How Globalisation Is Changing Research Agendas, Activities and Assessment Procedures within Research & Innovation

Deliverable 3.3

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SATORI

TABLE OF CONTENTS

ABSTRACT

This deliverable comprises a report on the ethical considerations of globalisation on research and innovation. The first part of the report contains a literature review on globalisation in research and innovation; a review of ethical issues arising from the globalisation of research and innovation; and a review of policies and actions to mitigate the undesirable and unethical consequences of the globalisation of research and innovation. The second part provides a closer examination of globalisation within research an innovation through six case studies.

EXECUTIVE SUMMARY

This deliverable comprises a report on the ethical considerations of globalisation on research and innovation. The first part of the report contains a literature review on globalisation in research and innovation; a review of ethical issues arising from the globalisation of research and innovation; and a review of policies and actions to mitigate the undesirable and unethical consequences of the globalisation of research and innovation. The second part provides a closer examination of globalisation within research an innovation through six case studies. The six case studies themes are:

- Responsible Supply Chain
- Scientific Misconduct
- Indigenous Knowledge
- Outsourcing of CO2 Emissions
- Clinical Research & Trials
- Brain-Drain

Each case study includes a preliminary review of the effects of globalisation within the theme and the corresponding ethical considerations. Interviews were then conducted with stakeholders to further illustrate findings of the review by focusing on specific incidents, actions, or policies involving the stakeholder within the respective theme.

1 INTRODUCTION

1.1 CONTEXT

The globalisation of research and innovation has taken many forms. There has been growth in terms of: multinational R&I in multinational organisations; relocation of company R&D to affiliates abroad; international trade in R&D services, patents, and licenses; international cooperation through R&D networks, alliances and agreements; recruitment of foreign R&D workers in public and private organisations; general global diffusion of knowledge and access to local resources; and internationally located company supply chains. Globalisation processes have also sped up over the last decades, facilitated by modern global information and communication systems and increasingly modularized innovation processes. Consequently, there have been corresponding ethical considerations that have emerged with the globalisation processes within research and innovation. It is these ethical considerations which the report aims to identify, along with the status quo attempts to address the ethical considerations. Additionally, the report attempts to identify the interplay of various actions that affect the ethical assessment procedures and any lacunae which presently exist within the system.

1.2 OBJECTIVES

The aim of this report is determine how globalisation is changing research agendas, activities and assessment procedures, and how these changes may cause problems for ethics assessment The report explores and measures the positive and negative impacts of the globalisation of research activities on their ethical dimension, taking account of efforts under way through international collaboration to address these concerns

The partners will conducted six case the considering the globalisation of research activities by various stakeholders, within academia as well as industry. The authors considered the globalisation of research activities by different stakeholders and standardized the format to allow the feeding of an accessible set of texts into the partners' subsequent discussions. Each of the case studies also provided a basis for discussion for Milestone 6, the "Policy and Legal Options for Developing Ethics Assessment for Research and Innovation within the Context of Globalisation" Conference. The results of the conference will then be incorporated into a policy briefing document.

1.3 METHODOLOGY

In order to develop the present text, the authors embarked on a two part process. Initially, a literature review was performed in order to gain a preliminary understanding of how globalisation affected research and innovation until the present day. After a general literature review, the partners identified multiple themes and issues that were relevant to ethics assessment practices. The literature review team then researched the specific themes further. After a group discussion, a consensus for 6 case study themes emerged. Each partner in charge of the case study then performed a more in depth literature review, identified interviewees for the case study, and developed a presentation to share with stakeholders at the "Policy and Legal Options for Developing Ethics Assessment for Research and Innovation

Within the Context of Globalisation" Conference. The case study presentations served as a foundation for discussion to identify actionable areas within the theme with the consortium partners could highlight and deliver a recommendation in the form of a Policy Briefing Document in month 20 of the SATORI project.

2 GLOBALISATION OF RESEARCH AND INNOVATION

2.1 INTRODUCTION

This chapter comprises a review of the literature on the globalisation of research and innovation (R&I). It provides an account of the ways in which the organisation of research, innovation and development has changed over the last few decades. In total, eight important aspects of changing research and innovation practices have been identified, each of which will be detailed in the sections below.

The globalisation of research and innovation has taken many forms. There has been growth in terms of: multinational R&I in multinational organisations; relocation of company R&D to affiliates abroad; international trade in R&D services, patents, and licenses; international cooperation through R&D networks, alliances and agreements; recruitment of foreign R&D workers in public and private organisations; general global diffusion of knowledge and access to local resources; and internationally located company supply chains. Globalisation processes have also sped up over the last decades, facilitated by modern global information and communication systems and increasingly modularized innovation processes.

It should be noted that the globalisation of R&I does not affect all regions of the world in an equal manner. Most R&I internationalization still takes place within a triad consisting of Europe, North America, and Japan, and developing nations are still in a subservient position with regard to globalized R&I activity (i.e., many processes are unidirectional). Nevertheless, there has been a dramatic increase in the size and level of globalized R&I activity in some developing nations, such as China, India, and Brazil. Furthermore, the level of R&I globalisation not only varies by region or country, but also by sector, with R&I in high-tech industries such as the pharmaceutical and communications industries being among the most globalized.

2.2 FACTORS UNDERLYING THE GLOBALISATION OF RESEARCH AND INNOVATION

2.2.1 GROWTH OF MULTINATIONAL RESEARCH AND DEVELOPMENT IN MULTINATIONAL ORGANISATIONS

The first modern (i.e., non-colonial) multinational corporations—defined as companies that own assets for the production of goods and services in more than one nation—started to emerge in the U.S. in the 1920s and 1930s.[1] Since that time, these corporations have increased in number and size, and, by extent, power. This is especially the case for the industrial sectors. In almost all global industrial sectors, there are now four or five leading multinationals that substantially control the production and direction of the sector.[2] The distribution of multinational corporations has also widened; many nations historically

[1] *Global Transformations and World Futures: Knowledge, Economy, and Society, Vol. 1.: Multinational Corporations*.
[2] Ibid.

excluded by lack of industrial development are now headquarters to multinationals.[3] Nevertheless, it is still the U.S., the U.K., Germany, France, and Japan that occupy a dominant position in this regard.[4]

Over the last decades, the growth of multinational corporations has been accompanied by a growth in multinational R&D in those organisations.[5] One of the major sources of competitive advantage for multinationals is their ability to leverage globally dispersed subsidiary-specific advantages and generate new knowledge through the synthesis of globally dispersed knowledge.[6] Along with increased multinational R&D, one sees an evolution from centralized or *multi-domestic* R&D structures (i.e., R&D that is centralized in one location or a few highly independent locations) to hub or network-like structures that are characterized by knowledge sharing and collaboration.[7] R&D structures are becoming less hierarchical and increasingly comprise interdependent units that are closely connected to one another through diverse and flexible coordination and control mechanisms.[8,9,10] A variety of typologies have been created of R&D configuration patterns within multinational companies.[11,12,13,14,15] For example, two authors find five archetypical patterns of global R&D configuration, which they name e*thnocentric centralized*, *geocentric centralized*, *polycentric decentralized*, *R&D hub*, and *integrated R&D*.[16]

In addition to multinational corporations, the previous century also saw the emergence of large multinational public research organisations, such as the European Organisation for Nuclear Research, the European Molecular Biology Laboratory, the European Bioinformatics Institute, the Intergovernmental Panel on Climate Change, and the International Thermonuclear Experimental Reactor. There is little research on the patterns of multinational R&D within these organisations.

2.2.2 Increased research and development activity in the non-Western world

Globally, there has been an increased focus on research and development (R&D) activities over the last few decades. This increased focus is apparent in measures such as R&D expenditures, peer-reviewed scientific articles published, number of researchers, and high-tech exports worldwide, all of which have grown.[17] The growth of R&D activity is not spread evenly, however; much of it has been in regions and countries outside the Western world.

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[3] Ibid.
[4] Ibid.
[5] Ibid.
[6] *Strategic Management Journal*, Vol. 23, No. 11, pp. 979–996.
[7] Li, C. R. (2014). Patterns of R&D Configuration and Evolution in MNCs. http://druid8.sit.aau.dk/acc_papers/plmpjbgr50qa3evr21tq18idqee6.pdf
[8] *Research Policy*, Vol. 28, pp. 231–250.
[9] *Research Policy*, Vol. 31, pp. 569–588.
[10] *Academy of Management Executive*, Vol. 16, pp. 55–66.
[11] *Long Range Planning*, Vol. 35, pp. 245–267.
[12] Li, C. R. (2014), op. cit.
[13] Von Zedtwitz, M. & Gassmann, O. (1999), op. cit.
[14] Von Zedtwitz, M., & Gassmann, O. (2002), op. cit.
[15] DeSanctis, G. et al. (2002), op. cit.
[16] Von Zedtwitz, M., & Gassmann, O. (1999), op. cit.
[17] National Science Board (2010). Globalisation of Science and Engineering Research: A Companion to Science and Engineering Indicators 2010. http://www.nsf.gov/statistics/nsb1003/.

The global expansion of R&D had always been largely one of investments by multinational companies moving from one advanced economy into another advanced economy.[18] Indeed, member states of the *Organisation for Economic Cooperation and Development* (OECD)—most of which can be considered advanced industrial nations—accounted for an estimated 82 percent of the total worldwide R&D in 2000.[19] However, the globalisation of R&D has recently entered a new phase, one of geographical widening and deepening. While total worldwide R&D has increased at a modest rate, there has been a dramatic growth of R&D activity in China, India, Brazil, and some developing nations in Southeast Asia.[20] China and India are now considered two of the biggest engines driving innovation, together being responsible for 20% of global investment in R&D.[21] Nevertheless, the globalisation of R&D is geographically far from all-encompassing, because large parts of Africa, South America and central Asia remain entirely off the global R&D map.[22]

In China, the ratio of R&D spending to gross domestic product (GDP) has more than doubled from 0.6 percent to 1.4 percent between 1996 and 2005.[23] This phenomenon has been characterized as a science and technology *take-off*.[24] The business sector accounts for most of the growth of China's total R&D intensity.[25] Much of it is also linked to foreign organisations, although R&D by domestic organisations has also been growing very quickly.[26]

The overall international growth of R&D activity is driven by enhanced science and technology capacities in countries around the world.[27] Crucial to building these capacities are governments, which have been (1) crafting strategic plans for science and technology, (2) investing funds in science and engineering R&D, education, facilities, and open markets, and (3) imposing further conditions that are favourable to R&D, relating, for example, to intellectual property rights.[28] Moreover, the globalisation and growth of R&D activity have been greatly facilitated by enhanced communications, access to R&D knowledge, training, and facilities, freedom of travel in many nations, and sharing of resources.[29]

The SATORI case study report on "brain drain" offers some examples of policy measures taken by developing countries that have helped to prevent emigration of skilled workers by building national science and technology capacities.

[18] *Regional Studies*, Vol. 24, pp. 495–512.
[19] *Science and Engineering Indicators, 2006*. Arlington, VA: National Science Foundation.
[20] *R&D Management*, Vol. 38, No. 3, pp. 241–252.
[21] Roland Berger (2012). Emerging markets drive innovation – China and India investing heavily in research and development. http://www.rolandberger.com/press_releases/512-ress_archive2012_sc_content/Emerging_markets_drive_innovation.html.
[22] Ibid.
[23] *Asia Pacific Business Review*, Vol. 13, No. 3, pp. 357–371.
[24] Ibid.
[25] Ibid.
[26] Ibid.
[27] National Science Board (2010), op. cit.
[28] Ibid.
[29] Ibid.

2.2.3 RELOCATION OF PRIVATE COMPANY R&D TO AFFILIATES ABROAD

Increasingly, over the past decades, private companies have been moving their R&D activities offshore. Offshoring is the relocation by a company of a business process—often an operational process, such as manufacturing—from one country to another.[30] There are two basic modes of offshoring R&D: one is to perform the R&D *in-house* at company affiliates abroad; another is to *outsource* the R&D.[31] This section discusses the former mode, in which R&D is relocated to foreign subsidiaries. The next section discusses the latter mode, in which R&D is contracted out to foreign unaffiliated companies or institutions.

The largest European, U.S., and Japanese firms have a long history of supporting R&D activities in other industrialized countries through subsidiaries. Western European firms are those most likely to locate their R&D outside their home country, followed closely by North American firms, and then by Japanese firms.[32] In 2006, the proportion of large firms in the EU with at least some of their R&D activity taking place abroad was about 65 percent.[33] Corporations have recently also moved to take advantage of the R&D capabilities of developing nations. In 2005, China and India were the third and sixth largest global destinations of R&D funding by multinational enterprises—while the U.S. and the U.K. were first and second.[34] Out of the 885 R&D-oriented *greenfield* (i.e., newly created, not resulting from mergers and acquisitions) foreign direct investment projects announced in Asia that year, 723 (or about three-quarters) were in China and India.[35] Interestingly, a number of companies in China and India have recently also started to globalize their R&D activities.[36]

The reasons why firms expand their R&D activities abroad can generally be grouped according to whether they serve an *asset-exploiting* strategy or an *asset-augmenting* strategy.[37,38,39] In the first case, the globalisation of R&D serves to transfer technological assets developed in the home country to the foreign subsidiaries where these assets are exploited, usually after some adaptation to the characteristics of foreign markets.[40,41] In the second case, companies make R&D investments abroad in order to acquire resources only available at foreign locations and to improve their stock of knowledge.[42] Nowadays, although both strategies are common, the globalisation of R&D is increasingly driven by an asset-augmenting motivation.[43]

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[30] http://en.wikipedia.org/wiki/Offshoring.
[31] *The Internationalization of Corporate R&D: Leveraging the Changing Geography of Innovation*. Stockholm: Swedish Institute for Growth Policy Studies (ITPS).
[32] Hall, B.H. (2009). The Internationalization of R&D. http://www.international.gc.ca/economist-economiste/assets/pdfs/research/TPR_2011_GVC/09_Hall_e_FINAL.pdf, p. 184.
[33] *Sharing the idea: The emergence of global innovation networks*. London: The Economist Intelligence Unit.
[34] *World Investment Report: Transnational Corporations and the Internationalization of R&D*. New York and Geneva: United Nations.
[35] Ibid.
[36] Ibid., p.6.
[37] *The Oxford Handbook of Innovation*, Oxford: OUP, pp. 318– 345.
[38] *Internationalisation of R&D: Trends, Issues and Implications for S&T policies*. Brussels: Organisation for Economic Co-operation and Development.
[39] *Journal of International Business Studies*. Vol. 40, pp. 5–19.
[40] *Managing the Global Firm*, Routledge: London, pp. 215–255.
[41] *Journal of Economic Behaviour & Organisation*, Vol. 65, No. 2, pp. 277–302.
[42] *Research Policy*, Vol. 26, pp. 85–103.
[43] *Industrial and Corporate Change*, Vol. 20, No. 2, pp. 585–603.

The specific reasons as to why European multinational companies move their R&D capacities abroad mainly relate to: (1) access to specialized R&D knowledge; (2) availability of researchers; and (3) reliability of the legal framework for R&D, notably the parts relating to the protection of intellectual property.[44] Moreover, the development of global information and telecommunications networks and modularized innovation processes are key enablers of R&D offshoring.[45]

In addition to national differences in terms of R&D activity by foreign companies, there are also significant differences between industrial sectors. Firms in industries with higher technological complexity tend to retain their technological activities in their country of origin.[46] Firms in more traditional sectors, such as the tobacco, food and drink, building materials, transport, mining and petroleum industries, tend to have the most foreign R&D activity.[47] The pharmaceutical and medical industries are at an intermediate level with above average foreign R&D activity.[48] In China and India, foreign R&D investment is mostly limited to the information and communication technology industry (which has by far the largest share), the health industry (i.e., pharmaceuticals, biotechnology, and various chemical, preclinical, and clinical services) and the automotive industry.[49]

2.2.4 INTERNATIONAL TRADE IN R&D SERVICES, PATENTS, AND LICENSES

In the last two decades, companies have increasingly been able to access knowledge and technologies produced or located abroad through international trade. R&D services, technologies, patents, and licenses have been imported and exported. International trade can occur between parent companies and foreign R&D affiliates, or between companies and other external public or private entities.

In addition to establishing company divisions abroad (as discussed in section 3), multinational knowledge-intensive firms are hiring external organisations in other countries to perform some of their R&D work, thus engaging in *offshore outsourcing*. They have not only been hiring R&D service providers in the developed world, but also, increasingly, those located in developing countries such as China and India.[50,51,52,53] Whereas access to specialized R&D knowledge is often the prime motive for outsourcing R&D to developed countries, access to lower cost labour is still the main motive for outsourcing R&D to developing countries.[54,55,56]

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[44] Ibid.
[45] *The Internationalization of Corporate R&D Leveraging the Changing Geography of Innovation*, Östersund, Sweden: Swedish Institute for Growth Policy Studies.
[46] Gammeltoft, P. (2006). Internationalisation of R&D: Trends, Drivers, and Managerial Challenges. International Journal of Technology and Globalisation, Vol.2, No. 1, pp. 177–199
[47] Ibid.
[48] *Review of International Political Economy*, Vol. 9, pp. 98–122.
[49] Bruche, G. (2009), A new geography of innovation—China and India rising, Columbia University Academic Commons. http://hdl.handle.net/10022/AC:P:8774.
[50] *Journal of International Management*, Vol. 13, No 1, pp. 7–21.
[51] *Journal of International Management*, Vol. 15, pp. 156–168.
[52] *Journal of International Management*, Vol. 15, 181–193.
[53] *Journal of International Management*, Vol. 15, No. 2, pp. 121–125.
[54] UNCTAD (2005), op. cit.
[55] Atkinson, R.D. (2007). The Globalisation of R&D and Innovation: How Do Companies Choose Where to Build R&D Facilities? http://www.itif.org/files/AtkinsonHouseRDOffshoreTestimony.pdf.
[56] Booz Allen Hamilton and INSEAD (2006). Innovation: Is Global the Way Forward? http://www.boozallen.com/media/file/Innovation_Is_Global_The_Way_Forward_v2.pdf.

Salaries for R&D personnel in a country such as China can be as low as 1/6th of those in the U.S.[57] Among the organisations offering R&D services there is some level of diversity; in many parts of Europe, for example, universities and other public research institutions are important players besides private companies. Offshore outsourcing is prevalent in such industries as pharmaceutics, electronics, software, and transportation.

Within the pharmaceutical industry, clinical trials are frequently outsourced.[58] Clinical trials occur on a global scale as companies and government sponsors in wealthy nations move them to less wealthy countries.[59] Many clinical trials are being conducted in developing countries in Asia, Africa and Latin America. Companies conduct clinical trials in these countries for the reasons that include: (1) the significantly lower costs of research due to cheaper human labour, (2) the large pools of potential research participants, (3) the increasingly expensive and time-consuming bureaucratic regulatory environment in many wealthy countries, and (4) the potential to overcome regulatory barriers for drug approval in these countries in which the population size alone offers the promise of expanding markets.[60]

The trade in patents and licenses is another aspect of the globalized R&D marketplace. Companies and institutions may sell or license their patent rights to other organisations around the world. The worldwide market for licenses was estimated to have been worth 100 billion dollars in 2003.[61] Foreign ownership of domestic inventions is increasing.[62] In early 2000, on average 15 percent of all inventions in OECD countries were owned or co-owned by foreign organisations and individuals, up from 11 percent in 1992.[63] In small, open economies such as Switzerland, Ireland and the Netherlands, the level of domestic ownership of inventions developed abroad is particularly high—respectively, 48, 42 and 30 percent.[64]

2.2.5 INTERNATIONAL COOPERATION THROUGH R&D NETWORKS, ALLIANCES, AND AGREEMENTS

There has been increasing international cooperation in public and private sector R&D around the world. International collaboration in R&D encompasses joint research projects, resource/data sharing, international conferences, efforts to build international databases, funding to maintain international laboratories, efforts to set technical standards, and technical assistance (or "development aid") in science and technology.[65]

In academic and publicly funded science and engineering, there have been international collaborations on research projects with scopes and scales so large that they require the sharing of research efforts, data sets, and equipment.[66] These include facilities such as the

[57] Atkinson, R.D. (2007), op. cit.
[58] *The New England Journal of Medicine*, Vol. 360, pp. 816–823.
[59] Ibid.
[60] Ibid.
[61] *Intellectual property as an economic asset: key issues in valuation and exploitation International conference European Patent Office – EPO-OECD-BMWA CONFERENCE SUMMARY REPORT*, Paris: OECD Publications.
[62] Karlsson, M. (2007), op. cit.
[63] Ibid.
[64] Ibid.
[65] *International Cooperation in Research and Development: An Update to an Inventory of U.S. Government Spending*. Santa Monica, CA: RAND Corporation.
[66] Ibid.

International Space Station, the Large Hadron Collider, the Gemini Telescope, the International Thermonuclear Experimental Reactor, and the Sesame X-Ray Synchrotron. Other joint projects concern research on topics with global significance such as climate change, earthquakes, and infectious diseases. Several intergovernmental organisations exist to coordinate global research, such as UNESCO, the UN Committee on Science and Technology for Development, and the International Council for Science.

In corporate R&D too, there is increasing international collaboration. The number of newly established international strategic technology alliances has increased considerably since the mid-1980s.[67,68] By the late 1990s, international partnerships represented about 50 percent of the total number of R&D partnerships.[69] The formation of these partnerships has been particularly extensive in the pharmaceutical and biotechnology industry (58 percent of total international partnerships in 2001) and information technology industry (28 percent of total in 2001).[70] About 80 percent of technology alliances from 1991 to 2001 involved at least one U.S.-owned company,[71] and the vast majority involved only Western firms.[72]

On a more basic level, the trend towards increased international collaboration is equally evident, with increasing international participation in the peer-reviewed literature and international co-authorship of scientific publications and patent applications. From 1995 to 2010, the number of internationally co-authored publications in the physical, natural, and social sciences more than doubled from 79.128 to 185.303 publications.[73] Many possible explanations have been proposed for this phenomenon, including the sharing of resources, ideas, and expertise.[74] In early 2000, seven percent of all patents were the result of international cooperative research.[75]

2.2.6 RECRUITMENT OF FOREIGN R&D WORKERS IN PUBLIC AND PRIVATE ORGANISATIONS

There has been an increasing international flow of R&D workers. Companies, universities and public research institutes have been recruiting foreign skilled workers for employment in the country of origin or at foreign subsidiaries. These workers may bring localized knowledge or high-level scientific and technological skills that organisations may be lacking.[76] Companies sometimes have internal exchange programmes for scientists and engineers.[77]

Attracting highly skilled researchers and engineers has also been a priority for policymakers. Driven by demands from companies and business associations, governments around the world are removing barriers for international mobility and have implemented various policies aimed

[67] *Cooperative Strategies and Alliances*, Oxford: Elsevier Science Ltd.
[68] Wagner, C., Yezril, A., & Hassell, S. (2001), op. cit.
[69] Hagedoorn, J., & Osborn, R.N. (2002), op. cit.
[70] UNCTAD (2005), op. cit.
[71] Karlsson, M. (2007). International R&D Trends and Drivers, op. cit.
[72] UNCTAD (2005), op. cit.
[73] *Science and Engineering Indicators, 2012*. Arlington, VA: National Science Foundation.
[74] *PLoS ONE*, Vol. 8, No. 9.
[75] Karlsson, M. (2007), International R&D Trends and Drivers, op. cit.
[76] Ibid.
[77] Ibid.

at attracting, retaining, repatriating and circulating talent.[78] Firstly, policymakers have pursued immigration regime reforms. Many countries have liberalized immigration policies, simplified immigration procedures and expedited application process, issued work permits for foreign researchers, and increased entry quotas and special funding programmes (e.g., post-doc programmes).[79] Secondly, they have provided tax discounts to attract foreign skilled workers. Countries that have done so include Australia, Austria, Denmark, the Netherlands, Sweden, and the U.K.[80] Thirdly, in an effort to repatriate skilled people from large diasporas, they have put in place policies to support expatriates who have returned, which involve funds for fellowship programmes, higher salaries and fixed-period tenures at universities or research institutions. Several networking initiatives have also been launched to link foreign researchers and engineers to their home countries.[81] Finally, policymakers have addressed other barriers to the international flow of skilled workers, which mostly relate to culture and language, accreditation of academic qualifications (e.g., the Bologna Declaration in Europe), and science and technology regulations (e.g., concerning ethics, safety and intellectual property).[82] The SATORI case study report on "brain drain" offers some detailed examples of policy measures that have been taken by countries to prevent emigration of skilled workers.

2.2.7 General global diffusion of knowledge and access to local resources

In the last few decades, there has been increasing global diffusion of knowledge and global access to local resources. One aspect is the increased unintentional diffusion of technological knowledge associated with manufacturing and distribution of innovative, high-tech products, which sometimes happens through *reverse engineering*[83] of imported goods.[84] Furthermore, there is increased global access to general R&D knowledge, training and facilities, which has been facilitated by advances in information and communications technology and transportation technology. Finally, there is increased global diffusion of *indigenous knowledge*, which can be defined as a cumulative, often tacit, body of knowledge, know-how, practices and representations maintained and developed by peoples with extended histories of interaction with the natural environment.[85] Indigenous knowledge has found use in, for example, screening efforts for bioactive compounds that could be used in medicines. The process of discovery and commercialization of new products based on biological resources is known as *bio-prospecting*, and has only recently begun to incorporate indigenous knowledge.[86] Other application areas of indigenous knowledge include agriculture and food science.

[78] *The Internationalization of Corporate R&D Leveraging the Changing Geography of Innovation*, Östersund, Sweden: Swedish Institute For Growth Policy Studies.
[79] *Swedish Open – The Need for Attracting Foreign Skills*. Stockholm: Invest in Sweden Agency.
[80] Karlsson, M. (2007). The Challenges of International Corporate R&D, op. cit.
[81] Ibid.
[82] Ibid.
[83] Reverse engineering is the process of extracting knowledge or design information from a finished product.
[84] Karlsson, M. (2007). International R&D Trends and Drivers, op. cit.
[85] ICSU and UNESCO (2002). Science, Traditional Knowledge and Sustainable Development. http://www.icsu.org/Gestion/img/ICSU_DOC_DOWNLOAD/65_DD_FILE_Vol4.pdf.
[86] *Proceedings of the National Academy of Sciences of the United States of America*, Vol. 109, No. 39, pp. 15835–15840.

2.2.8 EXPANSION OF COMPANY SUPPLY CHAINS INTO INTERNATIONAL LOCATIONS

The last few decades have witnessed the considerable expansion of supply chains into international locations, especially in the automobile, computer, and apparel industries.[87] Increasingly, companies have chosen to break down their production process into various distinct activities that are organized and performed in distinct locations spread across different countries or regions.[88] This spatial fragmentation of production involves the entire supply chain, beginning with the conception of the product and ending with its delivery. With global supply chains, companies aim to take advantage of differences in technologies, factor endowments (i.e., the amount of land, labour, capital, and entrepreneurship that a country possesses and can exploit for manufacturing), or factor prices (i.e., the prices of these production factors) across places.[89] The most commonly observed pattern corresponding to international fragmentation is the relocation by firms of their production activities in low-wage countries. This action is regarded as one of the main ingredients of the process of economic globalisation.[90]

3 A REVIEW OF ETHICAL ISSUES ARISING FROM THE GLOBALISATION OF RESEARCH AND INNOVATION

3.1 INTRODUCTION

Globalisation – 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" (Giddens 1990, p. 64) – is without a doubt a prominent feature of contemporary life. Concomitant with social, economic, cultural and political processes of globalisation, in recent decades there has been an intensification of the globalisation of different processes of scientific research and technological innovation (Gibbons et al. 1994; Archibugi & Iammarino 2002). Related to the globalisation of the many aspects of research and innovation, there has been an increasing attention to ethical issues in the globalisation of research and innovation. The present paper identifies and systematically reviews the most important ethical issues associated with the globalisation of research and innovation.

In this review, 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.

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

[87] *Global Operations and Logistics: Text and Cases*. New York: John Wiley & Sons, Inc.
[88] *International Economic Review*, Vol. 47, pp. 811–836.
[89] *Journal of Economic Perspectives*, Vol. 12, pp. 31–50.
[90] Fujita, M., & Thisse, J.F. (2006), op. cit.

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 research and development; 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.

3.2 ETHICAL ISSUES AT THE RESEARCH AND DEVELOPMENT STAGE

3.2.1 OUTSOURCING OF R&D TO DEVELOPING COUNTRIES

One of the aspects of the globalisation of research and innovation is the outsourcing (or off-shoring) 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 naïve patients, that is patients who have never received treatment, facilitates the recruitment of patients to be involved in a clinical trial. (European Commission 2003).

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.[91]

Under such circumstances, pharmaceutical firms and laboratories can resort to what has been described as *"double standards"* (or *"ethics dumping"*), which refers 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 (Macklin 2004). 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.

3.2.2 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 (first written in 1964, and since 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. Thus, 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 (Koelch et al. 2009). 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 (Silversides 2009). It can be suggested that one way of protecting potential research subjects from taking part in clinical trials that might be harmful to them is through the involvement of

[91] See e.g., <http://www.alnmag.com/articles/2011/01/animal-welfare-asia-aaalac-international-experience> (Accessed: 20 April 2015).

family and friends in the decision-making process. Thus for example a recent study found that 92 per cent of patients in India involved other people in deciding whether to take part in a trial (Berman-Gorvine 2009). This however can raise further questions regarding the autonomy of individual patients.

3.2.3 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 (Laughton 2007). 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" (Widdows 2011, p. 217). 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 (Nuffield Council on Bioethics 2002).

3.2.4 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 Widdows (2011) 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.[92]

[92] Widdows, 2011.

3.2.5 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. (World Medical Association 2013).

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 groups of trial participants. While one group was given Zidovudine, the other was given a placebo (Merson 1998). 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*.

3.2.6 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 (Saslis-Lagoudakis et al. 2012). 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 (Corinne 2013). 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.

3.2.7 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 (Brownsword 2009). Secondly, it can be argued that group consent approach does not properly address more fundamental issues coercion, exploitation and power structure (Widdows 2011).

3.2.8 BENEFIT-SHARING

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 (Moran 2000).

3.2.9 GLOBAL RESOURCE ALLOCATION AND DISTRIBUTIVE JUSTICE

The globalisation of research and development, 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 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 (Benatar 2004). 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.

3.2.10 SCIENTIFIC INTEGRITY AND RESPONSIBLE RESEARCH CONDUCT

Research misconduct, in which principles of scientific integrity are not adhered to, is a significant problem in science today (Ana et al. 2003; Fanelli 2009; Kakuk 2009). 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.

3.2.11 BRAIN-DRAIN IN DEVELOPING OR UNDER-DEVELOPED COUNTRIES

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"* (Cervantes & Guellec 2002). Thus, the problem of brain-drain is a global problem that requires global solutions (Pang et al. 2002).

3.3 ETHICAL ISSUES AT THE MANUFACTURING OR 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); (3) as well as the question and extent of adherence of supply chains to ethical standards.

3.3.1 SOCIAL EFFECTS

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 (Uttley 1993; Hendry 1995; Harland et al. 2005). 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 (Hendry 1995; Arnold 2000; Harland et al. 2005). 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.

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 (Harland et al. 2005). 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" (Harland et al. 2005).

3.3.2 ENVIRONMENTAL EFFECTS

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 (Yearley 2007; O'Brien & Leichenko 2000). 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. As Widdows put it: "one form of injustice compounds other injustices and the result is further disadvantage and injustice for those already at the bottom of the heap" (Widdows 2011).

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 (Babu et al. 2007). 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 (Babu et al. 2007). 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 (Moyers 1993; Miller 1995). 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.

3.4 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.

3.4.1 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.

3.4.2 ISSUES OF LIABILITY

The fact that certain developing countries have limited regulation and enforcement of product liability (Reimann 2003, p. 753) gives rise to the issue of (global) responsibility and liability for the products marketed and sold in such countries.

3.5 CONCLUSION

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 research and development, 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 (see e.g., Macnaghten 2014).

