**European Journal of Applied Ethics**
Vol. 1, 2012, Issue 1

# The Health Impact Fund and the Right to Participate in the Advancement of Science

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Taking into consideration the extremely harsh public health conditions faced by the majority of the world population, the Health Impact Fund (HIF) proposal seeks to make the intellectual property regimes more in line with human rights obligations. While prioritizing access to medicines and research on neglected diseases, the HIF makes many compromises in order to be conceived as politically feasible and to retain a compensation character that makes its implementation justified solely on basis of negative duties. Despite that current global health realities make such steps reasonable, the paper looks up the negative effects on one overlooked human right: the right to participate in scientific advancement.

*Keywords*: scientific participation; intellectual property; global poor; access to medicines; capacity-building; Thomas Pogge.

The Health Impact Fund (HIF) is seen by critics of the intellectual property regimes established after the TRIPS agreement as an important addition to make the current regime more compatible with the notion of across-the-border human rights responsibilities. If we treat the HIF as the single addition needed to make the regime more in line with international human rights obligation, especially as defined by human rights charters and further specified by general comments on the Covenant for Economic, Social and Cultural Rights, some conflicts will still remain unresolved, especially the impact our intellectual property regimes have on the human right to share in the advancement of science (Universal Declaration of Human Rights (UDHR) article 27.1).

In order to show how this deficit has slipped into the HIF proposal, I will discuss the different starting points both discourses have, to wit, the access to medicines debate and the general criticism of the intellectual property regimes, thereafter elaborate upon the actual conflict of rights and finally discuss what implication the current (and theoretically the post HIF) situation has for human rights and the relation among people of different nations.

### *Two Different Starting Points*

The Health Impact Fund is a proposal that aims at making medicines available for the global poor. It identifies three main problems of why medical innovation does not reach the poor: (1) drugs for diseases that predominantly affect the poor are not available, i.e. the availability problem, (2) there is a lack of medical infrastructure and (3) many medicines are priced way out of financial reach of over half of the world's population, i.e. the access problem. For two of those problems a solution is relatively easily achievable, those are the access and availability problems.[1] We can have an additional

[1] Compared to the huge costs of building a public health infrastructure, those are somewhat easier tasks to solve. There is also another very important reason to focus on medicines targeted for the poor: innovation in medicine that

incentive system that will make it profitable to invest on research and development, accompanied by a corresponding sales strategy, aiming at having the maximum impact on the health of as many people as possible. The goal will be maximizing quality-adjusted life years (QALY), and not the satisfaction of markets with high purchasing power, since that will dictate the size of the award the pharmaceutical producer can claim from the HIF if it decides to choose for that remuneration method.[2]

Thomas Pogge has elaborated the moral framework upon which the HIF is built up on trying to use solely negative duties: "While some passionately reject such human-rights-imposed positive duties and others passionately endorse them, I simply leave them aside here, without prejudice. To keep my argument widely acceptable, I conceive human right narrowly as imposing only negative duties."[3] The reason for doing so is mainly pragmatic: the HIF requires 6 billion dollars a year to start up – a wide array of people have to be convinced in order for the fund to come into existence.

After a well-argued and extensive criticism of the current trade regime, encompassing market entry regulations, intellectual property rights, recognition of dictators as legitimate persons to sell a country's resources and borrow vast sums of money in their peoples' name, among other issues, Pogge rightfully asserts that today's political order represents an institutional harm. We are violating our negative duty of not imposing an oppressive regime upon other people. Further he goes on with "[...] this negative institutional duty may impose positive obligations on advantaged participants: obligations to compensate for their contribution to the harm."[4] Under this line of argument the implementation of a HIF can be understood as an obligation based on compensation duties for harm caused.

Pogge achieves this justification at quite a high price:

1. Even if, on utilitarian terms, an injury with compensation is better than an injury without compensation, compensation is still a remedy for a harm that should not have come into being in the first place. We are compensating while harming. The HIF is an option for more conscious governments to counteract the negative influence the global regime that they are co-maintaining has – in itself, the drafters of the fund have to accept that there is not enough good will to change the current *status quo* and content itself in being hugely beneficial for the poor people of the world, while remaining a partial solution.

If rewards are necessary to make the system more efficient in bringing out new or more efficacious medicines, we have to keep in mind that incentive systems other than the current patent regime are conceivable[5] – whether they are also political feasible and more cost-effective is something that stands a different moral evaluation. A conceivable incentive system that is more human rights compatible, but much more difficult to realize, cannot be on moral grounds completely discarded by advocating for a more feasible but less compatible system. We as citizens of democracies can still be held morally accountable for a huge collective action problem.

This does not nevertheless excuse us from remaining in inaction. We as individuals still have the moral obligation, if doing so saves lives, to make compromises and settle for partial solutions until greater consensus can be reached. However there is still a big argumentative gap to be filled, in order to be able to call the HIF an incentive system that is the "most advantageous *permissible* regime" for the affluent[6], especially if this group is shaping the rules of the game of what counts as politically feasible and what not. Patents are not the only possible conceivable system of incentives and therefore not a fixed or indispensable constraint for shaping future orders. The moral evaluation of the HIF has to take a theoretical world with a completely different incentive system as a comparison and not only the post or pre Trade Related Intellectual Property Rights (TRIPS) agreement world.

