products. Thus, in some traditional medical systems in China or India such as acupuncture/acupressure or ayurveda, there is a history of attempts at or successful commercialisation of some products of traditional medical knowledge and attempts have even been made to codify them over time. This suggests a substantial interest in exploiting traditional knowledge to reap at least some commercial rewards. By contrast, in other cultures, such as for some Native American communities as well as aboriginal groups in Australia, such traditional knowledge is actively sought to be kept secret within the community in order the maintain the community's identity, and any attempt at commercialisation is therefore rejected. There can be further complexity even within communities. [4]

Since traditional knowledge, by definition, is produced within communities and based on tradition and historical legacy to a significant extent, the danger may be

[4] One study on traditional knowledge in Vietnam illustrates how, even if communities as a whole may wish for wider dissemination and commercialisation, this can be impeded by those who actually possess or control specific types of such knowledge, because it gives them power within these societies. (Le Quy An 2000 page 6)

not only that investment in such knowledge does not take place, but that even existing knowledge may be lost because of insufficient demand. Here again, cross-border issues are significant, as the loss of knowledge which was confined to a particular community implies a loss to humanity as a whole. Since this issue is closely tied with problems of dissemination and consumption of traditional knowledge, the problems and possible interventions are considered in more detail below.

IV. The dissemination and consumption of medical knowledge

The key issue in terms of dissemination/consumption of medical knowledge is *excludability*. There are two types of exclusion which are relevant: (a) exclusion from the medical knowledge itself, which can result from monopolistic control (as in patent regimes) or from inadequate dissemination (as in the case of traditional knowledge); and (b) exclusion from the products resulting from such knowledge, such as medicines or other medical techniques. Obviously, the emergence of new knowledge or even of new drugs and therapeutic techniques, is in itself not enough to ensure universal access, or even access to those who may be in the most need of it.

This problem has led, for example, to concerns about the effects of excessive patenting, and over-zealous interpretations of the TRIPs agreement.The effects of the patent regime are dramatically illustrated when the drug prices in countries with different patent regimes are compared. The Indian Patents Act, which even to date (that is, until the expected TRIPs-compatible revisions occurs through legal change) recognises only process patents in pharmaceuticals, allows for reverse engineering for chemical products, that is working out a process to manufacture using the end-product only. This patent regime, which has been in operation since the 1970s, has contributed to the major price advantage that Indian companies are able to offer, both because of the ability to engage in reverse engineering and because of the consequently more competitive nature of the domestic industry. This allows for very substantial differences in drug prices between India and other developing countries. [5] Clearly, the absence of generic competition allows for much higher prices than may be warranted by the actual expenditure involved in R&D for the drug.

The prohibitive costs of anti-viral drugs for the treatment of HIV-AIDS in the countries with the largest populations exposed to such threat, have been widely discussed and are now quite well known, as are the controversies involved in reducing the market power of patent holders of such drugs. (see Chandrasekhar and Ghosh, 2001, for a summary.) However, there are other drugs relevant for diseases which affect many poor people, especially in developing countries, which are also very highly priced because they are relatively new and therefore still covered by patent protection. [6]

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[5] Thus, for example, drug prices in Malaysia, where the patent laws did not allow for the emergence of a vibrant domestic drug industry, were between 12 and 200 times the prices of the same drugs in India in the 1990s. (Balasubramaniam 1995) Even Pakistan, a country with similar per capita income, had drug prices which were several multiples of those prevailing in India.

[6] For example, new antibiotics such as ciprofloxacin and norfloxacin are especially effective in the treatment of certain types of bacillary dysentery which are highly contagious, potentially lethal and widely prevalent in poor tropical countries. However,

The problems associated with access to essential drugs are especially disturbing given the nature of the international drug market. The world market for drugs is a huge one, but it is dominated by only 3 countries - the United States, Japan and Germany - which make up more than two-thirds of total sales. In fact, only 15 per cent of the world' population accounts for 86 per cent of drug spending, while the remaining 85 per cent of the world's population get only 14 per cent share. [Pecoul et al, 1997]. Obviously, this majority is mainly in developing countries.

