

Is e-Business in healthcare injurious to health ?

Data protection problems from inversion of private and public spaces in designing healthcare databases

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ABSTRACT

Healthcare development and delivery are significantly impacted by digitalised connectivity that enables instantaneous transfers of sounds, images and data. Healthcare databases are traded within and across borders by the entire range of medical and pharmaceutical services providers and insurance firms that organise the contribution side of healthcare. This trade is accelerated by new international regimes, TRIPS and GATS through innovative bundling of product-service linkages, new cross-border factor combinations and new value-creating services with networking. However, the design of healthcare databases presents complex problems of data protection and privacy. This paper analyses the risks of patient abuse and data misuse inherent in healthcare databases when private information held in public databases is commercially traded and information in public domains, privatised. The paper cautions that designs involving inversions of private and public spaces may increase disease burdens besides being socially unacceptable, legally untenable and economically unsustainable.

INTRODUCTION

In designs of e-businesses around healthcare development, healthcare delivery and healthcare administration, there has been very little discussion on authority and legitimacy of information flows across porous boundaries and the structuring and management of risks associated with such flows. The risk of failure is high due to three reasons. Firstly, the largest value segment concerns cross-border transactions regulated by partially enforceable national and international regimes based on GATS, TRIPS and other IPR rules which are quite new and poorly understood.

Paper presented at the eBRC 2001 Conference "Frontiers in e-Business Research", Tampere, November 5-7, 2001. The paper reports from the author's ongoing research work-in-progress as a sequel to his invited contribution on the impact of information technology on healthcare for the World Health Organisation's Commission on Macroeconomics and Health. The author thanks Risto Nuolimaa, Isher Ahluwalia, Vineeta Mathur, Zahis Shah and K.Vijayaraghavan for helpful comments. The usual disclaimer applies. © Copyright, Ajeet Mathur, 2001

Secondly, the efficiency of e-business designs consistent with equity for customers, service providers, contributors and governments is not well established because the impact of e-business designs on disease burdens has never been examined, not even by those who have the biggest stakes because of investments in e-businesses. Thirdly, the appropriateness of designs in terms of their congruence with desired, socially acceptable or legislated levels of data protection and privacy has never been seriously considered as posing any constraint on sustainability of e-business designs. This paper inquires into these three significant aspects that endanger e-Business in healthcare and reveals the core problem as inversion of private and public spaces.

When the term 'cybernetics' was coined by Norbert Wiener, with biology as its metaphor, it was anticipated that boundaries between life sciences and information technology (IT) would blur (Wiener, 1949). However, it could not be foreseen that silicon would become as important as carbon although the purposes of IT in control and communication are well known and well documented for over half a century (Wiener, 1950). When information transfers occur in open systems, shared databases, feedback loops and feedforward triggers, innovative bundling of product-service linkages in cross-border value chains appear to offer unlimited potential to virtual organisations as e-businesses for new modes and patterns of value-creation for sharing in the value so created. In this process, digitalised connectivity enabling instantaneous transfers of sounds, images and data lowers the threshold for control and communication of human beings as an unintended consequence.

The most remarkable feature of designs of e-Business so enabled is that value chains spread out in time and also in space, without consuming significant real time as friction of space. Nine kinds of value-creators are found in the networks that evolve: (1) Designers (2) Processors (3) Senders (4) Carriers (5) Conduits (6) Receivers (7) Information hoarders (8) Knowledge creators (9) Knowledge diffusers. These value-creators can be conveniently grouped into three main categories- natural persons, incorporated firms/organisations that satisfy special interest groups and local, regional or national government agencies. The rights and obligations of these actors determine how information flows may occur in open, transparent seamless webs and also into lockable containers. It is an important design question to know the balance between concerns over properties of open systems with problems of entropy in closed systems when information flows are designed to be secure and reliable. Questions of policy also arise over whether and how exclusive or inclusive property rights vest with the value-creators identified and whether the explicit and implicit contracts between them designed as between a buyer and seller or licensor and licensee are consistent with the rights and obligations of natural persons, firms, and governments to each other.

Research into these strategic questions concerns the core where law, economics and governance enmesh. With a view to crystallise the organisational and competence issues into researchworthy working hypotheses, empirical investigations were first conducted to study the state of the art of e-Business in healthcare and to conceptualise after analysing what is actually happening. Reported here are preliminary findings from the first stage of research completed together with the staggering implications and mind-boggling research questions that arise for the research work now in progress in international

collaborations under development between academia, businesses, media and governments.

STATE OF THE ART IN E-BUSINESSES IN HEALTHCARE

Based on empirical investigations undertaken during year 2001 to survey e-Business forms, it was found that healthcare related IT applications manifest in fifteen different forms of e-Business involving cross-border trade linking the nine different kinds of value-creators identified above. All of these applications were found stimulated by service providers who value choice and efficiency and some of these overlap and flow into each other with fuzzy boundaries between them:

Telemedicine

Telemedicine includes (but is not limited to) on-line consultations by patients and doctors through websites and email, distance referrals, emergency evacuations, ambulance services enabling advance transmission of images and data of the patient to reduce lead times of intervention on arrival in hospital. With experience, it may be possible to list which diseases and what procedures may be safely handled through telemedicine. Few facilities have substantial experience of telemedicine on a regular basis as a daily feature integrated into their services. However, it is widely believed such services are about to spread and there is some evidence that cross-border trade in telediagnosics and telepharmacology is growing rapidly.