2. Obligations to compensate address very limited positive duties.

This is the moral basis for the HIF. Let us turn to criticism of the intellectual property regime.

is publicly available is a public good. Even though medicines themselves can be scarce, the knowledge encompassed in medical innovation is of non-rivalrous consumption (except to some degree antibiotics). This means that the resources spent on medical innovation will not be lost by wars or civil unrest, as commonly happens with public health infrastructure.

[2] Hollis and Pogge [2008].

[3] Pogge [2010], p. 28.

[4] Pogge [2010], p. 52.

[5] We can think of a prize system like the one proposed by Love and Hubbard [2007].

[6] Pogge [2009], p. 551.

The criticism of the intellectual property regimes as established after the TRIPS agreement does not start from the same starting point as the consideration made by the precursors of the HIF. As an example we can state the position my colleagues and I have taken to the issue.[7] Building up on the work of Matthew DeCamp,[8] we state that there are three distributive effects an intellectual property regime has, those are (a) availability, (b) distribution of IP rights and (c) access. This criticism does not concentrate on a particular issue, like benefiting from the advancement of medicine while targeting a particular human right, *i.e.*, the right to health, but on the conflicts the intellectual property regime might pose to the fulfilment of human rights in general.

Our group does defend the existence of positive duties. Innovation does have a huge potential to positively (and also negatively) affect the provision of human rights. Securing human rights demands both negative and positive duties, as some communities will have a too hard time to fulfil human rights for their people on their own. Taking here personally a more radical direction, I believe that human rights are indivisible and should be protected as a whole at least up to a minimum threshold, much in line with Cristina Lafont.[9] We should not advocate the fulfilment of one human right at the cost of another, nor secure rights only selectively. Some often-neglected human rights are essential for human flourishing and to strengthen human capabilities.[10] One of such capabilities I find central is the capability to provide technical solutions for society's problems, based on the freedom to make use of one's mental faculties and to be able to care for one's cohabitants.[11] Therefore every society should be able to provide innovations and this liberty should not be reserved for a particular section of the world, nor seen as a luxury. Having this freedom comes with many practical advantages, advantages that are seen by some schools of thought as prerequisites for a well-functioning society, in this case a much broader scientific participation and therefore (at least potentially) a more inclusive deliberation on the effects of scientific innovation to society. Respecting the human right to share in the advancement of science implies a serious intention of capacity-building, something that would be quite hard, or impossible, to argue on the basis of solely negative duties.

We can briefly summarize: the HIF concentrates in developing and providing medicines for the poor, while the criticism of the IP regime is looking for an overall solution to counter the negative effects of the current *status quo* on human rights in general.

For constructive criticism, we need to ask ourselves what the possible negative effects on human rights are of advocating singlehandedly for the HIF.

### *The Life Sciences and intellectual Property Rights*

The HIF allows its users to retain their intellectual property rights. This has been severely criticized, and is a point I will elaborate upon in this section.

Intellectual property rights in the life sciences do not only allow its holders to keep competitors away from producing the same products for commercial purposes, but in many cases can constrain the research other companies can make in that area. Fine distinctions, as for example on a research exemption counting for research *on* the object, but not on research *with* the object, are in the life sciences not very clear, a fuzziness of which the company that can threaten infringements suits more credibly can benefit on a much higher level than smaller companies. This situation is aggravated by not having clear boundaries of where one's property begins and other people's property end.[12]

Analysing the differences of tangible property rights regimes in the developed and the developing world, Hernando de Soto came to the conclusion that one of the main causes for being trapped in poverty was the inability to get loans granted due to not being able to prove concrete property titles as a guaranty for investors.[13] Patents in the life sciences are exclusive rights titles over a quite uncertain area.[14] When a start-up company has only a few patents (or the promise thereof) it offers a quite weak collateral

[7] Korthals [2010]; Timmermann and Belt [forthcoming].

[8] DeCamp [2007].

[9] Lafont [2011a]; Lafont [2011b].

[10] Cf. Nussbaum [1997] and particularly in relation to UDHR article 27, see Timmermann [2012].

[11] Even though for the later one I take a wider interpretation, those two capabilities can be found on Martha Nussbaum's human capabilities list, see Nussbaum [2006].

[12] A general remark on this issue is offered by Eisenberg [2008].

[13] Soto [2000]. My interpretation of de Soto has been strongly influenced by Riles [2011].

[14] This problem is not limited to the life sciences, cf. Bessen and Meurer [2008, chap.3] before describing a series of conflict cases in different technology areas, state: "[a]n ideal patent system features rights that are defined as clearly as the fence around a piece of land. Realistically, no patent system could achieve such precision…" (idem, p. 46).

to future investors. A bigger company can spread the risk of not being able to provide a clearance of rights at a later stage of its research, while at the same time having a much bigger patent portfolio to counteract infringement threats of competitors and being able to afford a much larger department of business intelligence with the corresponding intellectual property experts. Those are multiple factors that favour bigger players.