4 POLICIES AND ACTIONS TO MITIGATE THE UNDESIRABLE AND UNETHICAL CONSEQUENCES OF THE GLOBALISATION OF RESEARCH AND INNOVATION

4.1 INTRODUCTION

Scientific and technological advances abound with the effects of continued globalisation. With this shift, ethical issues are also arising in fields of research and innovation, necessitating policy modifications to account for these changes. This review discusses the existing policies in place at both the level of the European Union as well as broader intergovernmental organisations which address ethical concerns arising due to the globalized nature of the current scientific landscape, particularly related to the stages of research and innovation. This includes direct applications of pre-existing policies developed by such institutions as well as implementation of new policies specific for this purpose. This review will discuss the framework of intergovernmental institutions including the United Nations; the United Nations Educational, Social, and Cultural Organisation; the World Health Organisation; the Organisation for Economic Cooperation and Development; the Council for International Organisations for Medical Sciences, as well as within the European Union and their policies respective to ethical concerns due to globalisation in research & innovation. Furthermore, there will be a discussion of specific actions taken with respect to such policies in order to mitigate potential ethical issues in R&I.

4.2 POLICIES OF GLOBAL INTERGOVERNMENTAL ORGANISATIONS

In this section, we will present the general structure of major intergovernmental agencies with significant roles in R&I policy-making. The organisational structures and their primary objectives will be discussed, particularly as related to R&I. Core policies from various intergovernmental and supranational regulatory bodies will be referenced, specifically their primary intents and modes of implementation. In addition, we will examine the manner in which such policies inform the standard of ethical action in the research process.

4.2.1 INTRODUCTION

The primary intergovernmental and supranational organisations in ethics-centred policy development related to R&I include the UN, UNESCO, OECD, WHO, and CIOMS. Amongst these, different organisations address specific issues within R&I policy, which will be broken down further in this paper. These organisations, both governmental and nongovernmental, are instrumental in developing ethics policies for research and innovation. As globalisation becomes more ensconced into the world's economic and social climate, these agencies have led the charge of ethical assessment and policy-making for new issues that have emerged. While certain long-standing policies related to human rights and ethics of R&I can be effectively applied in the context of globalized research, new regulation has also been introduced to incorporate relevant ethical issues that have been brought to the forefront more recently. These policies will be specifically addressed later in this review.

The United Nations (UN) is a socio-political intergovernmental institution comprised of 193 members states established to promote international solidarity and partnership. The core objectives of the organisation include: maintenance of international peace and security,

promotion of sustainable development, protection of human rights, upholding international law, and delivery of emergency and humanitarian aid.[93] The UN charter acts as a binding contract which member states must abide by; additionally, resolutions passed by the UN General Assembly or the other five fundamental organs have been ratified into law in certain member states. UN policies function contemporaneously with individual national legislation in order to achieve its goals and most successfully promulgate its aims.

The United Nations Educational, Social, and Cultural Organisation (UNESCO) is another key player in ethics policy development and dissemination. As a specialized agency of the UN, UNESCO also seeks to promote international cooperation but specifically through five major programmes which are education, natural sciences, social/human sciences, culture, and communication/information. UNESCO has a significant role in involving human rights for research projects, as it advocates for upholding freedoms and civil liberties for humankind. UNESCO has two predominant subcommittees specific to bioethics; the International Bioethics Committee and the Intergovernmental Bioethics Committee, both of which are instrumental in developing policy related the current affairs in the field. Also, the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), which is comprised of leading representatives from global science communities, is involved to a greater degree with ethics policy specific to R&I.[94] Prominent themes within UNESCO policy include: human rights and bioethics, and human rights related to the genome and genetic data.

From a more development standpoint, the Organisation for Economic Co-operation and Development (OECD) is also involved in developing ethics policy. As the major scope of the OECD is economics-focused, the issues that arise are more related to the innovation component of R&I. The OECD sets international standards aligned with its goals of enhancing global productivity and growth. Recommendations from the OECD address economic implications of research and innovation on populations, and seek to maintain well-being of citizens from this perspective.[95] These recommendations are targeted for both governmental institutions as well as the private sector. The OECD has developed a number of evidence-based research policies related to the ethics of R&I from an economic perspective for both developing and developed nations. Generally, the OECD attitude towards R&I is focused on utilizing the beneficial outcomes of innovation to economic health and to bolster international market cooperation. This can include resolution of "the economic challenges facing countries, along with the changing social landscape and the expectations surrounding innovation."[96] With regard to globalisation, the OECD seeks to establish and equal international platform for trade to ensure that emerging economies are able to compete with more established markets.

The World Health Organisation (WHO) is invested in ethics of R&I to protect the interests of human health throughout the research process. One of the monumental steps of the WHO was to publish the most widely accepted and referenced definition of health. The World Health Assembly is the main governing body, which establishes a consortium of health advocates with global representation from Member states. The WHO works with the UN in order to "position health in the debates and decision of UN intergovernmental bodies …and promote

[93]"What We Do | United Nations." *UN News Centre*. United Nations, 2015. Web.
[94]"COMEST." *World Commission on the Ethics of Scientific Knowledge and Technology*. UNESCO, June 2015. Web.
[95]"About the OECD." *OECD*. Organisation for Economic Co-operation and Development, n.d. Web.
[96] Olsson, Å. (2012). *Programme on Innovation, Higher Education and Research for Development IHERD*.

alliances and interagency approaches to address health issues."[97] Along with the UN system, the WHO also holds partnerships with national and supranational organisations, both for profit and non-profit, with invested interests in improving health and well-being. The WHO works to develop policy for health planning, to facilitate access to equitable and effective health services, and understand and address the environmental and social determinants of health. Ethical issues are handled by the Research Ethics Committee (ERC); this committee also reviews directly all research projects with human participants sponsored by the WHO.

The C*ouncil for International Organisations of Medical Sciences* (*CIOMS*) was established jointly WHO and UNESCO as a collaboration of numerous representatives from the biomedical sciences. Members include national and international medical and research institutions, a wide distribution which allows the organisation to incorporate a range of perspectives related to clinical research and innovation. CIOMS ethics subcommittee is at the forefront of integrating ethical issues that arise from a broad global vantage point, such as informed consent, subject recruitment, and standards of review.[98]

4.2.2 R&I POLICY

Innovation application to economic infrastructure

Innovation and Growth: Rational for an Innovation Strategy, is an example of OECD policy that centres on impact of globalisation for R&I. The document has developed a reform agenda in order to better support new information and communication technologies (ICT) on a global level and make "regulatory frameworks more conducive to innovation in a range of policy areas."[99] Examples include better management and public funding of science research, as well as tax credits or incentives for the private sector to encourage innovation. The system is intended to help resolve global challenges, including sustainable development and environmental problems. The document does not directly present ethical challenges, but refers to certain hurdles that have an ethical component, for example, support of entrepreneurs pursuing frontiers in science while maintaining rights for established corporations in similar industries. Additionally, the strategy contends that "globalisation has made imitation and counterfeiting both more rewarding (in an expanded market) and more feasible;" this generates ethical concerns of intellectual property and economic value of protecting ICT innovation as opposed to the open-sharing platform encouraged for other research. However, the OECD studies have determined that restrictive economic regulations in product and labour markets, and productivity growth are inversely linked, thus dissuading further innovation.[100]

Also in within scope of governance for R&I is the OECD Innovation Strategy. This policy was developed during the economic recession of 2008-2009, and thus reflects key changes recommended by the OECD to mitigate the detrimental effects and reverse damages. The policy suggests that governments can work to accommodate innovation by implementing "structural reforms in education and training policies, in entrepreneurship policies, in product and labour markets, in public research institutions, and [establishing policies such as pro-

[97]"WHO." *About WHO*. World Health Organisation, 2015. Web.
[98]"About Us." *CIOMS*. Council for International Organisations of Medical Sciences, n.d. Web.
[99]Organisation for Economic Co-operation and Development. *Innovation and Growth: Rationale for an Innovation Strategy*. Paris: OECD, 2007. Web.
[100]Organisation for Economic Co-operation and Development. *Economic Policy Reforms: Going for Growth 2007*. By Jean-Philippe Cotis. London: OECD, 2007.Web.

growth tax reform] to help develop networks and markets for knowledge."[101] The ethical component within the Innovation Strategy is the application of innovation to mitigation of global and social challenges. The most salient ethical points are related to parallel maintenance of flexibility to develop innovation by autonomous means and encouraging enterprises to promote valuable technologies that are cost-effective and applicable to current global challenges. For example, agriculture-centred technology for streamlining the food production process is crucial for resolving social challenges such as food shortage, but may possess as less substantial net financial return considering the necessary invested capital. In order to address such issues, the Innovation Strategy utilizes five priorities to guide government policy development and action. The underpinning priorities are: "empowering people to innovate, unleashing innovation in forms, creating and applying knowledge, applying innovation to address global and social challenges, and improving the governance and measurement of policies for innovation."[102] Furthermore, the policy acknowledges that R&D is not the only mode of innovation in today's climate; firms are capitalizing on "a wide range of complementary technological and non-technological changes and innovations," coupled with international collaboration to achieve progress. This subsequently generates the need for ethical regulations geared towards new technological methods of development, which may not have been already addressed in existing ethics frameworks. As the strategy also highlights the value of human capital in innovation, ethics policy regarding international study as well as diverse workplace environments must be developed. In total, the policy seeks to establish well-developed markets that are conducive to the development and application of innovation and long-term access to technological and scientific advances.

Responsibilities of the investigator

UNESCO has issued policy that engages the role of the investigator in the ethics process. The Recommendation on the Status of Scientific Researchers outlines a policy related to individuals conducting research within various national frameworks and the ethical nuances that inform their work. The document stipulates that member states can use to evaluate researchers fairly, and lend support for valuable and morally sound research. As the document is fairly dated, the international component of these guidelines is somewhat limited. The recommendation includes a clause encouraging member states to support "socio-economic development efforts that will contribute to the consolidation of an authentic culture and of national sovereignty."[103] Noticeably absent are the obligations and responsibilities of researchers conducting global trials to the participant pool and their greater communities, which have been addressed in other research ethics policies. UNESCO has issued a call for the revision of this document, originally developed in 1974, and the meeting to discuss revisions is due to convene in 2017.[104]

Furthermore, from an industry standpoint, responsibilities of pharmaceutical corporations in providing access to medications is addressed in the 2008 report to the General Assembly by the Special Rapporteur on the Right to the Highest Attainable Standard of Health (Paul Hunt)

[101]Organisation for Economic Co-operation and Development. *Ministerial Report on the OECD Innovation Strategy*. Paris: OECD, 2010. Web.
[102]*The OECD Innovation Strategy: Getting a Head Start on Tomorrow*. Paris: OECD, 2010. Web.
[103]*Recommendation on the Status of Scientific Researchers*. Rep. Paris: UNESCO, 1974. Web.
[104]"Call for Advice: Revision of UNESCO Recommendation on the Status of Scientific Researchers | United Nations Educational, Scientific and Cultural Organisation." *Ethics of Science and Technology*. UNESCO, 2015. Web.

entitled "Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines."[105] The guidelines refer specifically to the lack of access to essential medicines in Africa and South-East Asia, and stipulate that pharmaceutical corporations make some contribution towards research and development for neglected and tropical diseases. Note that this does not mandate that the companies conduct in-house research actively for such diseases.[106]

The WHO has published a set of operational guidelines for various stages of research ethics, which have been instrumental policies geared for resolving ethical disputes in global R&I. The blanket policy produced by the WHO is the Strategy on research for health, in which policy attempts to "organize and manage [evidence-based research for health] in a systematic and comprehensive manner."[107]The strategy is organized into a five-pronged approach addressing the following objectives: Organisation, Priorities, Capacity, Standards, and Translation. Key weaknesses in each realm are identified within the document, and potential resolutions to these problems are presented sequentially. The main role of ethics falls into the category of "Standards Assessment". The strategy presents the need to improve the implementation and compliance of international ethics and ethics assessment standards. The policy recognizes that the WHO cannot directly enforce these guidelines; however the Translation component addresses how these frameworks can be subsequently developed into regulatory policies.[108] An additional component calls for the standardization of accreditation for global ethics committees, following the recognition of a lack of oversight agency to ensure consistency. In addition to this, the "Priorities" objective includes provisions for facilitating research in neglected areas and cultivating international collaboration to reconcile disparities in research capacity due to resources or funding.

Accessibility to scientific data

Issues of accessibility to scientific data and publication present another concern in globalized research and innovation. Most intergovernmental and supranational institutions, including those discussed in this review, have adopted a somewhat liberal approach to sharing resources, citing that this is in the interest of advancing scientific and technological progress. The key difference is that this does not necessarily coincide with the policies of individual nations that may not be governed by legally binding regulation enforcing these guidelines. This may give rise to ethical concern due to the fact that most nations have differing positions on the degree and at which point the research should be accessible to both the rest of the scientific community, as well as to the public.

UNESCO policy regarding the value of dissemination of science and technology is included in the Declaration on Science and the Use of Scientific Knowledge. The document proclaims that the "building of scientific capacity should be supported by regional and international cooperation, to ensure both equitable development and the spread and utilization of human creativity."[109] According to the evaluation by the policy-makers, open access to information, enhanced partnerships between developed and developing nations, and science education for

[105]Hunt, Paul. *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*. Publication. New York: United Nations, 2008. Web.
[106] Ibid
[107]*The WHO Strategy on Research for Health*. Rep. Geneva: World Health Organisation, 2010. Web.
[108] Ibid
[109]*Declaration on Science and the Use of Scientific Knowledge*. Rep. Budapest: UNESCO, 1999. Web.

minorities in the sciences are all fundamental components of growth and global cooperation in math and science fields. Furthermore, the ethical expectations of scientists and researchers are laid out in the document; they are called upon to "maintain high standards of scientific integrity and quality control, share their knowledge, communicate with the public and educate the younger generation."[110] COMEST is referenced as a potential ethical guide for scientists to ensure that they act in an ethically fair and sound manner when conducting research internationally.

One specific instance of the accessibility policy is the Universal Declaration on the Human Genome and Human Rights, which encourages that genomic data for humans and other species be made accessible to all due to the scientific value and promotion of the welfare of humankind. This policy is discussed in depth in section 3.2.3 [111]

Establishment of ethics committees

Appropriate and consistent assessment of ethics by national and local ethics committees is a further point to address, particularly in light of globalized research. Initiatives have been taken to institute policies which provide a platform upon which institutional regulation can be based and all key ethical bases covered. The Operational Guideline for Ethics Committees That Review Biomedical Research from the WHO provides a recommended course of action specifically for research ethics committees (RECs). RECs serve as oversight regulatory bodies which conduct a comprehensive ethical review and vetting of the research process.[112]

4.2.3 DEVELOPMENT POLICY

The Millennium Development Goals (MDGs) represent a milestone in both global and national development efforts and still form the basis of the UN development policy. The set of eight goals was introduced in the so-called United Nations Millennium Declaration. The Declaration was adopted in September 2000, following a three day Millennium Summit of world leaders at the United Nations Headquarters in New York which was attended by 149 Heads of State and Government and high-ranking officials from over 40 other countries.[113] The Millennium Development Goals are:

(1) To eradicate extreme poverty and hunger;
(2) To achieve universal primary education;
(3) To promote gender equality;
(4) To reduce child mortality;
(5) To improve maternal health;
(6) To combat HIV/AIDS, malaria, and other diseases;
(7) To ensure environmental sustainability;
(8) To develop a global partnership for development.

The universally-agreed objectives were measurable and time-bound, with a deadline set for 2015.

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[110] Ibid
[111] *Universal Declaration on the Human Genome and Human Rights*. Rep. Paris: UNESCO, 1997. Web.
[112] *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. Publication. Geneva: World Health Organisation, 2011. Web.
[113] See more: http://www.un.org/en/events/pastevents/millennium_summit.shtml

As a specialized agency of the United Nations focusing on development, the United Nations Development Programme (UNDP), was requested to be the MDG Scorekeeper.[114] In collaboration with the United Nations Development Group (UNDG)[115] and the Inter Agency Expert Group (IAEG) on Targets and Indicators[116], the UNDP has been providing technical and financial support to help countries report progress on their national MDG targets, and developing the MDG National Report Guidelines, which are updated every few years to reflect emerging development priorities and agendas.[117]

Until 2015, the policies aimed at accomplishing the MDG, have had a considerable and universal impact. According to UNDP:

- Global poverty has been halved five years ahead of the 2015 timeframe.
- Ninety per cent of children in developing regions now enjoy primary education, and disparities between boys and girls in enrolment have narrowed.
- Remarkable gains have also been made in the fight against malaria and tuberculosis, along with improvements in all health indicators.
- The likelihood of a child dying before age five has been nearly cut in half over the last two decades, which means that about 17,000 children are saved every day.
- The target of halving the proportion of people who lack access to improved sources of water was also met. [118]

However, MDG also had important gaps and systemic shortcomings. Despite three of the eight goals have been achieved prior to the final deadline of 2015[119], there is still a large discrepancy between its initial level of ambition and its implementation. Furthermore, MDG perpetuated a "donor-recipient" type of relationship and did not pay sufficient attention to mobilizing development financing other than aid.

The end of 2015 is the target date for the achievement of the MDGs, but should also mark the beginning of the new framework for international development. Formal debate concerning the new international development framework first occurred at the 2012 Rio+20 Conference on Sustainable Development. The conference initiated an inclusive intergovernmental process to prepare a set of sustainable development goals (SDGs). The Rio+20 outcome document proposes that the SDGs must be "action-oriented, concise and easy to communicate, limited in number, aspirational, global in nature and universally applicable to all countries while

[114] The "Road map towards the implementation of the United Nations Millennium Declaration" (Annex – para. 4) notes that UNDP will coordinate the reporting on progress towards the Millennium Development Goals at the country level.
[115] The United Nations Development Group (UNDG) unites the UN funds, programmes, specialized agencies, departments, and offices that play a role in development in over 150 countries. The UNDG was constituted in 1997 following the UN General Assembly's endorsement of UN Secretary-General Kofi Annan's report "Renewing the United Nations: A Programme of Reform". See more: https://undg.org/home/about-undg/
[116] "The Inter-Agency and Expert Group (IAEG) on MDG Indicators includes various Departments within the United Nations Secretariat, a number of UN agencies from within the United Nations system and outside, various government agencies and national statisticians, and other organisations concerned with the development of MDG data at the national and international levels including donors and expert advisers. IAEG is responsible for the preparation of data and analysis to monitor progress towards the MDGs." See more: http://mdgs.un.org/unsd/mdg/Host.aspx?Content=IAEG.htm
[117]The last round of national MDG reports will provide a collective review, and key lessons learnt, for MDG achievement; and will help inform and shape the post-2015 development agenda." (See more: http://www.us.undp.org/content/washington/en/home/mdgoverview/mdg_goals/progress.html)
[118] http://www.undp.org/content/undp/en/home/mdgoverview/mdg_goals.html
[119] http://www.un.org/en/ecosoc/about/mdg.shtml

taking into account different national realities, capacities and levels of development and respecting national policies and priorities"[120].

In September 2015, it is expected that the world leaders gather again at the United Nations in New York to adopt a new agenda for sustainable development. The new global Sustainable Development Goals (SDGs) should build upon the achievements of the previous international development agenda (MDG) and will guide policy and funding for the next period of 15 years.

The UN is additionally providing assistance to countries to fulfil their national development goals. In general, such activities are conducted through the United Nations Development Action Framework (UNDAF). UNDAF is a programme document between a government and the United Nations Country Team (UNCT) that describes the collective actions and strategies of the United Nations in order to contribute most effectively to the achievement of national development priorities. In the 2007 Triennial Comprehensive Policy Review of operational activities for development of the United Nations system (TCPR), the General Assembly encouraged the UN development system to intensify its collaboration at the country and regional levels both through UNDAF and the common country assessment.

The OECD also supports development on global and national levels. OECD's Strategy on Development is a framework document that guides the Organisation's development efforts with a main goal to strengthen OECD's contributions to "higher and more inclusive growth in the widest array of countries"[121].[122]

The Strategy on Development identifies four interlinked thematic areas where OECD has "core competence, adds value to other international efforts, and responds to the demands of developing countries"[123], namely: innovative and sustainable sources of growth; mobilisation of resources for development; governance for development; measuring progress for development:

> One of the primary objectives of the OECD Strategy on Development is to support work on policy coherence for development (PCD), i.e. ensuring that broader policies pursued by countries are coherent with the goal to promote worldwide development. Since 2007, this work is being coordinated by the PCD Unit in the Office of the OECD Secretary-General.[124]

Furthermore, OECD believes that the policy coherence for development should be at the centre of the post-2015 agenda. The new framework will not prove as constructive if it does not ensure the convergence between major existing agendas, such as the Millennium Development Goals[125], the Rio+20 Sustainable Development Goals, the Global Partnership for Effective Development Co-operation, the G20 and the G8.[126]

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[120] http://unesdoc.unesco.org/images/0022/002219/221907E.pdf
[121] http://www.oecd.org/pcd/OECD_Strategy_on_Development.pdf
[122] Global development has in fact been repeatedly stated as the main commitment of OECD, since it is countries at varying levels of development that contribute to the achievement of global sustainable economic growth, simultaneously improving their policies through the mutual exchange of experiences and knowledge.
[123] See more: http://www.oecd.org/development/oecd-strategy-on-development.htm
[124] http://www.oecd.org/development/oecd-strategy-on-development.htm
[125] It is the OECD that championed a series of ambitious development objectives in 1996, including halving the proportion of people living in extreme poverty by 2015, which later became the basis for the MDGs.
[126] See more: http://www.oecd.org/pcd/Better-Policies-for-Development-2014.pdf

OECD adopted a comprehensive and inclusive approach to development, claiming that there is no "one-size-fits-all" strategy, and concluding that the heterogeneity of national conditions justifies the heterogeneity of growth models. Although OECD frameworks and mechanisms were originally developed for a set of advanced economies, today they are adapted for broader application, including a range of developing country partners.

OECD's activities contribute to the promotion of green growth, innovation, high-quality education and skills, efficient systems of taxation and investment, and strengthening of public services and infrastructure. "The OECD Economic Outlooks on Africa, Latin America and Southeast Asia are benchmark sources of analysis of the economic, social and political developments. The Middle East and North African region is engaged with OECD through a framework for policy sharing. The OECD also examines the coherence of its members' policies such as agriculture, trade, investment and migration in terms of their development impact."[127] It additionally contributes to international and regional processes aiming at improving the development architecture and ensuring better provision of global public goods.

4.2.4 HUMAN RIGHTS POLICY

The Universal Declaration of Human Rights, an example of cornerstone UN policy, has been frequently referenced with respect to human subjects' research in developing nations. The document was originally developed post-World War II in light of grave violations of basic human rights. However, the articles outlined in the Declaration are directly applicable to ethical concerns about the autonomous rights of human research subjects, with the UN providing clear provisions on the latitude of admissible actions. The policy is often referenced to ensure that the anchoring bioethical principles of autonomy, beneficence and justice are upheld for all global citizens; this can also be applied, however, to the conduction of R&I involving humans as a general guiding principle.[128,129]

The UDHR is closely related to and often referenced in context with the Universal Declaration on Bioethics and Human Rights (UDBHR) established by UNESCO. As it was developed far more recently, in 2005, the UDBHR is more specific in addressing concerns focused on bioethics concerns within research and innovation using human rights as a fundamental framework. The UDBHR primarily "addresses the States" but also provides guidance to decisions and practices" of other private and public groups or agencies.[130] The policy pioneered the co-representation of issues in both human rights and bioethics; many instances can be noted throughout the document in which due importance is placed on the fact that research must be adapted to individual and local norms and values. For instance, Article 14 contains the principle of social responsibility, in which it was acknowledged that research and innovation is inextricably linked to its social context and therefore must be understood within that context. Additionally, the UDBHR articulated then-emerging concerns of social responsibility between governments and macro-level institutions and individual citizens as related to human subjects' research and provided measures to mitigate these issues.

[127] http://www.oecd.org/pcd/OECD_Strategy_on_Development.pdf
[128] Beauchamp, Tom L., and James F. Childress. *Principles of Biomedical Ethics*. New York, NY: Oxford UP, 2001. Print.
[129] *The Belmont Report*. Publication. Department of Health, Education, and Welfare, 18 Apr. 1979. Web.
[130] *Universal Declaration on Bioethics and Human Rights*. Rep. Paris: United Nations Educational, Scientific, and Cultural Organisation, 2005. Print.

The Declaration of Helsinki, developed by the World Medical Association, and the Nuremberg Code are two examples of historically relevant policies which have been applied to evaluation of human rights, including for research trials. These are discussed in greater detail in section 3.2.3.A more recent policy related to human rights, which consolidates principles set for in the aforementioned documents, is the CIOMS International Ethical Guideline for Biomedical Research Involving Human Subjects. Developed in collaboration with the WHO, this CIOMS policy first references key policies that should be used as guiding frameworks when evaluating human rights for research purposes. Its three core tenets are reminiscent of both the Belmont Report and the Principles of Biomedical Ethics, both referenced earlier in this review and are as follows: respect for persons (autonomy and protection of vulnerable persons), beneficence, and justice.

The OECD has also recently developed a strategy on human rights within the OECD Guidelines for Multinational Enterprises. This publication is directed more towards corporations engaging in activities that may present circumstances in which rights can be infringed. While the guidelines defer to bulk of human rights to established documents which have already been discussed, there are specific provisions for enterprises to consider in conjunction with State legislation. This OECD policy does offer advice for corporations in cases where international human rights policy and local regulation conflict; according to these guidelines, the enterprise should honour human rights to the fullest extent in ways that do not violate domestic laws. The guidelines go on to state that " Leverage is considered to exist where the enterprise has the ability to effect change in the practices of an entity that cause adverse human rights impacts," and therefore has the ethical obligation to assume responsibilities for carrying out human rights due diligence.[131] The specifications of due diligence are outlined in detail in earlier sections of this policy.

Policymaking regarding ethical issues in research and innovation has continued well into the present day, with many committees and taskforces still being developed to address core issues.

The UN System Task Team on the Post-2015 Development Agenda has published a think piece entitled "Science, technology and innovation for sustainable development in the global partnership for development beyond 2015." Two main goals for this agenda are: increased role and responsibility of developing countries in innovation driven growth, particularly by "building technological and innovation capacities within countries as a whole."[132] Secondly, science, technology and innovation (STI) should be integrated with public policy initiatives, which can help to forge the path for influential research to reach the forefront of applied policy. Though not directly in reference to ethics policy, the think piece alludes to actions that can be taken in regards to these two major goals from an ethics standpoint, for instance, attributing responsibilities of building infrastructure equitably between public and private sectors.

[131]Organisation for Economic Co-operation and Development. *OECD Guidelines for Multinational Enterprises*. Paris: OECD, 2011. Web.
[132]*Science, Technology and Innovation for Sustainable Development in the Global Partnership for Development beyond 2015*. Rep. New York: UN System Task Team on the Post-2015 Development Agenda, 2011. Web.

4.2.5 ENVIRONMENTAL POLICY

The United Nations Environment Programme (UNEP) is an agency of the United Nations that coordinates its environmental activities, assisting developing countries in implementing environmentally sound policies and practices. It was founded as a result of the United Nations Conference on the Human Environment in June 1972 and has its headquarters in Nairobi, Kenya.

It was founded by Maurice Strong, its first director, as a result of the United Nations Conference on the Human Environment in June 1972 and has its headquarters in the Gigiri neighbourhood of Nairobi, Kenya. UNEP also has six regional offices and various country offices.

United Nations global conferences and intergovernmental policy bodies - especially the Commission on Sustainable Development (CSD) – have played crucial roles in the development of the global environmental framework.

UNEP work encompasses: assessing global, regional and national environmental conditions and trends; developing international and national environmental instruments; strengthening institutions for the wise management of the environment.

4.3 POLICIES OF THE EUROPEAN UNION

4.3.1 INTRODUCTION

The European Union (EU) is a political and economic coalition of 28 sovereign nations established after the end of World War II. The ideas underpinning the establishment of the Union were primarily pacifistic. It was envisioned that the promotion of economic cooperation and interdependency between its member states would be the best way to prevent future armed conflicts in Europe. However, the competencies of the organisation gradually expanded and a purely economic union soon evolved into an entity spanning a range of policy areas, from development aid to environment.

In the unique institutional set-up of the EU, the European Council brings together national and EU-level leaders, and establishes the broad priorities of the organisation. The Members of the European Parliament (MEPs), directly elected by European citizens, represent their voters in the European Parliament. The European Commission, whose members are appointed by national governments, promotes the interests of the EU as a whole. On the other hand, governments defend their own country's national interests in the Council of the European Union. In such a way, all three interests – the one of the EU's citizens, the one of the individual member countries and the one of the Union as a whole – should be represented on an appropriate decision making level.

Although the Treaty of Lisbon (entered into force on 1 December 2009) paved the way to a stronger, more interconnected union, the weighty constitutional elements that were originally a part of the document, have been since edited out. The EU remains a unique platform for cooperation between states; something between a federation and intergovernmental conglomerate. The EU administrative organs must tackle cross-border issues (on the basis of majority voting wherever possible), whereas Member States have and retain their powers for

issues determined at the national level. This is in accordance with the Article 5 of the Treaty on European Union (TEU), which states that

> the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level.

4.3.2 R&I POLICY

Research and innovation has been placed as a high priority on the EU policy agenda as it faces increased global competition in research and technology production, mainly from the other two members of the championing triad in the field (USA and Japan). Europe 2020[133], the 10-year strategy proposed by the European Commission in 2010, stipulates an investment of 3% of gross domestic product (GDP) in research and innovation across the public and private sectors combined by 2020.

However, it is worth mentioning that research became a formal Community policy only with the Single European Act in 1986. The objective cited in the document was to 'strengthen the scientific and technological basis of European industry and to encourage it to become more competitive at international level'.

Since 2000, the science policy of the European Union has been carried out through the European Research Area, which is a system that integrates the scientific resources of member nations and acts as a "common market" for research and innovation purposes. The central goals of the ERA include the promotion of mobility of knowledge workers as well as multilateral cooperation among research institutions of different EU member states. According to the section 1 of the article 179 of the Treaty on the Functioning of the European Union: "The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapters of the Treaties."

The fragmentation of research funding systems in Europe has long been recognized as an important factor preventing Europe from achieving its full research potential. "Since 1984, the European Union has run its research and innovation policy and funding on the basis of multiannual framework programmes. Seven framework programmes (FP1–FP7) have run between 1984 and 2013."[134] At the start of 2014, they were replaced by the Horizon 2020, a major financial instrument for implementing the innovation union, which will run from 2014 to 2020 with a budget of almost €80 billion. "The general objective of Horizon 2020 is to build a society and a world-leading economy based on knowledge and innovation across the whole Union, while contributing to sustainable development. It will support the Europe 2020

[133] Europe 2020 is a 10-year strategy proposed by the European Commission on 3 March 2010, aiming at "smart, sustainable, inclusive growth" with greater coordination of national and European policy and succeeding the Lisbon Strategy for the period 2000–2010.
[134] http://europa.eu/pol/pdf/flipbook/en/research_en.pdf

strategy and other Union policies as well as the achievement and functioning of the European Research Area (ERA)."[135]

The aforementioned initiative "Innovation Union" was introduced in 2010[136] in order to improve framework conditions and access to finance for research and innovation. The initiative consisting of more than 30 action points aims to strengthen the innovation chain and boost levels of investment throughout the Union. Amongst the goals of this initiative include: the creation of the single EU Patent and a specialised Patent Court, improvement of access to Intellectual Property Protection, the launch of "European Innovation Partnerships" between the EU and national levels to speed up the development and deployment of the technologies needed to meet the identified challenges, strengthening of links between education, business, research and innovation, and the promotion of entrepreneurship by supporting Young Innovative Companies, etc. At the national level, Member States will need to reform national (and regional) R&D and innovation systems to foster excellence and smart specialization. This includes implementation of joint programming and enhanced cross-border co-operation, as well as assurance of a sufficient supply of graduates in science and technology fields and development of curricula focused on and creativity, innovation, and entrepreneurship. It is also expected that they will prioritise knowledge expenditure, including by using tax incentives and other financial instruments to promote greater private R&D investments.

The European Union's executive body, the European Commission, established a special directorate-general for research and innovation, as a branch of administration dedicated specifically to the Union's R&I policy. In its efforts to define and implement the European Research and Innovation (R&I) policy, the Director-General analyses the national R&I policies, assesses their strengths and weaknesses, and formulates country specific recommendations where necessary. The DG has a particular focus on achieving the goals of the Europe 2020 strategy and its key flagship initiative, the Innovation Union.

The European Commission and Member States of the European Union (EU) benefit from the independent scientific and technical advice from the Joint Research Centre. It is the European Commission in-house science service that has seven scientific institutes – located at six different sites in Belgium, Germany, Italy, the Netherlands and Spain.

Another important public body is the European Research Council (ERC). Established by the European Commission in 2007, its goal is to fund the scientific and technological research conducted within the Union. It forms part of the framework "Horizon 2020" programme, and disposes with a budget of over €13 billion.

