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Praemonitus, praemunitus: Assessing the ethical dimension of the globalisation of science and technology

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Introduction

Globalisation can be understood as *"the intensification of worldwide social relations which link distant localities in such a way that local happenings are shaped by events occurring many miles away"* [1]. Globalisation is undoubtedly a prominent feature of contemporary life. Together with social, economic, and cultural processes of globalisation, there has also been an intensification of the globalisation of science and technology [2]. In recent years, there has been a growing awareness of ethical issues resulting from the globalisation of science and technology. For example, the globalisation of science and technology can result in "ethics dumping". "Ethics dumping" describes a situation in which a multinational company or corporation deliberately moves its laboratory experiments to a country that does not have ethical or legal standards for governing such laboratory experiments. In this way, the multinational company can get away with dubious and questionable practices, simply by moving them from one country to another country.

In recent years, there has been a growing awareness of ethical issues resulting from the globalisation of science and technology.

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The present article identifies and reviews the most important of such ethical issues in a systematic fashion. But why catalogue ethical issues resulting from the globalisation of science and technology? The answer partly rests in the fact that Uzbekistan is currently undertaking major steps to liberalise the economy, to improve the investment climate and to open up domestic markets to foreign businesses and investors. In particular, the process of attracting foreign direct investment (FDI) in the country will inevitably result in the establishment of various joint ventures, acquisitions and greenfield enterprises [3], which in turn will lead to the intensification of research and development activities with foreign partners. However, as this paper aims to show, an increase in science research and technology development with foreign partners can have its own ethical and moral perils. Hence, to prepare the country and society to avoid the negative effects and consequences of the scientific and technological globalisation, it is necessary first to have a clear picture of all possible ethical issues, particularly those which either remain unaddressed by the domestic legal framework or stand outside the domestic legislative agenda. In this way, a catalogue of ethical issues arising from the globalisation of science and technology offered in the present study provides policy makers, regulatory bodies, academic institutions, industry and business representatives in this country with an informative list of some of the major negative effects and implications of the globalisation of science and technology. Proverbially speaking, forewarned means forearmed.

In this article, research and innovation is broadly understood to consist of three different stages: (1) research and development (R&D), (2) manufacture and production, and (3) marketing and sales. During the first stage, a new product or a process is designed and developed; during the second stage, mass manufacture and production of the innovation in question takes place; during the third stage, the innovation in question is diffused within society. Research and innovation can be said to be globalised insofar as any of the above three stages occurs on an international or global level, thus involving globally distributed R&D, production and sales networks. The present review focuses on ethical issues that stem from the globalisation of any of the above three stages.

An increase in science research and technology development with foreign partners can have its own ethical and moral perils.

At the R&D stage of innovation, there exist a number of important ethical problems, such as issues pertaining to the maintenance of ethical standards in the outsourcing of R&D to developing countries; issues of informed consent and benefit-sharing in the development and patenting of

innovations on the basis of local knowledge and biological resources; issues of (global) resource allocation and distributive justice in funding clinical and medical R&D; issues pertaining to the impact of globalisation of research and innovation on scientific integrity and responsible conduct of research; as well as the issue of 'brain-drain' from developing countries as a result of the globalisation of R&D. Ethical issues that arise during the production and manufacture stage of innovation include issues concerning the adoption and maintenance of ethical standards in outsourcing production processes, with regard to the local workers or community (e.g., outsourcing of production to countries with lower wages or lower standards for health and safety and protection of human rights), the local environment (e.g., outsourcing of production processes, CO2 emissions and waste disposal to countries with lower environmental standards); as well as the question and extent of adherence of supply chains to ethical standards. Finally, at the marketing and sales stage there are ethical issues pertaining to accessibility or affordability of products and processes in different countries, as well as responsibility and liability for health, environmental and other harms that might result from the marketed and sold products.

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Ethical issues at the R&D stage

1. Outsourcing of R&D to developing countries

One of the aspects of the globalisation of research and innovation is the outsourcing (or offshoring) of R&D to developing countries such as India, Brazil and South Africa. Among chief reasons for such outsourcing, one can include the availability of cheaper labour and talent, cheaper infrastructure, lower health and environmental safety standards, etc. Important ethical issues become increasingly prominent in the area of outsourcing of pharmaceutical and clinical research and trials to such developing countries. Pharmaceutical research and trials usually consist of three different stages. The first is to test the toxicity and pharmacokinetics of the pharmaceutical innovation in question, which normally involves tests conducted on a smaller group of healthy people. The second is to evaluate the efficacy of the pharmaceutical, that is, whether or not it works as intended. The third is to compare the safety and efficacy of the pharmaceutical in question with those other existing alternatives. (Recently there has been a new addition – a fourth stage of pharmaceutical trials – that observes and records the long-term effects of the pharmaceutical

innovation, which can be conducted after the pharmaceutical is licensed.) The later stages of clinical trials require and involve larger population groups. The most important ethical issues are thus related to the use of people from developing countries for clinical trials that involve larger groups of people.