The importance of purchasing power in affecting not just the development of a drug but even its continued production is dramatically illustrated in the case of eflornithine (or DFMO) which is a drug to treat sleeping sickness. This disease, which is transmitted by the tsetse fly, is currently estimated to kill 150,000 people every year, mainly in Africa. The drug is currently not produced, because of "lack of commercial opportunities". Similarly, the drug for treating bacterial meningitis ceased being produced between 1995 and 1998 because of poor profitability (that is, low incomes of those affected by the disease) despite hundreds of thousands of sufferers each year, mainly in poor developing countries. (Pecoul et al, 1997) By contrast, the fastest growing segments of world drug production are non-essential drugs such as Viagra and anti-depressants, which are not life-saving drugs. Therefore, whether knowledge translates into products which can be effectively used, depends upon international distribution. But this need not remain only a problem for the current victims, since lack of control of disease can have spiralling, cross-border and inter-generational effects.

The difficulty of ensuring even a minimum degree of democratic access to life-saving drugs is compounded by the high degree of concentration in the international drug industry. This is associated with a range of monopolistic practices, including the use of brand names to generate market power and charge higher than warranted prices on many drugs. The issue is especially complicated because of the asymmetric information which characterises the drug market – since consumers do not know the actual composition of the drugs they are taking, often they rely on brand names to ensure quality or homogeneity. This may be warranted where other manufacturers are providing spurious combinations or cheaper substitutes, but this cannot be predetermined or claimed to be true in all cases. As a result, established manufacturers often use the advantage of the brand name to charge much higher prices even when other generic manufacturers are producing the same or equivalent drugs at much cheaper prices. Together, brand names and patents insulate drug companies from price competition. Market segmentation allows for wide variation in prices of the same drug charged not only by different companies and even by the same company in different markets.

The experience with the National Drug Policy in Bangladesh in the 1980s and early 1990s provides some indication of just how much brand names play a role in higher drug prices. The Drug Policy came into effect in 1982, specifying a list of 45 essential drugs at the primary health centre level, which were to be manufactured

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these drugs are more than ten times the cost of traditional but less effective drugs, which therefore tend to be more widely used. (Pecoul et al 1999)

and/or sold under their generic names only. MNCs were prevented from manufacturing simple products like common analgesics, vitamins, antacids, and so on. Prices of finished drugs were controlled. A decade later, it was found that essential drugs increased from 30 to 80 per cent of local production; drug prices fell in real terms; the proportion of drugs found to be substandard declined sharply from 36 per cent to only 9 per cent. (Zafrullah Chowdhury 1995)

Price discrimination strategies by drug companies can continue especially where policies of compulsory licensing and parallel imports are not used to break such market segmentation. However, it should be remembered that these two strategies in themselves are not solutions to the basic problems of drug development, pricing and access, although they should certainly be supported as part of a broader public health package.

IV (ii) The dissemination of traditional knowledge

There are real fears that some forms of traditional knowledge, which are of great potential value for science and public health, may actually die out because of lack of dissemination or insufficient training of practitioners. This problem is especially severe with respect to such community knowledge as exists in the oral tradition, or is vested in particular social groups only. [7] Such loss of knowledge is a loss for the whole world, and therefore traditional knowledge across the world, which is currently vested in different communities, needs to be protected and nurtured in the same way as any other crucial global resource.

Some of the problems of transmission and wider acceptance of the fruits of traditional medical knowledge stem from the fact that in most societies, research and training activities for traditional medicine have not as much public attention and financial support as would be necessary to sustain and to develop it. Partly because of this, typically the quantity and quality of safety and efficacy data are far from adequate to meet the demands placed by those used to more stringent modern testing techniques. [8] Clearly, not just wider acceptance but even sustained usage over time of such medication would require systematic public support to codify, test and publicise the knowledge.

Because of what is often a very individualistic patient-oriented form of treatment, traditional medical systems can be extremely difficult to adapt to large-scale, homogenised production. In addition, they tend to rely on natural products such as herbs and other combinations, which are typically used in very fresh forms. All this means that there are some important processes which will be crucial to the wider dissemination and commercialisation and even sustained transmission of traditional medicinal products and the associated knowledge. These include :

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[7] For example, in Peru, in which the traditional medical systems are known to be rich and where one-third of the population is estimated to have relied on traditional forms of medical treatment at some point, there are fears that the knowledge is being lost due to trans-culturisation. (Lama, 2000)

[8] Typically such data exist only for a relatively small number of plants and their extracts and active ingredients, as well as preparations containing them.