More commonly found e-businesses are structured around medical accounting applications, medical transcriptions, billing, book-keeping, continuing medical education networks linking hospitals and medical schools, surveys, and research networks among the whole range of healthcare services providers using email, internet, web-conferencing, video-conferencing, secure transfers of sounds, images, data, and contact between service providers and customers, and customers and insurers which improve efficiency, increase data-based decision-making, and reduce costs. Cross-border trade in these forms of telemedicine is estimated to be \$2 billion and growing.

Bioinformatics

The term medical informatics is recommended for use by health authorities but bioinformatics continues to be the more used expression. The application of biological techniques in shared task mode to investigate biotic matter, graphical front-ends for database interrogation and pool the results of simulation and modelling from day-to-day experimentation to eliminate false leads and reduce cycle times for development of treatments as for instance through the application of statistical techniques for creation of decision support systems is commonplace. Genomic research has required the production and processing of large amounts of data. Orienting computer sciences to applications derived from molecular biology has blurred the dividing line between life sciences and computer sciences. The design, development, linkages and dissemination of databases is one of the fast expanding areas of IT application in traded healthcare

development services. Scientific journals 'Science' and 'Nature' estimate bioinformatics to be a \$3 billion business already.

Pharmacogenomics

The comprehensive study of whole sets of genes and their interactions has been possible only with advanced IT applications especially developed with trade in services around them. The human genome sequence enables new diagnostic testing for disease susceptibilities and gene function. Efforts to determine 3-D structures of large numbers of proteins using experimental techniques and computer simulations may or may not reduce the need for animal testing but it already requires global scale trials.

The number of disease genes discovered upto year 2000 was 1206 with map-based gene discovery which is now being complemented and also replaced by sequence based gene discoveries with the availability of approximately 60 to 100 genome sequences of different species. As biomedical research shifts from a structural emphasis to a functional one, the analysis of multiple genes in gene families, pathways and systems dissects the molecular basis of disease to its bits. Detecting new metabolic disease pathways to intervene with them is a gigantic number crunching IT undertaking. The creation and pooling of databases to accelerate the processes of development of pharmaceutical products in time and reduces the costs of clinical trials. Firms can reach statistically significant population numbers in the precise categories where side-effects might be indicated or the medicinal drug established to be contra-indicated, in addition to reducing administrative costs of clinical trials. Numerous public-private cross-border partnerships have sprouted in this business segment. The magnitude of international trade is difficult to estimate because transfer pricing through intra-firm cross-border transactions and academia-industry cooperation is the main route.

Proteomics

Surveying genes is a good starting point to find potential drug targets but drug targets themselves are usually proteins. The study of the full set of proteins produced and encoded by a particular genome and the annotation of genes and complements of protein structures in terms of functions is still in its infancy. Proteins are much more complicated than nucleic acids because they are involved with many kinds of chemical reactions and can act in combination with each other. Also, more and more new proteins are being thrown up by mass spectrometry, chromatography and robotics. The dynamics of cellular processes to understand localisation, interactions, activities and functions of proteins requires huge amounts of data to be processed. Much research is needed on a worldwide scale before models and simulations can be sharpened for candidate molecules to be profitably spotted and targetted in biotechnology applications and this calls for syndication among cross-border teams. Proteomics is estimated to be a \$ 1 billion business by scientific journals like 'Nature' and much of the value-added is through cross-border trade in services.

Biotechnology

Technological applications that use biological systems, living organisms or derivatives

to make or modify products and processes for specific use covers the discovery and invention of biological processes for industrial and other purposes. It is listed here as a separate category from bioengineering because it is not limited to manipulation of genetic material in microbial organisms for the production of hormones, antibiotics etc. Biotechnology has linkages with downstream petrochemicals, spillover effects of breweries, farms, apiaries, aviaries and with the cataloguing of life forms of the oceans etc., a cross-border collective undertaking at sharing information in networks. It opens whole new low cost pathways for therapies where these can be economically sustained through scale and scope effects. No precise quantification of trade magnitude is possible without clearly demarcating what is excluded.

Genetic engineering

One of the fastest developing e-business segments in healthcare arises from the need for systematic cooperation on development of databases of gene sequences. Genetic codes and functions of biotic material to change characteristics of living forms by mitigating vulnerabilities and fragilities of genetically constituted matter and to isolate genes and identify target molecules by promoting understanding of disease mechanisms to design therapies through research on bio-chemical pathways requires global scale trials.

Combinatorial Cytochemistry

This is an emerging business segment for sharing in development of software and diagnostic tools to bridge biochemistry and morphology to identify specific chemical components and their useful combinations and functional properties in cellular domains through better understanding of organic chemistry. E-businesses promote long distance experimentation linking locations where the relevant microbial activity is abundantly hosted to places where specialisation networks are organised with the necessary laboratory equipment and infrastructure.

Pharmacokinetics

The development of databases on dynamic interactions between agro-chemicals, pesticides and animal secretions is a whole new field where IT enables scientists working at its frontiers and working in widely dispersed locations to share in the workload related to pest control, epidemiology and other applications.

Nano-engineering

The technology of using enzymes as assemblers for building or disassembling at molecular and sub-atomic levels is very costly for low volumes of output. Scale effects and learning curve effects required for developing commercial feasibility rely on networks of e-business value creators.

Neuro-engineering

The development and application of techniques to alter the characteristics of human brains with genetic, chemical, surgical and prosthetic engineering techniques and for

developing artefactual memory to add to biotic brain activity has spawned e-businesses around the designs of interventions and simulations.