The European Group on Ethics in Science and New Technologies, while commenting on *"the ethical aspects of clinical research in developing countries"*, has noted that there has been *"a trend to transfer clinical trials to countries where cost and constraints of regulation may be more favourable to their implementation, and where the high number of patients, and especially nanve patients, that is patients who have never received treatment, facilitates the recruitment of patients to be involved in a clinical trial"* [4]. Thus, the central ethical concern is that in pursuit of profits companies from developed countries conduct clinical research and trials in the developing countries with less concern for health and safety and with less financial expenditure than in their own countries. Besides lax regulatory environment, outsourcing of pharmaceutical research to developing countries can also be motivated by political corruption, postcolonial attitudes, high level of illiteracy and particular perception of medical research among local population, etc. Furthermore, it is not only clinical trials involving humans, but also trials involving animal testing (e.g., for purposes of testing pharmaceuticals, cosmetics, etc.) that are being outsourced to developing countries.

the central ethical concern is that in pursuit of profits companies from developed countries conduct clinical research and trials in the developing countries with less concern for health and safety and with less financial expenditure than in their own countries.

Under such circumstances, pharmaceutical firms and laboratories can resort to what has been described as *"double standards"* and/or *"ethics dumping"*, which refer to a situation in which research that is considered unethical in certain (developed) countries is conducted in (developing) countries with less stringent, or altogether non-existent, ethical regulations and standards [5]. Insofar as the human clinical trials are concerned, it is possible to identify the four most common concerns that frequently crop up in discussions of ethics dumping and double standards: (1) whether proper informed consent can be obtained from the research participants; (2) whether payment and other benefits offered to research participant constitute undue inducement; (3) whether there is a fair proportion of risk to benefit for research participants; (4) whether research participants are provided with the best standard of care. These and other issues are considered in more detail below.

2. Issues in and of obtaining informed consent

The most central ethical criterion in protecting research participants is informed consent – whether the research is conducted in the developed or the developing world. For the purpose of protecting the individual research participants, it is necessary to obtain their informed consent, before the research can go ahead. The emphasis on the necessity for informed consent has been established in the Nuremberg Code of 1947, which first articulated the codes governing scientific research to ensure the protection of individuals against the horrors perpetrated by the Nazis in the name of scientific progress and the greater common good. By adopting informed consent as a necessary criterion for assessing good ethical research, the intention was to make it impossible for harmful research and trials to be conducted. The importance of informed consent has further been reiterated in the Declaration of Helsinki of the World Medical Association (written in 1964, and amended nine times between 1975 and 2013).

Obtaining informed consent from potential research participants in the developing world becomes problematic given the high levels of illiteracy, especially within the rural areas. Thus, the level of literacy of a potential clinical trial subject can sometimes be used as one of the proxy measurements of the subject's ability to give informed consent. Nonetheless, possession of basic literacy cannot guarantee that a patient can fully comprehend the consequences of participating in clinical trials. For example, in Germany, literate parents of children asked to take part in a trial of a drug for hyperactivity and attention deficit disorder and hyperactivity had difficulties understanding the nature of the placebo comparative group of the trial in question and did not fully grasp that the main goal of the trial was research and not the provision of individualized medical care [6]. It is well-documented that there is *"the tendency among patients to have an optimistic bias and therapeutic misconceptions about trials"*, regardless of where the trial is conducted [7]. It can be suggested that a way of protecting potential research subjects from taking part in clinical trials that might be harmful to them is through the involvement of family members in the decision-making process. This, however, can raise further issues and questions regarding the autonomy of individual patients.

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3. Undue inducement

For clinical and pharmaceutical research to be considered ethical, besides obtaining the informed consent of potential participants, it is important to consider whether the financial compensation, as well as the other potential benefits offered for participation can come to constitute undue inducement [8]. Although research participants, particularly within the later stages of pharmaceutical trials are usually reimbursed for transportation, meals, etc., that is, expenses related to participation in the trial, even small amounts of monetary compensations such as these might exert undue influences on potential research participants in poor and underdeveloped countries. However, to prohibit clinical trials in such particularly poor places on the grounds that there is undue inducement is involved might itself be an unethical approach, since such a decision could be argued to be *"paternalistic or even an instance of colonialism: refusing the 'poor' options and choices on the grounds that the poor are not capable of making these decisions for themselves"* [9]. Moreover, if participation in a research or trial is the only way for a patient to access any kind of health or treatment, then would it be more ethical for the patient to have access to it in this manner, than not to have any medical check or treatment at all. This argument echoes some of the views expressed by participants of HIV research and trials as documented in the Nuffield report on the ethics of research related to healthcare in developing countries [10].