A number of European science agencies that operate independently of the European Union have an influence on the development of its research and innovation policies. Among these, we have identified the European Science Foundation, European Space Agency, and the European Higher Education Area, the latter being created by the Bologna process.

[135] http://www.europedia.moussis.eu/books/Book_2/6/18/02/02/?all=1
[136] http://europa.eu/pol/pdf/flipbook/en/research_en.pdf

4.3.3 DEVELOPMENT POLICY

The EU defines its development policy as seeking "to eradicate poverty in a context of sustainable development"[137]. Such a stance also guides the EU's international policy; the EU has established itself as the world's leading donor, providing over 50% of all global development aid.

The documents that form the basis of EU action on development are the Lisbon Treaty and the 2005 European Consensus on Development. The latter document is a policy statement made jointly by the 3 main EU institutions (Commission, Parliament and Council). The Consensus on Development identifies shared values, goals, principles and commitments which the Commission and EU governments will implement in their development policies. The goals include the reduction of poverty, the promotion of democratic values and the support for a nationally-led development, therefore managed by the beneficiary countries themselves, and based on national strategies and domestic resources. The EU governments have agreed to increase their Official Development Assistance to 0.7 % of GNI by 2015, with half the additional aid going to Africa.

Through its actions in the field of development policy, the EU fulfils its obligation to contribute to the achievement of the Millennium Development Goals. The Millennium Development Goals (MDGs) represent a set of eight international development goals established during the Millennium Summit of the United Nations in 2000 and to be achieved by 2015. Although the progress towards the goals is quite uneven, the EU has given major contributions through both its international and EU-based programmes (e.g. The Youth in Action EU Programme).

In order to maximize the development impact of other EU policies, the EU promotes Policy Coherence for Development. Policy coherence was first integrated in EU fundamental law in 1992 (Art. 208 TFEU) and further reinforced in the Treaty of Lisbon. Through Policy Coherence for Development, the EU seeks to minimize contradictions and build synergies between different EU policies that are likely to affect developing countries.

The EU is further committed to making aid more effective, having provided key input to the 2005 Paris Declaration on Aid Effectiveness and endorsed the 2011 New Deal on Aid Effectiveness. Relevant EU institutions further proclaim that the promotion of democratic values and practises such as human rights, fundamental freedoms, good governance, etc., represent an essential part of its development policies and relations with partner countries.

In 2011 the Commission set out a more strategic EU approach to reducing poverty; the 12-points Agenda for Change and a new policy and rules for budget support which resulted in a targeted and concentrated allocation of funding. The changes should guarantee that EU aid reaches the countries in greatest need, while countries already experiencing sustained growth or with sufficient resources of their own should get different types of EU assistance.

[137] http://ec.europa.eu/europeaid/policies/european-development-policy_en

4.3.4 HUMAN RIGHTS POLICY

Respect for human rights and dignity, together with the principles of freedom, democracy, equality and the rule of law, are values of great importance in all of the EU Member States. In fact, they form one of the major requirements for accession to the organisation. The EU's human rights policy encompasses civil, political, economic, social and cultural rights.

The EU actively promotes and defends human rights both within its borders and when engaging in relations with non-EU countries. "Within EU borders, those principles are embedded in the EU founding treaties, reinforced by the EU Charter of Fundamental Rights adopted in 2000, and strengthened still further when the Charter became legally binding with the entry into force of the Lisbon Treaty in 2009. Outside EU borders, the Lisbon Treaty stipulates that the Union's action on the international scene shall be guided by the principles which have inspired its own creation, development and enlargement and which it seeks to advance in the wider world: democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity and respect for the principles of the United Nations Charter and international law."[138] Furthermore, all cooperation (and trade) agreements with third countries contain a clause stipulating that human rights are an essential element in relations between the parties.

Every year, the Council of the European Union adopts its Annual Report on Human Rights and Democracy. This report is divided into two parts: the first one is thematic – it reflects the structure of the previously adopted Action Plan on Human Rights and Democracy and provides an assessment of the actions taken to address the Action Plan's priorities. The second part is geographical and covers EU actions in third-world countries, thus providing a detailed overview of the human rights status quo across the globe.

EU grants additional financial support in order to strengthen various civil society organisations. The European Instrument for Democracy and Human Rights (EIDHR), for example, provides means for non-governmental organisations promoting human rights, democracy and the rule of law; abolishing the death penalty; combating torture; and fighting racism and other forms of discrimination.

4.3.5 ENVIRONMENTAL POLICY

With over 500 Directives, Regulations and Decisions, the European Union has demonstrated an unprecedented degree of environmental legislation. The documents address issues such as acid rain, the thinning of the ozone layer, air quality, noise pollution, waste and water pollution. EU environmental policy is furthermore intertwined with other international and national environmental regulations and significantly impacts its member states.

The beginnings of the EU's environmental policy go back to the Paris Summit meeting of heads of state and government of the European Economic Community (EEC) in October 1972. Despite of the increasing international politicization of environmental problems in the 1970s, the primary reason for the introduction of a common environmental policy was from an economic vantage point. There was a concern among the stakeholders that diverse

[138] http://www.eeas.europa.eu/human_rights/about/index_en.htm

environmental standards could result in trade barriers and competitive distortions in the Common Market.

It is important to note that there was no explicit legal basis which would underpin the EU environmental policy, since it was not mentioned in the founding treaties of the EU. However, the Treaty text was interpreted dynamically enabling environmental policy to be regarded as an essential goal of the Community.

The EU environmental policy is shaped by all the main EU institutions. Traditionally, the European Parliament gained a reputation as a champion of environmental interests within the organisation. Its practices and structure provide an access point for those excluded from decision-making and a voice for green political parties. On the other hand, member states shape EU environmental policy by working within the Council of the European Union. The European Council, which until recently did not have a significant interest in environmental policies, started to play an increasingly important role, especially in the discussions about the EU climate change policy. It is the European Commission, however, that has an exclusive right to propose new environmental policy, as well as the responsibility to ensure the implementation of environmental rules. Apart from the EU bodies, environmental NGOs and other lobby groups have an influence on the policy making process.

Such a fragmented institutional and political structure facilitates the adoption of visionary environmental policy objectives, but in the same time undermines their implementation.

The EU climate and energy package 2020 (EC, 2008) sets ambitious objectives for 2020:

- 20% reduction in greenhouse gas emissions on 1990 levels;
- 20% of energy used is from renewable sources;
- 20% improvement in energy efficiency.

Roadmap, a long-term plan for moving to a competitive, low-carbon economy by 2050 (EC, 2011a), presents the EU vision on tackling the challenges of climate change. The plan presents milestones for achieving the goal of 40% reduction in EU CO2 emissions below 1990 levels by 2030, 60% by 2040, and 80% by 2050. Three main targets: 1) reduction of greenhouse gas emissions; 2) use of renewable energy; and 3) energy saving; are also confirmed in the Green Paper (EC, 2013a). Parallel to these, EU policy seeks to ensure that the energy system contributes to the competitiveness of the EU economy, while making energy more affordable to consumers.

In the light of the aforementioned ambitions, however, it is important to mention that some of the most significant EU environmental policies already experienced large setbacks. Namely, the European Union's Emissions Trading System (EU-ETS) was launched in 2005 and represents the largest carbon trading market in the world. The purpose of the EU-ETS is to limit the quantity of greenhouse gas emissions in the power generation and industrial sectors (by setting a cap) and distribute the right to emit through a system of tradable permits. The system has encountered serious criticism and faced accusations to represent an evident discrepancy between scientific and political interests.

The results of the first 2005-2007 EU-ETS phase were especially disappointing. In order to mitigate the possible influence on their home economies, the governments negotiated the right to propose how many permits to allocate to their national industries. Additionally, the European Commission figures show that the cap was set too high, since only three member

states had caps that were lower than baseline 2005 emissions levels. As a result, the permit prices fell as low as €0.03 per ton in December 2007. Although the caps have been tightened in the second (2008–2012) and the third (2012–2020) trading period, businesses still did not reduce their emissions (thanks to excess permits) and even started to make extra profits out of the EU-ETS by passing on the costs to consumers.[139] The EU recognized the weaknesses of the established system qualifying it as transitional[140] and effective only if linked with other major emissions trading systems. In that sense, the 2012 EU and Australia agreement on a pathway for linking the EU-ETS and the Australian emissions trading scheme was an important step in the establishment of a globally linked economy-wide cap-and-trade system. The agreement is also accompanied by the Union's efforts to introduce the new market mechanism in developing countries.

Following the singing of the Lisbon Treaty, sustainable development is mentioned as a basic objective of the EU in the new Article 3 TEU; in Article 21 TEU concerning the external action of the Union; and in Article 11 TFEU setting out the integration principle. This makes the EU legally committed to pursue sustainable development both internally and externally.

The post-2008 economic crisis led to a marked decline for long-term policy objectives such as sustainable development. A new 'Europe 2020' strategy that replaced the Lisbon Strategy in 2010 reduced the environmental dimension to energy and resource efficiency with the words 'sustainable development' not even mentioned.

However, the EU still remains an important global environmental actor. The organisation is a party to all major multilateral environmental agreements covering a large variety of environmental issues. The EU is also able to fully participate in international environmental negotiations, either as an observer in the UN context or as a party to the mother treaty in various Conference of the Parties (COPs) and Meeting of the Parties (MOPs). Moreover, ''Horizon 2020'', the EU's new research framework programme, dedicates significant space to issues such as stable energy supplies, global warming, public health, security of water and food resources. Taking into account the almost €80 billion budget of the programme, the European Union intends to provide significant funds for the research and innovation sector, especially in the fields aimed at finding responses to the aforementioned issues.

4.4 GENERAL POLICIES AND ACTIONS TO MITIGATE UNETHICAL CONSEQUENCES

In this section, we list some of the most prominent ethical issues arising from the globalization of research and innovation and match the relevant existing policies to these issues. The table displays the ethical issue, which organization oversaw the policy development, as well as relevant text from the policies that explicitly cite the ethical issue at hand. It is not an exhaustive list and cites only international instruments in order to provide a general context for the mitigation of unethical consequences arising from the globalization of research and innovation.

[139] http://ec.europa.eu/clima/consultations/docs/0005/registered/9825553393-31_friends_of_the_earth_europe_en.pdf
[140] http://ec.europa.eu/clima/policies/ets/linking/index_en.htm

Ethical Issue	Organisation	Policy	Relevant Text
Equal safety regulation for subjects in developed and developing countries	UN	Universal Declaration of Human Rights	
Accessibility of research data	UNESCO	UDBHR	Article 1 “equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries”.
Informed consent (autonomy of decisions, not group influence)	UNESCO	UDBHR	Article 6 “Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information”. “In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual’s informed consent.”
Informed consent (illiteracy/comprehension issues)	UNESCO	UDBHR	Article 6 ““The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice”.
Outsourcing to developing countries – reduced cost and constraints	WMA	Declaration of Helsinki	
Informed consent	CIOMS	International ethical guidelines for biomedical research involving human subjects	
Informed consent	WMA	Declaration of Helsinki	

Ethical Issue	Organisation	Policy	Relevant Text
Informed consent (illiteracy)		IRBs	
Equality for women	UNESCO	UDBHR	Preamble: "important way to evaluate social realities and achieve equity is to pay attention to the position of women".
Protection of indigenous knowledge and biological resources	International Labour Organisation	The Convention 169 on Indigenous and Tribal Peoples of 1989[141]	
Ethical supply chain and fair trade	United Nations	United Nations Global Compact	The UN Global Compact is a strategic policy initiative for businesses that are committed to aligning their operations and strategies with ten universally accepted principles in the areas of human rights, labour, environment and anti-corruption.[142]
Product liability	European Union	European Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.	By striking a fair balance of risk among citizens and producers, this legislation aims to converge consumers' interests with Single Market policies (namely free exchange of goods and elimination of competition distortions).[143]
Responsible marketing and advertising	WHO	The Sixty-third World Health Assembly, resolutions: WHA60.23 and WHA63.14.	Designing new and/or strengthening existing policies on food marketing communications to children in order to reduce the impact on children of marketing of foods high in saturated fats, trans-fatty acids, free sugars, or salt.

Table 1: Ethical issue, organisations and policies

[141] Available at: <www.ilo.org/ilolex/cgi-lex/convde.pl?C169> (Accessed: 1 June 2015).
[142] Available at: <http://www.sedexglobal.com/resources/useful-links/#sthash.IGEuI8TP.dpuf> (Accessed: 18 June 2015).
[143] Available at: <http://europa.eu/legislation_summaries/consumers/consumer_safety/l32012_en.htm> (Accessed: 18 June 2015).

4.5 CONCLUDING REMARKS

In presenting the policies of the United Nations; the United Nations Educational, Social, and Cultural Organization; the World Health Organization; the Organization for Economic Cooperation and Development; the Council for International Organizations for Medical Sciences, as well as within the European Union and their policies respective to ethical concerns due to globalization in research & innovation taken with respect to such policies in order to mitigate potential ethical issues in R&I, there are several concluding themes emerge. Human Rights doctrine is the most frequently invoked framework to protect the areas of ethical concern cited above. In addition, the policies are not simply reactionary, but proactive as well, as organizations are also drivers of research and innovation. The European Union is particularly active in the area of promoting research and innovation policy, with efforts such as Europe 2020, which has facilitated prudent policy development, particularly in the fields of sustainability, development, and environmental concerns. As globalisation of research and innovation continues, the need to continuously update policies in order to keep pace with the emergence of new areas of ethical concern will need to be highly prioritized, not only as a response to potential areas of ethical concern, but as a proactive part of research agendas.

5 CASE STUDIES

5.1 RESPONSIBLE SUPPLY CHAIN

5.1.1 INTRODUCTION

Responsible supply chain management is an increasingly popular approach that helps companies manage the social and environmental dimensions of their activity. Issues such as workers' rights, particularly fair wages, intellectual property rights, water and carbon footprint are frequently debated in the context of sustainability and corporate social responsibility strategies. Nevertheless, there are still a lot of misconceptions about the scope and application of these concepts in practice. The situation is extremely challenging for companies because of the lack of precise definition of these terms.

In recent years, the impact of business on humans' lives has become a salient feature of discussion. This is because, the process of globalisation and common acceptance of market-based economies resulted in a growing tendency to invest in emerging-economies, in many cases characterised as complex environments. Globalisation, particularly related to internationalisation of research and innovation (R&I) raises questions regarding typical moral values such as autonomy, freedom, dignity, privacy, justice, well-being, and responsibility. As far as innovation is said to be a key driver of economic development,[144] it may challenge these values due to its competitive aspect that allows companies to take the lead in particular markets.[145] Companies' cross-border activity particularly, the production process, have become "more geographically dispersed as companies increasingly locate different production stages across different countries through network of independent suppliers and their own affiliates".[146] The power of innovation to stimulate economic growth, support local economy but also promoting global human rights standards is a deeply-held belief of governments, investors, inventors, entrepreneurs, and the public.[147] Nevertheless, it may also have negative consequences. A responsible supply chain and responsible production, in the context of responsible innovation, is one of the greatest challenge that business struggles with.

This research explores and measures the positive and negative impacts of the globalized supply chain in its ethical dimension, taking account of efforts including international collaboration of governments, international organisations and private initiatives to address these concerns. The study draws further inspiration from the notion of Responsible Research and Innovation (RRI), which has become a prominent concept in European research and policy circles.[148]

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[144] Hanekamp, Gerd (Ed.), "Business Ethics of Innovation", Springer, 2007, [p. 1].
[145] Albach, H. (1994) The Transformation of Firms and Markets - A Network Approach to Economic Transformation Processes in East Germany, Stockholm: Alquis &Wiksell;
[146] Interconnected Economies, Benefitting from global value chains, OECD 2013, http://www.oecd.org/sti/ind/interconnected-economies-GVCs-synthesis.pdf
[147] Dedrick J., Kraemer K.L., Linden G., "Who Profits from Innovation in Global Value Chains? A Study of the iPod and notebook PCs", Prepared for the Sloan Industry Studies Annual Conference Boston, MA May 2008.
[148] Owen, R., MacNaghten, P. and Stilgoe, J. (2012), Responsible research and innovation: From science in society to science for society, with society, Science and Public Policy 39(6): 751-760.

This section is divided in four main parts. In the first, we provide general information about the responsible supply chain (definitions of the most important terms, impacts on countries of origin and hosting countries, ethical issues involved) as well as briefly discuss some actual strategies aimed at management of the supply chain. The second part consists of a case study of Sedex.

This practical dimension of the study gives an in-depth analysis of the issue at stake, tackles the real problems and potential solutions.

5.1.2 GENERAL DISCUSSION OF THE ISSUE

According to the members of the Global Supply Chain Forum "Supply Chain Management is the integration of key business processes from end user through original suppliers that provides products, services, and information that add value for customers and other stakeholders."[149] It is about

> the management of a network of relationships within a firm and between interdependent organizations and business units consisting of material suppliers, purchasing, production facilities, logistics, marketing, and related systems that facilitate the forward and reverse flow of materials, services, finances and information from the original producer to final customer with the benefits of adding value, maximizing profitability through efficiencies, and achieving customer satisfaction.[150]

It requires, therefore, the management of relationships among manufacturers, intermediaries, and end users and provides means of developing competitive advantage and positioning strategy.[151] The term "Responsible Supply Chain Management" (RSCM) is closely related to the concept of Corporate Social Responsibility (CSR)[152] and the core aspect is companies' responsibility on management of their supply chain. Regarding the definition of the RSCM, on the one hand according to the International Chamber of Commerce (ICC):

> Supply chain responsibility, also referred to as responsible sourcing, can be broadly defined as a voluntary commitment by companies to manage their relationships with suppliers in a responsible way. As a result of their purchasing activities, companies may have some opportunities to influence constructively their suppliers' social and environmental performance. This can be done using several incentives, including information and training, as well as audits of suppliers' practices. Whatever mechanism is used, the most effective way to achieve sustained improvement over time is through the development of a long-term collaborative relation between corporate buyers and their suppliers, through which suppliers can internalize change by participating in the shaping of social and environmental performance objectives, based on their own perception of their business capacity and needs.[153]

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[149] Douglas M. Lambert, "Supply Chain Management", [p. 2], http://www.eng.auth.gr/mattas/foodima/lamb1.pdf.

[150] Stock, J. R., & Boyer, S. L., "Developing a consensus definition of supply chain management: A qualitative study", pp. 690–711 in *International Journal of Physical Distribution & Logistics Management*, 39(8), 2009, [p. 708].

[151] Wise, R., & Baumgartner, P., "Go downstream: The new profit imperative in manufacturing", pp. 133-141 in *Harvard Business Review*, 77(5), 1999.

[152] Recently, instead of "Corporate Social Responsibility, the notion "Corporate Responsibility" is growing in popularity among practitioners and academics.

[153] International Chamber of Commerce (ICC), "ICC guidance on supply chain responsibility", Paris 2007, [p. 2], http://www.iccwbo.org/Advocacy-Codes-and-Rules/Document-centre/2007/ICC-Policy-Statement-on-Supply-Chain-Responsibility/.

On the other hand, the United National Global Compact (UNGP) refers to "supply chain sustainability", which is understood as:

> the management of environmental, social and economic impacts, and the encouragement of good governance practices, throughout the lifecycles of goods and services. The objective of supply chain sustainability is to create, protect and grow long-term environmental, social and economic value for all stakeholders involved in bringing products and services to market.[154]

While the first definition emphasizes the voluntary character of companies' commitment to undertake a more responsible approach to their supply chain, the second definition focuses on management of the impacts on stakeholders that a company may have, and strives for a proactive approach to incorporating good environmental, social and governance practices into supply chains.[155] The view that both the definitions promote is the need for cooperation between a company, its suppliers, stakeholders and other actors engaged in the supply chain. These relations play a crucial role and should be based on trust, mutuality and promise fulfilment.[156]

5.1.3 GLOBAL TRENDS

"Responsible supply chain", "ethical supply chain", "sustainable supply chain"

The use of the terms has changed over time. A few years ago, "ethical supply chain" and the "sustainable supply chain" were commonly used terminology; the term "responsible supply chain management" reflects recent developments and a broader understanding of responsible business. The notion "ethical" refers to business ethics with a focus on anti-corruption, and "sustainability" evokes a clear reference to the environmental considerations.[157] Therefore, the RSCM intends to grasp a wider array of corporate responsibilities.

5.1.4 ETHICAL ISSUES

The cross-border activity of companies, outsourcing production, or sourcing from suppliers in developing or emerging economies, can deliver significant benefits including reduction of costs, and contribution to much needed development.[158] For a developing country, this would mean a creation of new jobs, bringing resources to the country, and for instance, investment in the local infrastructure. The cross-border activity of companies includes also operating across legal jurisdiction in countries "lacking the capacity to regulate the behaviour of transnational firms operating in their territory, or may feel hesitant to do so for fear of putting their investment at risk."[159] This includes setting and enforcement of regulations, taxes and other

[154] Global Compact Network Australia, http://www.unglobalcompact.org.au/new/issue-areas/supply-chain-sustainability/.
[155] Ibid.
[156] O. C. Ferrell , Mary Margaret Rogers , Linda Ferrell & Jennifer Sawayda, "A framework for understanding ethical supply chain decision making", pp. 260-287 in *Journal of Marketing Channels*, 20:3-4, (2013), [p. 262].
[157] Based on the interview with Sedex.
[158] Global Compact Network Australia, http://www.unglobalcompact.org.au/new/issue-areas/supply-chain-sustainability/.
[159] Tanja Börzel, Jana Hönke, "Mining Companies and the Voluntary Principles on Security and Human Rights in the Democratic Republic of Congo", SFB-Governance Working Paper, Series, No. 25, Research Center (SFB) 700, Berlin, October 2011, [p. 7].

issues affecting the costs of production.[160] The host country might also lack willingness to adhere to global human rights standards itself.

Supply chain management involves many ethical and human rights considerations. These considerations might however vary depending on the sector, the length of the supply chain, the host country, and the specific local context. In general, companies should avoid implication in human rights abuses at the domestic level in host states, particularly given the complex environments they operate in. Some host countries often have weak legal frameworks, unstable governance structures and questionable systems of protecting and human rights - this makes human rights abuses more likely.

The report on the RSCM, CREM[161] and SOMO[162] address five unsolved CSR issues related to the supply chain:[163]

1. Child labour

Child labour is often regulated by legislation, at the national and international level, nevertheless, the execution remains a problem. Furthermore, children may work in informal economy of a country. For this reason it is difficult to trace, monitor and fully eliminate.

2. Freedom of association and collective bargaining

Some of the developing countries neglect the right of employees' to associate, either in the national laws of the countries, and even in practice, it is poorly enforced. One of the approaches that companies have to ensure this right, is using alternative means of collective gathering.

3. Adequate standards of living

One of the main challenges in this respect is the lack of the clear definition of "living wage" of employees. The pressure imposed on suppliers with regard to lead time and production costs, causes unfair price levels in supply chains. This may lead to unfair practices towards workers, and also affect price levels for SMEs down the supply chain.

4. Loss of Biodiversity

The elimination of the loss of biodiversity throughout companies' supply chains is challenged by the complexity of impacts that a company might have.

5. Unfair price levels

[160] Ibid., [p. 8].
[161] CREM – a company providing consultancy, research and training in the field of sustainable development on international, national and local scale. http://www.crem.nl.
[162] SOMO - The Centre for Research on Multinational Corporations (SOMO) is an independent, not-for-profit research and network organisation working on social, ecological and economic issues related to sustainable development. http://www.somo.nl.
[163] Marjon van Opijnen, Joris Oldenziel, "Responsible Supply Chain Management: Potential Success Factors and Challenges For Addressing Prevailing Human Rights and Other CSR Issues In Supply Chains of EU-Based Companies", European Union 2011, [p. 23].

Tackling unfair price levels is influenced by market mechanisms, macro-economic and investment policies and hardly influenced by one single company. The unfair price level is also a result of import barriers and domestic subsidies.

5.1.5 POLICIES AND INITIATIVES AIMED AT GOVERNANCE AND MANAGEMENT OF THE SUPPLY CHAIN

The legal framework for the RSCM can be analysed on various levels. As RSCM is perceived as part of companies' corporate social responsibly, the same general CSR framework is valid for the RSCM.

CSR is an internationally recognised concept, regulated to some extent at the international, regional, and country level. Internationally recognised principles, guidelines and tools on CSR, both at the European and global level may be found in the following documents:

- United Nations Guiding Principles on Business and Human Rights,
- United Nations Global Compact,
- OECD Guidelines for Multinational Enterprises (OECD Guidelines),
- ILO Tri-partite Declaration of Principles on Multinational Enterprises and Social Policy,
- ISO 26000 Guidance Standard on Social Responsibility (ISO 26000)

The European Commission refers to the aforementioned documents as "an evolving and recently strengthened global framework for CSR,"[164] therefore on the basis of these instruments the Commission has built its CSR strategy. Furthermore, companies make the public references to the following instruments:[165]

- International Bill of Human Rights consisting of the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, and the International Covenant on Civil and Political Rights and its two Optional Protocols,
- European Convention on Human Rights,
- ILO Core Conventions and the Declaration on Fundamental Principles and Rights at Work (Instruments of the ILO),
- Global Reporting Initiative (GRI).

Despite general CSR instruments, there are many initiatives at the governmental level, company level (cross-sectoral and sectoral level), and multi-stakeholder initiatives related to supply chain management.

The most recent development in responsible supply chain management, is the G7[166] agreement on concrete steps for implementing labour, social and environmental standards in

[164] European Commission, "An Analysis of Policy References made by large EU Companies to Internationally Recognised CSR Guidelines and Principles", March 2013, http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr/csr-guide-princ-2013_en.pdf.

[165] European Commission, "An Analysis of Policy References made by large EU Companies to Internationally Recognised CSR Guidelines and Principles", March 2013, [p. 3], http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr/csr-guide-princ-2013_en.pdf.

[166] G7 is an informal group of industrialized democracies including the U.S., Canada, France, Germany, Italy, Japan, and the U.K. Following the Russian annexation of Crimea, the G7 nations decided in March 2014 to meet without Russia until further notice. See e.g. https://www.g7germany.de/Webs/G7/EN/G7-Gipfel_en/Geschichtlicher-Ueberblick_en/historical-overview_node.html

textile supply chains. The G7 recognises the decent work and sustainable production as the global norm.[167]

Another initiative at the global level is a joint initiative by the Organisation for Economic Co-operation and Development (OECD) and WTO - Trade in Value Added (TiVA). The initiative focuses on the value added by each country in the production of goods and services that are consumed worldwide. Within the initiative, a number of indicators were designed to better inform policy makers by providing new insights into the commercial relations between nations.[168]

5.1.6 SECTORAL ANALYSIS

Electronics

To ensure better understanding of the ethical and human rights issues at stake and their complexity, this section addresses the challenges for a particular example of electronics sector. The study provides also with the initiatives related to the RSCM in the electronics sector.

Electronics is a highly competitive sector, where companies' existence and a success depends on innovations. Information and communication technology companies produce a wide variety of electronic goods, such as laptops, mobile-phones, TVs and their components.[169] The world leaders in electronics are companies from the U.S., followed by Japan and Europe.[170] According to research conducted by CREM and SOMO in this regard, the challenges of the supply chain in electronics include three phases:

- the extractives phase – in which metals and mineral used in electronic products are mined;
- the production phase – during which electronic products are manufactured and assembled;
- the disposal phase – during which redundant or obsolete products are disposed of.[171]

The challenge for responsible supply chain management in electronics is mostly caused by a complexity of links in the supply chain. Problems may occur therefore in the following stages of the supply chain:

- Outsourcing and supply chains (complex supply chains including thousands of smaller companies; weaker relations and knowledge of suppliers and the monitoring systems, risks of human rights violations including child labour; violation of worker rights);[172]
- Mining (conflict minerals - various metals such as tin, tungsten, tantalum and gold sourced from conflict areas, e.g. from the Democratic Republic of Congo; destruction of the environment; serious health risks for the mine workers);[173]

[167] http://www.bmz.de/g7/en/Entwicklungspolitische_Schwerpunkte/Menschenwuerdige_Arbeit/index.html
[168] http://www.oecd.org/sti/ind/measuringtradeinvalue-addedanoecd-wtojointinitiative.htm.
[169] Marjon van Opijnen, Joris Oldenziel, "Responsible Supply Chain Management: Potential Success Factors and Challenges For Addressing Prevailing Human Rights and Other CSR Issues In Supply Chains of EU-Based Companies", European Union 2011, [p. 128].
[170] Ibid.
[171] Ibid.
[172] Ibid., [p. 129].
[173] Ibid., [p. 130].

- Manufacturing – precarious work (informal employment; violation of worker rights; water consumption, irresponsible disposal of chemical or toxic substances);[174]
- Disposal recycling of electronics waste (degradation of environment, risks for human health).[175]

An important aspect of the development of electronic devices are minerals. Some of these minerals come from conflict-affected and high-risk areas, such as the Central African Republic, Colombia, and the Democratic Republic of Congo. Without any doubt, the minerals trade has been partly responsible for fuelling deadly conflicts that have displaced 9.4 million people.[176] The positive aspect of companies involved in mining and trade in minerals is their potential to generate income, growth and prosperity, sustain livelihoods and foster local development.[177] However, operating in complex environments in situations, may also put these companies at risk of contributing to or being associated with significant adverse impacts, including serious human rights abuses and conflict.[178]

The overall principle that companies should apply to all aspects of their activity is due-diligence, an on-going, proactive and reactive process through which companies can ensure that they respect human rights and do not contribute to conflict.[179]

Some of the examples of initiatives in regard to the RSCM in electronics include:

- **Ethical Trading Initiative (ETI):** ETI is a leading alliance of companies, trade unions and NGOs that promotes respect for workers' rights around the globe. They strive for a world where all workers are free from exploitation and discrimination, and enjoy conditions of freedom, security and equity. http://www.ethicaltrade.org/

- **Good Electronics:** Good Electronics is a strict not-for-profit network bringing together networks, organisations and individuals that are concerned about human rights, including labour rights, and sustainability issues in the global electronics supply chain, including but not limited to trade unions, grass roots organisations, campaigning and research organisations, academia, and activists. http://goodelectronics.org/

- **Milieu Project Sierteelt:** The MPS Group not only develops and administers certificates, it also carries out certification itself. MPS offers also various courses in this specialised field. http://www.my-mps.com/en/

- **Apparel Industry Partnership's agreement:** Workplace code of conduct. http://www.uiweb.uidaho.edu/fcs223/AIP%20Workplace%20Code%20of%20Conduct.htm & The AIP developed a code of conduct and principles on code implementation.

[174] Ibid., [pp. 131-132].
[175] Ibid., [p. 132].
[176] https://www.globalwitness.org/campaigns/conflict-minerals/conflict-minerals-europe-brief/.
[177] OECD, "OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas", Second Edition, OECD Publishing, [p. 12].
[178] Ibid.
[179] OECD (2011), *OECD Guidelines for Multinational Enterprises*, OECD, Paris; OECD (2006), *OECD Risk Awareness Tool for Multinational Enterprises in Weak Governance Zones*, OECD, Paris; and, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework* (Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, A/HRC/17/31, 21 March 2011).

http://www.natlconsumersleague.org/worker-rights/105-worker-safety/300-apparel-industry-partnership-celebrating-10-years-of-fighting-sweatshops

- **International Labour Organization:** The main aims of the ILO are to promote rights at work, encourage decent employment opportunities, enhance social protection and strengthen dialogue on work-related issues. http://www.ilo.org/pardev/public-private-partnerships2/supply-chains/lang--en/index.htm

- **Fair Labour Association (FLA):** Since 1999, the FLA has helped improve the lives of millions of workers around the world. As a collaborative effort of socially responsible companies, colleges and universities, and civil society organizations, FLA creates lasting solutions to abusive labour practices by offering tools and resources to companies, delivering training to factory workers and management, conducting due diligence through independent assessments, and advocating for greater accountability and transparency from companies, manufacturers, factories and others involved in global supply chains. http://www.fairlabor.org/

- **Workers' Rights Consortium:** The Consortium is an independent labour rights monitoring organisation, conducting investigations of working conditions in factories around the globe. Our purpose is to combat sweatshops and protect the rights of workers who make apparel and other products. http://www.workersrights.org/

- **Conflict-free Tin Initiative:** The CFTI is a multi-stakeholder project focused on realistic and sustainable solutions to the issues of "conflict minerals" from the DRC and adjoining countries. http://solutions-network.org/site-cfti/

- **Conflict Free sourcing Initiative:** The CFSI offers companies and their suppliers an independent, third-party audit that determines which smelters and refiners can be validated as "conflict-free," in line with current global standards. http://www.conflictfreesourcing.org/ & the Electronic Industry Citizenship Coalition and the Global e-Sustainability Initiative are the founders of CFSI. http://www.eiccoalition.org/initiatives/conflict-free-sourcing-initiative/

In May 2015, the Members of the European Parliament (MEPs) voted in favour of a strong and binding law to tackle the deadly trade in conflict minerals.[180] As the result, European companies importing four key minerals – tin, tungsten, tantalum and gold – would be obliged to ensure their purchases are not contributing to conflict or human rights abuses in other countries.[181] This would also mean, that European companies importing minerals for production of such electronic goods would be required to source minerals responsibly for the first time.[182]

5.1.7 CASE STUDY: SEDEX

Here, we discuss the initiatives undertaken by Sedex. The case study is based on an interview with Jo Webb – Head of Stakeholder Relations.