Bio-engineering

IT databases are just beginning to be used for containment of health hazards caused by contamination through cost-effective and time-saving interventions, enabled by sharing resources. It is feared by many that the sharp increase in the incidence of drug resistance may not be due to anti-biotic overuse only. Bio-engineering has enabled transfer of genes between unrelated species of animals and plants. Antibiotic genes may inadvertently spread and recombine to create drug resistant pathogens. IT enables global databases to track this, and virtual organisations as e-businesses are important elements in the value chain.

Distributed intelligence network engineering

The capacity to put biological forms or other intelligent artefacts to computational uses for number crunching applications is used among networks of software programmers, systems analysts, data-entry operators to combine artefacts with life forms ranging from human beings to microorganisms.

Quantum computing

Nano-engineering applications to miniaturisation and in applications such as in the harnessing of bio-silicon quantum effects is a new development that is being researched further. IBM's Blue Gene project in collaboration with Oakridge National Laboratory combines advanced protein science with cellular architecture supercomputer design where cells contain circuits for storage and communications. Major firms like IBM, HP, Motorola, Sun, Fujitsu and Hitachi diversified into life sciences, each of them aided by networks of hundreds of e-businesses that they support.

Robotics

The cooperative development of kinetically intelligent machines and systems like spiders in use on the web to process large amounts of information is most advanced in Japan. Robotics applications generate choices during emergencies, in accidents and surgeries and to extensively use expert systems and neural nets in artificial intelligence applications.

Space biology

The designing and sharing of experimental data to support life forms using solar sailing in nearby asteroids and for manned distance missions requires considerable experimentation but also simulations linking supercomputers to specialists in life sciences through bridging functions performed by e-businesses..

New technologies associated with new e-business forms breed new forms of dependence. With the exception of telemedicine that could spread with and without

cross-border trade, the techno-commercial viability of these fifteen new fields is cross-border in scope. These IT-enabled technologies have raised new hopes and new fears and are variously viewed as a boon and as a risk. For instance, services trade in space biology would require international agreements on healthcare and environmental obligations on the lines of the Antarctica Treaty for explorations beyond planet Earth before firms would make strategic alliances in this regard. Nanotechnology and genetic engineering can also be used by terrorists. International regulations on such trade will be necessary for security reasons. Neuroengineering could be used to involuntarily collect data from other human brains requiring a review of privacy rights and data protection laws. An example of this is found in Europe in the work of the Data Protection Commission (1998). Almost all of the technologies mentioned above carry environmental and health risks which call for regulations of some sort. The perversion of medical knowledge and skills towards involuntary, uninformed and coercive participation in trade in genetic material, expropriation of organs, biological experiments in eugenics, ergonomics, safety is very hard to prevent. In the twentieth century such experimentation occurred on minorities in a number of countries. Information and communication technologies now enable such experimentation to be undertaken from a distance.

The greatest transformative impact of IT has arisen in robotics involving the design of expert systems approximating artificial intelligence with learning capability. IT systems, on the basis of learning, could be making decisions not under the control of identifiable humans or collectivities of human agents and be communicating amongst themselves in languages not immediately intelligible even to their original programmers (Warwick, 1998). The solutions to introduce human supervision to mitigate this invariably complicate issues of privacy and data protection (Barlow, 1996, Raymond, 1999, Perri 6, 1999). This has implications for the law of liability and the doctrine of remoteness in ways that belonged only to the realm of fiction in the past. Neither of the fictional characters Dr Faust or Mephistopheles can be held liable for their actions any more than the Late H.G. Wells can be held accountable for his scientist character who produced the special food that caused infants to grow into giants in his story "The Food of the Gods".

There are various types of international collaborations for transnational governance of the risks that have arisen for the growing services trade facilitated by information technologies and telematic connectivity. Decision-makers involved in different sectors and activities choose from among them or create new alternatives. In the case of the healthcare industry, the establishment of the International Conference on Harmonisation of Technical Requirements developed a consensus around nested regulation involving harmonisation of regulatory standards through international agreement enforced nationally, within which national systems function (Aggarwal, 1998). Due to the life and death nature of consequences that any possible impact on healthcare- traditionally a national domain- may involve, there are signs that other international trade regulations could evolve to cope with the new dimensions of risks introduced by IT. One way of analysing the risks is to study forms of e-businesses in healthcare delivery and healthcare development as a first step and then to analyse their designs in a second-stage analysis to map the associated risks. For convenience, the e-business matrix of

healthcare can be visualised as follows:

Figure 1 e-Business in Healthcare

VALUED IN	HEALTHCARE DELIVERY	HEALTHCARE DEVELOPMENT
SERVICES	Telemedicine	Pharmacogenomics
RESEARCH	Bioinformatics	Proteomics
SECURITY	Robotics	Nanocomputing
WELL-BEING	Pharmacokinetics	Biotechnology

Note: The business models and designs associated with the nine value-adders identified previously can now be viewed in terms of the nature of service or dis-service by transposing the above matrix distinguishing where IT is a tool for health from where healthdata is a tool for IT to analyse the two-way causal connections and to denote the e-business arena in terms of its design characteristics (refer Figure 2 below).

Figure 2: The Design of eBusiness in Healthcare

	Healthcare Delivery	Healthcare Development
IT in Healthcare	SERVICES eB2C	RESEARCH eB2B
Healthdata for IT	SECURITY eT2B eT2G eT2C	WELLBEING eB2B eG2C eB2C

At this juncture, a word about the notations and abbreviations used above is in order together with the explanatory framework.

