own budget and the main control over personnel and financial questions. The ministerial control is only professional. This and the procedures to nominate and denominate the institute's general director constitute its independent status.

Although its opinions are not binding in character and only consultative for governmental institutions, this fact does not touch the agency's independence in general. Furthermore, HFSO is not subject to extensive external lobbying, as it is not in the position to decide on sanctions and other risk management tasks.

In contrast to other European food safety institutes HFSO's independence is weakened by the absence of a management board and by an Advisory Board dominated by government representatives and experts, whose independence from economic or other interests remains still unclear. Because HFSO lacks laboratory capacities it relies on external expertise. Moreover the lack of resources and the fact that MARD decides on the budget limits the agencies possibilities to act. "All this underlined the Office's lack of political independence."[47]

According to Fabrizio Gilardi's[48] index of formal independence the value of 0.3234 confirms these weaknesses.

VI. Quo Vadis HFSO?

Compared with other European countries the reshuffle of the food safety system and the establishment of a new agency in Hungary were not influenced by the BSE crisis, since "BSE didn't really shake Hungary"[49]. By creating HFSO a central point for risk assessment and coordination in a fragmented system was set up. And in conjunction with Hungary's EU accession a partner for EFSA was built. After the national scandal in 2004 and the crisis-induced broad reform processes in 2006/07 the system changed fundamentally – from fragmentation and chaos to a bi-institutional and clearly separated structure. After the last change HFSO's coordination role is marginal, but its focus is much clearer now.

Taking into account its small size and the lack of resources HFSO cannot be compared with other national institutes (e.g., France or Germany). But despite being a small institution, which neither counts as a powerful player within the Hungarian system nor fulfils the principles of good governance perfectly, it takes over almost the same tasks as its huger equivalents; it cooperates smoothly with the EU and its sister organisations. So the foundation of HFSO can be seen as an important improvement in a post-communist state.

Its future is uncertain, especially after the 2010 elections. The current government under premier Viktor Orbán and its conservative party Fidesz pursues new priorities. And HFSO's role after its dismissal as chief coordinator is still unforeseeable. Whether the small Office can survive is still an open question.

47 Ferencz *et al.*, "Food Safety Regulation in Hungary", *supra* note 2, at p. 386.

48 Fabrizio Gilardi, *Delegation in the regulatory state: Independent regulatory agencies in Western Europe* (Cheltenham: Edward Elgar, 2008), at p. 140.

49 Anna Vári, Interview, *supra* note 34.

Intellectual Property

This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.

Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis

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This article examines the issue of risk in research and development (R&D) pertaining to new pharmaceuticals, especially those aimed at neglected diseases and/or relevant primarily to the developing world. In partic-

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ular, the article considers the role of patent pools and other forms of non-proprietary models as alternatives to patents (and other types of intellectual property rights) in R&D for new pharmaceuticals. The article concludes that that these mechanisms still achieve very little output and can therefore not currently be considered as viable alternatives to the use of patents in pharmaceutical R&D. Another relevant finding is that many of the existing collaborative initiatives and partnerships for R&D in neglected diseases actually rely on different forms of intellectual property rights.

I. Introduction

Traditionally, reduction of risk in pharmaceutical research and development has centred on patents and the intellectual property (IP) system. Among R&D-intensive industries, the biopharmaceutical sector is generally considered as one of the riskiest. Development costs for the average drug are currently estimated at $1.3 billion, and the time before it is brought to market at 15 years.[1]

The cost and length of clinical phases, aimed at verifying the safety, efficacy and quality of a new drug, have shown the fastest growth. The cost of the accumulation and compilation of data in a pharmaceutical registration file (put together in clinical trials) is around $467 million, more than 60 % of the total R&D cost.[2] A single clinical trial today typically involves almost 160 procedures and takes at least 780 days.[3] Moreover, industry figures suggest that as few as one out of 5,000 molecules screened actually make it onto the market as pharmaceutical drugs and that only three out of ten prescription drugs generate revenue that exceeds the average cost of research and development.[4]