Sedex

[180] https://www.globalwitness.org/press-releases/european-parliament-defies-lobbying-vote-strong-conflict-minerals-regulation/.
[181] Ibid.
[182] Ibid.

Our mission is to drive collaboration, increase transparency and build the capacity that's needed to raise standards across all tiers of the supply chain. We offer the world's largest collaborative platform for managing and sharing ethical supply chain data, along with leading-edge services which multi-national companies use to understand, monitor and manage supply chains risks and improve standards. Our global membership totals over 38,000 buyers, suppliers and audit firms, including key sustainability thought leaders.

Sedex (www.sexdexglobal.com) is a not for profit membership organisation working with buyers and suppliers around the world to deliver improvements in responsible and ethical business practices in global supply chains.[183] Formed in 2004, Sedex offers the world's largest collaborative platform for managing and sharing ethical supply chain data, along with leading-edge services which multi-national companies use to understand, monitor and manage supply chains risks and improve standards[184] Key markets include Europe, Asia, Africa, North America and Latin America. Sedex is also expanding its reach into newer countries such as Australia.[185] Sedex brings together more than 38,000 companies from across 28 sectors in over 150 countries, including those sectors engaged in R&I, e.g. chemicals, engineering, IT, telecom & electrical, drugs and pharmaceutical products.[186] Sedex is not a standard setting body, and does not have a code of conduct or provide certification, rather its role is to enable companies to effectively share and manage supply chain information, with the aim of driving continuous improvement.[187]

Sedex's mission is to drive collaboration, increase transparency and build the capacity that's needed to raise standards across all tiers of the supply chain. Firstly, the organisation works to ease the burden on suppliers facing multiple audits, questionnaires and certifications; and secondly, Sedex drives improvements in the ethical performance of global supply chains.[188] Sedex's core product is a secure, online database that allows members to store, share and report on information in four key areas: labour standards; health & safety, the environment, and business ethics.[189] Sedex members are divided into three groups that reflect the different levels of functionality available in the Sedex system – Buyer membership, Buyer/Supplier membership and Supplier membership.[190]

In general, buyers can benefit from Sedex membership through having access to an electronic system that collects and analyses information on ethical and responsible business practices in the supply chains of its respective customers.[191] Furthermore, Sedex offers a variety of reporting tools that enable buyers to keep track of their suppliers' performance, in addition to providing access to an advanced Risk Assessment Tool.[192] Through participating in the Sedex network, suppliers can share ethical information with multiple customers in an efficient and cost effective way.[193] By enabling the opportunity to share the same data with many customers, Sedex helps reduce the need for multiple audits, allowing both parties, the suppliers and customers, to concentrate on making real improvements.[194]

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[183] http://www.sedexglobal.com/about-sedex/
[184] http://www.sedexglobal.com/about-sedex/
[185] Sedex, "Sedex Annual Review 2013/14: Bringing transparency to global, multi-tier supply chains", [p. 3]. Note: Global spread of Sedex members according to Sedex Annual Review 2013/2014: Asia & Australasia 44.4 percent, Europe 37.51 percent, North America 7.04 percent, Africa & Middle East 5.0, South & Central America 6.06 percent.
[186] Sedex, "Sedex Annual Review 2013/14: Bringing transparency to global, multi-tier supply chains", [p. 6].
[187] http://www.sedexglobal.com/about-sedex/
[188] http://www.sedexglobal.com/about-sedex/
[189] http://www.sedexglobal.com/about-sedex/
[190] http://www.sedexglobal.com/about-sedex/members/
[191] http://www.sedexglobal.com/about-sedex/what-we-do/
[192] http://www.sedexglobal.com/about-sedex/what-we-do/
[193] http://www.sedexglobal.com/about-sedex/what-we-do/
[194] http://www.sedexglobal.com/about-sedex/what-we-do/

Sedex is code neutral organisation, therefore it does not require prospective members to adhere to specific criteria in order to become members. Sedex membership is about showing the commitment to drive improvements in a company's supply chain. Sedex allows companies to decide themselves how they want to proceed and assists companies in this process by providing them with a number of tools to facilitate the assessment.

The assessment consists of six key steps:

1. Supply chain mapping – Sedex helps companies to understand who their suppliers are, allowing them to map their suppliers down to multiple tiers.

2. Sedex on-line member only Self-Assessment Questionnaire (SAQ) – Through the questionnaire, Sedex asks members common questions regarding internationally accepted Labour Standards, Health & Safety, The Environment and Business Ethics requirements. Members also provide input through addressing key indicators of risk and maturity in terms of managing social, governance and environmental issues. Sedex is a cross-sector/multi-sector organisation, therefore while there is only one SAQ, depending on the suppliers profile the questionnaire filters questions that are relevant for that specific profile. Currently, Sedex is working on introducing a new modular functionality to provide greater specification for certain customers or sectors.

3. The Risk Assessment tool – Sedex has developed this tool in partnership with global risk experts Maplecroft. The tool analyses hundreds of indices and factors including human rights violations, political risk, corruption risks, and child labour alongside management proficiency and ability to mitigate risk of the individual site.[195] The risk assessment is especially important for large companies with complex supply chains, because it can help them to understand where to prioritize their focus.

4. Audit (assessment) – The Sedex Associate Auditor Group (AAG) developed the Sedex Members Ethical Trade Audit (SMETA), as a response to member demand for an ethical audit report format that could be more easily shared.[196] SMETA aims to reduce the duplication of effort in ethical trade auditing, thus benefitting retailers, consumer brands, and their suppliers.[197] According to Sedex, SMETA is "not a code of conduct, a new methodology, or a certification process."[198] It is an audit procedure reflecting the compilation of good practice in ethical audit technique.[199] Around 10,000 audits are uploaded to the Sedex platform per year. When Sedex first launched the SMETA methodology, 90 percent of the audits uploaded onto the platform were based on company code for audits whereas now 90 percent of the audits are performed against SMETA, demonstrating the success of the initiative. SMETA is now one of the most used audit methods worldwide. According to Jo Webb, "a part of its success is that we included audit companies, brands, retailers and suppliers in its development."

5. Reporting – According to Sedex, improving awareness of a company about its supply chain can help to mitigate risk and protect its reputation. In order to enhance a company's supply chain visibility, Sedex offers in-depth, analytical reports that highlight trends, alerts a company to potential risks and help it to prioritize its resources. The huge amount of data stored by Sedex, offers not only the ability to address risks but also provides examples of good practices that can inspire and guide change.

[195] http://www.sedexglobal.com/member-services/risk-assessment/
[196] http://www.sedexglobal.com/ethical-audits/smeta/
[197] http://www.sedexglobal.com/ethical-audits/smeta/
[198] http://www.sedexglobal.com/ethical-audits/smeta/
[199] http://www.sedexglobal.com/ethical-audits/smeta/

6. Capacity building – Sedex offer various capacity building tools, such as the Sedex Supplier Workbook. The workbook is a free, publicly available document offering practical guidance to help suppliers across the world to understand what 'good practice' looks like when working towards the Ethical Trading Initiative (ETI) and other Code requirements. The Workbook also offers advice on how suppliers can reach these requirements. Therefore, Sedex aims to build capacity at the bottom of the extended supply chain.

As regards the main ethical risks in the supply chain, Jo Webb notes that the key risks can be very varied. Common non-compliances in social audits include health and safety issues as well as non-compliance related to wages and working. Other issues such as discrimination, bullying and bonded labour can be harder to tackle as they are not always as easy to find through the audit process. Data from a briefing by Sedex shows that fire safety non-compliances make up a 1/3 of all health and safety non-compliances globally[200] and this level of data mining helps companies understand global trends and scale of issues. Jo Webb feels that the question regarding the main ethical risks in the supply chain is complex, not only because the risks vary depending on the sector and the local context, but also because some forms of non-compliance gain more media attention e.g. modern slavery, whereas other issues such as corruption are harder to uncover.

When asked about managing difficult relations with a host country that could be defined as a complex environment, Job Webb suggested that the SMETA methodology allows the auditor to raise issues regarding non-compliance against both the ETI base code (a measurable version of ILO conventions) and local laws. In her opinion, the first thing is to understand where issues exist against local law versus international frameworks. The next step involves working with a supplier to address and meet the minimum legal standards. However, if a supplier does that already, it can be challenging to move them to aim for an aspirational, higher level standard. Nevertheless, the interviewee addressed different approaches that companies can use. First of all it is the purchasing power based on a customer requirement, secondly it is about demonstrating the business benefit to the supplier addressing them. Furthermore, cooperation and working with others can bring about great change. Sedex is an example of an organisation in which companies work together on the same aligned framework. The collective effect of a number of companies asking for the same information, may significantly influence the behaviour of an individual company. Jo Webb emphasized, the need for standardization around international frameworks. Different legislation or standards in different countries only fragments the issue for the supply chain and can make it more confusing for suppliers. This fragmentation also reduces the willingness of companies and other actors to respond to lots of different standards. Webb added "(i)f it is one, they can meet and satisfy the majority of requests."

Regarding the effectiveness of the current legal framework of corporate responsibility, the interviewee noticed that from one stand point, there are a lot of companies and organisations that would say voluntary standards are effective instruments. She added that some larger companies are in favour of legislation, because they feel it will level the playing field. In Webb's opinion, there are clever ways of looking at how legislation works, e.g. there has been quite a lot of debate within the legal profession about the modern slavery bill that was launched in the UK, and the effectiveness of a disclosure based rule versus strengthening of existing legislation to expand it to require reporting to cover human rights in the supply chain. The interviewee emphasized that this a question of the effectiveness of voluntary standards. Legislation has a role to play in levelling the field, however, the additional administration burden placed on the supply chains, and particularly SMEs, should be taken into account. The crucial point is that legislation should be enforced. Many of the supply chain risks are tackled in legislation, however, the legislation is not enforced. The issue that Webb highlights is "the need to have a balance between appropriate legislation combined with effective enforcement."

[200] http://www.sedexglobal.com/wp-content/uploads/2013/09/Sedex-Briefing-Fire-Safety-August-2013.pdf

In terms of the European approach to responsible supply chain management, Jo Webb feels that "it is a very difficult road, that has to be treated very carefully, even when well-intentioned, the more and more standards that are created, the more and more legislation is created (…) causing a huge amount of confusion within the supply chain." There are a lot of existing initiatives, standards, methods and local legislation on supply chain management, e.g. the UN Guiding Principles on Human Rights and Business, the UN Global Compact, ETI base code and the ILO Conventions. However, for a supplier, it is extremely difficult to know which standards or frameworks are relevant. In the opinion of the interviewee, there are some European frameworks, but they need to address their actual goal, which is to support capacity within smaller suppliers, and the most effective means of doing that. Clarity at the international level is crucial.

Jo Webb suggests that a cross-sector approach to responsible supply chain management should be based on collaboration. Furthermore, such an approach should not try to "reinvent the wheel", but look at different legislation, initiatives, mechanisms and standards that already exist. Supply chain policies should be grounded in implementation, because a policy has to be implemented in order to succeed. The interviewee advised seeking guidance from persons and institutions that implement these policies, including audit companies, researchers, people on the ground, regarding the practical aspects of their implementation.

5.1.8 CONCLUDING REMARKS

The success of working towards more responsible management of supply chains heavily depends on the involvement and contribution of other actors, such as governments, suppliers, NGOs and communities.[201] According to Ferrell (et al.) "the unbalanced focus on technological innovations requires oversight by supply chain members to develop programs that inform about mutual ethical risks and to address solutions to ethical and social issues. This makes it necessary to have communication and coordination about ethical decisions throughout the supply chain."[202]

5.2 SCIENTIFIC MISCONDUCT

5.2.1 INTRODUCTION

Scientific research misconduct – which can involve a fabrication and falsification of research results or plagiarism of other people's scientific work – is a significant problem today.[203] Fabrication, falsification, plagiarism and other questionable or irresponsible practices can affect the scientific community both *internally* (e.g., by making the identification of reliable research difficult for other scientists) and *externally* (e.g., by compromising public trust in scientific enterprise as a whole). The seriousness of scientific research misconduct should not be underestimated. For example, between 2009 and 2014, a European guideline was in place, issued by the European Society of Cardiology, which recommended the use of so-called beta-blockers for protecting the heart during non-cardiac surgery. This guideline was largely based on a 1999 study conducted a surgeon, Dr. Don Poldermans, which aimed to show that the risk

[201] Responsible Supply Chain Management Potential Success Factors And Challenges For Addressing Prevailing Human Rights And Other Csr Issues In Supply Chains Of Eu-Based Companies Executive Summary Marjon Van Opijnen Msc Ma (Crem) Joris Oldenziel Ma (Somo), [P. 1].
[202] O. C. Ferrell , Mary Margaret Rogers, Linda Ferrell & Jennifer Sawayda, "A framework for understanding ethical supply chain decision making", pp. 260-287 in *Journal of Marketing Channels*, 20:3-4, (2013), [p. 265].
[203] Fanelli, Daniele, "How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data", *PLoS ONE*, Vol. 4, No. 5, 2009, e5738.

of cardiac arrest in non-cardiac surgeries was reduced by 90 per cent if beta-blockers were used. Dr. Poldermans was also the then chairman of the committee which issued the guidelines. In 2012, a scientific integrity committee ruled that the results of studies conducted by Dr. Poldermans had been fabricated, including his 1999 study on beta-blockers. The guideline was subsequently abolished in 2014, after British researchers published a paper raising the possibility that using beta-blockers might in fact increase the risk of cardiac arrest, and that by following an established guideline UK doctors may have caused as many as 10,000 deaths each year.[204]

There is evidence that cases of scientific research misconduct are increasing at a rate much higher than that of global scientific output.[205] While the pressure to publish and to have significant research results contributes to the problem of scientific research misconduct,[206] the issue of scientific research misconduct can be further exacerbated by the globalisation of scientific research.[207] The present study aims to explore the impact of globalisation on scientific research integrity and misconduct, with a focus on possible causes and frequency of research misconduct, as well as existing and proposed responses to research misconduct.

5.2.2 DEFINING RESEARCH MISCONDUCT

There is not a universally accepted definition of scientific research misconduct. A recent joint meeting of the British Medical Journal (BMJ) and the Committee on Publication Ethics (COPE) restated an earlier definition of scientific research misconduct as ‘‘Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards’’.[208] The Norwegian Committee on Scientific Dishonesty defines research misconduct as “all serious deviation from accepted ethical research practice in proposing, performing, and reporting research”.[209] However, such a broad definition of scientific research misconduct is rather unsatisfactory, since it does little to properly delineate between what can and what cannot be counted as research misconduct. Specifically, a loose definition of scientific research misconduct of this kind can make it difficult to distinguish ‘honest error’ from intentional misconduct, and can also lead to scientific disputes becoming accusations of misconduct.[210] Hence a narrower and specific definition of scientific research misconduct is required.

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[204] Husten, Larry, “Medicine or mass murder?: guideline based on discredited research may have caused 800,000 deaths In Europe over the last 5 years”, *Forbes*, 2014. http://www.forbes.com/sites/larryhusten/2014/01/15/medicine-or-mass-murder-guideline-based-on-discredited-research-may-have-caused-800000-deaths-in-europe-over-the-last-5-years.

[205] Van Noorden, Richard, “The trouble with retractions”, *Nature*, Vol. 478, 2011, pp. 26-28.

[206] Angell, Marcia, “Publish or Perish: A Proposal”, *Annals of Internal Medicine*, Vol. 104, No. 2, 1986, pp. 261-262.

[207] Resnik, David, B., “International standards for research integrity: An idea whose time has come?”, *Accountability in research*, Vo. 16, No. 4, 2009, pp. 218-228.

[208] BMJ & COPE, “A Consensus Statement on Research Misconduct in the UK”, BMJ & COPE High Level Meeting, 12 January 2012. http://publicationethics.org/files/A_consensus_statement_on_research_misconduct_in_the_UK.

[209] Nylenna, Magne, Daniel Andersen, Gisela Dahlquist, Matti Sarvas, and Asbjørn Aakvaag, “Handling of scientific dishonesty in the Nordic countries,” *The Lancet*, Vol. 354, No. 9172, 1999, pp. 57-61.

[210] Smith, Richard, (2000) “What is research misconduct?”, *Journal of the Royal College of Physicians of Edinburgh*, Vol. 30, 2000, pp. 4-8.

For this reason, the question of definition of scientific research misconduct was a much debated issue in the US at the turn of the century.[211] Given the need for a clearer definition of scientific research misconduct, in 2000 the US Office of Science and Technology Policy created a longer and clearer definition of scientific research misconduct (OSTP 2000), according to which scientific research misconduct is defined as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results". Here 'fabrication' is explained as "making up data or results and recording or reporting them"; 'falsification' as "manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record"; and 'plagiarism' as "the appropriation of another person's ideas, processes, results, or words without giving appropriate credit".[212] Furthermore, in addressing scientists' concern about the implication of such a definition for 'honest errors' and academic disputes, the definition goes on to clarify that "research misconduct does not include honest error or differences of opinion"[213].[214] Moreover, the proposed description of scientific research misconduct as "falsification, fabrication and plagiarism" was echoed in the Singapore Statement, adopted at the Second World Conference on Research Integrity in Singapore in 2010, according to which "researchers should report to the appropriate authorities any suspected research misconduct, including fabrication, falsification or plagiarism".[215]

It must however be noted that apart from the above three forms of scientific misconduct – *fabrication, falsification and plagiarism* – scientific integrity can also be undermined by certain other 'questionable', or 'irresponsible', research practices,[216] practices that undermine the integrity and trustworthiness of scientific research, such as publishing a scientific work more than once, falling short of declaring conflicting or competing interests, reporting research findings in a selective manner (e.g. by excluding certain data without proper disclosure), improper listing of authors (e.g. so-called 'guest-authorship' or 'ghost authorship' in which co-authorship is attributed to those who have made little or no contribution to the work), using misleading analytical methods and tools, and so on.[217] Thus, Brian Martinson and colleagues[218] have argued that in order to safeguard the integrity and trustworthiness of science, it is highly important to look beyond falsification, fabrication and plagiarism, to a wider range of questionable or irresponsible practices such as the above.

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[211] Rennie, Drummond, and C. Kristina Gunsalus, "Regulations on scientific misconduct: lessons from the US experience", in Stephen Lock, Frank Wells, and Michael Farthing (eds.), *Fraud and Misconduct in Biomedical Research* (3rd edition), BMJ Books, London, 2001, pp. 13-31.

[212] Office of Science and Technology Policy, Federal Policy on Research Misconduct, Federal Register, Vol. 65, 2000, pp. 76260-76264. http://www.gpo.gov/fdsys/pkg/FR-2000-12-06/html/00-30852.htm.

[213] Ibid.

[214] It also offers three requirements for identifying research misconduct: (1) there must be *"a significant departure from accepted practices of the relevant research community"*; (2) the misconduct must be *"committed intentionally or knowingly, or recklessly"*; and (3) the allegations of research misconduct must be proven *"by a preponderance of evidence"*.

[215] Singapore Statement on Research Integrity, 2nd World Conference on Research Integrity, 21-24 July, Singapore, 2010. http://www.singaporestatement.org/statement.html.

[216] Martinson, Brian, C., Melissa S. Anderson, and Raymond de Vries, "Scientists behaving badly", *Nature*, Vol. 435, June 2005, pp. 737-738.

[217] Angell, Marcia, "Publish or Perish: A Proposal", *Annals of Internal Medicine*, Vol. 104, No. 2, 1986, pp. 261-262.

[218] Martinson, Brian, C., Melissa S. Anderson, and Raymond de Vries, "Scientists behaving badly", *Nature*, Vol. 435, June 2005, pp. 737-738.

5.2.3 WHY IS RESEARCH MISCONDUCT ETHICALLY WRONG?

There are several reasons why scientific research misconduct is ethically wrong. In a discussion of research ethics, David Resnik[219] identifies at least four different reasons why misconduct in scientific research can have serious moral implications. First, scientific misconduct, in particular, fabrication and falsification of research and experiment results, can undermine one of the main purposes of scientific research – gaining knowledge and avoiding error. Second, research misconduct can also negatively affect the values and norms that are of great importance to the kind of scientific research that requires cooperation and collaboration among scientists from different disciplines, institutions, organisations and counties, such as trust, accountability, mutual respect and fairness. Third, research misconduct can diminish and compromise public trust in and support for scientific practice as a whole. This diminishing of the public trust and support can have further implications for public funding of scientific research. Fourth, research misconduct can have serious implications for the health and safety of other people, as well as for animal welfare. Thus, for example, a scientist or a laboratory that has falsified or fabricated research results in a pharmaceutical or clinical trial might eventually cause physical or mental harm to patients.

To these four reasons identified above, one can also include the possibility that scientific research misconduct can have damaging implications for the economy, especially within modern day knowledge economies. However, to date there appears to have been no studies of economic damages caused by scientific research misconduct. This can be due to the fact that economic impact, especially in cases of fraud carried out for years, may be very difficult to empirically quantify. Moreover, a recent article, entitled 'Fraud in Science: A Plea for a New Culture in Research', published in *European Journal of Clinical Nutrition*,[220] notes that "despite numerous cases of research misconduct being made public, this issue is still a taboo topic among the scientific community".

5.2.4 CAUSES OF RESEARCH MISCONDUCT

Why does research misconduct happen? As funding and the promotion of researchers especially within academic institutions are closely tied to their publication output, scientists can be pressured into publishing as many times as possible (hence the infamous *"publish or perish"* dictum that one frequently hears within academic circles). This pressure to publish can have a number of undesirable implications for the integrity of science, such as fabrication, falsification and plagiarism, as well as seeking quick results by undertaking trivial studies, reporting the same study in instalments and the improper listing of authors.[221] Nonetheless, it would be rather inadequate to assert that the 'pressure to publish' is the sole explanation of scientific misconduct. Thus, for example, Smith notes that "all human activity is associated with misconduct",[222] or as Ana and colleagues have recently noted: "Wherever there is

[219] Resnik, David B., "What is Ethics in Research & Why is it Important?", National Institute of Environmental Health Sciences, 2011. http://www.niehs.nih.gov/research/resources/bioethics/whatis/.
[220] Müller, M. J., B. Landsberg and J. Ried, "Fraud in science: a plea for a new culture in research", *International Journal of Obesity*, Vol. 38, No. 4, April 2014, pp. 572-576.
[221] Angell, Marcia, "Publish or Perish: A Proposal", *Annals of Internal Medicine*, Vol. 104, No. 2, 1986, pp. 261-262.
[222] Smith, Richard, "Research misconduct: the poisoning of the well", *Journal of the Royal Society of Medicine*, Vol. 99, No. 5, 2006, pp. 232-237.

human activity there is misconduct".[223] Furthermore, as an explanation the 'pressure to publish' is also inadequate, since as a loose notion, it can contain in itself a number of more concrete causally contributing factors. Indeed, as will become clear below, one can be pressured into publishing as frequently as possible, not only because one is seeking promotion or funding. Hence, there is a need for a more thorough and nuanced analysis of possible causes of scientific misconduct.

A more robust empirical analysis of the causes of scientific research misconduct was produced by Davis and colleagues in 2007. In this study, the authors collected data, in the form of statements extracted from closed case files and documents including investigative reports, witness statements, transcripts and correspondence of the Office of Research Integrity (ORI). Once collected, 44 different concepts were assigned to these statements. The resulting 44 concepts were then grouped into the following seven clusters: (1) personal and professional stressors, (2) organizational climate, (3) job insecurities, (4) rationalizations *A*, (5) rationalizations *B*, (6) personal inhibitions, and (7) personality factors. The first cluster ('personal and professional stressors') concerns not only structural factors such as 'publish-or-perish pressure', but also a variety of situational stressors that may attenuate researchers' abilities to conduct research with integrity. The second cluster ('organizational climate factors') concerns not only the larger organization, but also what might be regarded as group-level factors, those which characterize the environment of the laboratory. These factors strengthen the argument that institutions such as universities and smaller units within those institutions might play an important role by creating an atmosphere that facilitates misconduct through various forms of alienation. The third cluster ('job insecurity factors') concerns the factors pertaining to the individual rather than to his or her work environment. These factors could be interpreted as weaknesses in the ability of the individual researcher to withstand what may well be ordinary work pressures which other researchers learn to handle effectively. The fourth and the fifth clusters ('rationalizations *A* and *B'* respectively) address a variety of rationalizations offered by the ORI respondents. According to the authors of the study, it appears that once misconduct is identified, offending researchers have a tendency to offer reasons for their behaviour, most of which externalize the responsibility and blame to others or external factors, such as denial of an injury, denial of responsibility and condemnation of the condemners. The sixth cluster ('personal inhibitions') is the smallest of all clusters, containing only two items: difficult job and frustrations, factors which appear to be work-related frustrations mainly stemming from the limitations of the individual rather than from the work environment. The seventh cluster ('personality factors') contains personality factors such as impatience, amnesia, laziness, character flaw and personal need for recognition.

Yet in another earlier work, Mark Davis has examined the role (regional or national) culture in scientific research misconduct.[224] Applying theories from sociological criminology, the author posits that the culture some researchers bring may be at odds with the norms of academic science and may emphasize ends more than means. As such, culture simply may be one of several causal factors in research misconduct and should be considered in the spirit of objective scientific inquiry. Finally, Davis has argued that recognising the role of culture in the adherence to research ethics underscores the importance of education and training of both

[223] Ana, Joseph, Tracey Koehlmoos, Richard Smith and Lijing L. Yan, "Research Misconduct in Low- and Middle-Income Countries", *PLoS Medicine*, Vol. 10, No. 3, 2013, pp. 1-6.
[224] Davis, Mark, S., "The role of culture in research misconduct", *Accountability in Research: Policies and Quality Assurance*, Vol. 10, No. 3, 2003, pp. 189-201.

researchers and administrators in the responsible conduct of research and cultural diversity in an increasingly globalising world.

5.2.5 HOW FREQUENT IS RESEARCH MISCONDUCT?

Although some authors have noted that there has been an increase in the number of cases of scientific research misconduct, there has been relatively little empirical and quantitative research regarding the frequency of research misconduct. A recent quantitative study conducted by Ferric Fang and colleagues[225] into 2,047 biomedical research articles indexed by PubMed as retracted on 3 May 2012 revealed that only 21.3 per cent of retractions were attributable to error. 67.4 per cent retractions were attributable to scientific research misconduct, including fraud or suspected fraud (43.4 per cent), duplicate publication (14.2 per cent), and plagiarism (9.8 per cent). The study has further found that the percentage of scientific articles retracted because of fraud has increased approximately ten fold since 1975. The remainder were accounted for by miscellaneous or unknown reasons and causes. Thus, for articles in which the reason for retraction is known, three quarters were retracted because of misconduct or suspected misconduct, while only one quarter was retracted for error.

While the above study offers an insight into the frequency of occurrence of certain specific forms of scientific research misconduct, there remain serious difficulties in obtaining a complete picture of the prevalence and frequency of research misconduct, since most cases of scientific misconduct and fraud might simply be unpublicised.[226] In a similar vein, Richard Smith, notes that most cases of scientific research misconduct "probably" do not become public: "they are simply not recognized, covered up altogether; or the guilty researcher is urged to retrain, move to another institution, or retire from research".[227] Thus, from this perspective, while it is difficult to obtain good data on the frequency and prevalence of cases of scientific misconduct, it is quite plausible that there remain an underestimated number of cases of research misconduct, especially in those countries and academic institutions that lack tools and devices for safeguarding scientific integrity against research misconduct. Hence, Smith's suspicion that some disciplines, institutions and countries might seem to have more cases of misconduct simply because they have actually begun to face up to the problem.

But what about the developing countries, many of which are investing heavily in research? While there have been a number of high profile cases of misconduct in these countries, very little has been published on research misconduct in these developing countries.[228] A recent work by Ana and colleagues offers what might best be described as an initial sketch of research misconduct in low- and middle-income countries.[229]

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[225] Fang, Ferric, C., R. Grant Steen and Arturo Casadevall, "Misconduct accounts for the majority of retracted scientific publications", *Proceedings of the National Academy of Sciences*, Vol. 109, No. 42, 2012, pp. 17028-17033.
[226] Lock, Stephen, "Misconduct in medical research: does it exist in Britain?", *BMJ*, Vol. 297, 1988, pp. 1531-1535.
[227] Smith, Richard, "Research misconduct: the poisoning of the well", *Journal of the Royal Society of Medicine*, Vol. 99, No. 5, 2006, pp. 232-237.
[228] Ana, Joseph, Tracey Koehlmoos, Richard Smith and Lijing L. Yan, "Research Misconduct in Low- and Middle-Income Countries", *PLoS Medicine*, Vol. 10, No. 3, 2013, pp. 1-6.
[229] Ibid.

5.2.6 RESEARCH MISCONDUCT IN THE GLOBAL AGE

International standards for research integrity are important for several reasons. First, because research is often international in scope, it is necessary to have ethical standards that transcend national boundaries to resolve disputes that may arise when the parties come from different countries.[230] For example, suppose that a reviewer from country A suspects that an article submitted by authors from country B plagiarizes a previously published article from country A. Suppose, also, that government organizations from country A and country B have different definitions of plagiarism. The authors could argue that their behaviour does not qualify as plagiarism according to their country's rules. It may be difficult to resolve this issue without appealing to a common definition. Second, scientists can appeal to international integrity standards in the absence of local standards.[231] For example, if a developing nation has no regulations pertaining to data fabrication or falsification, then international standards could be used to evaluate scientific conduct. The Helsinki Declaration has functioned as a standard of conduct for research with human subjects in the absence of local laws.[232] Third, well-recognized, clear, and coherent international integrity standards can encourage the development of local standards. Countries that lack local standards for the conduct of research can use international standards as a model for the development of their own rules and policies. Some countries have used the Helsinki Declaration as a guide for developing their own policies, for example.[233] Fourth, international standards for research integrity can foster trust among scientists working in different countries. Investigators who are planning an international collaboration appeal to international standards as a benchmark for authorship, publication, data sharing, and other important concerns. If an ethical dispute arises during the collaboration, the investigators can appeal to a common benchmark.[234]

5.2.7 EXISTING AND PROPOSED RESPONSES TO RESEARCH MISCONDUCT

In addressing the problem of scientific research misconduct, according to Smith, the main emphasis should be placed not so much on reporting and investigating suspected cases of scientific misconduct, but on "raising the overall level of scientific integrity".[235] Thus, in addition to creating a list of unethical or questionable practices that scientists and researchers should avoid, there is also a need for codes of good practice, as well as a need for teaching integrity instead of simply warning against misconduct:

> Once their consciousness is raised, researchers will realize that they are constantly presented with ethically difficult questions around analysis of data, authorship, conflict of interest, informed consent, and a dozen other issues. There are usually not 'right' answers that can be read from a

[230] Resnik, David, B., "International standards for research integrity: An idea whose time has come?", *Accountability in research*, Vo. 16, No. 4, 2009, pp. 218-228.
[231] Ibid.
[232] Brody, Baruch A., *The Ethics of Biomedical Research: An International Perspective*, Oxford University Press, New York, 1998.
[233] Ibid.
[234] Resnik, David, B., "International standards for research integrity: An idea whose time has come?", *Accountability in research*, Vo. 16, No. 4, 2009, pp. 218-228.
[235] Smith, Richard, "Research misconduct: the poisoning of the well", *Journal of the Royal Society of Medicine*, Vol. 99, No. 5, 2006, pp. 232-237.

rulebook. Rather, researchers need to be able to think their way through the complexities to reach an ethically defensible answer.[236]

In addition to the above proposal, Smith contends that there is also an important role to be played by a national body to provide leadership in safeguarding the integrity and trustworthiness of scientific enterprise.[237] Such a body, accordingly, needs to raise consciousness about the problem, provide guidelines on good practice, encourage research and teaching, offer help with investigations of misconduct, as well as provide a place for whistle-blowers' to report concerns and for the hearing of major cases or appeals against local judgements.[238] One problem with local bodies –such as universities or hospitals – is that they frequently lack competence or commitment in tackling cases of scientific misconduct. These local bodies can also face a conflict of interest in that they fear that openly reporting and investigating a suspected case of research misconduct might damage the reputation of these local institutions.[239]

What are different countries doing to safeguard the integrity and trustworthiness of science against various acts of misconduct? In the US, there is the Office of Research Integrity (ORI), founded in 1992, an agency of the Department of Public Health and Scientific Research that is tasked with monitoring and preventing scientific research misconduct, as well as drawing up regulatory codes. In Europe, something similar has been done very recently: the European Science Foundation presented the European Code of Conduct for Research Integrity[240] during the second World Conference on Research Integrity that took place in Montreal in 2010. This Code contains guidelines for good scientific practice, and methods to prevent and control negative behaviours. However, as is specified in the text, "it is not a body of law, but rather a canon for self-regulation"[241] and "it is not intended to replace existing national or academic guidelines, but to represent a Europe-wide agreement on a set of principles and priorities for the research community".[242] For these reasons, although more and more scientific institutions and academic organizations have put in place structures to promote research integrity, in many European countries the decisions of research integrity authorities are still not legally binding.