- codifying the knowledge in accessible and standardised formats,
- providing resources and logistical support for testing of products
- ensuring some degree of standardisation of the dosage and quality of products,
- standardising the knowledge and qualifications of practitioners
- increasing the shelf life of traditional medical products.

There is a significant tension between any process of dissemination and commercialisation, which is clearly necessary and even urgent, and the possibility of bio-piracy and theft of traditional knowledge, which has become one of the most prominent concerns especially in the recent past. Bio-piracy is most evident in the intellectual property claims which are made on various fruits of traditional knowledge which may exist in non-codified form. It is obviously problematic in terms of rights and claims of the communities involved, since it involves (arguably false) claims to novelty and invention for traditionally evolved knowledge, divests scarce biological resources to monopoly control of corporations thus depriving local communities and indigenous practitioners, and creates market monopolies and excludes the original innovators from their rightful share to local, national and global markets. (Research Foundation for Science, Technology and Ecology, 2000) But it can even be adverse from a public health perspective, since it may result it high prices of medical products or therapeutic forms which effectively exclude or reduce the access of large numbers of lower income groups and may even exclude the very communities from which the knowledge originally came.

Unfortunately, there are all too many examples of bio-piracy through patenting in the recent past. [9] Such tendencies have prompted calls for measures to protect traditional knowledge from bio-piracy for commercial purposes. There is the further danger that expanded and accelerated bio-prospecting can lead to over-exploitation of ht enatrual resource in question. Commercial interest can lead to over-harvesting and unsustainable patterns of extraction and use of medicinal plants in particular. [10]

Currently there is no one international protocol governing traditional medical knowledge, despite the Convention on Biodiversity, and in fact the incentives that currently operate in the international economy are likely to encourage rather than discourage bio-piracy for commercial benefit. One of the most commonly suggested ways in which to deal with this relates to evolving mechanisms of benefit-sharing. These tend to operate very much within the existing international IPR regime, by accepting not only the patentability of such knowledge but also the desirability of

[9] Thus, there have been attempts (both successful and unsuccessful) to patent knowledge about the different healing properties of several medicinal plants of South Asia, knowledge of which has been part of community knowledge for centuries. These plants include neem (margosa), turmeric, aloe vera and pomegranate, among others.

[10] The use of the products of the Yew-tree in production of the anti-cancer drug Taxol has led to a devastation of the Yew forests in Himachal Pradesh and other hill regions of north India. The recent commercialisation and explosion in demand for kava (Piper methysticum), a plant endemic to the South Pacific, has placed unsustainable pressure on supply sources which were previously geared only to serve local use. (Sahai, 2000)

such assignment of intellectual property rights, and focussing essentially on the distribution of the gains from such rights.

Thus, the Mataatua Declaration (1993) made the following demands with respect to community-held traditional knowledge :

- "Establish an appropriate body with appropriate mechanisms to: preserve and monitor the commercialism or otherwise of indigenous cultural properties in the public domain; generally advise and encourage indigenous peoples to take steps to protect their cultural heritage; allow a mandatory consultative process with respect to any new legislation affecting indigenous peoples cultural and intellectual property rights.
- Develop, in full cooperation with indigenous peoples, an additional cultural and intellectual property rights regime incorporating the following: collective (as well as individual) ownership and origin - retroactive coverage of historical as well as contemporary works; protection against debasement of culturally significant items; co-operative rather than competitive framework; first beneficiaries to be the direct descendants of the traditional guardians of that knowledge; multi-generational coverage span."

This is a very widely held position, and there are even some examples which have been cited of the effective implementation of such a strategy in particular contexts. Thus Sahai (2000) describes the benefit-sharing experience with respect to the leaves of "arogyapacha" plant, traditionally eaten by the Kani tribe of the Eastern Ghats in Northern Kerala, India, which was developed as a commercial strength-giving product "Jeevani" in 1995. While transferring the technology for production of the drug to a pharmaceutical firm, it was agreed to share the licence fee on a 50:50 basis. In addition to this, 2 per cent of royalty from sales will go to the tribal community. The proceeds from this are being managed by a Trust which was set up for the purpose, with 60 per cent of Kani households represented. Of course this was possible largely because of the small number of Kani population, their limited geographical spread and their relatively homogenous and less stratified society.