Applications where IT is a tool in the aid of healthcare concern e-business to consumer (eB2C) services for healthcare delivery and the e-business to business (eB2B) database management and processing for research into healthcare development. The well-being dimension of healthcare is a developmental responsibility shared amongst consumers, businesses and governments carrying with it eB2B, eB2C and e-government to

consumer (eG2C) possibilities of information transfers. Of these, eB2B is predicated on the premise that public-private partnerships through governments will enable exclusive extraction of data from databases for private profit justified on grounds of promoting economic welfare better than would be the case if governments or consumers were to organise publicly or cooperatively without introducing incentives for private profit into this equation. The IT-intensity of eB2B with its associated high entry capital costs is widely regarded as the main reason why private participation and incentives are required in pursuing the new pathways in healthcare development. The pursuit of eB2B applications poses fundamental design questions that concern the security of control and communication networks so that e-terrorist to business (eT2B), e-terrorist to consumer (eT2C) and e-terrorist to government (eT2G) dis-services can be avoided. All this points to the need to analyse the changing industry structures for trends in healthcare which was completed in the first phase of research in August 2001.

INDUSTRY STRUCTURES

Healthcare accounts for about 8 % of world GDP and is a \$4 trillion industry. In the past decade of the 1990s, the largest firms increased the geographic scope of their healthcare development activities as evidenced by the increase in the ratio of their foreign assets to total assets. In the case of five of the largest pharmaceutical firms, this ratio doubled during this period. There was also consolidation in the industry with horizontal integration among firms in developed country locations and vertical integration between developed and developing country locations. A growing segment of the healthcare development value chain was found represented by nodes functioning as e-businesses taking the forms depicted in Figures 1 and their corresponding designs reflected in Figure 2.

When e-businesses in healthcare were surveyed together with their principal patrons and affiliates among the big pharma firms, it transpired that e-businesses being small innovative ventures created essentially to serve specific and limited mandates in principal-to-principal (P2P) legitimacy are seldom aware of their responsibilities under, for example, EU law and WTO regimes. Consequently, questions concerning breaches of privacy and data protection have not significantly featured in their concerns. This neglect has assumed serious dimensions after the issues raised in the case of Birna Thordardottir versus Iceland. In the context of consumer violations and breaches of rights of natural persons the doctrine of presumed consent exposes insecure databases to abuse also in the hands of potentially malevolent bioterrorists, besides known benevolent "healthterrorists". It is therefore necessary to conceptualise the precise risks in the designs of systems.

RISKS IN DESIGNS OF SYSTEMS

Health databases are more than clinical histories or medicine inventories and doctors' addresses maintained for the benefit of patients. Trading in sensitive data about patients and doctors for insurance purposes or other commercial purposes to target profiles and

the licensing of such databases to third parties with or without prior consent of individuals concerned raises several issues. The rights to privacy are easily breached when confidentiality cannot be secured by coding the data or disconnecting the data from personally identifiable features in databases which are kept open for updating entries in old records or creating new records. The Civil Appeal by Birna Thordardottir versus Director General of Public Health of Iceland concerned the plaintiff's objections to inclusion in a public health sector database (Thordardottir, 2001). Such an objection is consistent with rights protected under Article 8 of the European Convention on Human Rights although this matter has not yet been put to test in the European Court in Strasbourg. In less developed countries where privacy protection is weak or unenforceable, the moral hazards arising from what information brokers may do are considerably greater.

Clinical databases are easily linked to databases regarding genealogy and molecular genetics. Such extensive and sensitive personal data has potential misuses. The principle that such data be stored only at its place of origin and used only for the original purpose for which it is collected is easily violable and compliance with this rule is impossible to enforce. Personal data on whole nations and ethnic groups can therefore be exploited in ways that endanger public health and disrupt peace. The scientific and commercial value of such databases would remain with those who have the means to maintain and update these databases and link them to other databases in their possession. This could accentuate the information and technology gaps between developed and less developed countries. The requirement that such databases be maintained under international control with requisite safeguards for equal access by all countries already exist in certain forms but the fact is they are neither being observed nor discussed in policy fora or academic journals as proof of what has been crowded out.

Information about genotypes and phenotypes are personal identifiers. Even if decryption keys to such databases were sealed or lost or destroyed it would still be possible to make new

keys using information from genealogy, genetics and molecular biology. Without enforceable international agreements on biological weapons, such databases are a standing invitation to health terrorism in the hands of mercenaries, rogue states and other unmentionables capable of (a) triggering humanitarian emergencies or (b) fostering permanent dependencies using the power to disrupt health as a pressure point.

Healthcare databases cannot be securely designed for large sizes for technical reasons (Anderson, 1996). Besides, The introduction of healthcare databases and maintaining them may add to costs and increase health expenditure per capita. Healthcare spending is not like other consumer spending in several important respects. Firstly, it is not promotable as a goal in itself and such spending, except in its preventive or prophylactic aspect, is inversely proportional to good health, a promotable goal. Secondly, the healthcare spending is context-sensitive to the cost of diagnosis and treatment of specific illnesses which differ in propensity across countries and also regions within countries. International comparisons on the basis of spending per capita say nothing about how much of the health need was met and at what cost per diagnosis or what cost per treated illness (Navarro, 2000; Rosen, 2001 make this point to question rankings on

healthcare in the World Health Report 2000). Fairly detailed cost information on these lines would be needed to know whether IT and e-businesses add to costs or reduce costs in relation to the burden of disease. Also, such data requires to be obtained consistently over a period of time to know how the cost changes. Meanwhile, a few salient features may be observed from WHO estimates for 1999 which reveal the following disease burden for WHO regions summarised in Table 1 below:

TABLE 1. DISEASE-DEATH MATRIX BY WHOM REGION (1999)			
REGION	POPULATION <i>(in thousands)</i>	DEATHS FROM COMMUNICABLE DISEASES <i>(in thousands)</i>	DEATHS FROM NON COMMUNICABLE CONDITIONS <i>(in thousands)</i>
AFRICA	616, 435	6, 131	3, 529
SOUTH-EAST ASIA	1, 508, 242	4, 272	8, 697
EASTERN MEDITERRANEAN	485, 266	1, 060	2, 754
WESTERN PACIFIC	1, 666, 776	1, 102	9, 876
AMERICAS	813, 065	570	4, 564
EUROPE	871, 845	438	4, 227
WORLD TOTAL	5, 962, 628	13, 573	33, 647

Source: WHO Data, 2000

Note: (1) The WHO databases count deaths due to maternal and perinatal conditions and nutritional deficiencies together with deaths due to communicable diseases. In the above table these deaths have been totalled in deaths due to non-communicable conditions.

(2) The WHO classification is used for regions in the above table. Western Pacific includes China, South-East Asia includes India and the Eastern Mediterranean includes Pakistan. For the categorisation of countries into WHO regions, see World Health Report, 2000, pp 204-205.

From Table 1, it may be seen that the bigger killers in the world are non-communicable diseases and these are suffered in the greatest numbers in the Western Pacific and South East Asia region. Only in the case of Africa, deaths due to communicable diseases outnumber deaths due to non-communicable diseases. A further decomposition of data for Africa reveals that in deaths due to communicable diseases, infectious and parasitic diseases (other than HIV/AIDS) are responsible for 75 % of the deaths. The diagnosis and low-cost treatments for almost all of these are well known and on the essential drugs list of WHO as off-patent generics. IT has enabled global databases of suppliers and

inventories to be maintained. Therefore these deaths may be regarded as preventable. IT may further deliver marginal benefits in the development of faster or cheaper diagnosis or treatment here but this is not an area where IT can be expected to be either necessary or sufficient. The real gain from connective IT technologies and their e-business forms lies in the expansion of choice for diagnosis and cost-effective treatment of those of the communicable diseases and non-communicable conditions which are hard to diagnose or difficult to treat and for which gestation periods of treatment innovation may be shortened. The rising incidence of the non-communicable disease burden may be mitigated when data on risk factors in less developed countries is recorded and analysed (Beaglehole and Bonita, 2001)

Thus, in the information sharing and information flows that are enabled by the new information and communication technologies, in order to assess their impact on healthcare and on trade in healthcare it is necessary to know how much of the information flows in value chain designs is concerned with production of healthcare commodities and services that either improve efficiency or reduce costs or increase choice or cause innovations that enable all three. This is complicated by the structural incongruence which may be summarised in the following manner:

- Health responsibilities remain with national governments as public goods.
- Financing of healthcare is borne through contributions and insurers.
- The power to develop and deliver healthcare is organised mainly by business firms.
- The authority to accept or not accept loss of privacy and personal data protection rests with consumers as natural persons.

The private space of individual natural persons can be encroached by governments in various guises and the requirements of collective public good is one of them. The human genomes of the populations of Tonga, Estonia and Iceland have already been bought and patented by private companies (<http://vector.cshl.org/eugenics.html>) In these cases, national governments sold the medical histories and dna information of their citizens to private firms to ostensibly aid the cause of healthcare development. In doing so, the public domain was used to legitimise the extraction of personal and private data through the agency of government into the classified sovereign domain and the information so organised was channeled as information flows from restricted sovereign domain into private databases for unlimited purposes under corporate control causing the entire data (a non-renewable resource) to be not only privatised but also become excluded from other claimants including the owners of their own information themselves. I refer to this phenomenon as inversion of private and public spaces which may be understood at three distinct levels:

- as a set distributional questions about apportioning costs and benefits between private and public actors.
- as a set of functional problems of data protection and privacy.
- as a problem with spatial consequences for health security, population biology and international business.

The risks in designs of systems arise because the three different levels above become

inseparable from each other when data entry requirements of open databases must inevitably expose such databases to frequent access at various points of contact-knowable and unknowable. The public nature of private information and the private nature of public information thus renders and reinforces authority and responsibility to become and remain discrepant. Encryption solutions neither resolve the dilemma nor realign authority and responsibility because databases can be legitimately traded globally under GATS for commercial purposes and data protection laws have, at best, limited national or regional jurisdiction. This situation has effectively abridged rights of natural persons and extended privileges of artificial juridical persons to those of natural persons with and through the blessings of governments. The vulnerabilities for e-Business designs are increased because unsustainabilities inherent in questionable practices that foster creation of value based on jurisdictional voids between what is unlawful or illegal but unjusticiable and that which is legal but not authorised remain unsettled. Value creation by any of the nine categories of value-adders could get nullified by transactions costs in such situations and this could well occur without warning signals usually associated with loss of profitability or weakening strategic health. The health of e-businesses cannot be regarded as secure unless questions raised in this paper about legitimacy of public-private partnerships is resolved by testing the potential and actual arrangements with reference to reductions of disease burdens.