The European Code of Conduct for Research Integrity appears to have been unsuccessful in one important regard. Thus, for example, Godecharle and colleagues, in their study published on *The Lancet*, have pointed out that "the observed heterogeneity in guidelines within and between European countries results in a confusing situation".[243] The study by Godecharle and colleagues offers an analysis of the guidelines on research integrity in the 27 countries of the European Union (plus Switzerland, Lichtenstein, Norway and Iceland). The study shows a very fragmented scenario: Denmark and Norway are the only two countries to have a specific

[236] Ibid.
[237] Ibid.
[238] Ibid.
[239] Ibid.
[240] European Science Foundation (ESF) and All European Academies (ALLEA), A European Code of Conduct for Research Integrity, 2012.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf.
[241] Ibid.
[242] Ibid.
[243] Godecharle, S., B. Nemery and K. Dierickx, "Guidance on research integrity: no union in Europe", *The Lancet*, Vol. 381, 2013, pp. 1097-1098.

law on scientific misconduct, while other countries, in addition to not having laws about this topic, have guidelines in which scientific misconduct is defined and judged in different ways. For example, in Sweden, carelessness is considered more serious than fabrication of data, while this is the opposite case in Finland, and fabrication of data is considered equivalent to fraud. Moreover, according to the study, in twelve European countries, it was impossible to identify any such guideline. In Europe, the issue of scientific research misconduct has also found its place among the projects included in Horizon 2020, one of the goals of which is "to assess the possibility to unify the codes, principles and methods at EU and international level".[244] Whether, and to what extent, this will be achieved still remains to be seen.

According to Pieter Drenth, the principal author of the European Code of Conduct for Research Integrity, there have been a number of reasons and factors that have prompted the creation and adoption of the European Code of Conduct for Research Integrity. Firstly, "the concern with respect to scientific integrity has always been one of the main … domains of interest for academies", and therefore, "it [the issue of scientific research integrity] has received high priority for quite some time already in academies … and certainly in the European association of academies (ALLEA)". Secondly, there have also been concerns about the "increase in the public exposure of cases of misconduct", which is, according to Drenth, "a very important concern for science". And finally, with the globalisation of research and innovation, "more and more research is being done in international collaboration":

> Of course national boundaries never were limitations to scientific collaboration, but during the last number of decades the internationalisation really assumed very considerable proportions … and that means that more and more integrity problems are not just only problems of one institute or one university or even one country … but it becomes an international issue. It's clear that the requirements of research integrity apply equally strong in international, collaborative research.

Furthermore, according to Drenth, the European Code of Conduct for research Integrity has emerged in response to a situation in which two different values are at stake: first, the trustworthiness of *"science as such"*, and, second, public trust in scientific enterprise. Here, the most important of concerns for the academy is "the protection of science as such": "if you violate norms of integrity", "if you don't follow the rules of scientific integrity", then "there is no way to distinguish [between] the true and the false", which is "for science as such a very essential condition". Additionally, there have been concerns regarding public trust in scientific enterprise. According to Drenth, as a result of research misconduct in sciences, "the media will emphasise that science cannot be trusted anymore", and "science as a valuable source of information, and as a dependable basis for decision-making will also be lost". This, Drenth argues, would be a serious loss for society, given that "proper science … is important for the development of society", "for the development of welfare and wellbeing of individuals in society".

In writing the European Code of Conduct for Research Integrity, there have been a number of similar systems of codes and standards that have inspired and influenced the content and substance of the European Code. Thus, according to Drenth, in writing the European Code, the authors have consulted a number of interesting integrity requirements for scientific publication produced by the Committee on Publication Ethics (COPE). Furthermore, the

[244] Horizon 2020, Developing governance for the advancement of responsible research and innovation. http://www.2020-horizon.com/Ethics-in-Research-Promoting-Integrity-i1671.html.

authors of the European Code have familiarised themselves with the Global Science Forum, an initiative by the OECD. It is also worth noting that, prior to the writing of the European Code, Drenth has also conducted a personal survey among all the presidents of academies of sciences in Europe, in which Drenth asked two questions: (1) to what extent concerns for the scientific integrity had a high priority in their academies, and whether it had resulted in a code of conduct within their academies; (2) whether they would feel that a European approach would be helpful or useful, and whether the European association of academies could have an instrumental role or function in the promotion of responsible research. The responses received, according to Drenth, revealed that, in Europe, there is "a variety of approaches, patchwork of codes, standards or regulations", and that these codes and standards are "not very harmonised with respect to the total European picture".

In writing the European Code of Conduct for Research Integrity, there have been a number of difficulties and challenges. According to Drenth, a first problem had to do with "the question of universality of norms and values with respect to scientific research". While there exist numerous different codes of conduct for scientific integrity in Europe, this variety of codes *"partly"* has to do with the differences in traditions, culture, history, as well as with the differences in legal contexts within different European countries. As a result of this, according to Drenth, one of the main difficult questions was how universal the codes to be formulated should be. To address the issue of universality, the European Code does now contain two sets of recommendations: first, *"basic requirements for responsible research"* which can be universal and applicable throughout Europe; and, second, *"practical, procedural aspects"* which may vary within different countries, institutions or disciplines. A second problem, according to Drenth, was the issue of how to define science. That is, whether science should be understood sufficiently broadly to include the arts and humanities, or whether science should be interpreted narrowly to comprise natural sciences only. The question of definition of science is thus important in setting norms for responsible conduct of research, since depending on the particular definitions, these norms can be said to apply to this or that scientific discipline. A third problem, according to Drenth, was the fact that there is "always" "a grey area" between what is acceptable and what is unacceptable as research behaviour in science. Finally, a fourth problem, according to Drenth, was determining relevant procedures for dealing with cases of scientific research misconduct.

According to Drenth, the European Code of Conduct for Research Integrity has one main objective – "to stimulate and further the emergence of institutional settings that will enforce research integrity within their own walls". Hence, the European Code is hoped to become "a basis for the development or improvement of a national or institutional code":

> What we hope is that these institutional codes – of course, they are fine, and they should exist also, but then sometimes they could be compared to the European code to see what is lacking in their own code of conduct, or what could be reformulated, so that it will be in better harmony with the European code. It also could work as a stimulus for countries and institutions within countries that do not have anything as yet, and the time we created the code there were still a number of countries where no serious or systematic approach was visible.

In addition, according to Drenth, the European code was hoped to go beyond the European boundaries and inspire or influence other similar codes concerning scientific integrity and research misconduct.

Efforts to harmonise guidance and regulation of scientific research integrity throughout Europe and worldwide, according to Drenth, are both *desirable* and *feasible*. Drenth notes that "the level of organisations and boards of academies, there is no doubt that this [harmonisation of regulation of scientific integrity] is both desirable and should be implemented, should be realised". Yet, when it comes to the question of feasibility, much depends on how much effect such harmonisation efforts will have on individual institutes and universities. Thus, for example, there are countries with well-organised, centralised, bodies that oversee regulation of scientific research integrity and misconduct. For instance in the Netherlands, according to Drenth, there is a very strong cooperative relationship between the academy, the national science foundation and the organisation of the universities. Within this context the Dutch have created a national organ for research integrity, appointed by the three constituencies – the academy, the national science foundation and the universities. As such, this body for research integrity can exert strong influence "from the central office on individual universities". However, Drenth notes, not all countries have such systems in place.

5.3 INDIGENOUS KNOWLEDGE

5.3.1 INTRODUCTION

Bioprospecting can be understood as the systematic search for novel bio-chemical compounds in wild life for the purposes of developing and commercialising new pharmaceutical, cosmetic, food and other kinds of products and innovations. Over the past four decades, bioprospecting has begun incorporating traditional or indigenous knowledge in the search for new biochemical compounds.[245] As most of the global biodiversity resides within developing countries,[246] it is frequently the case that companies and laboratories from rich countries engage in bioprospecting in the biodiversity-rich developing world. Hence, from this perspective, bioprospecting can be seen as one of the forms of the globalisation of research and innovation, in which companies from the developed global North come into contact with the indigenous peoples and communities from the developing global South.

Bioprospecting can sometimes become an instance of biopiracy that can be understood as "the unauthorized extraction of biological resources and/or associated traditional knowledge from developing countries"[247] or "the patenting of spurious 'inventions' based on such knowledge or resources without compensation".[248] In order to avoid the phenomenon of bio-piracy, appropriations of forms of knowledge and/or samples of biological materials should be not exploitative but beneficial to the indigenous groups and communities in question[249]. But what precisely is to be done to ensure that ethnomedicinal forms of bioprospecting are ethical? It

[245] Balick, Michael, J., "Ethnobotany and the identification of therapeutic agents from the rainforest", in Derek J. Chadwick and Joan Marsh (eds.), *Bioactive compounds from plants*, Chichester, Wiley & Sons, UK, 1990, pp. 22-31.
[246] Macilwain, Colin, "When rhetoric hits reality in debate on bioprospecting", *Nature*, Vol. 392, 1998, pp. 535-540.
[247] Dutfield, Graham, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, Earthscan, London, 2004.
[248] Ibid.
[249] Schroeder, Doris, "Sharing of Benefits" in Henk A.M.J. ten Have and Bert Gordijn (eds.), *Handbook of Global Bioethics*, Springer, Dordrecht, 2014, pp. 203-223.

has been proposed[250] (as well as implemented on numerous occasions) that the benefits resulting from the commercialisation of traditional forms of knowledge and local biological resources should be shared with the indigenous custodians of such knowledge and biological resources in a manner that is both fair and equitable.

This present work aims to critically explore the principle of benefit-sharing, by focusing on the case of the benefit-sharing agreement negotiated and signed between the San tribes of the Kalahari and the South African Council for Scientific and Industrial Research (CSIR). The agreement concerns the sharing of benefits resulting from the commercialisation of a bio-chemical compound derived from the Hoodia plant. The benefit-sharing agreement reached between the San and the CSIR is one of the earliest instances of benefit-sharing agreements that recognised the communal rights of indigenous groups as custodians of traditional knowledge[251]. Moreover, it has been hailed as setting a precedent for the negotiation of future benefit-sharing agreements between indigenous communities and government agencies, or commercial companies[252]. For these reasons, it is worthwhile to take a closer critical look at the San-Hoodia benefit-sharing case in order to assess whether implementations of the principle of benefit-sharing offers a solution to the issue of differentiating between bioprospecting and biopiracy.

5.3.2 BIO-PROSPECTING, BIO-PIRACY AND THE PRINCIPLE OF BENEFIT-SHARING

Bioprospecting is defined by the *Encyclopedia of Biodiversity* as "the systematic search for genes, natural compounds, designs, and whole organisms in wild life with a potential for product development by biological observation and biophysical, biochemical, and genetic methods".[253] According to archaeological and fossil records, humans began using plants as medicines in the Middle Paleolithic age, around 60 thousand years ago.[254] To date numerous medicines and pharmaceuticals have been developed on the basis of plants traditionally used in various ethnomedicinal systems.[255] According to the World Health Organisation (WHO), approximately a quarter of medicines are derived on the basis of bio-chemical compounds found in plants.[256] In addition to its value for medicine, bioprospecting has been hailed as a source of funding for the conservation of biodiversity.[257]

[250] One of the earliest of such proposals appears in the Convention on Biological Diversity of 1992, discussed in more detail in the subsequent section.
[251] The statement comes from a Satori interview with Roger Chennells, a lawyer who represented the South African San communities during their negotiations with the South African Council for Scientific and Industrial Research (CSIR).
[252] Ibid.
[253] Mateo, Nicolas, Werner Nader and Giselle Tamayo (2001) "Bioprospecting", in Simon Asher Levin (ed.), *Encyclopedia of Biodiversity* (Vol. 1), Academic Press, Massachusetts, U.S., 2001, pp. 471-488.
[254] Solecki, Ralph, S. "Shanidar IV, a Neanderthal Flower Burial in Northern Iraq", *Science*, Vol. 190, No. 4217, 1975, pp. 880-881.
[255] Fabricant, Daniel, S., and Norman R. Farnsworth, "The value of plants used in traditional medicine for drug discovery", *Environmental Health Perspectives*, Vol. 109, No. 1, 2001, pp. 69-75.
[256] Saslis-Lagoudakis, C. Haris, Vincent Savolainen, Elizabeth M. Williamson, Félix Forest, Steven J. Wagstaff, Sushim R. Baral, Mark F. Watson, Colin A. Pendry and Julie A. Hawkins, "Phylogenies reveal predictive power of traditional medicine in bioprospecting", *PNAS*, Vol. 109, No. 39, 2012, pp. 15835-15840.
[257] Rausser, Gordon C., and Arthur A. Small, "Valuing Research Leads: Bioprospecting and the Conservation of Genetic Resources", *Journal of Political Economy*, Vol. 108, No. 1, 2000, pp. 173-206.

Recent discoveries of novel bio-chemical compounds and advances in the production of plant-based innovations[258] have revived scientific interest in bioprospecting. Over the past four decades, bioprospecting has adopted ethnomedicinal approaches which incorporate traditional or indigenous knowledge in the search for new biochemical compounds.[259] While the number of plants used in traditional medicine globally has been estimated to be in the range of 10,000 - 53,000,[260] only a small portion of this number has been screened for useful bio-chemical compounds[261] and the plants from some regions have received less attention from researchers: for instance, only 1 per cent of tropical floras have so far been examined.[262] In discussing the need for bioprospecting for new crops and plants, Heiser pointed out the importance of encouraging more bioprospecting studies among the indigenous peoples before their cultures and ways of life would disappear.[263] Given these facts, it would seem that bioprospecting activities are very likely to continue way into the future.

Most global natural resources are plentifully available within the territories of developing countries, such as Brazil, India, Indonesia, and South Africa, countries where systems of traditional medicine are based on such natural resources. As Macilwain notes, "by a twist of fate, the world's biological resources are distributed in approximately inverse proportion to its material wealth".[264] Thus, for example, while the United Kingdom has around 1,800 plant species, Peru has about ten times more – 18,000 plant species.[265] Given that most of the global biological diversity exists in the developing countries of the global South, and most pharmaceutical companies from the developed countries of the Global North, it is often the case that these pharmaceutical companies conduct bioprospecting activities in the biodiversity-rich global South. From this standpoint, bioprospecting can be regarded as one of the forms of the globalisation of research and innovation.

As noted earlier, plant collecting and bioprospecting are among the historically enduring human activities. However, a combination of several recent techno-scientific, economic and socio-political factors have created conditions in which certain instances of biological exploits can be regarded as instances of bio-piracy: firstly, there has been a process of decolonisation of many countries, especially in the global South, with the related process of widespread recognition of human rights as well as indigenous rights; secondly, there have been scientific and technological developments which have increasingly made it possible to access and manipulate the very building blocks of life itself; and finally, there have been economic and legal changes which have altered the institutions of ownership and regulation of biological

[258] Ro, Dae-Kyun, Eric M. Paradise, Mario Ouellet, Karl J. Fisher, Karyn L. Newman, John M. Ndungu, Kimberly A. Ho, et al., "Production of the antimalarial drug precursor artemisinic acid in engineered yeast", *Nature*, Vol. 440, No. 7086, 2006, pp. 940-943.
[259] Cox, Paul Alan, and Michael J. Balick, "The ethnobotanical approach to drug discovery", *Scientific American*, Vol. 270, June 1994, pp. 82-87.
[260] McChesney, James D., Sylesh K. Venkataraman and John T. Henri, "Plant natural products: Back to the future or into extinction?", *Phytochemistry*, Vol. 68, No. 14, 2007, pp. 2015-2022.
[261] Soejarto, D.D., H.H.S. Fong, G.T. Tan, and H.J. Zhang, et al., "Ethnobotany/ethnopharmacology and mass bioprospecting: issues on intellectual property and benefit-sharing", *Journal of Ethnopharmacology*, Vol. 100, 2005, pp. 15-22.
[262] Gurib-Fakim, A., "Medicinal plants: Traditions of yesterday and drugs of tomorrow", *Molecular Aspects Medicine*, Vol. 27, 2006, pp. 1-93.
[263] Heiser, C.B., "Economic botany past and future", *Economic Botany*, Vol. 40, 1986, pp. 261-266.
[264] Macilwain, Colin, "When rhetoric hits reality in debate on bioprospecting", *Nature*, Vol. 392, 1998, pp. 535-540.
[265] Ibid.

and epistemic resources[266]. Thus, in this historically new environment, certain kinds of bioprospecting activity can be regarded as instances of bio-piracy, in particular when they involve exploitative and unjust appropriation of knowledge or biological resources from indigenous communities and groups.[267]

As can be gleaned from the above discussion, what makes biopiracy ethically wrong is that it involves exploitative relationship between the bioprospecting party and the indigenous community. But then, why is *exploitation* wrong? If one player exploits the carelessness of her opponent, say, in a game of chess, such exploitation does not necessarily amount to ethical wrongdoing. Exploitation can be said to be wrong when it characterises a relationship in which one actor wrongfully gains what the other actor has undeservedly lost.[268] Thus ethically wrongful exploitation is akin to *"theft, robbery and being cheap"*.[269] Furthermore, wrongful exploitation can be distinguished into three classes:[270]

(1) Exploitation as *free-riding* – exploiters fail to benefit other parties *completely*;
(2) Exploitation as *wrongful gain* – exploiters benefit other parties *insufficiently*;
(3) Exploitation as *extortion* – exploiters fail to benefit others *authentically*.

Thus, bioprospecting can become an instance of biopiracy when it involves any of these three classes of exploitative relationship. It thus seems that in order to ensure that a company or research organisation is not engaged in biopiracy, such organisations must consider whether their appropriations of forms of knowledge or biological samples are not exploitative in any of these three senses of the term, but beneficial to the groups and communities in question. Hence, there is a moral reason for protecting communal goods of disadvantaged indigenous groups.

The acknowledgement that there are communal goods that are in need of protection can also be seen in the fact that a number of recent international guidelines and conventions have made the obtaining of free prior informed consent from indigenous communities a requirement for parties that intend to appropriate their traditional knowledge or local biological resources. Thus, for example, the Convention 169 on Indigenous and Tribal Peoples of 1989[271], the Convention on Biological Diversity of 1992[272], Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization of 2002[273], and the UN Declaration on the Rights of Indigenous People of 2007[274] require that a bioprospecting party should obtain prior informed consent from indigenous peoples before accessing their biological resources, traditional knowledge or practices. This insistence on gaining informed consent from indigenous peoples is a relatively new phenomenon, and is

[266] For a more detailed discussion of these factors, see Robinson (2010), Chapter 1, pp. 1-22.
[267] Robinson, Daniel, F., *Confronting Biopiracy: Challenges, Cases and International Debates*, Earthscan, London, 2010.
[268] Mayer, Robert, "What's Wrong with Exploitation?", *Journal of Applied Philosophy*, Vol. 24, No. 2, 2007, pp. 137-150.
[269] Ibid.
[270] Ibid.
[271] http://www.ilo.org/ilolex/cgi-lex/convde.pl?C169.
[272] http://www.cbd.int/doc/legal/cbd-en.pdf .
[273] http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.
[274] http://www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf.

meant to be an important measure in protecting indigenous people from unjust and unethical exploitation by government agencies, research organizations or commercial companies.

However, the requirement of obtaining prior informed consent from indigenous people should come in addition to other safeguards that can help prevent the exploitation of indigenous communities and groups.[275] It is in this regard that the principle of benefit sharing can be particularly useful. According to the benefit-sharing 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. Thus, for instance, in accord with 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).[276] There have been cases in which the benefit-sharing approach has worked very well. Thus, for example, when a group of scientists studied 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'*.[277] 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.[278] The above exchange is typical of a benefit-sharing agreement as governed by the UN Convention on Biological Diversity.

This interpretation of the principle of benefit-sharing is considered to be the narrower - established – sense of the principle. Yet, there is also a second – broader – understanding of the principle of benefit sharing, according to which, benefits resulting from scientific research should be shared with all of society, and not just with those who have provided access to the resources in question. This understanding of the benefit-sharing principle – which Schroeder describes as *"aspirational"* – is expressed in the UNESCO's Declaration of Bioethics and Human Rights (2005), which states that "benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries".[279] According to this interpretation, sharing of benefits of scientific research is more properly seen as a universal human right, and not simply the right of the indigenous people, despite the fact that it was their traditional knowledge or biological resources that has led to the commercially or otherwise valuable innovation. According to Schroeder, the narrower sense of the benefit-sharing principle, described above, corresponds to the concept of *"justice in exchange"*,[280] which determines whether a certain exchange of goods is just or not, while the broader sense of the said principle is more in line with the concept of distributive justice, which seeks a fair distribution

[275] Widdows, Heather, *Global Bioethics: An Introduction*, Acumen, Durham, 2011.
[276] Human Genome Organization (HUGO) Ethics Committee, Statement on Benefit Sharing, 2000, http://www.hugo-international.org/img/benefit_sharing_2000.pdf.
[277] Moran, Katy, "Bioprospecting: lessons from benefit-sharing experiences", *International Journal of Biotechnology*, Vol. 2, No. 1/2/3, pp. 132-144.
[278] Ibid.
[279] Schroeder, Doris, "Sharing of Benefits" in Henk A.M.J. ten Have and Bert Gordijn (eds.), *Handbook of Global Bioethics*, Springer, Dordrecht, 2014, pp. 203-223.
[280] Ibid.

of existing resources among a certain relevant group.[281] The focus of the rest of the discussion will be on the established sense of the benefit-sharing principle.

5.3.3 CASE STUDY: THE SAN-HOODIA BENEFIT-SHARING AGREEMENT

This section takes a closer look at the San-Hoodia benefit-sharing agreement. The discussion in this section begins by introducing the San people, their traditional use of the Hoodia plant, the story of the commercial development of the plant, as well as the signing of two benefit-sharing agreements: the first, between the San and the Council for Scientific and Industrial Research (CSIR), and, the second, between the San and the Hoodia Growers Association. In discussing the San-Hoodia benefit sharing agreement, the present section highlights some of the key challenges in the drafting, signing and implementation of the benefit-sharing agreement in question, as well as the role of various stakeholders – indigenous peoples and their representatives, the state, commercial companies and multinational corporations – in dealing and resolving such challenges. In doing this, the case study also makes use of the information obtained in an interview, conducted for the SATORI project, with Roger Chennells, a lawyer based in South Africa[282], who represented the San peoples in their numerous negotiations with the CSIR.

The San peoples

The San peoples of Africa, sometimes known as the 'Bushmen',[283] are considered to be the oldest inhabitants of southern Africa, who have lived in small, nomadic, hunter-gatherer groups for millennia.[284] The San peoples are also considered to be the progenitors of the rest of the humankind.[285] There are currently 100.000 San living in a territory that spans South Africa, Zimbabwe, Zambia, Angola, Namibia and Botswana.

While the consensual and egalitarian way of life of the San has had to adjust to the conditions of modern life, the San have suffered from a gradual loss of traditional culture as well as societal breakdown accompanied and worsened by alcohol abuse.[286] While some have argued that the former hunter-gatherer lifestyles has left the San with little ability and power to improve their material conditions,[287] others have suggested that it is the non-hierarchical and consensual nature of their decision-making processes that is the source of their present

[281] Schroeder, Doris and Thomas Pogge, "Justice and the convention on biological diversity", *Ethics and International Affairs*, Vol. 23, 2009, pp. 265-278.
[282] http://www.chennellsalbertyn.co.za/ourteam.html.
[283] Hitchcock, Robert K., Kazunobu Ikeya, et al. (eds.), *Updating the San: Image and Reality of an African People in the 21st Century*, *Senri Ethnological Studies*, Vol. 70, National Museum of Ethnology, Osaka, 2006.
[284] Lee, Richard B., "Foragers to First Peoples: The Kalahari San Today", *Cultural Survival Quarterly*, Vol. 26, No. 1, 2002, pp. 9-12.
[285] Soodyall, Himla, *The prehistory of Africa: Tracing the lineage of modern man*, Jonathan Ball Publishers, Cape Town, 2006.
[286] Silvain, Renee, "Drinking, fighting and healing: San struggles for survival and solidarity in the Omaheke region", in Robert K. Hitchcock, Kazunobu Ikeya, et al. (eds.), *Updating the San: Image and Reality of an African people in the 21st century*, *Senri Ethnological Studies*, Vol. 70, National Museum of Ethnology, Osaka, 2006, pp. 131-150.
[287] Diamond, Jared M., *Guns, germs and steel: a short history of everybody for the last 13, 000 years*, Random House, London, 1998.

disempowerment.[288] Nonetheless, many see the San as victims of a long and brutal colonial history. Thus, for example, during the apartheid years in South Africa, the San were categorised as coloured. As a result, the San owned no land, had to work as farm labourers or domestic servants in white households, while their language, culture and hunting practices gradually disappeared. Today, although a minority of San own their own land as an outcome of the end of the apartheid, the majority still exist in conditions of dismal poverty and powerlessness, in areas dominated by other, more powerful, African peoples. A recent assessment of the San peoples in the region has concluded that the San peoples are still one of the most marginalised groups among the indigenous southern African communities.[289]

Currently, a number of non-governmental organisations (NGOs), which have emerged in the past couple of decades, are assisting the San in achieving appropriate levels of development.[290] Moreover, in 1996, the San formed the Working Group of Indigenous Minorities in Southern Africa (WIMSA),[291] an advocacy organization tasked with representing the San peoples from South Africa, Namibia and Botswana. The advocacy organisation in question has been successful in bringing the cultural and linguistic diversity of the San peoples under a single cultural umbrella, as well as in uniting the different San communities across national borders. As these organizations have developed, there has been an associated increase of power and capacity of the San peoples to determine their own future.[292]

Indigenous knowledge and use of hoodia

For centuries, the San peoples used a local plant called *Hoodia gordonii* as an appetite suppressant that helped the San to stave off hunger and thirst in harsh desert conditions. However, the first recorded use of the plant appears to have been by the eighteenth-century botanist Francis Masson, who wrote about discovering 'Stapelia gordoni'.[293] Another naturalist, Rudolf Marloth, wrote of southern African natives who used it as a substitute for food and water:

> The sweet sap reminds one of licorice and, when on one occasion thirst compelled me to follow the example of my Hottentot guide, it saved further suffering and removed the pangs of hunger so efficiently that I could not eat anything for a day after having reached the camp.[294]

While the use of the plant is attributed to the San as one of the main native southern African communities, the wider distribution of certain species of the Hoodia plant suggests that there

[288] Colchester, Marcus, *Salvaging nature: indigenous peoples, protected areas and biodiversity conservation*, World Rainforest Movement, Montevideo, 2003. http://wrm.org.uy/wp-content/uploads/2013/04/Salvaging_Nature.pdf.
[289] Suzman, James, *An Introduction to the Regional Assessment of the Status of the San in Southern Africa*, Legal Assistance Centre, Windhoek, Namibia, 2001.
[290] Kuru Family of Organisations (KFO) Annual Report, Ghanzi, Botswana, 2006. http://www.kuru.co.bw.
[291] Working Group of Indigenous Minorities in Southern Africa (WIMSA), http://www.wimsa.org.za.
[292] Wynberg, Rachel and Roger Chennells, "Green Diamonds of the South: An Overview of the San- Hoodia Case" in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science+Business Media B.V., Dordrecht, 2009, pp. 89-124.
[293] Masson, Francis, *Stapelia Nova: or, a collection of several new Species of that genus discovered in the interior of Africa*, W. Bulmer & Co, London, 1796.
[294] Marloth, Rudolf, *The Flora of South Africa* (vol. III), Wheldon & Wesley, London, 1932.

has been extensive use of the plant as a substitute for water and food, by certain other indigenous groups that reside in the same region, including minority groups such as the Nama, Damara and Topnaar in Namibia.[295]

Commercial research and development of hoodia

In 1963, the South African Council for Scientific and Industrial Research (CSIR) included the Hoodia plant for examination in their project on edible and poisonous plants of South Africa, a project that aimed to provide information to the South African Defence Force about the nutritional and toxic qualities of wild plants growing in the region.[296] Using existing scientific literature, as well as laboratory experiments with mice, the CSIR researchers identified certain species of Hoodia as an appetite suppressant. However, the CSIR scientists lacked evidence in order to be able to file for a patent. Specifically, the CSIR lacked technology that could assist in identifying and isolating the bio-chemical compound responsible for the hunger and thirst suppressing qualities of the plant.[297] However, having acquired high-field nuclear magnetic resonance spectroscopy technology in 1986, the CSIR succeeded in identifying the needed bio-chemical compounds of the plant.[298] Finally, after several years of secret R&D, in 1995 the CSIR filed a patent application for the use of the appetite suppressing bio-chemical compounds of the plant.[299]

In 1997, the CSIR reached a licensing agreement for the further development and commercialisation of the product with Phytopharm,[300] a small British pharmaceutical company that specialises in the development of medicines based on plants. This licence agreement gave Phytopharm a global license to develop, produce and market products based on the Hoodia plant. After years of research and development concerning the Hoodia-based medicine in a programme called P57, in 2004, Phytopharm granted an exclusive global licence to consumer giant Unilever plc for Hoodia bio-chemical extracts, with their potential incorporation into already existing food brands, as well as their development as a mass-market weight-loss product.[301] According to the terms of this agreement, Unilever and Phytopharm would work together on an extensive R&D programme, conducting safety and efficacy tests; while Unilever would also take responsibility for increasing agricultural capacity for the cultivation of Hoodia, through an expansion of cultivation activities in southern Africa, namely, in South Africa and Namibia.[302]

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[295] Wynberg, Rachel and Roger Chennells, "Green Diamonds of the South: An Overview of the San- Hoodia Case" in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science+Business Media B.V., Dordrecht, 2009, pp. 89-124.
[296] Ibid.
[297] Ibid.
[298] South African Council for Scientific and Industrial Research (CSIR), Adding Value to South Africa's Biodiversity and Indigenous Knowledge through Scientific Innovation, 2001. www.csir.co.za.
[299] South African Patent no.: 983170.
[300] Wynberg, Rachel and Roger Chennells, "Green Diamonds of the South: An Overview of the San- Hoodia Case" in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science+Business Media B.V., Dordrecht, 2009, pp. 89-124.
[301] Ibid.
[302] Ibid.

Between 2004 and 2008, the research and development activities around the Hoodia extracts reached an advanced stage, including pharmaceutical safety trials, as well as the cultivation of approximately 300 hectares of Hoodia in South Africa and Namibia.[303] In addition to this, an agreement was reached between Unilever and Cognis, a chemical company, in order to develop a multi-million extraction facility for Hoodia in the Western Cape Province of South Africa.[304] Unilever had plans to develop a Hoodia-based product for its line of Slim Fast® beverages.[305] This situation however changed in 2008, when Unilever announced that it intended to abandon its plans to develop Hoodia as a functional food, because of safety and efficacy concerns.[306] In further communication to South African government departments, Unilever announced that it would cease all 'drying, transport, trials and any other activity associated with Hoodia in South Africa' as from 31 March 2009, and that Phytopharm plc would take over a proportion of existing cultivation in South Africa and, to a limited extent, Namibia.[307] In response to these developments, Phytopharm announced that it remained optimistic about future opportunities for the development and commercialisation of their Hoodia-based product, and that it would seek other partners in order to further develop, manufacture and market Hoodia-based products.[308]

The benefit-sharing agreement with the CSIR

Until 2001, the San remained unaware of the process of commercial development of the Hoodia drug, and the CSIR did not acknowledge the contribution of the San.[309] As quoted in *The Observer*, the CEO of Phytopharm claimed that the San had not initially been part of their discussions with the CSIR representatives, because Phytopharm believed that the San people had no longer existed, while in fact there are more than 100 thousand San people living in Angola, Botswana, Namibia, and South Africa.[310] Later however, defending its initial position, Phytopharm claimed that its reluctance to engage in talks with the San people stemmed from Phytopharm's desire not to raise unrealistic financial expectations on the part of the San people with promises that potentially might not be met. However, in a recently conducted interview for the SATORI project, Roger Chennells, the San's long-time lawyer, said that the remarks made by Phytopharm concerning their belief in the non-existence of the San communities, were rather *"silly"* and *"ignorant"*. The Phytopharm's real reason for not engaging with the San earlier, according to Chennells, has most likely to do with secrecy and competitiveness among businesses in their development of commercially valuable products.