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4. A fair proportion of risk to benefit

Another of the issues encountered in assessing ethically good research in developing countries has to do with the difficulty of ascertaining a fair proportion of risk to benefit for clinical trial participants. According to this condition, benefits of the trials for the participant must be proportionate to the risk involved in participating in the trial. The emphasis on a fair proportion of risk to benefit primarily stems from ethical concerns to protect the patient. However, with the globalisation of research and innovation, a difficulty may arise in determining what can be a fair proportion of risks to benefits, given that what counts as a fair distribution of risks and benefits in one locality might be unfair in other localities of the globe. Such a disparity in judgment has largely to do with the fact that considerations of what is a fair proportion of risk to benefit

is usually made by research ethics committees, while there is no global homogeneity governing and regulating how such committees should be formed and how they should function. Nevertheless, as Heather Widdows notes, *"there is significant overlap in the way they function in practice and, as international pharmaceutical companies and research networks function across jurisdictions, harmonization is increasingly taking place. What is important is that all international research goes through a series of ethics reviews and core ethical issues are at least considered"* [11].

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5. Standard of care: best global or best local?

Ascertaining a fair proportion of risk to benefit furthermore requires that in developing a new drug a pharmaceutical company or laboratory must know how effective their new innovation is in relation to already existing drugs and treatments. Thus, for example, according to the Declaration of Helsinki:

The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

- The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
- Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option. [12].

However, the question of what constitutes *"the best current proven intervention"* can become a source of controversy under conditions of the globalisation of research and innovation. Consider, for example, the Zidovudine case, which involved a clinical trial conducted by GlaxoSmithKline in 1985 (then called Burroughs Wellcome) aiming to assess the effectiveness of an anti-retroviral drug, called Zidovudine, to lessen the chances of transmissions of HIV from the mother to a baby during pregnancy or childbirth. Being a placebo-controlled trial, it consisted of two

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groups of trial participants. While one group was given Zidovudine, the other was given a placebo [13]. As can be seen, this trial did not answer the requirements of the Declaration of Helsinki, according to which any new drug must be evaluated against *"the best current prophylactic diagnostic and therapeutic methods"*. Thus, by giving a placebo, the trial participants in the placebo group were put at risk of serious and irreversible harm. When questioned about their actions, the conductors of the trial defended themselves by claiming that since there was no locally available medicine anyway, their decision to give the group a placebo was ethically justified. Put differently, their claim was that the participants in the placebo group were not harmed, since they would not have been able to get globally available alternatives in their locality. Thus, in the Zidovudine case, the conductors of the trial construed 'the best available' as the actually available (or affordable) locally rather than best available globally.

6. Bio-prospecting and bio-piracy

Besides outsourcing of clinical trials to developing countries, the globalisation of R&D can also take the form of bio-prospecting, which can be understood as the systematic process of discovery and commercialization of new bio-chemical compounds [14]. While bio-prospecting can also consult indigenous knowledge about local biological resources in search of new bio-chemical compounds, bio-prospecting can become bio-piracy, once it involves an exploitative appropriation of indigenous knowledge or biological resources [15]. Thus, in such situation, in order to ensure that bio-prospecting does not become bio-piracy, it is important that any appropriation of knowledge or biological resources from an indigenous community is not exploitative but beneficial to the group in question. A review of literature on research ethics and global bioethics can show that at least two different models have been proposed to deal with communal ethical issues pertaining to groups: (1) group consent and (2) benefit-sharing. Below the two approaches receive further elaborations.

7. Issues of obtaining group consent

When bio-prospecting research involves indigenous groups or communities, it is sometimes required that the researchers should first gain some form of group consent from the indigenous group or community.

However, this approach towards communal ethical issues has its own shortcomings. Firstly, it can be argued that just like in the case of individual informed consent, if something is chosen, it might not necessarily be ethical [16]. Secondly, it can be argued that group consent approach does not properly address more fundamental issues coercion, exploitation and power structure [17].

8. Is benefit-sharing possible?

A better solution to communal ethical issues is the benefit-sharing approach According to this approach, it is necessary to share the benefits gained from bio-prospecting research with those groups and communities that provided forms of knowledge or samples of biological resources. According to the Human Gene Organisation (HUGO), indigenous groups can be offered benefits such as health care, public-health-services technology transfer and contribution to the local community infrastructure (e.g., schools, libraries, sports, clean water).