OTHER RISKS

The greatest security risk surrounds databases of whole populations which can be maintained privately to target specific populations or ethnic groups within them (Mathur, 2001). For the first time in history, "ethnic cleansing" and civil wars can be started without conventional weapons. One of the dangers of the otherwise welcome public-private partnerships in the offing is the nature of license they provide to firms building databases by conducting long-distance large scale clinical trials in which could have uses in eugenics or bioterrorism if global health databases remain under private ownership or monopoly public control of one country.

Corresponding to these developments, it is noteworthy that certain new terms have appeared for use from calendar year 2001 onwards in the medical lexicon for the first time. A strange epithet "*Microsporidia, unclassified*" has been coined to cover what were previously called antigens and protozoan and, "*includes newly defined organisms as well as some that will never be classified to the genus and/or species level because of loss of specimen or other information*" (National Library of Medicine, 2000, page I.16). Among other new terms of the new millenium year 2001 are "*imaging*" defined as "*the process of generating computer-assisted 3-D images*" (raising the perplexing question of how images and information so enabled by the IT revolution could get lost even if specimens are mislaid by human error), "*genomics*" defined as "*the systematic study of complete DNA sequences (genomes) of organisms*", "*gene order*" defined as "*the sequential location of genes on a chromosome*", "*shiga toxins*", a class of toxins that inhibit protein synthesis by blocking RNA, and "*bioterrorism*", defined as "*malevolent use of bacteria, viruses or toxins against people, animals and plants*" (National Library of Medicine, 2000).

It is widely acknowledged that the next generation of life-saving medicines would arise from genetically modified microorganisms based on advances in genomics and proteomics. The term "microorganism" is not defined anywhere in the Budapest Treaty (Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purposes of Patent Procedure, 1977, as amended in 1980) and has conventionally included tissue cultures and plasmids.

There is only one country (U.S.A.) that could obtain information on all microorganisms deposited under the Treaty and only firms authorised by that country could put to use such microorganisms. This situation has arisen over a period of time. All of the International Depository Authorities were located in developed countries until 1995. There are none at all in two countries-Brazil and India, where a large variety of microorganisms naturally occur. An IDA in China was established in 1995. The Chinese depository is neither designed nor allowed to conserve plant seeds, protozoa, animal cell lines, and plant cell lines. The facilities in UK, Japan, Canada and France are disallowed from conserving Level 4 viruses. Japan, Netherlands and Russia are further not permitted to conserve microorganisms for recombinant DNA experiments and Level 3 viruses. The ones in Australia and Belgium are barred from receiving nucleic acid preparations and phages, recombinant genetic material, plasmids (DNA molecules), oncogenes, RNA, human cell lines and all forms of cryogenically conserved cells though UK is allowed to hold these. U.S.A is the only country allowed to conserve all forms of microorganisms. The present situation amounts to a monopoly which has trade implications and also health security consequences for all countries. It is difficult to share the optimism of Feachem (2001) that "*It is plausible that by 2010, the centre of gravity of innovation in drugs and vaccines will have moved noticeably towards developing countries*" when the biotechnology divide is poised to accentuate. However, when Feachem (2001) predicts that the biotechnology divide is going to be worse than the digital divide and declares his support for what are termed "public-private partnerships"- a way of describing the need for realignment of financial incentives for the big pharma companies to be concerned about the national health responsibilities of governments in least developed countries, he is probably accurate in mapping a three-way divide between more secure, less secure and insecure populations.

The cultivation of microorganisms is practically indistinguishable from the work that regularly goes on in breweries, university research laboratories, pharmaceutical firms and other places. The BWC Convention (Biological Weapons Convention of 1972) signed by 159 countries (with 141 ratifications) bans the production, use and stockpiling of bacteriological weapons. Pharmacological processes and advances in biotechnology require the cultivation of microorganisms which have multiple uses because diseases have to be studied if cures are to be found. The justification for conserving microorganisms is difficult to establish *a priori* before clinical trials have been made if clinical value were to be the only criteria for conserving microorganisms. In this context, it is worth recapitulating that Article I of the BWC Convention states:

"Each State Party to this Convention undertakes never in any circumstance to develop, produce and stockpile or otherwise acquire or retain microbial or other biological

agents or toxins, whatever their origins or method of production of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes"

The drafters of the BWC Treaty understood the overlap dilemma quite well. This can be noticed from Article X of the BWC Treaty which reads as follows:

*"The State Parties to this Convention undertake to facilitate, **and have the right to participate** in the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so **shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes"** (highlighting, mine).*

The rights referred above in the BWC Treaty (signed and ratified by U.S.A. too) also find mention in the Convention on Biological Diversity, 1992 (Biodiversity Treaty) which recognises the country of origin of genetic resources. The reason is that clinical utility is not the only value of microbiological diversity. Microorganisms have an important critical function in biological balance. Microorganisms dominate the biosphere, have always done so and will always do so (except for the relatively recent possibilities, in evolutionary time, of human intervention in the biosphere). Any sudden change in profiles of microorganisms in an ecological niche will only cause the entry of new varieties with new properties (pathological consequences, for instance) in that niche. Documenting, understanding and preserving microbiological diversity is important for its own sake and for understanding the stability and inter-dependence of eco-systems. Article 7(d) of the Biodiversity Treaty explicitly provides for maintaining and organising data with regard to conservation of life forms and its Article 16(3) caters for developing countries to be provided access also to biotechnology protected by patents. There is little discussion on the progress made or not made with regard to these provisions. U.S.A is not a signatory to the Biodiversity Treaty signed and ratified by 157 countries.