[303] Ibid.
[304] Ibid.
[305] Stafford, Lindsay, "After another cancelled partnership, the future of *Hoodia* remains unclear", *HerbalEGram*, Vol. 6. No. 2, 2009. http://cms.herbalgram.org/heg/volume6/02%20February%20/*Hoodia* Nixed.html.
[306] Perri, Celeste, "Unilever, Phytopharm May Scrap Hoodia Partnership (Update2)", Bloomberg.com, 14 November 2008, http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a16qfcRvmXYw.
[307] Wynberg, Rachel and Roger Chennells, "Green Diamonds of the South: An Overview of the San- Hoodia Case" in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science+Business Media B.V., Dordrecht, 2009, pp. 89-124.
[308] Ibid.
[309] Ibid.
[310] Barnett, Antony, "In Africa the *Hoodia* cactus keeps men alive. Now its secret is 'stolen' to make us thin", *The Observer*, 17 June 2001, http://www.theguardian.com/world/2001/jun/17/internationaleducationnews.businessofresearch.

Moreover, in the initial stages, CSIR and Phytopharm were reported as having argued that it would be difficult to identify the real owners of traditional knowledge, or that there might be a situation in which one indigenous group could have historically stolen the knowledge from another group: "potential scenarios seemed endless and intricate" (Wynberg & Chennells 2009). However, such attitudes and responses on the part of the CSIR and Phytopharm ignored existing conventions and guidelines on the protection of the rights of indigenous people and global biodiversity, including Convention 169 on Indigenous and Tribal Peoples of 1989, the Convention on Biological Diversity of 1992, and the African Union's Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resource (Ekpere 2001).

However, in June 2001, the situation began to change, when an NGO, Biowatch South Africa, informed the foreign press about the CSIR-Phytopharm licence agreement and its potentially exploitative nature. Following the international coverage of the issue that led to a heightened global interest in the affair, the San began to mobilise. According to Wynberg and Chennells,

> …it was ironic that the CSIR's failure to consult with the San prior to the patent application considerably strengthened the bargaining and political leverage of the San, who, having secured the moral high ground, now had a high-profile case being followed keenly throughout the world. By contrasting images of emaciated San and obese Westerners and reinforcing popular notions of 'biopiracy' on the part of large pharmaceutical companies, the media captured the public's imagination and embarrassed the CSIR and Phytopharm, and this in turn encouraged the CSIR to enter into high-level negotiations with the San.[311]

Thus, the San, with the assistance of their lawyer Roger Chennells, objected by drawing attention to the fact that the unique qualities of the Hoodia plant were traditionally communal knowledge of the San, passed from generation to generation for thousands of years. Seeking the recognition of the collective ownership of this knowledge by the San people, they began a long process of negotiation with CSIR that eventually ended with the signing of the benefit-sharing agreement.

In the negotiations, the CSIR initially offered 3 per cent of their royalties to the San, to which the San responded by claiming 10 per cent. The negotiations continued for about 18 months,[312] with both sides making strong arguments in support of their claims. Finally, in March 2003, the CSIR, represented by the South African Minister of Arts, Culture, Science and Technology, and the San, represented by the South African San Council reached a benefit-sharing agreement. According to the signed agreement,[313] the San communities would receive 6 per cent of all royalties, as well as 8 per cent of the milestones payments received by the CSIR from Phytopharm. In accordance with the Provisions 1.5 and 2 of the agreement, the San would be receiving these payments for the whole period in which the CSIR received payments from Phytopharm.[314] The agreement furthermore required that payments would be made not to individuals, but only to a beneficiary community, when the latter makes an

[311] Wynberg, Rachel and Roger Chennells, "Green Diamonds of the South: An Overview of the San- Hoodia Case" in Rachel Wynberg, Doris Schroeder and Roger Chennells (eds.), *Indigenous Peoples, Consent and Benefit Sharing: Lessons from the San-Hoodia Case*, Springer Science+Business Media B.V., Dordrecht, 2009, pp. 89-124.
[312] Ibid.
[313] Ibid.
[314] Ibid.

official request, articulating a detailed plan of expenditure, as well as the details of a bank account opened by officially recognised San representatives. Moreover, the received funds were to be used for purposes determined by the communal representatives of the San, purposes such as raising the well-being and the standard of living of the San peoples. Thus, as required by the agreement, a trust was established that included representatives from the CSIR and San communities in South Africa, with transparent and strict rules for determining the distribution of the funds to be received.

It must also be noted that in addition to the benefit-sharing agreement with the CSIR, the San also reached another benefit-sharing agreement with the South African Hoodia Growers Association (South African San Council and Southern African Hoodia Growers 2006). In 2005, the San people were approached by a group of South African Hoodia growers, who were aware of their duties to share benefits with the San community in accord with the South African Biodiversity Act of 2004 (South African San Council and Southern African Hoodia Growers 2006). As these products were not directly related to the use of Hoodia extracts protected by Phytopharm's P57 patent, the San were thus free to enter yet another benefit-sharing agreement with the Hoodia growers, which did not breach the terms of their earlier benefit-sharing agreement with the CSIR (see e.g. Wynberg & Chennells 2009).

5.3.4 CONCLUSION

According to Roger Chennells (2015), the benefit-sharing agreement reached between the San and the CSIR, can be considered as one of the *"early"* and *"landmark"* cases "recorded in the framework of international practice", and "widely researched", "where indigenous people organised themselves and signed an agreement with the patent holder, where traditional knowledge was the key component of the patent". Thus, there are reasons to believe that the San-Hoodia case of benefit-sharing has the potential of setting a precedent for future benefit-sharing agreements to be negotiated between indigenous communities and government agencies, or commercial companies.

But what have we learned from the foregoing discussion of this benefit-sharing agreement? What important lessons and conclusions can be drawn about the case? To answer these questions, it is important to understand the roles different actors, stakeholders, and structural factors played in the process that eventually led to the signing of this agreement. On the one hand, we must identify those actors or factors which can be, in general, described as having played a positive role in the case, and on the other hand, we must understand those actors or structural elements which might be responsible for the existence of some the difficulties and challenges that the San people faced in protecting their rights as the custodians of traditional knowledge about the remarkable properties of the Hoodia plant.

As stated by Chennells, "two primary parties" can be identified as having played important roles in the San-Hoodia benefit-sharing case: the Council for the South African Council for Scientific and Industrial Research (CSIR) and the various people from the San communities. The CSIR's role was significant in that "they were very approachable, and were very listening, and were keen to negotiate". Chennells further adds that "it was in their [that is, in the CSIR's] interest to negotiate, in fact". At the same time, the efforts put in by the various

members of the San community are also commendable, according to Chennells, especially in that they "all had different views, but eventually got together onto one committee".

In addition to these two parties, Chennells remarks that "there were no … other NGOs or other organisations that played a major role. [However] I could say that one organisation called Biowatch was following the Hoodia patent before it was publicised. They played a role as well". Indeed, as has already been noted in the previous subsection, one of the main contributions of this NGO (Biowatch South Africa) was that they alerted the international press, following which The Observer printed a leading article[315] on the case, thus drawing the international community's attention to the plight of the disadvantaged indigenous communities, and the potentially exploitative nature of the patent concerning their traditional knowledge of the Hoodia plant.

However, there also were a few factors that presented some challenges to the San communities in attaining the benefit-sharing agreement with the CSIR. First of all, there were, what Chennells has described as "organisational" issues – namely that, while "the San people come from three different countries, speaking at least 7 or 8 different languages", "they were trying to form a negotiating team over the long distances", "a team that was sufficiently capable to negotiate against a highly educated research body". The task of assembling such a team of representatives under the existing conditions was, according to Chennells, "in itself a massive challenge" for the San peoples.

Besides the organisational issues, as Chennells has pointed out, the situation for the San communities was further exacerbated by the lack of domestic laws protecting their rights as disadvantaged custodians of traditional knowledge. Chennells notes that while "the Convention on Biological Diversity was formed in 1992, in 2001 our government had not yet formed a law". Indeed, it was only in September 2004 that the South African government circulated The National Environmental Management: Biodiversity Act 10 of 2004 (Biodiversity Act), requiring that a benefit-sharing agreement be developed with holders of traditional knowledge where their knowledge is used for bioprospecting. According to Chennells, one could "blame the government, for taking so long because we had to negotiate in the lack of legislation. There was a [legislation] gap". There was no legal and political support coming from the South African government, and thus "the San were alone and had to organise everything themselves".

In the context of the issues and challenges faced by the San described above, Chennells emphasised the role of international law (in particular the Convention on Biological Diversity), as well as the importance of *"capacity-building"* among the local communities, in ensuring the protection of the rights of the indigenous peoples in situations similar to the one in which the San people found themselves slightly more than decade ago.

With regard to international law, Chennells maintains that:

[315] Barnett, Antony, "In Africa the *Hoodia* cactus keeps men alive. Now its secret is 'stolen' to make us thin", *The Observer*, 17 June 2001, http://www.theguardian.com/world/2001/jun/17/internationaleducationnews.businessofresearch.

> If it wasn't for the CBD [the Convention on Biological Diversity of 1992], I don't think that anything would have happened… the CBD created international law, [while] we didn't have domestic law at that time. We signed, in 2001, the agreement, and our domestic law came out only in 2004. So the international law was decisive, conclusive and very important.

Furthermore, according to Chennells, international laws change "the ethos within a country": "Once [a country has] signed the international law, then the country is obliged to follow the law internally".

Having said this, Chennells has also pointed out that while it is "essential" to have effective laws protecting the rights of indigenous peoples as custodians of traditional knowledge, it is not "sufficient": "Having effective rights and effective laws is very important. But the communities often need additional help in order to access those rights".

The claim that having the relevant laws is *essential* but *insufficient* also lends support to the importance of *capacity-building* among the indigenous peoples. In fact, according to Chennells, capacity building is "the biggest problem facing the indigenous people":

> Generally their capacities are very low, and they are vulnerable to the type of advice they receive. It is one of the major issues facing indigenous peoples. … They're negotiating against powerful first world type organisations. They have very … different education, but they also come from various world views … different worlds, I think. The clash of different worlds, civilizations.

Finally, when asked about whether he would make any recommendations concerning the betterment of international laws, on the one hand, and the widening of capacity-building efforts among the indigenous peoples, Chennells answered in the following manner. With regard to international laws, Chennells wishes that they could be "more fair to the developing world", as well as be "more simplified and quick", given that international laws are always negotiated and thus are "slow and cumbersome". With respect to capacity-building, Chennells thinks that the task of capacity-building among the indigenous peoples should be the responsibility of all – the local community, the state and the international community.

5.4 OUTSOURCING OF CO2 EMISSIONS

5.4.1 INTRODUCTION

According to a draft report on climate change from 2014[316] prepared by the Intergovernmental Panel on Climate Change (a body of scientists and other experts appointed by the United Nations that periodically reviews and summarizes climate research)[317] rich Western countries are outsourcing CO2 emissions and emissions of other greenhouse gases to rising economies.[318] These economies undertake CO2-intensive manufacturing of products that are then consumed by Western countries. Companies therefore take advantage of the "legal" emission of greenhouse gases.[319]

This research explores and measures the positive and negative impacts of the outsourcing of CO2 in terms of its ethical dimensions, taking account of efforts under way through international collaboration of governments, international organisations and private initiatives to address these concerns. The report is divided into two main parts. In the first part, we provide general information and legal framework for the outsourcing of CO2 emission and briefly discuss the emission trading mechanism. The second part consists of a case study of Green April.

The case study includes also comments from B Corporation. This practical dimension of the study allows an in-depth analysis of the issue at stake, identifying the real problems and potential solutions.

Kyoto Mechanisms

The Kyoto Protocol is an international agreement which extends the provisions of the United Nations Framework Convention on Climate Change (UNFCCC).[320] The latter was adopted in 1992 and its aim is to "achieve, in accordance with the relevant provisions of the Convention, stabilization of greenhouse gas concentrations in the atmosphere at a level that would prevent dangerous anthropogenic interference with the climate system".[321] However, by 1995, parties to the UNFCCC realised that it was an inadequate tool to reduce the emissions of greenhouse gases.[322] Thus on 11 December 1997 they adopted the Kyoto Protocol, which eventually

[316] IPCC, "Climate Change 2014: Impacts, Adaptation, and Vulnerability", http://www.ipcc.ch/report/ar5/wg2/

[317] Justin Gillis, New York Times, "U.N. Draft Report Lists Unchecked Emissions' Risks", 26 August 2014, http://www.nytimes.com/2014/08/27/science/earth/greenhouse-gas-emissions-are-growing-and-growing-more-dangerous-draft-of-un-report-says.html?smid=tw-share&_r=2

[318] See e.g. The Guardian, CO2 emissions are being 'outsourced' by rich countries to rising economies. Retrieved from: http://www.theguardian.com/environment/2014/jan/19/co2-emissions-outsourced-rich-nations-rising-economies

[319] The Guardian, *CO_2 emissions are being 'outsourced' by rich countries to rising economies*. http://www.theguardian.com/environment/2014/jan/19/co2-emissions-outsourced-rich-nations-rising-economies

[320] Please compare: http://unfccc.int/kyoto_protocol/items/2830.php

[321] United Nations Framework Convention on Climate Change, 1992. http://unfccc.int/resource/docs/convkp/conveng.pdf

[322] For more information: http://unfccc.int/essential_background/items/6031.php

entered into force on 16 February 2005. Currently, there are 192 Parties to the Protocol,[323] including 191 States and 1 regional economic integration organisation (European Union).[324] At the core of the Protocol was an agreement to reduce emissions by an average of 5.2% below 1990 levels of greenhouse gases by the year 2012 (first commitment period).[325] National targets range from 8% reductions for the European Union and some others to 7% for the US, 6% for Japan and 0% for Russia.[326] In 2012, the Doha amendment was adopted, which established the second commitment period starting in 2013 and ending in 2020[327]. The amendment has been so far ratified by 30 countries.[328]

The Kyoto Protocol, establishes three mechanisms:[329]

1. Emissions Trading –specified in Article 17, allowing countries that do not reach their emissions limits to sell the excess to other countries.[330]
2. Clean Development Mechanism – a project-based mechanism regulated in Article 12, which allows "credits from emission reduction projects in poorer countries to be used by rich countries to meet their own commitments under the Kyoto Protocol".[331]
3. Joint Implementation – like the Clean Development Mechanism, it is also a project-based mechanism. It is stipulated in Article 6 and "enables countries with binding targets to get credit from projects carried out in other countries with binding targets".[332]

Although there are many other instruments to fight the greenhouse effect, such as carbon taxes[333], emissions trading seems to be the dominant one.[334] There are several reasons for this. First of all, this is due to its central place under the Kyoto Protocol. Secondly, it is far more difficult for the countries to approve carbon taxes and lobby groups are very often against them. What is more, "trading may increase management attention on carbon owing to the 'carrot' of profit opportunities, whereas taxes operate only by the 'stick' of additional business costs".[335] In other words, the financial benefits associated with carbon trading are more likely to encourage the reduction of emissions than carbon taxes.

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[323] Kyoto Protocol to the United Nations Framework Convention on Climate Change, 1997. http://unfccc.int/resource/docs/convkp/kpeng.pdf
[324] For more information: https://unfccc.int/essential_background/convention/status_of_ratification/items/2631.php
[325] Bachram, Heidi, „Climate Fraud and Carbon Colonialism", *Capitalism Nature Socialism*, Vol. 15, No. 4, 2004.
[326] Kyoto Protocol to the United Nations Framework Convention on Climate Change, 1997. http://unfccc.int/resource/docs/convkp/kpeng.pdf
[327] For more information: http://unfccc.int/kyoto_protocol/doha_amendment/items/7362.php
[328] http://unfccc.int/kyoto_protocol/doha_amendment/items/7362.php
[329] For further details: http://unfccc.int/kyoto_protocol/mechanisms/items/1673.php
[330] United Nations, *Framework Convention on Climate Change, Kyoto Protocol, Mechanisms, Emissions Trading*. Retrieved from: http://unfccc.int/kyoto_protocol/mechanisms/emissions_trading/items/2731.php
[331] Hepburn, Cameron, "Carbon Trading: A Review of the Kyoto Mechanism", *Annual Review of Environment and Resources*, Vol. 32, 2007, pp. 375-393.
[332] Ibid.
[333] This is a tax the level of which is connected to the level of CO_2 emission. For further details see: http://www.worldbank.org/content/dam/Worldbank/document/Climate/background-note_carbon-tax.pdf
[334] Hepburn, Cameron, „Carbon Trading: A Review of the Kyoto Mechanism", *Annual Review of Environment and Resources*, Vol. 32, 2007, pp. 375-393.
[335] Ibid.

Notwithstanding the fact that emission trading is common, it does however raise some ethical doubts and many wonder whether "it is an ethical method of avoiding dangerous climate change".[336] Caney and Hepburn[337] identify five main ethical arguments against emissions trading:

1. owning what should not be owned;
2. alienating responsibilities that one should perform oneself;
3. allowing trades that are disadvantageous to the vulnerable;
4. putting a price on the natural world;
5. converting what ought to be a fine into a fee.

According to the first argument, carbon trading leads to a situation in which people own something that should not be owned, which cannot be accepted, as humans do not have property rights in the natural world. This conception is however highly criticised, because it would mean that people are not allowed to have any property whatsoever, such as land, food, water etc. The second argument is connected with the term "non-delegable duties", which refers to duties that one should fulfil on his own, instead of outsourcing them to someone else. Those who support this thesis claim, that "high emitting countries should not pay others to discharge 'their' duty".[338] The third argument appears in two versions. One is the "Paternalist Argument" and the second is the "Unreliable Trustees Argument". According to the first version, people should be protected from themselves, because they can make poor judgments and therefore they make wrong decisions. Caney and Hepburn think however, that this can easily be refuted, because the companies that trade emissions cannot be considered to have morality. The second version of this argument refers to a situation in which greenhouse gases allowances are allocated to trustees who take care of the interests of a certain group of people (in the context of emission trading, it would be States managing the interests of their citizens). The trustees can however be unreliable, and for that reason those who support this argument claim, that "states should not be allowed to sell all of their emission rights, because that would risk harming their citizens".[339] The fourth argument is somehow similar to the first one – it is believed that carbon dioxide cannot be sold, for it does not have a value. According to the last one, emissions trading might give the impression that polluting is allowed as long as one buys emissions allowances.

Paige[340] discusses two additional ethical issues which have not been covered by Caney and Hepburn. The first one is a so-called "carbon colonialism", which describes the situation when agents from the developing world are placed in a situation "where they are trapped into reducing their emissions in order to cover the increasing (or non-diminishing) emissions of other, richer, agents located in the developed world".[341] The second one is the crowding-out effect. Proponents of this argument claim that emissions trading undermines the ethical motivations and values aimed at protecting the environment and replace them with "financial motivations associated with profiting from participation in emissions allowance markets".[342]

[336] Paige, Edward A., „The ethics of emissions trading", *WIREs Climate Change*, Volume 4, August 2013, pp. 233-243.
[337] Caney, Simon and Cameron Hepburn, *Carbon trading: unethical, unjust and ineffective?*, 2011. http://www.cccep.ac.uk/Publications/Working-papers/Papers/50-59/WP59_carbon-trading-caney-hepburn.pdf
[338] Ibid.
[339] Ibid.
[340] Paige, Edward A., „The ethics of emissions trading", *WIREs Climate Change*, Volume 4, August 2013, pp. 233-243.
[341] Ibid.
[342] Ibid.

What is more, "financial incentives, and particularly those associated with the trading of environmental allowances, corrode environmental morale over time by inculcating amongst participants the norm that there is nothing blameworthy in emitting any amount of an environmental pollutant so long as they have the wherewithal to offset their polluting activities through activity on the relevant market".[343]

Emission Trading in the European Context

The world's biggest emissions trading market is the EU Emissions Trading System (EU ETS).[344] It was established in 2005 to reduce the emissions of carbon dioxide and other greenhouse gases (-20% by 2020 and -85-95% by 2050). Each year, the overall volume of greenhouse gases that can be emitted by companies is decided at the EU level. The companies receive allowances for every tonne of carbon dioxide, nitrous oxide (N_2O) and perfluorocarbons (PFCs). Allowances are allocated either through auctions, which are "held by companies appointed by national governments"[345] or companies can receive them for free from governments. If companies exceed their limits, they must pay fines. However, if they have been granted higher limits than needed, they can sell their emissions allowances to other countries. Kyoto Protocol's Clean Development Mechanism and Joint Implementation are also recognized within the ETS and companies can use credits obtained from these sources.[346]

Carbon Leakage

A serious problem related to emissions trading is carbon leakage, which is "the increase in CO_2 emissions outside the countries taking domestic mitigation actions divided by the reduction in the emissions of these countries".[347] In other words, this phenomenon refers to a situation whereby companies, for economic reasons, decide to transfer their production to other countries that have more lax constraints on greenhouse gas emissions.[348] Carbon leakage occurs especially in energy-intensive industries.[349] Due to the fact that it can result in an increase in the total value of emissions, some serious steps have been taken within the EU to overcome this problem. Every five years, the Commission adopts a list, which specifies the sectors exposed to a serious risk of carbon leakage.[350] The first one was adopted in 2009 and the second one in October 2014.[351] The sectors listed receive special treatment and a higher share of free allowances, so that they can remain competitive.[352]

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[343] Ibid.
[344] European Commission, *The EU Emissions Trading System (EU ETS)*, October 2013. Retrieved from: http://ec.europa.eu/clima/publications/docs/factsheet_ets_en.pdf
[345] Ibid.
[346] Ibid.
[347] Metz, Bert, Ogunlade Davidson, Peter Bosch, Rutu Dave, Leo Meyer (Eds.), *Contribution of Working Group III to the Fourth Assessment Report of the Intergovernmental Panel on Climate Change*, Cambridge University Press, New York, 2012.
[348] European Commission, *The EU Emissions Trading System (EU ETS)*, October 2013. Retrieved from: http://ec.europa.eu/clima/publications/docs/factsheet_ets_en.pdf
[349] For more information: http://ec.europa.eu/clima/policies/ets/cap/leakage/index_en.htm
[350] Please compare: http://ec.europa.eu/clima/policies/ets/cap/leakage/index_en.htm
[351] Commission Decision of 27 October 2014 determining pursuant to Directive 2003/87/EC of the European Parliament and of the Council, a list of sectors and subsectors, which are deemed to be exposed to a significant

Attempts to stop carbon leakage seem however to be insufficient, because according to the recent report of the Intergovernmental Panel on Climate Change, we are now facing a new kind of a challenge – an outsourcing of carbon dioxide. The report says, that "a growing share of CO_2 emissions from fossil fuel combustion in developing countries is released in the production of goods and services exported, notably from upper middle income countries to high income countries".[353]

CO2 Footprint

The carbon footprint, which is the amount of gaseous emissions of a particular country[354], is usually measured by calculating the total greenhouse gas emitted within its borders.[355] However, this method appears to be no longer adequate, as rich countries (USA and European countries) tend to move production (and, as a consequence, pollution) from their territory to China and other rising economies (since 2000, the annual CO_2 emissions for China and other rising economies have doubled to approximately 14 gigatonnes a year).[356] This helps them to hide their real contribution to the greenhouse gas emission. High standards of living in developed countries come therefore "at the expense of CO_2 emissions produced with technologies of low efficiency in less affluent, developing countries".[357] 92 percent of the global increase of greenhouse gases in years 2012-2040 is expected to come from countries which are not members of the OECD and 45 percent of this total growth will come from China alone.[358] There is now a serious debate concerning who should be held responsible for emissions of greenhouse gases in a situation, in which goods are produced in one country but eventually are consumed in another one.[359]

It is also worth mentioning that the phenomenon of CO_2 outsourcing does not only appear at the international level, but also within borders of particular countries, which means that richer provinces are using poorer ones for their advantage. This refers especially to China, where 57 percent of its emissions "are related to goods that are consumed outside of the province where they are produced".[360] New carbon policies (setting up higher targets for reducing emissions in some of the provinces) have been adopted to overcome this problem, but it remains unclear

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risk of carbon leakage, for the period 2015 to 2019. Retrieved from: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0746&from=EN

[352] European Commission, *The EU Emissions Trading System (EU ETS)*, October 2013. Retrieved from: http://ec.europa.eu/clima/publications/docs/factsheet_ets_en.pdf

[353] Intergovernmental Panel on Climate Change, *Climate Change 2014. Mitigation of Climate Change. Summary for Policymakers and Technical Summary*, 2015. Retrieved from: http://www.ipcc.ch/pdf/assessment-report/ar5/wg3/WGIIIAR5_SPM_TS_Volume.pdf

[354] Wiedmann, Thomas and Jan Minx, "A Definition of Carbon Footprint". In: Pertsova, Carolyn C., *Ecological Economics Research Trends*, 2008, Chapter 1, pp. 1-11.

[355] The Guardian, *What are 'outsourced emissions'?*. Retrieved from: http://www.theguardian.com/environment/2011/apr/14/outsourced-emissions

[356] The Guardian, *CO_2 emissions are being 'outsourced' by rich countries to rising economies*. Retrieved from: http://www.theguardian.com/environment/2014/jan/19/co2-emissions-outsourced-rich-nations-rising-economies

[357] Kuishuang Feng, Steven J. Davis, Laixiang Sun, Xin Li, Dabo Guan, Weidong Liu, Zhu Liu and Klaus Hubacek, „Outsourcing CO_2 within China", *PNAS*, Vol. 110, No. 28, July 2013.

[358] Wang, Alex L., „Regulating Domestic Carbon Outsourcing: The Case of China and Climate Change", *UCLA Law Review*, Vol. 61, 2014.

[359] The Guardian, *CO_2 emissions are being 'outsourced' by rich countries to rising economies*. Retrieved from: http://www.theguardian.com/environment/2014/jan/19/co2-emissions-outsourced-rich-nations-rising-economies

[360] Kuishuang Feng, Steven J. Davis, Laixiang Sun, Xin Li, Dabo Guan, Weidong Liu, Zhu Liu and Klaus Hubacek, "Outsourcing CO_2 within China", *PNAS*, Vol. 110, No. 28, July 2013.

whether they will be effective. There is a serious risk that these policies can only lead to additional carbon leakage and CO_2 outsourcing.[361]

5.4.2 CASE STUDY

Green April

This case study is based on an interview with Green April and additional desk study.

General information about the firm

Green April is a consulting firm specialised in strategy and sustainability.[362] Its mission is to create better business; profitable and responsible towards customers and employees, as well as the environment and society. Green April works mostly with large multinational companies in the food, transport, built environment and energy production sectors. Its work comprises CSR strategy & implementation, project execution & finance

Green April believes that sustainability is a necessity to meet the needs of present & future generations but also the opportunity of a lifetime for industry. Green April's projects are about reduction of impact, building the right strategy and align this with the corporate strategy. It combines knowledge of strategy with corporate finance and technical knowledge. It is rather a qualitative way of working, which is based on case-by-case approach. However, there is always the same pattern. One should look in what area the company has the biggest impact and determine the best way of reducing it whilst creating value for the company.

Green April staff consists of people with various background and all with consulting experience. Educational backgrounds are engineering, financial, MBA and journalism. Green April normally runs five to six projects at the same time and carries out work in small teams. It uses both its own employees as well as an external network of associates, who are needed in case specialised knowledge is required.

In its work, Green April does not use one specific methodology or tool, but conceptually all projects aim at helping companies to reduce impact and create value to the maximum extent possible. Essentially, this includes defining where the company has impact, what stakeholders value as being most important, what strategy to pursue, how to manage it, which projects to undertake and how to communicate about it. Creating value from sustainability can be a company specific or sector specific activity depending on the value for the end user.

Green April's Opinion on emission trading

1. Essentially emission trading is more effective than carbon taxes because market mechanisms ensure reduction measures are implemented where they are most cost-effective. This means climate targets are met at the lowest possible cost.

However, the current set-up with the EU ETS emission trading system has imperfections:

1. The current CO2 price does not create enough incentive to meet climate goals. We believe there are several reasons for the current low price environment; over-allocation of free allowances for certain industries, the fact that there is no global overarching system for emissions reductions and the fact that the largest emitters (China, India, USA) do not have

[361] Ibid.
[362] http://www.green-april.eu/ (only in Dutch)

obligations to reduce their emissions. Emitters do not have enough incentive to implement reduction projects. Price estimates for a 'more fitting system' range from 40 EUR to 70 EUR per tonne of CO2. These are prices at which companies we work with indicate that they would need to significantly implement changes in their CO2 profile and hence their operations in order to keep costs levelled.

2. The cap-and-trade initiatives around the globe such as the EU ETS or those in for example South Africa, Chile, Vietnam and the US (Regional Greenhouse Gas Initiative – RGGI) do not have global coverage. This could pose an incentivize for multinational companies to transfer emission-heavy activities to countries without coverage by a CO2 reduction system.
3. The flexible mechanisms (Clean Development Mechanism (CDM and Joint Implementation (JI)) under the Kyoto Protocol include some questionable types of projects, such as an ultra-supercritical coal power plant (which is not actually displacing emissions) and a super-mega hydro power project (which could require displacing a large group of inhabitants)
4. The enforceability on a global scale is very difficult. In the EU ETS there is a penalty for not handing in an amount of carbon credits/allowances matching the CO2 emitted by a company (100 EUR per tonne). Under the Kyoto Protocol there is no such thing, which is problematic. For example when it became clear Canada was to exceed their Kyoto target they simply pulled out of the Protocol without any repercussions.

5.4.3 CONCLUSION

The success of working towards more responsible management of CO2 emission may be perceived as a shared responsibility of governments, companies and international organisations. This responsibility includes governments' responsibility to address the outsourcing of C02 emissions and provide a regulatory framework that requires companies to consider their entire carbon footprint, including that of their suppliers. Furthermore, companies have a responsibility to benchmark each other. A multi-stakeholder approach should be introduced with the involvement and contribution of other actors, such as suppliers, NGOs and communities. There is a strong need for coordination in governance, both at national and international levels. Therefore, what should be done is addressing the fragmentation of responsibility in reducing CO2 emissions by individual nations and coordinating programmes and investment both within the EU, and between the EU and other international organisations.[363]

[363] The summary is the result of the session on outsourcing of CO2 emission that took place as part of the SATORI conference "SATORI Policy and Legal Options for Developing Ethics Assessment for Research and Innovation Within the Context of Globalisation" organized by UNESCO in Paris, 24-26 June 2015.

5.5 CLINICAL TRIALS

5.5.1 INTRODUCTION

Clinical research and trials[364] have been subject to greater international scrutiny due to the global awareness of the scientific and medical atrocities committed during World War II chronicled during the trials collectively known as the "Nuremberg Doctors Trials". The subsequent 1947 Nuremberg Code is considered an initial international benchmark that establishes internationally recognizable ethical principles for human-subjects research. Since then, and in light of the rise of multinational research efforts produced through greater globalisation of research enterprises, international efforts to address the ethical concerns coinciding with globalized human-subjects research have accelerated the establishment of a complex system of legal and political instruments combined with a network of regional, national, and international actors committed to the consideration and mitigation of ethical issues accompanying clinical research and trials.

The aim of this case study is to highlight lingering and novel areas of potential ethical concern specifically related to the globalisation of clinical research and trials. The study simultaneously attempts to identify the best practices to address gaps which may exist as a consequence of shifts in research agendas within a globalized contexts.

5.5.2 GENERAL DISCUSSION

A Brief History of Clinical Trials

This section briefly outlines basic developmental landmarks pertaining to modern clinical trials.