There have been cases in which the benefit-sharing approach has worked very well. Thus, for example, when a group of scientists have been studying plants in the Kani community in the Thiruvananthapuram forest in India in 1987, they discovered that people from the local community could resist fatigue far more effectively by eating a certain plant called *"arogyapacha"*. Once the scientists developed a synthetic and commercial energy-enhancing product on the basis of this plant, they allocated a part of their profits to the local community and implemented enhanced cultivation of the plant for the indigenous community in question [18].

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9. Fair global resource allocation

The globalisation of R&D, in particular in the area of medicine and pharmaceuticals, might also give rise to global ethical issues pertaining resource allocation and distributive justice. Thus, for example, one might question, from the viewpoint of normative political ideal of (global) justice, whether it is justifiable to develop expensive and technologically sophisticated medical treatments, while most people in the world lack access to basic health care. Those who adopt a strong cosmopolitan approach would consider the disparity between different territories and regions of the world as unjustified, by arguing that no ethical grounds could be

used to justify giving expensive treatments to some while others lack basic health care. Yet, those who adopt a weak cosmopolitan approach might endorse basic or minimal rights to healthcare, by arguing that a basic standard of public health care should be available worldwide, yet once such a basic standard of healthcare is in place, it is ethically permissible that there be additional, costly and sophisticated, treatments for those who can afford them.

A related global ethical issue is what has been called 'the 90-10 disequilibrium', which refers to the fact that that only 10% of total health-related R&D is allocated to 90% of the global disease burden [19]. Put differently, 90 % of the global disease burden is made up of diseases that affect the global poor, such as malaria, but only 10 % of the total money spent on pharmaceutical R&D is allocated for fighting these diseases. This problem is further exacerbated by the patent system ever since the adoption of TRIPS (the Agreement on Trade-Related Aspects of Intellectual Property Rights) by the WTO in 1994. One of the main adverse implications of this agreement has been the fact that it made the production of generic drugs difficult (in developing countries such as Brazil and India), while it made the sale of such drugs prohibited in underdeveloped countries that lack the necessary infrastructure to produce such generic drugs.

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10. Scientific integrity and responsibility

Research misconduct, in which principles of scientific integrity are not adhered to, is a significant problem in science today [20]. Although there can be a number of causes of scientific misconduct, the issue is further exacerbated by the globalisation of scientific research. Firstly, with the globalisation of research, scientists and researchers are increasingly coming under the pressure to publish and have significant results faster due to increase in scientific competition, in particular within the knowledge economies. Secondly, the globalisation of research makes it more difficult to identify good research, given the divergent standards for scientific integrity in different parts of the world. Thirdly, with the globalisation of research there has been a growing need to publish in certain – globally widespread – languages such as English, as a result of which, those researchers lacking the required linguistic skills are increasingly feeling the pressure to plagiarise research by those who possess better linguistic skills.

11. Issues of brain-drain

The globalisation of research and innovation, in particular the globalisation of R&D, also contributes to the migrations of skilled scientists and workers from developing countries to the developed countries. Although not all instances of such migration of skilled people are necessarily be negative, it can contribute to what has been described as *"brain-drain"* [21]. Hence, the problem of brain-drain is a global problem that can require both global and local solutions [22].

Ethical issues at the manufacturing and production stage

Besides the ethical issues arising in the R&D stage of innovation, there are as well ethical issues in the production and manufacture phase of innovation, which include issues concerning the adoption and maintenance of ethical standards in outsourcing, or off-shoring, of production processes with regard to: (1) local workers and community (e.g., outsourcing of production to countries with lower wages or lower standards for health and safety and protection of human rights); (2) local environment (e.g., outsourcing of production processes, CO2 emissions and waste disposal to countries with lower environmental standards).

1. Social implications

One of the main reasons for such outsourcing or off-shoring of production and manufacture processes to developing countries is frequently said to be reducing costs and freeing up assets in the short term [23]. Besides short-term cost savings, there can be other reasons pertaining to efficiency, such as making it possible for companies to focus their efforts on 'core' activities [24]. Nevertheless, as in the R&D stage of innovation activities, outsourcing of production processes to developing countries can be motivated by the availability of cheaper labour and talent, cheaper infrastructure and raw materials, as well as lower standards in the protection of employee health, occupational and environmental safety, etc.