In fact, this example may serve to highlight the difficulties of trying to implements strategies of community benefit-sharing that rely on commercial intellectual property rights. There are several definitional issues to start with. What constitutes the community? Does it relate to all the population or to its representatives or to a segment of it? Does it refer only to those who are resident in the relevant locality? How are other generations (past and future) accounted for? Then there are questions of how of ensure that monetary or financial returns are used to the benefit of the "community", however defined. Which is the best agency for this? Who decides how the money is to be spent? And in stratified communities (whether stratified on the basis of class, gender or any other social category) how can it be ensured that the benefits will be equally or democratically spread rather than concentrated among a few? Finally, there are logistical questions of how such resources are to be garnered and managed. All in all, there are formidable difficulties in actually assigning what are essentially private intellectual property rights, to a community as a whole.

To a substantial extent, such difficulties stem from the more basic problem with respect to the notion of private intellectual property, which runs fundamentally counter to the very concept of traditional or community knowledge. Of course, all knowledge in societies rests on a bed of tradition and history of intellectual development, and even the marginal increments to knowledge which are nowadays sought to be patented as inventions are very dependent upon this previous knowledge base. But when the base itself is sought to be patented, this inevitably creates a philosophical and even a practical problem. Who exactly is to be rewarded for such knowledge? The earlier generations which developed it or the current generation which has received it and maintained it, or the future generations which will be its repository? And what if it spreads to other areas and other peoples who are not part of the original community?

It can therefore be argued that to insist on forcing community knowledge into the straitjacket of the currently popular notion of private appropriability of the fruits of knowledge, is fundamentally misguided. Instead, it may be more useful to insist on the irrelevance of all patenting in such areas, that is to deny the possibility of product patents for all matters relating to natural products, whether in the pharmaceutical or food industries, and to allow only process patents for the products of nature or any extensions of them.

This in turn means that other forms of public intervention have to be considered, primarily along the lines of increased funding for the recording, codification and dissemination of such knowledge and for testing along accepted principles. These need to be engaged in both at national and international levels, given the strong cross-border externalities in consumption of such knowledge.

V. Global strategies to harness medical knowledge for public health

Obviously, appropriate national policies remain absolutely essential to the implementation of any public health strategy which seeks to ensure that commercial knowledge is created and made available to the public benefit. However, it is apparent that many of the problems that have been discussed above are broader than can be dealt with adequately by national strategies alone, especially in poor developing countries. In any case, national policies themselves are increasingly influenced and determined by international regimes, including agreements such as TRIPs, and by the structure of the international market for drugs and other diagnostic and therapeutic technologies. Further, as we have seen, several of the problems mentioned here fall in the category of Global Public Bads, and need to be dealt with accordingly at a global level. Since the protection of public health should have primacy over commercial interests, it is necessary to revise those aspects of international trade agreements and other such international regimes which directly or indirectly have implications for public health at both national and global levels. Accordingly, some proposals for revision are briefly noted below, followed by further proposals relevant for national along with other international strategies which are relevant from a GPGH perspective.

Of course, it is important to note that economic and political forces affect the behaviour and interaction of the major players in this system : national governments, international organisations and private industry. In recent times civil society organisations of various sorts, representing different groups (such as consumers), have

also become significant, especially in terms of having a voice in the international arena and possibly in certain national contexts as well. The relation between the various players is complex, and there is evidence of shifting coalitions across issues. While governments may face conflicts in terms of decisions that affect different lobbies, the activities of international organisation are also subject to political pressure from the governments of "dominant" countries.

In this context, some of the possible global-level interventions are mentioned below.

Changes to the TRIPs regime :

1. Article 27.3 (b) of the TRIPs Agreement, relating to the patenting of life-forms, should be removed or dramatically diluted.
2. Article 29 of TRIPS, which requires disclosure in the case of patent applications, should also cover all patent applications which use the fruits of traditional knowledge.
3. For all inventions based on nature – that is, plant-based pharmaceutical or food innovations, only process patents should be allowed, and not product patents. This will control both bio-piracy and theft of traditional knowledge, and monopolies in these product categories.
4. The possibility of patenting genes needs to be seriously reconsidered.
5. Even apart from this, special status should be given to essential health care products with respect to their patenting for private commercial purposes.
6. The scope for compulsory licensing needs to be made wider and the use of it to prevent monopolistic practices should be encouraged rather than discouraged through the TRIPs regime. Ideally, the TRIPs Agreement should contain a positive list of industries and product categories for which compulsory licensing is recommended, determined on the basis of their importance from a GPGH perspective.