Meanwhile, the Pharmaceutical Research and Manufacturers of America (PhRMA) have successfully blocked BWC inspections in U.S.A. on the plea that such inspections could lead to loss of proprietary business information and add to their costs, despite evidence to the contrary from safeguards in place during BWC inspections in UK, Canada, Spain, Germany, Switzerland, Spain, Denmark, Finland, Iceland, Norway, Sweden, Austria and Iran. The new American President backed away from the verifiability provisions of BWC in July 2001 although it is not clear whether this is a negotiating tactic or U.S.A's impending disengagement from adhering to the BWC. IT could enable global databases to be legitimately shared when countries adhere to international regimes but IT could also accentuate the biological divide and increase the risk of deliberate disease if access to biological information is skewed.

Intellectual Property Rights are private rights and IT enables novel organisms to be

designed and manufactured against which vaccines or antibiotics would be useless. That could force countries to countervail the situation to assert public rights by invoking Article 32 (b) of the Vienna Convention on the Law of the Treaties that the interpretation of a treaty's terms "should not produce manifestly absurd or unreasonable results" or with an even stronger alternative viz.. to repudiate this and other international treaties under Articles 56 (1) (b) and 56 (2) of the Vienna Convention on the Law of Treaties paving the way for acute international disorder if the inequity in access to knowledge technologies of life sciences is seen as a permanent non-negotiable feature of the present world order. Canada successfully cited Article 32 (b) of the Vienna Convention in its health sector dispute with the EU at the WTO and the next destination is therefore not a matter of theoretical speculation.

This also concerns questions of whether and how and where TRIPS promotes R&D are connected to the question of what rewards are justifiable for innovation once we recapitulate what the rewards were instituted for in the first place. Intellectual Property Rights belong to a field of law where there is no semantic agreement between what the law is designed to protect in different country jurisdictions. This semantic gap provides incentives for exploiting intellectual property rights internationally. However, this is only a small part of a bigger problem. In most jurisdictions, an invention is regarded unpatentable if it is merely a discovery of a law of nature or if it is only an extension of an application of a prior art already known (not "new") or if it does not involve an "inventive step" or if it is not "useful" . These terms find mention in TRIPS Article 27.1 but none of these terms are defined under TRIPS. Further, Article 6 ("nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights"), Article 30 (exceptions on legitimate interests of third parties) and Article 31 (allowing use of patents, inter alia, in "other circumstances of extreme urgency") of TRIPS were consciously left in their present form to enable flexibility and variation in differing national interpretations. Also, Article XII of GATS specifically caters to exemptions for macro-economic imbalances that cause threats to balance of payments.

However, one obligation under TRIPS stands out. While countries may find reasons or loopholes to deny patents for diagnostic, therapeutic, surgical methods, plants and animals, and biological processes for the production of plants and animals, the category microorganisms and microbiological processes cannot be denied patents. Signatories to TRIPS may exclude from patentability practically anything to protect, inter alia, human health (27.2 of TRIPS) as long as exploitation of patents is not prohibited by law but in exclusions from patentability, microorganisms are explicitly excepted.

At the time when the first inventions came to be protected by law to provide incentives for inventors, new discoveries and inventions were largely a matter of "hit and trial " or "intuition" or "combinative ingenuity". The development of the scientific processes together with shifts away from individuals to laboratories and research and development firms has brought science to a stage where incremental steps are not much more than extensions of what was previously known or knowable until the point when thresholds are crossed when more laws of nature are revealed. Moreover, it is a well documented fact that discoveries and inventions occur simultaneously at different locations by people who are not in contact with each other far too frequently than can be attributed to

chance or coincidence or espionage.

The justification for product patents arises because of anomalies that would proliferate without them. For example, if someone designs a piece of electronic medical equipment by a process of trial and error it would classify as an invention if it could be differentiated from previous such pieces of equipment. But if someone designs the same piece of equipment with optimal use of electrical circuits and material alloys by taking signal capacities into consideration through ANOVA statistical methods, it is not an invention! In the case of pharmaceutical products, although some drugs are inventions, others are naturally occurring molecules which are discoveries. The prohibitively high entry costs and entry barriers in the industry and the long lead times in research and development to extract, isolate and purify substances involves steps which could be new and inventive and it takes time and money in trials to prove a medicinal drug and further time to recoup the upfront costs through branded manufacturing and distribution and these were the justifications for product patents. It is strange that this logic has been applied to patent DNA sequences because the value of a DNA sequence is in decoding its naturally occurring knowledge content, not in the physical substance or its description as information. Since messenger RNA occurs in nature, it is difficult to reconcile that cDNA, a translation of the DNA sequence which also occurs in nature should be regarded patentable (Bobrow and Thomas, 2001). Yet, claims for patents on genomic DNA sequences, complementary DNA (cDNA), expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs) have been accepted before anyone (including the patent holder) knows what genetic information of any therapeutic significance they contain, thus conferring advance exclusive property rights on potential disease genes. Bobrow and Thomas (2001) point out that *"components of functional genetic units in the human body are integral parts of the same biological mechanism that interacts with other gene products...if DNA sequences of all of these components are identified and treated as separate inventions, any useful product is highly likely to cross boundaries of several patents"*.