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Although developing countries and regions into which production processes are outsourced in this way might come to enjoy increased levels employment and GDP, the globalisation of production processes can also give rise to exploitative power relations, where outsourcing companies gain benefits from softer or non-existent legislation on matters of human rights and environmental protection [25]. Outsourcing of production to countries with non-

democratic, authoritarian or corrupt governments that place economic gains above social concerns can result in child labour, forced labour, trampling of employee rights, abuse of employees, disregard of occupational health and safety standards, etc. Moreover, it must be noted that global outsourcing of production processes frequently has adverse socio-economic effects on wage and employment levels within developed countries as well. Thus, for example, due to international economic competition, there can be a *"downward pressure on domestic salaries"* [26].

2. Environmental implications

The environment is undoubtedly one of the prominent areas in which some of the negative effects of the globalisation of technological innovation are increasingly being felt [27]. There has thus been a proliferation of issues, such as global warming and climate change, environmental degradation (including water, soil and air pollution) resulting from the depletion of natural and non-renewable resources, global problems pertaining to waste disposal.

The burdens of environmental side-effects of technological globalisation are likely to be distributed disproportionately to the poor countries of the world. The already vulnerable regions of the world are less capable to mitigate such environmental effects. Thus, for example, rises in sea-level will have a huge impact on low-lying and low-income states, such as Bangladesh, and/or on small island states, such as Maldives. Although this is in part to geographical location of these countries, there are as well factors pertaining to the increasing global technological divide. Most of these countries cannot afford the technological adaptations that richer countries can possess: rises in temperature are better dealt with by countries possessing drought management infrastructure; hurricanes and tsunamis are more easily dealt with by those living in appropriate housing rather than those inhabiting shanty towns; most environmental catastrophes are more easily dealt with by richer countries that can provide immediate aid to catastrophe affected regions.

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All three stages of innovation activities produce waste. This is particularly true of the production and manufacture stage of innovation. Interestingly, in the age of digital information technologies, some of the hazardous waste comes from the so-called 'clean technologies', such as computers, high-tech and electronic equipment [28]. Thus, for example, the processes of production of microchips entail the

utilization of a variety of highly hazardous and toxic chemicals, such as arsine, acetone, ethylene glycol and xylene [29]. Richer or developed countries sometimes engage in global traffic in hazardous and toxic waste that involves the shipment of waste from the more developed countries to less developed countries with lax environmental laws and regulations [30]. As a consequence of such outsourcing of waste disposal, certain places of the globe turn into waste dumping grounds, such as the city of Guiyu in the Guangdong region of China, which is the largest e-waste recycling place in the world.

Interestingly, in the age of digital information technologies, some of the hazardous waste comes from the so-called 'clean technologies', such as computers, high-tech and electronic equipment

Ethical issues at the marketing and sales stage

Finally, at the marketing and sales stage of innovation activities, the most notable of the ethical there are ethical issues pertaining to accessibility or affordability of products and processes in different countries, as well as responsibility and liability for health, environmental and other harms that might result from the marketed and sold products.

1. Issues of affordability

One of the ethical issues that arises in the marketing and sales stage of innovation activities is the issue of accessibility and affordability of products and innovations in those developing countries where international companies and multinational corporations come to monopolise the sales of certain goods that serve basic needs (e.g., pharmaceuticals, foods, etc.) and sell these goods at prices unaffordable in those developing countries.

2. Issues of liability

The fact that certain developing countries have limited regulation and enforcement of product liability gives rise to the issue of (global) responsibility and liability for the products marketed and sold in such countries [31].

Concluding remarks

As can be seen from the above review of some of the most prominent ethical issues stemming from the globalisation of research and innovation, most of the ethical issues have to do with the fact that research and innovation activities and practices in different countries and regions of the world are subject to rather divergent, or altogether lacking, regulatory and governing standards and practices. Under such circumstances, the globalisation of research and innovation – whether in its R&D, production

and manufacture or marketing and sales stages, can easily lead to what has been described as the problem of 'double standards' and/or 'ethics dumping'. In this context, any attempt to harmonise and bridge the ethical gaps must be thoroughly thought through, given that such attempts might involve a cross border diffusion of ethical and regulatory standards which can potentially lead to a global imposition of values and interpretation, and thus become instances of moral or ideological imperialism or neo-colonialism.

Further it should be borne in mind that when considering the R&D phase of science and technology, the present article has mainly focused on moral and ethical issues surrounding the participation of human subjects in clinical and pharmaceutical trials and experimentation. However, this somewhat biased focus on the role of human subjects in medical and pharmaceutical research is not without defence, insofar as these areas of research and innovation are widely considered to be among the most morally charged, given their frequent involvement of vulnerable human subjects, as well as the impact these areas can have on the wellbeing of entire groups and communities.

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