Other global interventions

(Several of these would require the implicit or explicit involvement of the WHO and related international bodies.)

Interventions related to the production of medical knowledge

1. Many drugs are currently developed primarily with public funding. Governments – especially in rich countries – should evolve policies (which could be developed in consultation with WHO) to make such drugs available to poorer groups and to populations in poor countries, at affordable rates.
2. There should be global strategies to ensure the development of essential medical technology. A Global Fund for essential medical research is one important suggestion, but linking it to new taxes (as is proposed in some "Tobin Tax" type proposals) may not be so useful as that could delay and perhaps prevent the emergence of such a Fund. Instead, the demand for such a Fund should be treated as a matter of urgency, to which resources should be allocated on priority basis.

3. Incentives such as market exclusivity for certain drugs should be discouraged as these are liable to misuse and can create global monopolies.
4. The international community should evolve explicit protocols that prohibit or prevent some governments (influenced by powerful corporate lobbies) from exerting unilateral pressure on governments of other countries, especially developing countries, to adopt legislation on patents, health care or services that is not in the interests of public health.

Interventions related to dissemination

1. There is a strong case for centralised international purchase funds for existing drugs or treatments known to be useful in dealing with diseases common to poor populations. Such funds (which could combine public and private donor resources in various ways) would guarantee manufacturers large sales volumes and would therefore encourage private production of certain essential drugs.
2. There is need for an international body (once again, possibly working in collaboration with WHO) to set standards for deciding upon and monitoring drug efficacy and quality, for both modern and traditional medicinal products.
3. International resources also need to be allocated towards organising, codifying, testing and disseminating various forms of medical knowledge emanating from traditional medical systems across the world. WHO could be the sponsoring and organising agency for such a process.
4. Reliable data on the costs of developing new drugs should be made public and the specific contributions of different agents (public and private) towards developing particular drugs should also be made generally available to the public on a regular basis. Once again, this could be taken up by the WHO.

Interventions related to consumption

1. Public health systems need to be geared to greater and more rapid transmission of forms of medical knowledge. This dominantly involves training health care practitioners at a national level, but such activities could be supported (especially financially) at a global. New technologies such as the Internet provide cheap and easy ways of transmitting such knowledge and should be used more extensively.
2. The public in general needs to be better informed about the nature of pharmaceutical and other medical technologies which it is using. Once again, using media such as the Internet to inform patents and other consumers about aspects of drugs in use and their differences, as well as in costs, is something that could be organised with a global orientation, by WHO and others.

V. Conclusion

What emerges from this discussion is that a GPGH perspective is useful and important in the case of medical knowledge. The public good characteristics of knowledge mean that investment in knowledge cannot be left to the market or private agents alone (because it would then be below socially desired levels and the direction also need not be socially optimal). Further, since many of the positive and negative effects of investment in knowledge are cross-border in nature, even individual governments need not intervene to the extent that is socially desirable, and there is clearly a case for co-ordinated joint action or intervention by international bodies such as the WHO. Some of the possible interventions have been outlined in the previous section. However, this area of investigation is one which is largely unexplored in terms of research. Therefore, there needs to be more analysis of both the existing problems and possible solutions in this area. Some of the issues and questions that could form part of a future research agenda covering medical knowledge as a GPGH include the following :

- The nature of medical innovation itself, and the degree to which it is actually influenced by the extent of private appropriability, or, more simply, do patents actually encourage more innovation ?
- The role played by international monopolies – both public and private – in limiting access to innovation and knowledge, and particularly access in developing countries.
- The experience of international regulation in other areas, and the lessons they can provide for international co-operation and joint regulation in this area.
- The extent to which varying national standards of medical regulation and control spill over in terms of cross-border effects on the efficacy of disease control.
- The scope for new international incentives for developing on and disseminating the fruits of traditional knowledge.

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