Patents have played an important role in mitigating these risks and incentivising investment in biopharmaceutical R&D. Indeed, it is estimated that between 60 and 65 percent of inventions in the pharmaceutical industry would not have been developed or introduced in the absence of patents.[5]

Another relevant issue is the large gap in biopharmaceutical R&D between drugs produced for developed and developing regions. In particular, the lion's share of drugs are still consumed in the developed world, with 95 % of sales of new medications taking place in the US, Europe and Japan.[6] Moreover, while consumption is surging in certain developing countries (the E7 countries – Brazil, China, India, Indonesia, Mexico, Russia and Turkey – are expected to account for around one fifth of global pharmaceutical sales by 2020[7]), most of the R&D in the pharmaceutical industry still takes place within the frameworks of mature and developed markets. In other words, conditions that affect mostly poor populations in developing countries – this includes several different parasitic, bacterial and viral infections, such as tuberculosis and malaria – still require new medications and treatments. This means that there is a second layer of risk in the developing world, in the sense that the above trend is likely to continue even as the developed world enjoys increasingly sophisticated drugs that allow for longer and higher quality lives.

Identifying this risk, the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) created a Global Strategy and Plan of Action for fostering innovation and improving access to healthcare products in developing countries.

Certain non-traditional solutions have been considered in the framework of this global strategy to address risks associated with developing pharmaceutical drugs for neglected diseases, especially where intellectual property rights (IPRs) are concerned. In particular, WHO members are asked to "examine the feasibility of *voluntary patent pools* of upstream and downstream technologies to promote innovation of and access to health products and medical devices".[8] Furthermore, the strategy invites members to "ex-

1 PhRMA (2011), "Pharmaceutical Industry Profile 2011", Inside cover, available on the Internet at <http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf> (last accessed on 27 October 2011).

2 H. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries* (Duke University, July 2002), p. 5 and Figure 1; Data is adjusted to 2003 R&D expenditures.

3 Tufts Center for the Study of Drug Development (2008), "Growing Protocol Design Complexity Stresses Investigators, Volunteers", Impact Report 10, No. 1.

4 Tufts Center for the Study of Drug Development (2006), "New Drugs Entering Clinical Testing in Top 10 Firms Jumped 52 % in 2003–2005", Impact Report 8, No.3.

5 E. Mansfield, "Patents and Innovation: An Empirical Study", 32(2) *Management Science* (1986), pp. 173–181.

6 IMS Health (2008), MIDAS MAT.

7 PricewaterhouseCoopers (2011), "Pharma 2020 – the vision", available on the Internet at <http://www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-vision-path.jhtml> (last accessed on 27 October 2011).

8 WHO (2008), *Global strategy and plan of action on public health innovation and intellectual property*, p. 14, available on the Internet at <http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf> (last accessed on 27 October 2011).

plore and, where appropriate, promote a range of incentive schemes for research and development, for example *through the award of prizes*, with the objective of addressing diseases which disproportionately affect developing countries" [emphasis added].[9]

This implies that one important reason for the neglecting of diseases which disproportionately afflict developing countries is that patents do not adequately address the risks in pharmaceutical R&D aimed at these markets. The suggested solution is to mitigate risk on both levels – the development of drugs in general and the development of drugs for financially unattractive markets specifically – with alternative solutions, including patent pools.

The creation of patent pools as a way of promoting and facilitating innovation in essential pharmaceutical drugs is a relatively new and still-debated idea. Patent pools are a specific arrangement involving the cross-licensing of patents and other IP by participants with the goal of accessing essential technologies for particular products.

In the past, patent pools have been successfully applied to IT, consumer electronics and other industries with a high volume of patents. They may not, however, be applicable to the pharmaceutical and biotechnology industries in the same way. Therefore, this study aims to investigate *empirically* whether patent pools and related arrangements are effective in actually promoting R&D.

II. Background and methodology

This study understands patent pools to fall under a broad approach to R&D which promotes collaborative and open innovation. This approach tends to involve a critical perspective on the IP system. In this context, the study seeks to assess the viability of alternatives to the IP system, including patent pools.