Federally funded pharmaceutical inventions in U.S.A. subsidise about half of the American Pharmaceutical industry's research costs with State-aid. When blind-alleys have been eliminated by the application of federal funds, gifts of drugs developed in the national institutes and laboratories are made to enable private capital to develop and commercialise the final product. Evidence of this is recorded in the Testimony of Ralph Nader and James Love before the Special Committee of the U.S. Senate on February 24, 1993 (<http://www.cptech.org/pharm/pryor.html>) Pharmaceutical companies' costs mainly consist of expenses to acquire patent rights, obtain FDA approval and preserve exclusive marketing rights. Universities pledge exclusive rights to the outcome of their government funded research to private firms in exchange for cash incentives and financing of buildings and laboratories as in the Wisconsin-Geron, Berkeley-Novartis, Washington-Pharmacia and Colorado-Ribozyme examples which are only four illustrative cases among 120 such instances of co-operation in U.S.A. There is a good case for competition policy harmonisation at the international level without which comparisons of costs, prices, profits and volumes entail significant effects of subsidies in developed countries that protect competitiveness. TRIPS caters to this circumstance through the enabling Article 31 (k), relevant excerpts of which state:

"Members are not obliged to apply the conditions.....where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive"

The reluctance of National Institutes of Health to dilute intellectual property rights in commercial licenses to final products developed by firms through parallel licensing of therapeutic agents and compounds to WHO or some similar other global institution is understandable from the perspective of Bayh-Dole Act which was aimed at enhancing American competitiveness, not global healthcare. Whether new public-private partnership initiatives of the kind envisaged by Sachs (2001) may circumvent this technicality, remains more uncertain than the continued existence of statutes (in U.S.A, Italy, Australia, Philippines, India, China, Malaysia, Singapore, New Zealand, Ireland, Switzerland and the U.K.) whereby governments may lawfully ignore patents if public interest requires them to do so. The situation is complicated further by the inviolability of independent justice systems to interpret public interest when writs of mandamus are invoked against governments by individual citizens or in class action suits.

All kinds of services are marketed as "products". Whether they are regarded patentable or not could make a difference to market structures, intensity of competition, cost and price structures for such services and to incentives for pre-emptive patenting. The need to distinguish the exploitation of patents subsidised by State-aid from those that reflect investments in R & D by companies is important. It is not clear whether compulsory licensing is automatically hindered in the case of the former by the application of Article 5 of the Paris Convention for the Protection of Industrial Property (once three years have elapsed from the date of patent) and whether Article 28 of TRIPS would stand in the way of production for exports (the article only mentions import restrictions) as in EU's dispute case against Canada at the WTO (WT/DS/114). In this situation, a patent looks less like a certificate of ownership and may at best be treated as a ticket to litigation. A weak patent backed by a big firm is more effective than a strong patent held by a small firm which cannot afford to defend it. Despite the fact that almost half of the litigated American patents (46 % to be precise) were invalidated by courts between 1990 and 1998, leading private patenters of human gene uses (Incyte Genomics, Human Genome Sciences, Celera Genomics, Hyseq and Millenium) have made more than 27,500 patent applications and between them obtained 812 U.S. patents upto February 2001.

If there is a consensus that TRIPS causes welfare losses of different magnitudes to different countries, either TRIPS could be renegotiated and modified or supplemented by a scheme of international credits and debits. This could take an innovative form, for instance in e-currency units for the IT-aided deliveries of healthcare and in pooled funds for common causes under international regimes. TRIPS could also be left as it is but that could force the WTO dispute panels of the future to re-write TRIPS and encourage countries to make their own national interpretations of it until then. What makes the TRIPS discussion increasingly irrelevant is the fact that American law was recently amended to ensure that compliance with obligations under TRIPS by a country does not prevent that country being put on the "watch list" under the Special 301 provisions of U.S.A's Trade Act in relation to trade related intellectual property rights.

CONCLUSIONS

The limits to human uses of human beings are constraints on organisation designs in the Wienerian tradition (Wiener,1950). E-businesses in healthcare are especially vulnerable because their viability and sustainability depends on how healthcare development, healthcare delivery and healthcare administration services techno-economically structure socially and legally acceptable digital connectivity for information flows of sensitive data. More research is required into inadequacies of cross-border transactions and infirmities of the world trading system with regard to intellectual property rights and services. It is also necessary to research stakeholder interests with regard to costs, efficiency and choice to evaluate models that blend efficiency of e-business designs with equity for customers, service providers, contributors and governments (Brundtland, 1999; Sachs, 2001). Also, the impact of e-business designs on disease burdens needs to be evaluated in cost-benefit terms (World Bank, 1993; WHO, 2000). The inversion of private and public spaces may require to be legitimised (Sachs, 2001), validated (Mathur, 2001), compensated (Bear, 2001) or reversed (Anderson, 1996). The difference between competitive success and competitive demise for e-businesses in healthcare may well lie in locating choices for designs whose success would not invite the risk of potentially increasing the disease burden or concentrating power in so few hands that anxieties and fears over abuses or misuses ends up being injurious to health of people and to health of businesses.

The uncertainty over prospects for global databases concerning microorganisms from which the next generation of life-saving medicines would emerge poses health security hazards on an unprecedented scale to all countries. Not much can be concluded about motives and powerbases of those influencing policy without more clarity through further research and empirical analysis at disaggregated levels in specific countries and in specific kinds of applications among clusters of health development service providers and communities to identify the necessary and sufficient conditions that would make e-businesses in healthcare sustainable. The imminent expansion of cross-border trade through e-businesses in healthcare requires research also into institutional questions where law, economics and governance intertwine and to understand how the discrepancy between *responsibility* for healthcare, *authority* to design its value chains, and the *power* and *capacity* to organise its delivery may be resolved in the interests of sustainable development of all concerned.

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