Contemporary Anglophone texts trace what can be identified as clinical trials research to Biblical times.[365],[366], [367] The most frequently cited story King Nebuchadnezzar II's attempt to study the diet of vegetarian versus meat-eating royal children in order to determine the superior diet. The same chronologies cite Avicenna's "Canon of Medicine", which outlines basic principles for testing potential therapeutic interventions, as another landmark in the development of clinical research.[368] The most commonly accepted modern, controlled clinical trial appears to be James Lind's mid-Eighteenth Century evaluation of potential cures for scurvy, conducted while he was serving as a surgeon on a ship. His 1753 "Treatise on Scurvy" thoroughly outlines his trial demonstrating orange and lemons as superior treatments over other available treatments In addition to recounting his trial, Lind notably included a literature review on existing texts on scurvy, indicating even greater attention to procedural considerations.[369]

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[364] World Health Organization: For the purposes of registration, a clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. http://www.who.int/topics/clinical_trials/en/

[365] Collier R. Legumes, lemons and streptomycin: A short history of the clinical trial. CMAJ.2009;180:23–24

[366] http://genome.wellcome.ac.uk/doc_WTD020948.html

[367] http://www.accordclinical.com/clinical-study/clinical-trials-history/

[368] Bhatt A. Evolution of Clinical Research: A History Before and Beyond James Lind. *Perspectives in Clinical Research*. 2010;1(1):6-10.

[369] ibid

The 1800s heralded a shift to the broader use of clinical trials and with it came a focus on study design. This era saw the first use of placebos, defined for the first time in the 1811 edition of Hooper's Medical Dictionary as "an epithet given to any medicine more to please than benefit the patient."[370] It was the same era in which the term "clinical trials" is presented in print text, as early as 1818 in "The Practice of Medicine" publication. Austin Flint's use of a placebo in 1863 during the treatment of rheumatism, which Flint describes in his "A Treatise on the Principles and Practice of Medicine" signalled the first recorded use of a planned placebo in a controlled trial.[371] Other significant dates in the advancement of clinical trial methods include the first double blind controlled trial of Patulin for the common cold in 1843-1944 and the first randomized controlled curative trial in 1946.

The rise of academic research centers and pharmaceutical corporations would spur in clinical research. Pharmaceutical companies in the late 1800s systemized and supported research labs for the development of medical drugs. Advancements in chemistry and engineering led to the development of safe and effective vaccination of previously incurable diseases. World War I mobilized national governments to take an increasing interest in the development of pharmaceutics, as demonstrated with the interest taken in penicillin. Today, clinical research trials are highly expansive affairs with clinical trials having been registered in over 180 countries to date.[372]

Oversight of Clinical Research and Trials: The Rise of International Efforts

Laudable advancements were made in clinical trials methodology during the early 1900s. At the same time, public recognition of potential and actual abuses in medical research led to the creation of policies to address these concerns. National legislation, such as the 1906 *Pure Food and Drug Act* in the United States of America and its subsequent legislation attempted to address the highly unregulated arena in which medical interventions were being sold. Medical scientific abuse in human subjects' research would take international centre stage with the first 1946 Nuremburg Doctors Trial. Included in the indictment of German doctors tried for War Crimes during World War II was the consideration of unethical medical experimentation:

> War crimes: performing medical experiments, without the subjects' consent, on prisoners of war and civilians of occupied countries, in the course of which experiments the defendants committed murders, brutalities, cruelties, tortures, atrocities, and other inhuman acts. Also planning and performing the mass murder of prisoners of war and civilians of occupied countries, stigmatized as aged, insane, incurably ill, deformed, and so on, by gas, lethal injections, and diverse other means in nursing homes, hospitals, and asylums during the Euthanasia Program and participating in the mass murder of concentration camp inmates.[373]

The creation of the Nuremberg Code, which aimed to provide the basic tenets of ethical human subject research at the conclusion of World War II in response to the atrocities of Nazi human experimentation, signalled the rise of international attention to the consideration of

[370] ibid
[371] ibid
[372] Richter, Trevor A. "Clinical Research: A Globalized Network." PloS one 9.12 (2014): e115063.
[373] https://en.wikipedia.org/wiki/Doctors'_trial

ethical research conduct especially that related to human subjects research.[374] This code would later be augmented by the Declaration of Helsinki in 1964, guided by the World Medical Association, an international and independent confederation of free professional Medical Associations, also created in the post-World War II climate.[375] It was in the same environment that the World Health Organization (1948) and United Nations Educational, Scientific and Cultural Organization (UNESCO) (1945) were created. These two organizations would jointly establish the Council for International Organizations of Medical Sciences (CIOMS) in 1949, whose 1993 *International Ethical Guidelines for Biomedical Research Involving Human Subjects* serves as an elaboration and guiding text cited by institutions from regional to international levels.

Current Globalisation trends in Clinical Research and Trials

Geographic distribution of multinational studies

Trevor Richter notes in "Clinical Research: A Globalized Network", a study examining the rise of globalisation of clinical research by analysing registrations in the ClinicalTrials.gov database, that registered clinical trials have been conducted in 185 countries.[376] 89% of the 123,774 studies involved only one country. 15,543, or 11% of the total studies, were multinational trials. Richter states "The increased globalisation of clinical research has arisen for several reasons, but primarily due to the need for faster and more economically efficient studies."[377] He presents the following statistics represented in Figure 1 below. Explosive growth in the number of initiated multinational studies occurred for a period of two decades beginning in the early 1990s, reaching a peak in 2009. From 2009 to 2014, there was a decrease in initiated multinational studies, including the annualized average number of countries per multinational study, which remains between six and seven countries per study since 2003.

Richter's work further shows that Europe accounts for 60.64% of global connections in multinational studies, making it the most highly interconnected geographic region engaging in multinational studies. Coupled with North America and Asia, these three regions account for 85% of all global connections. Over the last 20 years, South American countries representation in multinational research has doubled from 2.5% to 5.3% while the proportion included Asia has nearly tripled from 4.7% to 12% percent. The USA is the dominant individual country over the period, but Europe as a whole is the geographic region with the highest amount of participation in multinational trials – with at least one European country participating in 58.1% of all multinational studies.

[374] Annas, George J., and Michael A. Grodin. "The Nazi doctors and the Nuremberg code." J. Pharmacy & Law 4 (1995): 167-245.
[375] www.wma.net
[376] Richter, Trevor A. "Clinical Research: A Globalized Network." PloS one 9.12 (2014): e115063.
[377] ibid

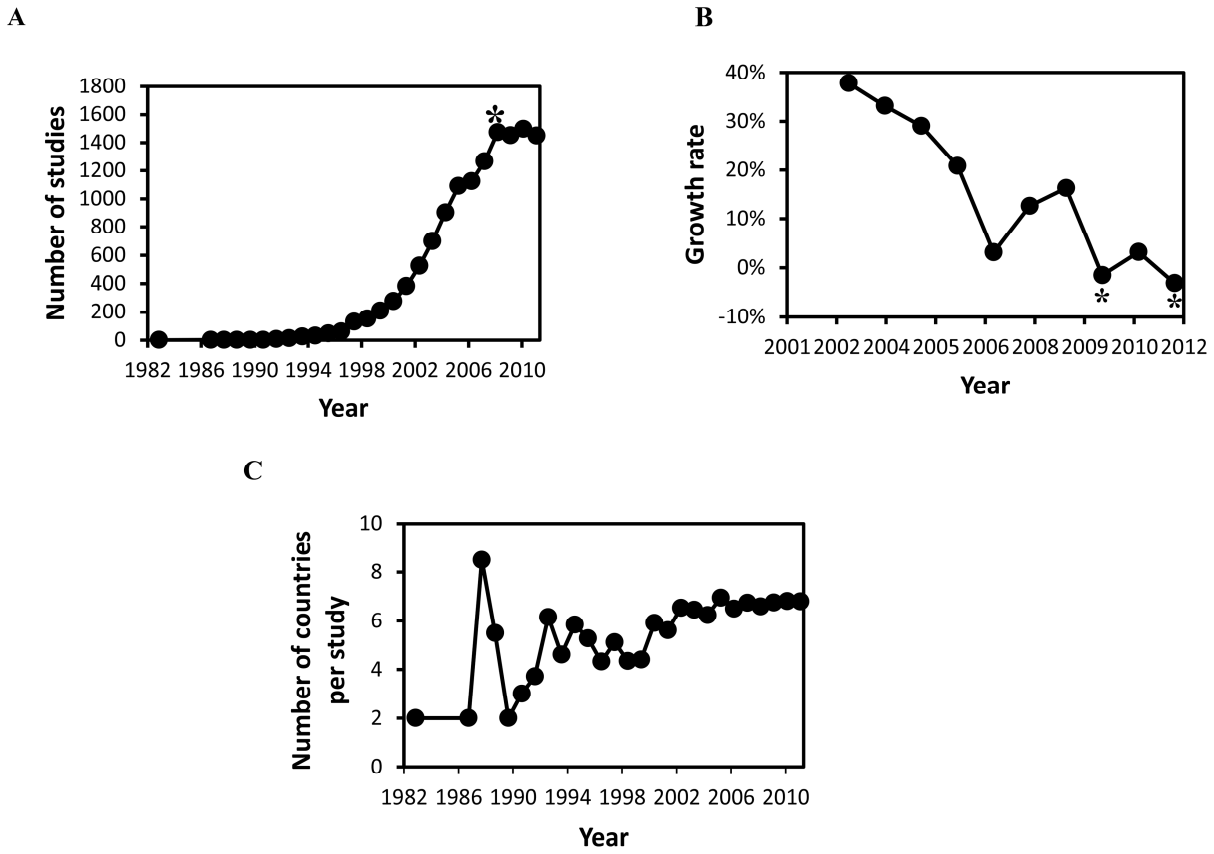

Figure 1: Historical trends in multinational studies registered at ClinicalTrials.gov.
(A) Number of multinational studies per year. The asterisk (*) indicates the peak in growth in 2009. (*B*) Year-over-year growth in the number of multinational studies for the period 2003–2012. The asterisks (*) indicate years that had negative growth. (*C*) Average number of countries per multinational study for the period 1982–2012.

Reasons for globalised, multinational studies

Globalisation is not unique to clinical research and the industry is subject to similar trends in overall research and development. However, there are unique conditions that may help explain the trend in clinical research. Glickman et al[378] cite three potential reasons for trials moving to newer markets. The first is substantial cost savings due to lower labour costs associated with labour markets in developing countries. Second, the development time is shortened in other markets as patient recruitment occurs as an accelerated pace. Third, Glickman et al indicate that greater regulatory presence of well-intended but inefficient and expensive regulations in North America and Europe have driven research to countries with less of a regulatory burden.

[378] Glickman, Seth W., et al. "Ethical and scientific implications of the globalization of clinical research." New England Journal of Medicine 360.8 (2009): 816-823.

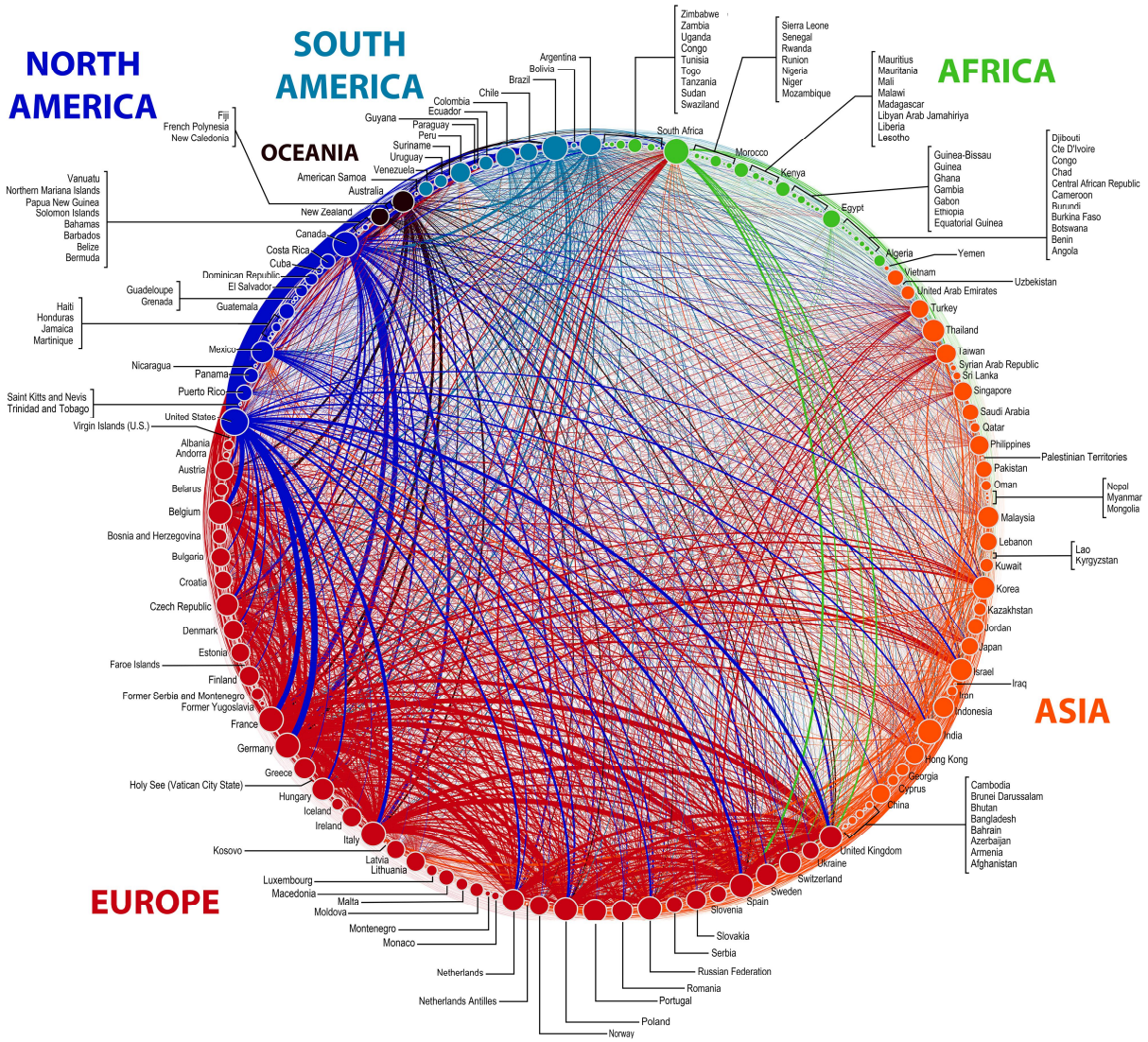

Figure 2[379]. Global connectivity of countries involved in multinational clinical studies.

Lines represent connections between countries that reflect participation in the same study. The thickness of the lines is proportional to the total number of connections between those countries. Each dot (node) corresponds to a country that has participated in a multinational study. The size of the nodes is proportional to the total number of multinational studies. Only countries that participated in at least 1 multinational clinical trial were included in the network.

Non-financial, practical reasons may also be driving the push towards multi-national studies. The more developed clinical research industry in North America and Europe, which accounts for the greatest percentage of multinational studies, indicates the disparity between the abilities to perform clinical research. Simply put, most countries do not have the resources to be conducting the trials on their own. Secondly, in addition to patient recruitment speed, patient populations in developing countries facilitate the studies of conditions that are not present in North America or Europe, such as studies related to malaria or rare health events.[380]

[379] Richter.

[380] Lang T, Siribaddana S (2012) Clinical Trials Have Gone Global: Is This a Good Thing? PLoS Med 9(6): e1001228. doi: 10.1371/journal.pmed.1001228

Conducting trials in different populations also tests efficacy of the medical interventions in those populations, which can bear on the decision to bring a pharmaceutical to market. Additionally, some countries, such as China, require that if an intervention is going to be marketed in that country, the trial for the drug must have been completed in the same country.

Contract Research Organizations

Contract Research Organizations (CRO), i.e., groups which conduct clinical research and trials on a contract basis for another organization, have helped accelerate the trend towards multinational studies. Schuman reports, "According to the clinical-trials information company Thomson CenterWatch, CROs played a substantial role in 64% of phase 1, 2, and 3 clinical studies in 2003 (for about $7.6 billion in contracts), as compared with 28% in 1993 (for $1.6 billion)".[381] CROs benefit from specializing in performing clinical research or coordinating the research at third-party sites geographically located away from host institutions. They can also specialize in recruiting patient populations and often cite this as one of their benefits. CROs will also coordinate the administrative activities of conducting the clinical research in a host countries system. Altogether, CROs represent a more financially friendly alternative to the existing academic centre collaborations, local training and capacity building, or conducting trials themselves overseas, all of which were more common in the twentieth century.

Clinical Research Hubs – political promotion

Governments have been keen to promote their countries as potential markets for clinical research and trials. In the European context, the EU has made efforts to harmonize the application process for clinical trials with the Clinical Trials Directive[382] in part to simplify the application process and promote the Eurozone as a hub for research and innovation.

Elsewhere, India has aggressively pushed to increase its role in clinical research and trials. Vinay Kamat explains,

> Buoyed by initial optimism, the Indian government put its re- sources behind the industry by describing it as a "sunrise industry" deserving of aggressive support through a "tax holiday" (exemption from service tax on drug testing) based on the expectation that it will attract huge foreign investment funds, leading to jobs in the biopharma industry and national prestige (Bhatt, 2004; Prasad, 2009). "This is very much in keeping with a post-1990s ideology of economic liberalization that has been prominent in Indian elite and policy circles whose idea of India is as India Inc" (Sunder Rajan, 2006: 68). At the time, proponents claimed that "the Indian clinical research industry could attract US $1.5 billion of revenue from U.S. and European sponsors by 2010, creating a demand for more than 10,000 investigators, trained in good clinical practice (GCP) and supported by nearly 50,000 clinical research professionals" (Sahoo & Sawant 2007: 51). The Indian pharmaceutical industry, members of the Indian clinical trials industry, CROs, Confederation of Indian Industry, corporate hospitals and research investigators, in particular, are eager to become part of the lucrative multi-billion dollar global pharmaceutical industry. They have repeatedly called attention to the so-called "spillover"

[381] Shuchman, Miriam. New England Journal of Medicine. 10/4/2007, Vol. 357 Issue 14, p1365-1368.
[382] http:// http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf

benefits of clinical trials through related business opportunities that could make India a major hub for global biotechnology research.[383]

The EU and India's policies are only two examples, but underscore the relationship of research populations to the political context. The policies of the political state directly affect the availability of citizens to be solicited for trials participation, and in some instances even promoted as a resource due to the population's greater genetic variability composition.

5.5.3 ETHICAL CONSIDERATIONS OF GLOBALISATION OF CLINICAL RESEARCH AND TRIALS

Inconsistent application of International standards

The aforementioned international response to medical misconduct has blossomed into an international network of governmental, non-governmental, and private actor industry to address the ethical issues surrounding human subjects' experimentation. The *Declaration of Helsinki* and *The International Ethical Guidelines for Biomedical Research Involving Human Subjects* are two of the most commonly cited international texts proclaiming international standards for the conditions which must exist for ethical research to be conducted. Since their introduction, each has been revised, leading to a debate as to the status of previous versions of the instruments. The World Medical Association, the organization which led the development of the *Declaration of Helsinki* and currently oversees it, claims there are no versions, simply the declaration as it exists in its most recent form.

The Declaration of Helsinki from the World Medical Association has historically been regarded to be amongst the predominant benchmarks for the assessment of ethics in clinical trials and other human subjects' research. While these gold-standard ethical guidelines have been implemented appropriately in certain research settings, this is not universally true. Additionally, there has been a degree of pushback from pharmaceutical approval agencies as well as manufacturers in order to avoid adopting more stringent ethical demands.

The Food and Drug Administration (FDA) has previously referred to guidelines set forth by the Declaration of Helsinki in regulatory documentation related to clinical ethics. However, stringent stipulations incorporated into the 2004 revision of the document have prompted the agency to revise regulation to eliminate all reference to the Declaration of Helsinki. This particularly refers to the inclusion of controversial clauses that "limit the use of placebos in drug trials and increase the responsibilities of trial sponsors towards research participants."[384] The revision mandates that experimental drug trials offer the current standard of care to research participants as the control as opposed to conducting placebo trials; the FDA argues that this compromises the scientific integrity of the research. Furthermore, the new Declaration of Helsinki escalates the responsibilities of trial sponsors to research participants and communities. It obliges sponsors to ensure direct benefit for the research participants in terms of compensation and adequate care for the trial period, but also life-time access to the best level of care available following the study endpoint. Moreover, the community benefit

[383] Kamat, Vinay R., (2014), Fast, cheap, and out of control? Speculations and ethical concerns in the conduct of outsourced clinical trials in India, Social Science & Medicine, 104, issue C, p. 48-55, http://EconPapers.repec.org/RePEc:eee:socmed:v:104:y:2014:i:c:p:48-55

[384] Wolinsky, Howard. "The Battle of Helsinki: Two Troublesome Paragraphs in the Declaration of Helsinki Are Causing a Furore over Medical Research Ethics." *EMBO Rep EMBO Reports* 7.7 (2006): 670-72. Web.

obligation is much greater according to the new standards, to which the FDA has reacted quite antagonistically citing ambiguity in community responsibility. Rather than basing regulation on the WMA document, the FDA has taken a different route and instead plans to refer to the guidelines established in "Good Clinical Practice: Consolidated Guidance" (GCP) by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), a consortium of drug regulatory authorities and members of the pharmaceutical industry.[385] Though the GCP guidelines do hold equal validity on a global platform, it is questionable from an ethical standpoint to a) refer to previous outdated versions of the Declaration of Helsinki which the WMA considers inoperative and b) to eliminate reference to a document once utilized as an ethical standard. The FDA is not alone in this regard; the European Commission also refers to the 1996 version of the Declaration of Helsinki in its directives on clinical trials and practice.[386] By shifting the standard of reference from the Declaration of Helsinki to other ethical policies, the FDA and similar regulatory bodies may be circumventing decrees that reflect shifts in the universal ethics standard.

Ethical Reflections on Conducting Ethical Research in multinational settings

Ethical reflections on multi-national clinical research have resulted in competing theories on how multi-national clinical research and trials should be conducted. Perhaps the most well-known is the Emanuel *et al*[387] model, which proposes benchmarks for evaluating whether clinical research in developing countries hits the ethical imprimatur. A table of these principles and benchmarks are presented below.

Vinay Kamat warns against an overemphasis on the ethical propriety of individual trials, citing "The current discursive emphasis on the hype, speculation and dangers surrounding the offshore outsourcing of clinical trials to emerging economies like India has its limitations, in that it potentially distracts stakeholders, regulatory authorities and policy makers from attending to 'the real issues' of vast health inequalities."[388] For Kamat, the greater ethical consideration is the focus of the population enlisted in the trials and whether the research is representative of the health issues prevalent in the population. He compounds his warning by stating national interests in developing markets places target populations at odds with this ideology. If a target population is resourceful for medical interventions that will ultimately be used in other markets and the nation of that population is promoting that fact, the health issues of the target population may go unheeded, thus producing a greater ethical concern for the globalization of clinical research.

[385] Goodyear, M. D E, T. Lemmens, D. Sprumont, and G. Tangwa. "Does the FDA Have the Authority to Trump the Declaration of Helsinki?" *BMJ* 338.1559 (2009): n. pag. Web.
[386] European Commission. *Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Relating to the Implementation of Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use*. Luxembourg: Office for Official Publications of the European Communities, 2001. Web.
[387] Emanuel, Ezekiel J., et al. "What makes clinical research in developing countries ethical? The benchmarks of ethical research." *Journal of Infectious Diseases* 189.5 (2004): 930-937.
[388] Kamat, Vinay R. "Fast, cheap, and out of control? Speculations and ethical concerns in the conduct of outsourced clinical trials in India." *Social Science & Medicine* 104 (2014): 48-55,

Principles	Benchmarks
Collaborative partnership	Develop partnerships with researchers, makers of health policies, and the community.
	Involve partners in sharing responsibilities for determining the importance of health problem, assessing the value of research, planning, conducting, and overseeing research, and integrating research into the health-care system.
	Respect the community's values, culture, traditions, and social practices.
	Develop the capacity for researchers, makers of health policies, and the community to become full and equal partners in the research enterprise.
	Ensure that recruited participants and communities receive benefits from the conduct and results of research.
	Share fairly financial and other rewards of the research.
Social value	Specify the beneficiaries of the research—who.
	Assess the importance of the health problems being investigated and the prospective value of the research for each of the beneficiaries—what.
	Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long-term research collaboration, and/or health system improvements.
	Prevent supplanting the extant health system infrastructure and services.
Scientific validity	Ensure that the scientific design of the research realizes social value for the primary beneficiaries of the research.
	Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health-care interventions to which they are entitled.
	Ensure that the research study is feasible within the social, political, and cultural context or with sustainable improvements in the local health-care and physical infrastructure.
Fair selection of study population	Select the study population to ensure scientific validity of the research.
	Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social value.
	Identify and protect vulnerable populations.
Favorable risk-benefit ratio	Assess the potential risks and benefits of the research to the study population in the context of its health risks.
	Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.
Independent review	Ensure public accountability through reviews mandated by laws and regulations.
	Ensure public accountability through transparency and reviews by other international and nongovernmental bodies, as appropriate.
	Ensure independence and competence of the reviews.
Informed consent	Involve the community in establishing recruitment procedures and incentives.
	Disclose information in culturally and linguistically appropriate formats.
	Implement supplementary community and familial consent procedures where culturally appropriate.
	Obtain consent in culturally and linguistically appropriate formats.
	Ensure the freedom to refuse or withdraw.
Respect for recruited participants and study communities	Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
	Ensure that participants know they can withdraw without penalty.
	Provide enrolled participants with information that arises in the course of the research study.
	Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participants at least as good as existing local norms.
	Inform participants and the study community of the results of the research.

Table 2: Ethical principles and benchmarks for multinational clinical research[389]

[389] Emanuel, Ezekiel J., et al. "What makes clinical research in developing countries ethical? The benchmarks of ethical research." *Journal of Infectious Diseases* 189.5 (2004): 930-937.

5.6 BRAIN-DRAIN

5.6.1 INTRODUCTION

Brain drain is the process of emigration of highly skilled workers, especially researchers, to countries, where they have better employment possibilities. This phenomenon is by many regarded a serious threat, for it deprives countries of origin of human capital that cannot be easily replaced or compensated through financial resources or transfer of skills, and which as a consequence negatively affects their development potential. Many policies and strategies were developed to overcome this problem, they include for example tax incentives for the returnees or establishing advanced research institutions. Many countries, such as South Korea or India, have successfully overcome brain drain and encouraged the highly-skilled to return home. However there are voices that emigration of highly-skilled is not necessarily a negative phenomenon, which should be fought by all means, but it should be rather regarded as an opportunity to exchange both knowledge and experience, leading to new scientific breakthroughs (benefit-sharing).

This report is divided in two main parts. In the first we provide general information on the brain drain (definitions of the most important terms, impacts on countries of origin and hosting countries, ethical issues involved) as well as briefly discuss some actual strategies aimed at overcoming brain drain. The second part is the case study of the Foundation for Polish Science, which developed a programme encouraging researchers staying abroad to come and carry out research in Poland.

5.6.2 GENERAL DISCUSSION

The term **"brain drain"** was first used in the 1960s to describe the phenomenon of the migration of skilled scientists and engineers from UK to other countries, especially the USA.[390] Nowadays, it refers either to the "immigration of trained and talented individuals or 'professionals' from less developed to highly developed or quickly developing regions in the world"[391] or to the "emigration of a nation's most highly skilled individuals".[392] Docquier and Rapoprt[393] define high-skill immigrant as a "foreign-born individual aged 25 or more, holding an academic or professional degree beyond high school". These are mostly scientists and academics.[394]

Global trends

Without a doubt, global migration is increasing. In 2013, there were almost 232 million international migrants and the global migrants stock is growing faster and faster (during the

[390] Matthew Godwin, Jane Gregory and Brian Balmer. (2009). *The Anatomy of the Brain Drain Debate in the UK*.
[391] Ismail Maimunah , Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[392] Gibson, John and David McKenzie, "Eight Questions about Brain Drain", *Journal of Economic Perspectives*, No. 25(3), 2011, pp. 107-128.
[393] Docquier, Frédéric and Hillel Rapoprt, "Globalisation, Brain Drain and Development", *Journal of Economic Literature*, No. 50(3), 2012, pp. 681-730.
[394] Gibson, John and David McKenzie, "Eight Questions about Brain Drain", *Journal of Economic Perspectives*, No. 25(3), 2011, pp. 107-128.

period 1990-2000 it grew at an average of approximately 2 million migrants per year and in the following decade the number accelerated to 4.6 million migrants per year).[395] The absolute number of highly-skilled people emigrating is also increasing. The phenomenon of brain drain affects mostly island states in Latin America, Caribbean and in Africa, as well as small countries.[396] In this context, it is worth mentioning that the majority of highly skilled persons born in Guyana, Barbados and Trinidad are living abroad.[397] Apart from the country size, other relevant factors explaining the brain drain include: the level of development of the country of origin, socio-political environment (for example, the possibility that the government will be destabilized) in addition to the geographical and cultural proximity between the country of origin and host country.[398]

Approaches to "brain drain" over the decades

In the history of studies on brain drain, one can distinguish three approaches to its impacts on host countries and countries of origin.[399] The first one dates back to the 1960s and considers skilled migration to be positive, not only for the host country but for country sending the migrants as well. This approach emphasized the contribution of emigrants to science and technology. It was also believed that the highly skilled would send remittances to their country of origin, so that any losses would be compensated.

The second approach was developed in the 1970s and underlined the negative consequences of brain drain for the sending countries. Brain drain was viewed as contributing to enhancing inequalities in the world, "with rich countries becoming richer at the expense of poor countries".[400] High-skilled emigration was also viewed as contributing to a higher unemployment rate and lower gross domestic product.

The 1990s gave rise to the third approach (the so-called new economics of brain drain), according to which, under certain circumstances, brain drain can bring positive effects to the country of origin of migrants. There are four types or sources of potential benefit:[401]

- effect of induced education –the possibility of migration alone contributes to an increases of investments in education;
- return migration – on their return, the highly-skilled contribute to economic development through bringing human and social capital;
- remittances – transfer of emigrants' income to their home country;
- diaspora effects – foreign direct investments by emigrants or their companies.

[395] UN DESA, OECD, *World Migration in Figures,* 2013 Retrieved from: http://www.oecd.org/els/mig/World-Migration-in-Figures.pdf
[396] Ibid.
[397] Ibid.
[398] Docquier, Frédéric, Olivier Lohest and Abdeslam Marfouk, "Brain drain in developing countries", *World Bank Economic Review*, No. 21 (2), 2007, pp. 193-218.
[399] Docquier, Frédéric and Hillel Rapoprt, "Globalisation, Brain Drain and Development", *Journal of Economic Literature*, No. 50(3), 2012, pp. 681-730.
[400] Ibid.
[401] Brzozowski, Jan, *Brain Drain or Brain Gain? The New Economics of Brain Drain Reconsidered*, 2008. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1288043

Reasons for migration

There are numerous reasons why the highly-skilled decide to emigrate, including the following:[402]

- better employment opportunities as well as more attractive working conditions abroad, such as higher salaries or higher level of job security;
- underemployment in the home country, which refers to a "condition in the job market, where an employee is paid either less than his/her capabilities or works part-time due to less availability of decently paid full-time work";[403]
- higher standard of living in the host country.

"Brain gain", "reverse brain drain", "brain waste"

Another significant term is "brain gain", which is being used to describe two types of situation. First of all, it can refer to a situation in which highly-skilled professionals enter a particular country.[404] However, unlike brain drain, it is not analysed from the perspective of the country of origin, but of the host country instead. In other words, the same movement of high-skilled professionals can have different meanings depending on the point of view. For the country of origin it is brain drain, whereas for the host country, the phenomenon is a brain gain. The term in question is also often used to describe the situation whereby emigration of the highly-skilled leads to a "rise in human capital levels in the home country".[405] In this context, on seeing the success of the high-skilled living abroad, other people also decide to emigrate. They decide to acquire a better education, but eventually do not end up migrating or they emigrate but return soon after. If it had not been for the possibility of migration, these individuals would not have acquired new skills and knowledge. Thus, the emigration of the highly-skilled may lead to an increase in human capital in their home country and, in some situations, may bring positive effects.