Since there are currently only two known patent pools in the pharmaceutical and biotechnology industry, this study went a step further and looked at other initiatives that are not patent pools per se, but represent the same general tendency. It examined seven initiatives which fall under the broad category of collaborative and open innovation, including patent pools, in order to see if such efforts have actually resulted in the development of new pharmaceutical drugs aimed at developing countries (and, hence, mitigated the risks associated with R&D in neglected diseases). The study further examined the presence of visible outputs and the extent to which these are related to promoting innovation, rather than just facilitating access to existing drugs.

The study considered the following initiatives: the Pool for Open Innovation Against Tropical Diseases, Medicines Patent Pool (UNITAID), Bill and Melinda Gates Foundation, Rockefeller Foundation, Global Alliance for Vaccines Initiatives (GAVI), Research for Development/UK Department for International Development (DFID) and Clinton Health Access Initiative.

For each initiative, seven indicators were examined:

- *Focus*, including the type of disease, the socioeconomic level of targeted countries, the mode of collaboration (such as licensing, grant-making, etc.) and the aim of the initiative;
- *Orientation*, i.e., whether the initiative aims to promote research into new drugs, access to existing drugs, or both, and whether it focuses more on general public health activities or on clinical R&D;
- *Recipients*, including research-based and generic companies, international and non-profit organisations and developing country governments;
- *Donors* or sponsors, including research-based companies, governments, international organisations and private philanthropic organisations;
- *IP policy* or approach taken by the initiative, ranging from traditional models of IP (such as retaining ownership or the use of royalty-based licensing) to more open models, including restricted licensing terms (i.e. limited royalties) and alternative payment models such as research prizes and advanced market commitments;
- *Inputs*, including applications for contributions, grants and philanthropic endowments
- *Outputs*, including advanced R&D and manufacturing efforts such as phase III or IV clinical trials; patent applications; registration applications and product sales; and access and distribution efforts.

Three points should be made. First, these initiatives are not necessarily equivalent in terms of end-users, donors, inputs and outputs. For instance, with patent pools, donations generally involve patents and IP themselves; in product development partnerships (PDPs), on the other hand, they also include research grants and funding. Furthermore, for patent pools,

9 WHO, *Global strategy and plan of action on public health innovation and intellectual property, supra* note 8, p. 16.

outputs are primarily in the form of licensing deals and patent applications, while they are more likely to take the shape of clinical trials or product approvals for PDPs.

Second, there is a great deal of overlap between many of the relevant initiatives. For example, funding and grants from different initiatives are often directed toward the same intermediary organisations, and hence the same R&D efforts and outputs.

Third, there is quite a bit of variation when it comes to IP policies – given that these types of collaborative initiatives are relatively new, there are no de facto standards like those that exist in the IT and software industry (e.g., the use of FRAND terms in licensing agreements, or the agreed definition of terms that are fair, reasonable or non-discriminatory).

III. Findings

Table 1 encapsulates the research findings. Based on the seven indicators discussed above, it provides a summary of the activities and efforts of seven different initiatives which focus on projects in the field of pharmaceutical drugs for neglected diseases. It also offers an assessment of the extent to which patent pools and other forms of open innovation are used in the seven initiatives in order to enhance R&D for new drugs, and the success of such mechanisms in terms of their ability to actually produce and deliver new drugs. As the table demonstrates, there are currently a number of relevant programmes and projects within these initiatives, with a wide range of objectives, partners, funding, structure and outputs.

*Table 1: Analysis of initiatives aimed at prompting research and development of pharmaceutical drugs for neglected diseases**