Other important terms are the **"reverse brain drain"**, which refers to the phenomenon of the return of the professionals to their home country[406] and **"brain waste"**, which occurs when highly-skilled "emigrate to forms of employment that do not require them to apply as a high level of skills and experience as utilized in their previous work".[407] The former is highly beneficial for the countries of origin, not only because they get back their human capital, but also due to the fact that migrants have gained experience and acquired new skills. The phenomenon of the reverse brain drain is often the result of successful initiatives undertaken by the country's government, which lead to economic growth and eventually convince the

[402] Iqbal Shah, Javed, "Brain Drain: Why People Leave their Motherland? (implications for the Developed and Developing Economies)", *Journal of Managerial Sciences*, Vol. 5, No. 1, 2011.
[403] Ibid.
[404] Kelo, Maria and Bernd Wächter, *Brain Drain and Brain Gain. Migration in the European Union after Enlargement*, 2004. Retrieved from: http://www.aca-secretariat.be/fileadmin/aca_docs/documents/reports/Migration.pdf
[405] Gibson, John and David McKenzie, "Eight Questions about Brain Drain", *Journal of Economic Perspectives*, No. 25(3), 2011, pp. 107-128.
[406] Ismail Maimunah , Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[407] Simona Milio, Riccardo Lattanzi, Francesco Casadio, Nicola Crosta, Mario Raviglione, Paul Ricci and Fabio Scano. (2012). *Brain Drain, Brain Exchange and Brain Circulation. The Case of Italy Viewed from a Global Perspective.*

highly-skilled to return home.[408] Other important factors for returning to one's home country include family and lifestyle reasons, for example raising children in one's own culture.[409]

As far as the brain waste is concerned, there are numerous reasons why the emigrants cannot find satisfactory employment that corresponds to their qualifications. These reasons are as follows: [410]

- administrative barriers, which make it impossible for emigrants to work in specific sectors;
- discrimination;
- possibility of application of human capital only in the country of origin, which refers mainly to the lawyers and sociologists;
- problem regarding the recognition of diplomas;
- "nominal skills", which are presented on a diploma but do not correspond to their "real skills".

Ethical issues

The phenomenon of brain drain involves many ethical issues. First of all, the concept of distributive justice helps to understand why the highly-skilled decide to emigrate. According to theorists writing on distributive justice, goods and opportunities are distributed unevenly across different regions and access to them is often based on such arbitrary grounds as for instance place of birth.[411] People who consider this highly unjust may decide to leave their home countries in search for better opportunities abroad. It seems, that particularly sensitive to injustice are the highly-skilled,[412] for they tend to be more ambitious. "Elites who feel more injustice are more likely to migrate to a better country. For instance irrational difference of income to life cost ratio between home and host country is a main factor influencing brain drain."[413]

Another important issue is the problem of depriving developing countries of human capital that cannot be easily replaced or compensated through financial resources or transfer of skills, which negatively affects the development potential of the country of origin.[414] This has occurred in Kenya, where the emigration of academic staff has led to a lower quality of higher

[408] Ismail Maimunah , Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[409] Gibson, John and David McKenzie, "The Economic Consequences of "Brain Drain" of the Best and Brightest: Microeconomic Evidence from Five Countries", *The Economic Journal*, Vol. 122(560), 2012, pp.339-375.
[410] Brzozowski, Jan, *Brain Drain or Brain Gain? The New Economics of Brain Drain Reconsidered*, 2008. Retrieved from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1288043
[411] Sager, Alexander, "The Implications of Migration Theory for Distributive Justice", *Global Justice: Theory Practice Rhetoric*, Vol. 5, 2012.
[412] Salmani Davood, Gholamreza Taleghani and Ali Taatian. (2011). "Perception of social justice implications in brain drain management in Iranian educational institutions", *Education, Business and Society: Contemporary Middle Eastern Issues*, Vol. 4, No. 1, pp. 19-32, 2011.
[413] Ibid.
[414] Ferracioli, Laura. (2014). "Immigration, Self-determination, and the Brain Drain", *Review of International Studies*, Vol. 41, Issue 1, 2015, pp. 99-115.

education.[415] This seems to be a vicious circle - the greater the degree of emigration, the lower the potential for development, which again forces more people to emigrate. This leads to the question as to whether countries should impose certain restrictions on the outflows of the highly-skilled.[416] Many also claim, that "brain drain decimates (…) educational systems in developing countries" and failure to stop it can cause both social and economic catastrophe.[417] However, some believe that brain drain is inevitable and should not be considered "another deplorable negative outcome of a globalized open world, but rather a challenge for attracting the best from wherever one can get them".[418] They think that governmental restrictions only make it impossible for young scientists to grow to their full potential and that "science as a global social enterprise needs continuous stimulation by difference and diversity".[419] In this context, migration of the highly-skilled can be regarded as an opportunity to exchange both knowledge and experience, leading to new scientific breakthroughs. The concept of benefit-sharing is used to stress out that brain drain is not necessarily a zero-sum game, where rich countries keep getting richer and the poor poorer – "the creation and exchange of knowledge are the greatest positive-sum game that humanity has invested. HSM[420] is a vital part of that game, a joint venture from which both source and receiving countries have the potential to gain. HSM policies should aim to distribute fairly the benefits of expanded migration, rather than seek to limit migration or knowledge flows".[421]

Policies aimed at overcoming brain drain

There are many ways in which states deal with high-skilled emigration in terms of policy. Lowell has identified the following policy responses to the "**six Rs**".[422] These are:

- return of migrants to their source country – encouraging migrants to return, for example, through tax incentives;
- restriction of international mobility – emigration policies impeding taking jobs abroad;
- recruitment of international migrants – covering the loss of professionals by attracting foreigners;
- reparation for loss of human capital (tax) – the idea that the host countries compensate the countries of origin for the loss of human capital, or that emigrants submit taxes to the countries of origin.
- resourcing expatriates (diaspora options) – technology transfers between the host country and country of origin or remittances and monetary flows;
- retention through educational sector policies – strengthening domestic educational institution in order to encourage students to stay;

[415] Odhiambo, George O., "Academic Brain: impact and implications for public higher education quality in Kenya", *Research in Comparative and Inernational Education*, Vol. 8, No. 4, 2013.
[416] Ferracioli, Laura. (2014). "Immigration, Self-determination, and the Brain Drain", *Review of International Studies*, Vol. 41, Issue 1, 2015, pp. 99-115.
[417] Gibson, John, David McKenzie, "Eight Questions about Brain Drain", *Journal of Economic Perspectives*, No. 25(3), 2011, pp. 107-128.
[418] Markl, Hubert, "Brain drain: a non-political perspective", *European Review*, Vol 14, Issue 1, 2006, pp. 23-31.
[419] Ibid.
[420] High-skill migration
[421] Hart, David M., "From Brain Drain to Mutual Gain: Sharing the Benefits of High-Skill Migration", *Issues in Science and Technology*, Fall 2006.
[422] The six Rs are: return (migration), restriction (migration), recruitment (migration), reparation (monetary), resourcing (diaspora options), and retention (opportunities). Lowell, B. Lindsay, *Policy Responses to the International Mobility of Skilled Labour*, International Migration Papers 45, International Labour Office, 2002.

- retention through development – encouraging individuals to stay in the country through economic growth.

Below you can find some actual strategies and policies developed in different regions aimed at fighting the negative impacts of brain drain.

European Union

The European Union has developed numerous instruments to attract foreign scientists and researchers to the EU to increase European scientific potential. The so-called Researchers Directive is particularly relevant here.[423] According to article 1, its purpose is to lay down "the conditions for the admission of third country researchers to the Member States for more than three months for the purposes of carrying out a research project under hosting agreements with research organisations". Pursuant to article 7, if researchers comply with certain obligations, they shall be admitted to the territory of the Member States. The conditions for entry include valid travel documents, a hosting agreement with a research organisation and a statement of financial responsibility (when appropriate). Researchers shall also "not be considered to pose a threat to public policy, public security or public health". Article 12 guarantees equal treatment, as far as recognition of diplomas, working conditions, branches of social security,[424] tax benefits and access to goods and services are concerned. The Directive has served its purpose of increasing the access of the researchers from third countries to the EU. In 2007, the total number of permits was 239. The 2010 figure was 3 713.[425] The highest increases were observed in The Netherlands (from 216 in 2008 to 1 422 in 2010, an increase of 558%); Germany (from 100 in 2007 to 412 in 2010, an increase of 313%); and Ireland (from 73 in 2007 to 297 in 2010, an increase of 307%).[426] The majority (52,2%) of researchers were from the fields of natural sciences with the most popular disciplines being engineering, information technologies and health sciences.[427]

Another important act is the Blue Card Directive[428], the aim of which is to "facilitate the admission of highly qualified migrants and their family members by harmonising entry residence conditions throughout the EU and by providing for a legal status and a set of rights".[429] It also touches upon the problem of brain drain in the context of minimising this

[423] Council, Council Directive 2005/71/EC of 12 October 2005 on a specific procedure for admitting third-country nationals for the purpose of scientific research, OJ L 289, 3 November 2005, pp. 15-22. Retrieved from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:289:0015:0022:EN:PDF

[424] They refer to branches of social security in the meaning defined in the Council Regulation (EEC) No 1408/71 of June 1971 on the application of social security schemes to employed persons to self-employed persons and to members of their families moving within the Community and cover (article 4): sickness and maternity benefits, invalidity benefits, old-age benefits, survivors' benefits, benefits in respect of accidents at work and occupational diseases, death grants, unemployment benefits and family benefits.

[425] International Centre for Migration Policy Development, *Implementation and Impact of the Researchers Directive (Directive 2005/71/EC)*, 2012.

[426] Ibid.

[427] Ibid.

[428] Council, Council Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purposes of highly qualified employment, OJ L 155, 18 June 2009, pp. 17-29. Retrieved from: http://www.etuc.org/sites/www.etuc.org/files/blue_card_en_1.pdf

[429] European Parliament, Council, *Communication from the Commission to the European Parliament and the Council on the implementation of Directive 2009/50/EC on the conditions of entry and residence of third-country nationals for the purpose of highly qualified employment,* 2014. Retrieved from: http://www.europarl.europa.eu/meetdocs/2014_2019/documents/com/com_com(2014)0287_/com_com(2014)0287_en.pdf

phenomenon in developing countries. The Blue Card is the document allowing highly-skilled non - EU citizens to reside and to work in the territory of a Member State. 3,664 Blue Cards were granted in 2012 and in 2013 the number increased to 15,261.[430] Most of the cards were granted by Germany (14 197 in 2013).[431] Of particular importance are articles 3(3) and 8(4), which guarantee the so-called **ethical recruitment.** According to the latter, "Member States may reject an application for an EU Blue Card in sectors suffering from a lack personnel of qualified workers in the countries of origin".[432] Such rejections are based on the agreements between Member States and third countries, which list professions, which not fall under the Directive (article 3(3)). Although no Member State has entered into such an agreement yet, some of the states, e.g. Germany, in order to assure ethical recruitment did transpose the possibility to reject a Blue Card application.[433]

South Korea

South Korea, similarly to other Asian countries, had a serious brain drain problem. "Between 1953 and 1972, a total of 10 412 (5 373 in science & engineering fields) requested permission to study in the United States".[434] South Korea has however successfully overcome the brain drain problem and is now becoming one of the most advanced democratic societies in the world. This is the result of numerous reforms aimed at reversing these negative tendencies. The first attempts dates back to 1962, when the first "Five-Year Economic Plan" was drawn up, which was focused on human capital development. "For the past 60 years, human resource has been the key factor for Korea's economic development".[435] Another substantial reform is a three-stage nanotechnology initiative, which was developed in 2001.[436] During the first stage (2002-2005), the National Nano Fab Centre and the Korea Research Centre were established in order to develop a basic research and educational hub. The second stage (2006-2010) involved the further development of basic research and education, in addition to a focus on the practical application of findings. The third stage is scheduled for 2011 to 2020. By 2020, South Korea plans to become "one of the three leading nations in the field of nanotechnology".[437] It is also worth mentioning the Korea Education Development Institute, which in 2001 "identified and implemented human resource development and management as key strategies for regional development".[438] All of these undertakings have helped Korea to

[430] Ibid.
[431] Ibid.
[432] Council, Council Directive 2009/50/EC of 25 May 2009 on the conditions of entry and residence of third-country nationals for the purposes of highly qualified employment, OJ L 155, 18 June 2009, pp. 17-29. Retrieved from: http://www.etuc.org/sites/www.etuc.org/files/blue_card_en_1.pdf
[433] Please see section 19a (2.3) of the Act on the Residence, Economic Activity and Integration of Foreigners in the Federal Territory. http://www.gesetze-im-internet.de/englisch_aufenthg/residence_act.pdf
[434] Yoon, Bang-Soon L, "Reverse Brain Drain in South Korea: State-led Model", *Studies in Comparative International Development*, Vol. 27, No. 1, Spring 1992, pp. 4-26.
[435] Ismail Maimunah, Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[436] Ibid.
[437] Ibid.
[438] Ibid.

become one of the most innovative countries,[439] which not only encourage Korean to return home[440] but also attract talents from abroad.[441]

India

There used to be a tendency for young scientists and researchers from India to immigrate to the USA in search for work.[442] Between 1995 and 2005, Indian immigrants founded 15,5% of all Silicon Valley start-ups[443]. Nowadays, this tendency is being reversed as a result of some intensive developments in India, especially of science parks focusing on pharmaceutical industry.[444] Varma and Kapur[445] between 2007 and 2008 conducted a survey on approximately 260 students of Indian Institutes of Technology (IIT) and identified the following trends:

- a greater number of students deciding to stay in India;
- those students who have gone abroad are determined to return;
- IIT students tend to find a job after completing their undergraduate programmes rather pursuing postgraduate education;
- if these students do continue their education, they change their fields from chemical engineering, civil engineering, computer science and others to management or finance.

The decision to either stay in India or to return from abroad (reverse brain drain) seems to be based on the new economic reality, i.e. better career opportunities and the quality of work life.[446]

Portugal

Heitor, Horta and Mendonça[447] analysed the flow of doctorates in the years 1970-2010 and observed a positive flow of PhDs into Portugal, specifically active researchers working in

[439] James P. Andrew, Emily Stover DeRocco and Andrew Taylor. (2009). *The Innovation Imperative in Manufacturing. How the United States Can Restore Its Edge*. Retrieved from: http://www.themanufacturinginstitute.org/~/media/6731673D21A64259B081AC8E083AE091.ashx
[440] Kang, Tae-jun "*South Korea's War on Brain Drain*", 2014. Retrieved from: http://thediplomat.com/2014/09/south-koreas-war-on-brain-drain/
[441] Ismail Maimunah , Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[442] Docquier, Frédéric and Hillel Rapoprt, "Globalisation, Brain Drain and Development", *Journal of Economic Literature*, No. 50(3), 2012, pp. 681-730.
[443] Varma, Roli and Deepak Kapur, „Comparative Analysis of Brain Drain, Brain Circulation and Brain Retain: A Case Study of Indian Institutes of Technology", *Journal of Comparative Policy Analysis*, Vol. 15, No. 4, 2013, pp. 315-330
[444] Ismail Maimunah, Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[445] Varma, Roli and Deepak Kapur, „Comparative Analysis of Brain Drain, Brain Circulation and Brain Retain: A Case Study of Indian Institutes of Technology", *Journal of Comparative Policy Analysis*, Vol. 15, No. 4, 2013, pp. 315-330
[446] Ismail Maimunah , Mageswari Kunasegaran and Roziah Mohd Rasdi, "Evidence of Reverse Brain Drain in Selected Asian Countries: Human Resource Management Lessons for Malaysia", *Organisations and Markets in Emerging Economies*, Vol. 5, No. 1(9), 2014.
[447] Heitor, Manuel, Hugo Horta and Joana Mendonça, "Developing human capital and research capacity: Science policies promoting brain gain", *Technological Forecasting and Social Change*, Vol. 82, 2014, pp. 6-22.

higher education and private research institutes. Due to public funding for the establishment of scientific institution and training of human resources, Portugal succeeded in modernizing higher education and business based R&D, which increased its capacity to attract talent. 76. 3% of PhD holders, whose degrees in years were gained abroad between 17970 and 2008 and recognized in Portugal, are working in Portugal. In the years 1970-2010, in particular the following science instruments were used:

1. doctoral fellowships – "centralized programme orientated towards the advanced training of human resources, independently of university hierarchies";[448]
2. competitive funding programme for R&D projects – programmes promoting research activities;
3. post-doctoral fellowships – this policy focused on "promoting the internationalization and mobility of doctorates";[449]
4. promotion of scientific culture – science education in schools and the public understanding of science;
5. performance-based funding of research units – promoting research capacity through institutional building;
6. international partnerships with leading universities and research institutes – internationalization of academic staff;
7. post-doctoral research contracts programme – attracting researchers with both a doctorate and experience;
8. sponsored research chairs – this instrument was aimed at attracting senior academics (both Portuguese and foreign) to Portuguese universities.

5.6.3 CASE STUDY: FOUNDATION FOR POLISH SCIENCE

Polish accession to the European Union in 2004 substantially boosted the outflows of highly-educated individuals.[450] The share of highly educated Polish emigrants increased from 10% (before the accession) to 16,5% (after the accession).[451] Their main destination is Germany. Interestingly, the accession has significantly decreased the number of researchers immigrating to the USA. Żebrowska and Konarzewski[452] have analysed the magnitude of the emigration of Polish researchers to the USA. According to their findings, between years 1996 and 2012, the Embassy of the Republic of Poland in Washington processed a total of 1,017 applications filed by highly skilled researchers (holders of PhDs, MDs and MS degrees). Between 1996 and 2004, the number of applications increased (from 30 to 90 applications per year). However, after the accession there was a gradual decrease and now the number of application is at the level of 10 per year. Two factors were identified as contributing to this trend. First of all, after 2004, Poland significantly increased R&D funding, from 1,7 billion dollars in 2004 to 3,9 billion dollars in 2011, which contributed to creating more favourable working conditions for scientists. Moreover, several programmes were initiated aimed at bringing back young Polish researchers, such as Homing Plus developed by the Foundation for Polish

[448] Ibid.
[449] Ibid.
[450] Luiza Ionescu. (2014). *Emigration from Eastern Europe with a Focus on Brain Drain.*
[451] Ibid.
[452] Grażyna Żebrowska, Marek Konarzewski. (2014). *Choosing between the United States and the EU: Emigration of Polish Researchers, 1996-2012.*
http://www.sciencediplomacy.org/article/2014/choosing-between-united-states-and-eu

Science (*Fundacja na rzecz Nauki Polskiej*, FPS)[453]. These two factors not only contributed to fewer Poles going to the US, but they also encouraged many Polish scientists to return home from across the world.

In this report, we will discuss the initiatives undertaken by the Foundation with the aim of bringing back Polish scientists, with a particular emphasis on the Homing Plus programme. The case study is based on two interviews - with Dr Dariusz Łukaszewski – the coordinator of the Homing Plus programme and with one of its beneficiaries, who however wishes to stay anonymous-as well as on reports concerning the migration of Polish scientists published by the FPS.

The Foundation for Polish Science is a non-governmental institution, which was established in 1991. It is one of the largest research funding sources in Poland.[454] According to its website, the Foundation "realizes its statutory purposes through: support for distinguished scholars and research teams in all fields of inquiry, modernization of research facilities, assisting innovative ventures and commercialization of scientific discoveries and inventions".[455]

The Homing Plus Programme was addressed (the closing date for submitting applications was in 2013) to young scientists, both from Poland and abroad, who had received their PhD degree up to 4 years before the application and who were staying abroad for more than 9 months. Researchers were offered financial support in the form of scholarships (up to 5 000 PLN per month) and research grants (up to 80 000 PLN per year). The duration of their research projects was two years. Dr Łukaszewski admits however that it was too short and it was only enough to become acquainted with how research is conducted in Poland, but not to "fully unleash one's potential".

The funding came mainly from the Programme Innovative Economy[456], and was therefore targeted at research from the areas of the bio (biotechnology, bioengineering, environment protection, biological development in agriculture, new medical techniques), info (information technology, intelligent networks, optoelectronics, computational sciences), techno (emerging technologies, nanotechnologies, mechatronics, chemical engineering) sciences and technologies.[457] However, FPS noticed that researchers from other fields were also interested in obtaining grants and therefore it decided to carry out a few editions of the so-called Homing Plus BIS, which was aimed at supporting researchers representing the fields of humanities and theoretical sciences, such as sociology, philology, mathematics and theoretical physics. To this end, FSP used its own financial resources.

Recruitment was carried out in the form of open competition, which was addressed to all researchers who complied with formal requirements. Researchers were expected to deliver the general concept of their projects as well as the employment promise in a research institute or university. They also had to find a mentor, whose task was to assist them with the project and

[453] https://www.fnp.org.pl/oferta/homing-plus/
[454] Other important sources are National Science Centre (*Narodowe Centrum Nauki*) and the National Centre for Research and Development (*Narodowe Centrum Badań i Rozwoju*).
[455] http://www.fnp.org.pl/en/o_fundacji/mission-and-statute/
[456] To learn more about this programme, please see: http://www.poig.2007-2013.gov.pl/english/Strony/Introduction.aspx
[457] http://www.fnp.org.pl/assets/Bio_techno_info_obszary-tematyczne.pdf

who was also responsible for the content-related supervision of their work. The application was then evaluated by at least three reviewers (one from Poland and two foreigners). The final step involved an interview carried out by the interdisciplinary panel of experts. The researcher is required to discuss the concept of their research as well as to explain the choice of the particular research institution. When deciding who should be given grants, the panel takes into account research excellence, the feasibility of the project, in addition to the suitability of the selected research institute for that particular project. The panel does not perform any kind of ethical assessment. Nevertheless, for some of the projects (for instance clinical trials) it is a legal requirement to obtain the consent of a competent bioethics committee. In addition, FSP has drawn up its own Code of Ethics and ensures that it is followed.

Every half a year, the projects are subject to evaluation, based on financial criteria (determination as to whether funding is being spent in compliance with its purpose) as well as substantive criteria (determination as to whether work is carried out in compliance with the research plan). In the event of serious inconsistencies, and, as a consequence, a negative evaluation, FSP may be even forced to terminate the project. It has never happened though. There were some minor problems, but they were rather of an administrative nature, for the researchers who came to Poland often did not have specific knowledge of legal matters, which mostly refer to the public procurement system. In such cases there were only some shifts with the project's schedule.

Homing Plus was not FPS's first programme in the area of researchers' mobility. In the 1990s, when staying in foreign institutes was considered a luxury, the Foundation decided to help Polish researchers to get 12-month postdoctoral internships abroad. The Kolumb programme was launched in 1995 and the final edition was in 2012. Similarly to Homing Plus, it was based on open competition and scholarships. When it became easier for the Polish researchers to get the postdoctoral internships abroad have, the Foundation realized that in many cases the researchers were staying abroad with no intention to come back. Therefore it decided to take steps aimed at encouraging them to return to Poland. Firstly, as a part of the Kolumb programme, the Foundation offered Kolumb's beneficiaries research grants, which were in particular intended to cover the costs of equipment in Poland. Soon after, the Homing Programme was launched, followed by Homing Plus. These two programmes differed in scale (the latter is a bigger undertaking) and the way in which the projects were funded. FPS set also up the Welcome programme, the aim of which was to encourage outstanding foreign researchers to carry out their projects in Poland by means of compensating the disparities in salaries abroad and in Poland. It was rather a small programme with only 11 beneficiaries. The projects were longer than those of Homing Plus (they lasted for 3-5 years) and the scholarships and research grants were higher (the former amounted 200 000 – 350 000 PLN per year and the latter 1 000 000 PLN per year). The Foundation plans to launch another programme in the future, similar to Homing Plus, but it is now in the conceptual phase and therefore concrete details are not yet available.

According to Dr Łukaszewski, Homing Plus served its purpose of bringing researchers back to Poland and can therefore be considered a success. There were 360 applications, from which 117 beneficiaries were selected, who mostly came from Germany (24 beneficiaries), USA (20 beneficiaries), UK (14 beneficiaries), Canada (8 beneficiaries), France (8 beneficiaries) and the Netherlands (7 beneficiaries). The beneficiaries were mostly Poles and there were only 5 foreigners (from Switzerland, Spain, UK and Italy). It is worrying, because it indicates that Poland may not be attractive for the foreign researchers. After completing their projects, the

majority of researchers decided to stay in Poland, where they set up their own research teams or started working on their postdoctoral dissertation. Detailed evaluation of the programme will be available after all of the researchers finish their projects (they are expected to do so by the end of December 2015).

Dr Łukaszewski thinks that emigration of Polish researchers used to be a serious problem but the situation is beginning to change. He admits that many researchers go abroad to stay there permanently, but the number of individuals deciding to return home is increasing. He also points out that one should not use the term emigration in the context of European Union, because all the researchers and scientists form one huge European research area. Circulation of researchers can in many cases be considered positive, for it enables the free flow of knowledge and experience. The actual problem is the fact that, even though many Polish researchers are willing to return home, they are often unable to do so due to financial reasons. This is why funding programmes, like those of FPS, are often crucial factors in helping individuals in their decision to return to Poland.

There are many reasons for researchers to go abroad, but according to Dr Łukaszewski the wish to see how research is conducted somewhere else is particularly important. However in his opinion, the differences between Poland and other countries, especially in terms of availability of research equipment and its quality, are decreasing.

While according to one of the programme's beneficiaries interviewed for the purpose of this study, this general statement is true; the serious problem of Polish science is the lack of innovation. There were some breakthroughs (for example, research on graphene), but they should rather be considered exceptions. One of the main reasons for the general lack of creativity may be the attitude of the scientific community towards risk. When researchers are given grants, they are expected to present concrete results, so they are reluctant to carry out research, which indeed may be risky in terms of possible failure, but which can also turn out to be real game changers. They prefer to "play safe" and only carry out research which brings certain results. This significantly undermines development. The beneficiary admits, that abroad researchers also must present results, but the attitude towards possible failures is far more liberal and therefore they are not afraid of taking risk. Further reasons for why researchers decide to emigrate include:

- salaries, which are much higher abroad;
- access to research funds, which is based on more transparent and honest criteria abroad (many surveyed believe that grants in Poland are often given because the applicant knows the "right people" and not because of his achievements);
- the desire to meet an outstanding person, especially Nobel prize winner as well as to see other interesting countries;
- in many universities, in order to start working on a postdoctoral dissertation, it is a requirement to go abroad for an internship.

One should also mention here the FPS's report[458] (based on a survey of 160 researchers of both Polish and foreign origin), which shows that, with regard to science, Poland is still behind other developed countries. According to one of the surveyed, "intensity of research,

[458] Łazarowicz-Kowalik, Marta, *Zainteresowania pracą badawczą w Polsce wśród naukowców pracujących za granicą*, 2011.Retrieved from: http://www.fnp.org.pl/assets/Raport_badanie_FNP_naukowcy_pracujacy_za_granica_052011.pdf

personal engagement, and amount of hard work involved are much higher in foreign teams (especially in the US) as compared to even very good Polish teams".[459] Others note also that abroad, the motivation for intensive work and the willingness to take on projects involving new methods are much higher than in Poland. Notwithstanding these rather negative opinions on Polish science, only 15% of the surveyed categorically excluded the possibility of working in Poland and the majority of them (68%) would consider such an option. Most of the respondents from the second group were of Polish origin (70%). It should not however be interpreted, as if they are ready to return to Poland, but rather that they are open to such a possibility. The foreigners would decide to work in Poland, but only if it would be complementary to their work abroad and it would not involve staying in Poland permanently and abandoning their current position. However, some are of the view that the situation in Poland is improving.[460]

Both Dr Łukaszewski and the beneficiary noted that Poland is unable to attract many foreigners, which corresponds to the results of the above mentioned survey conducted by the FPS. Low internationalization can be considered a problem, because researchers coming from abroad can bring new ideas and points of view, in addition to sharing different approaches to research. "A breath of fresh air" cannot be overestimated, because without it science can easily reach a point of stagnation. According to Dr Łukaszewski, the factors which could increase Poland's attractiveness are the achievements of Polish research teams, as well as legal regulations simplifying the process of carrying out research and guaranteeing the independence of research institutions. The beneficiary believes that in order to guarantee a more friendly research environment the attitude towards success need to change, which in Poland is quite negative – success is not considered something, which one can be proud of and many believe that a successful person must have acted deceitfully. More transparent funding procedures and less bureaucracy are also necessary.[461]

In addition to FPS, the National Science Centre (*Narodowe Centrum Nauki*, NSC), undertakes initiatives touching upon the issue of brain drain. In September 2015, it plans to launch a programme called "Polonez", which, similarly to Homing Plus is addressed to the holders of PhD degree, who before submitting application were staying abroad. The laureates will be offered a 12 to 24 month internship in one of the Polish research institutions in addition to a salary (€4 050 per month), mobility allowance (€300 per month), family allowance (€300 per month), research grant and the opportunity to participate in research and non-research trainings organised by the NSC.[462]

5.6.4 CONCLUSION

In most of cases, emigration of researchers is considered by the countries of origin a serious threat, and they develop many policies and strategies in order to overcome this problem. South Korea, for instance, invested in the development of nanotechnologies, which helped it to become one of the most innovative countries and as a result encouraged Koreans to return home. Another good example of strategies leading to reverse brain drain is India, which established many science parks. However, since for the hosting countries immigration of researchers from less developed countries is highly beneficial, they also develop certain

[459] Ibid.
[460] Ibid.
[461] Ibid.
[462] For more information: https://www.ncn.gov.pl/sites/default/files/pliki/2015_03_28_POLONEZ_ENG.pdf

policies concerning brain drain, aimed at encouraging the inflow, rather than preventing it. The European Union for instance, has drawn up the so-called Researchers Directive, which introduces a simplified entry and residence procedures for third-country nationals willing to carry out research in one of the Member States.

The example of the Homing Plus programme developed by the Foundation of Polish Science shows that a good way of encouraging researchers to return to their countries of origin is to offer them research grants and scholarships. In Poland, one of the main reasons for young scientists to emigrate is low salaries, therefore financial motivators turned out to be effective. However, there were not many foreigners who decided to submit applications. One reason for this may be the fact that Poland is not very attractive in terms of research. Although there are many new science centres with sophisticated equipment, innovation is lacking. In Poland, there are not many scientific breakthroughs, thus foreigners prefer to carry out research in more reputable places. The achievements of Polish research teams seem to be therefore an important factor in attracting foreigners. This, however, would require a change in the mentality and attitude toward risky undertakings and would involve launching social campaigns aimed at encouraging to undertake innovative research projects rather than carrying out reforms.

It is worth mentioning that many people claim that the migration of researchers does not necessarily need to be a zero-sum game, where rich countries keep getting richer and poor poorer. They refer to the concept of benefit-sharing to emphasize that it can be regarded as an opportunity to exchange both knowledge and experience, which could lead to new scientific discoveries. This might be true if there is a “brain circulation”, which means that researchers decide to go abroad with the intention to return later. However in the case of many countries, for example Kenya, they do not come back, which is detrimental for a country’s development. Therefore the only way to reverse this trend seems to be investment in R&D and improving research and employment conditions in universities and other science institutions.

6 CONCLUSIONS

The globalisation of research and innovation continues to affect ethics assessment procedures, and notably, ethics assessment procedures are themselves now becoming more globalised as well. The interplay of the research and ethics assessment necessitates the understanding that ethics assessment procedures are a constitutive part of research and not simply a monitoring mechanism. While the fields within research and innovation are incredibly broad and global, the ethical underpinnings of each are remarkably similar.

The rise of globalisation has been understood in this report namely, but not limited to, multinational R&I in multinational organisations; relocation of company R&D to affiliates abroad; international trade in R&D services, patents, and licenses; international cooperation through R&D networks, alliances and agreements; recruitment of foreign R&D workers in public and private organisations; general global diffusion of knowledge and access to local resources; and internationally located company supply chains. The acceleration of these practices have highlighted lacuna which presently exist due to gaps between the pace of research and innovation and the attention given to the ethical considerations which emerge thereof. The issues which emerged, principally: outsourcing of research and development to developing countries; informed consent; undue inducement; a fair proportion of risk to benefit; standard of care; bio-prospecting and bio-piracy; group consent; benefit sharing etc., are not novel ethical principles. Indeed, they build upon existing principles that have traditionally been considered in the course of ethical assessment practices. However, the dimensions and application of these principles on a global scale begs for query into the feasibility of a standardized, harmonized and global system of ethics assessment.

Just as the relevant ethical principles emerging due to globalisation are not new in theory, simply in form, the methods for addressing the ethical principles should build upon the frameworks that already exist. As noted in this report, globalisation includes the rise of intergovernmental organizations and efforts to address the rise of multinational efforts. Consequently, a system of local, national, and international instruments and practices presently exist, and must be accounted for when developing future policy and legal options for research ethics within the context of globalisation.