	Focus	Orientation	Customers	Donors	IP policy	Input	Output**
Pool for Open Innovation	Donation of essential patents and know-how to drive R&D on 16 NTDs	Clinical/ R&D focus (but promoting access is also implied)	EIDD, South Africa TIA, iThemba	GSK, Alnylam, MIT, UC Berkeley, CalTech, MMV (patent holders)	Minimum licensing terms include: worldwide, non-exclusive, royalty-free license for LDCs	2,300 patents available in pool (at least 800 provided by GSK)	MOUs to identify compounds and set licensing terms, as well as collaborate R&D: GSK/ iThemba and GSK/EIDD
UNITAID Medicines Patent Pool	Create one-stop-shop for obtaining licenses for existing ARV treatments and drive R&D	Clinical/access focus (small focus on R&D of new formulations)	Particularly generic companies operating in developing countries (intended)	US NIH (patent holder), Gilead Sciences	Royalty-based unless patent holder decides to provide license on different terms	4 medicines for HIV and Hepatitis B, plus set of patents relevant for HIV medicines	Opportunity to license 4 products for producing lower cost versions; no R&D thus far
Bill and Melinda Gates Foundation	Grants to entities involved in R&D on developing country diseases and improving access	Both clinical/ R&D and public health/access focus	Wide range of non-profit and research organisations and partnerships	Bill Gates, Melinda Gates, Warren Buffet	Grantees must use IP rights in a way that facilitates access to their technologies by developing countries	$13 billion on 1,767 projects between 1994-2009; majority targeting R&D	Stage III clinical trials for RV144, rotavirus, malaria vaccines and anti-TB drug
Rockefeller Foundation	Grants to entities working in health system and public health policy, and limited clinical R&D	Public health focus, with small clinical/ R&D focus	Various public and non-profit research and healthcare entities	Rockefeller Foundation endowments	Generally promotes open and user-driven models	166 grants to global health projects, including DART, TB Alliance, MMV	Broad support may include: Stage III clinical trials for anti-TB drug; 7 anti-malarial drugs in Stage III and IV trials

	Focus	Orientation	Customers	Donors	IP policy	Input	Output**
GAVI	PDP funding development and supply of vaccines to developing countries	Both clinical/ R&D and public health/access focus	72 developing countries	Gates Foundation, La Caixa Foundation, European Commission, many developed countries	Promotes tiered pricing, with price and supply guarantees for developing countries (whilst maintaining exclusivity)	Pilot AMC donations of $1.5 billion, IFFIm funding raised over $2 billion	PneumoAMC available for countries; pentavalent vaccine in market; rotavirus vaccine in late stage clinical trials
DFID	Funds PDPs' R&D on HIV/ AIDS and NTDs	Both clinical/ R&D and public health/access focus	Range of research organisations and PDPs	UK development aid	Supports a range of "push" and "pull" mechanisms	2010-11 budget of £7.8 billion; currently funding 22 projects	10 anti-TB/ malarial products in late stage clinical trials or market; 7 HIV/AIDs vaccines/ drugs in late stage clinical trials
Clinton Health Access Initiative	Funds and assists developing countries in price negotiations for second-line HIV/AIDs and malaria drugs and diagnostics	Clinical (access) and general public health focus	Developing countries	Clinton Foundation endowments	None, based on existing evidence	CHAI model of price negotiations and direct negotiation support (used by 70 countries for HIV/ AIDS and 14 for malaria)	Agreed price reductions for 40 ARVs (30% for second-line ARVs and 60% for paediatric ARVs) and 10 HIV/ AIDs tests

* The table represents aggregate analysis of many different research projects carried out as part of the seven initiatives under consideration. All data and resources are with the author and available upon request.

** There is some overlap in the outputs of certain initiatives.

Overall, the research findings suggest that the emphasis placed by international organisations, such as the WHO, on patent pools and other related mechanisms for the purpose of promoting the development of new pharmaceutical drugs for neglected diseases may be at least partly misplaced.

This study found that, although a great number of projects and programmes overall are funded by the initiatives discussed here, relatively few are involved in actual R&D efforts aimed at developing new pharmaceutical drugs. In fact, a significant portion of the efforts under these initiatives focuses more on introducing *existing* medications – including generic drugs – to developing countries than on R&D for new drugs. In other words, the patent pools and other forms of non-proprietary models aim at the introduction of cheaper alternatives to existing drugs rather than the stated objective of promoting the development of new drugs for neglected diseases.

At the same time, the results of this study indicate that the use of supply and purchase guarantees and other mechanisms that attempt to offset R&D costs may in some cases be more effective in the development and production of new pharmaceutical drugs for neglected diseases. In particular, some intermediary initiatives, such as the TB Alliance and Malaria Vaccine Initiative, seem to have successfully implemented these models to bring several products to developing country markets. In other words, models which involve some kind of compensatory mechanism for IPR holders which is directly linked to specific drugs or technologies may be more efficient than patent pools.

It is important to note that the study did not take into account the extent to which IP-based transactions may have played a role in R&D activities prior to receiving funding from the initiatives discussed here. In other words, the study did not examine transactions by the licensee or grantee prior to benefiting from the initiative, which may have involved the use of IPRs. The knowledge accessed in this way may have been a building block for the product developed under funding from the initiative, yet may not have been obtained under the initiative's chosen approach to knowledge transfer. Therefore, it is not possible to make an informed conclusion that the output of these initiatives is directly linked to alternative mechanisms for sharing knowledge, since IPRs may have played a role in these outputs as well.

With specific regard to patent pools, such mechanisms are still in the initial stages and it is therefore also difficult to evaluate their effectiveness in driving R&D in neglected diseases. Even so, it can be noted that participation is limited (the Medicines Patent Pool has only two participants, even though it has existed since 2008) and several existing participants (both donors and customers) in the Pool for Open Innovation are known to have already been involved in collaborative efforts prior to joining the pool.

IV. Final implications

While more open and collaborative models of R&D may certainly be important – and on the rise – in the biopharmaceutical industry, it is not yet clear that patent pools per se and other related models that advocate the use on non-proprietary transactions will actually be relevant in this context. Rather, it would seem that the use of proprietary models, i.e., IPRs in combination with different financing mechanisms, may be more effective in such collaborative models. This could, for instance, include the option to agree on different types of compensatory mechanisms with rights holders in advance so as to ensure that a future stream of pharmaceutical drugs may be provided at an agreed price.

Last, but not least, it is also important to make a distinction between the use of patent pools for the sake of enhancing generic competition and for enhancing innovation; the latter may be more problematic than we initially think. As a result, it seems that proprietary models – not least patents – currently remain the most effective way of mitigating risk in the R&D of new pharmaceutical drugs, including in developing countries.

Lifestyle Risks

This section discusses the regulation of "lifestyle risks", a term that can apply to both substances and behaviours. Lifestyle risks take place along the line of "abstinence – consumption – abuse – addiction". This can concern substances such as food, alcohol or drugs, as well as behaviours such as gambling or sports. The section also addresses the question of the appropriate point of equilibrium between free choice and state intervention (regulation), as well as the question of when risks can be considered to be acceptable or tolerable. In line with the interdisciplinary scope of the journal, the section aims at updating readers on both the regulatory and the scientific developments in the field. It analyses legislative initiatives and judicial decisions and at the same time it provides insight into recent empirical studies on lifestyle risks.

Fat Taxes in the EU Between Fiscal Austerity and the Fight Against Obesity

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I. Introduction

To discourage unhealthy eating and limit the population's intake of fatty foods, thereby alleviating the current obesity "epidemic", an increasing number of countries across the industrialised world are considering levying taxes on unhealthy food.[1] A "fat tax" may be defined as a tax or surcharge placed upon fattening foods, beverages or individuals with the aim to decrease consumption of foods that are linked to obesity.[2] This is not an entirely new idea – some theorists, starting with Arthur Pigou, a 20th-century English economist, have long presented the arguments for imposing special taxes on goods and services whose prices do not reflect the true social cost of their consumption.[3] Examples of Pigouvian taxes are duties on cigarettes, alcohol, gambling and

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1 See, e.g., OECD, *Obesity and the Economics of Prevention: Fit not Fat* (2010).

2 See, e.g., Hanna Rosin, "The Fat Tax: Is It Really Such a Crazy Idea?", *The New Republic*, May 18, 1998.

3 A.C. Pigou, "II, Chapter IX: Divergences Between Marginal Social Net Product and Marginal Private Net Product", in *The Economics of Welfare* (1932).