There is also a concern, that today's intellectual property regimes do not only fail to foster but might even endanger the co-existence of other ways of promoting innovation.[15] When seeking exclusive rights becomes predominant, it will be difficult for groups to maintain other traditional ways in bringing out innovations, especially those that are based on loose systems of reciprocal sharing, as with seed-exchange practices by small-scale farmers. Further, if exclusive rights, especially patents, are held by a small group of people, the decision-making power to shape further innovations and achieve considerable market shares is reserved to this group.[16] This tendency goes in two ways against the democratization of science, it endangers diversity in innovation processes and it concentrates decision-making of what targets are worthwhile to pursue and to be placed as products on the market to a small privileged group.[17]

As an additional factor, the overlapping property claims in patents play a significant role. This is especially a problem when broad patents are issued on newer promising molecules or genes.[18] When such patents are issued, much of the follow up research on that molecule has to seek freedom-to-operate from the original patent holder and this under a position of very unequal negotiation power. In many cases this cannot be fixed beforehand by more careful patent granting by patent offices, since the importance of the new molecule is often seen after its initial development. The same counts for enabling technologies that are shared among various platforms. This is of especial concern for developing countries, as it will be very difficult to establish national innovative capacities if many research tools are controlled by multinational corporations that operate with much higher research budgets. Since such situations might arise quite often with research on neglected diseases, I will elaborate upon that point in the next section.

*Neglected Diseases: an equal start?*

Deliberating on the issue of neglected diseases, an area where big pharmaceutical companies have comparatively little expertise, we might come across the thought that concerning these diseases those companies and developing world industry or public institutions will have roughly an equal start.

The moment the HIF is implemented, a huge incentive is created for doing research in previously non-lucrative areas such as neglected diseases. We can easily expect that the diseases that will be targeted first, are the ones affecting the greatest number of people (thus receiving the highest pay-offs) and that what fits the metaphor of "low hanging fruits."

Conceptualizing such a race, we might see that there are some advantages of being closer to (or in) the countries where such diseases are prevalent. People might have better samples of the pathogens and access to herbal medicines developed by indigenous communities. The question is for how long can that group benefit of such a head start if the methods that enable them to race, not merely the start, are so disproportionally advantageous for only one side, taking into account the huge accompanying infrastructure that saves time by having the newest machines, huge gene banks, highly trained personal, being able to communicate directly with most of the specialists in the field and having the possibility to search through most of the journals ever published?

Another issue of concern is that the HIF requires innovation to be protected by patents in order to be able to apply for the fund's rewards. This is very much in line with the general trend of favouring break-through research at the cost of small-scale innovation[19] – a preference that is questionable when widespread impact is the central goal of the fund.[20]

[15] On the other hand, some open innovation models are actually only conceivable with IP, as will be discussed below.

[16] A similar insight is offered by DeCamp [2007], pp. 214-219.

[17] I would like to thank Guido Ruivenkamp and Osmat Jefferson for bringing this point to my attention.

[18] A case study offered by the Nuffield Council on Bioethics [2002, p. 41] briefly illustrates how the USPTO granted exclusive rights over the gene that codes for the CCR5 receptor before its role in HIV/AIDS was known.

[19] Relating this point, see Thompson [2010] for a brief historical overview exemplified by U.S. agriculture innovation financing.

[20] There are some discrepancies towards what the central goal of the fund might be, *e.g.* Coles and Frewer [2011], p. 4, state: "it is essential for the HIF to clarify whether it sees its purpose primarily as a mechanism for encouraging the pharmaceutical industry to develop products for neglected

We cannot assume that an innovation that is in the public domain, i.e. not covered by patents, is necessarily dispersed in form of useful products among the world's population.[21] Cheaper objects of innovation or implementations thereof, does not mean for free – if no one is being remunerated for making those improvement possibilities known, the most likely result is that they will not be passed on. A strict concern for impact should take also those kinds of innovations into account and foster their implementation; this is of especial consideration if the impact fund idea is to be translated into other areas, *e.g.* agriculture or climate change mitigation and adaptation.

The preference for patented technologies has serious global justice concerns. First, one of the requirements of patentability is that the invention involves an inventive step (non-obviousness). What counts as being non-obvious is relative to the state of knowledge to someone skilled in the art at the time of patent application. Therefore, an inventive step ten years ago might not be regarded as such nowadays. Being out-dated, by having older equipment, no access to the newest literature and little acquaintance with the most actual research methods, makes it more difficult to satisfy the 'inventive step' criterion based on the current state of the art (although it does not make it impossible). The invention might still be able to achieve a high impact or have an industrial application, but might not survive the patent office's non-obviousness requirement and thus fail to be covered by a patent, something that is good for having more knowledge available in the public domain, provided it is not maintained as a trade secret, but comes at the expense of researchers of primarily poorer institutions.

A second concern has its roots in the novelty requirement for patentability. The novelty requirements forbid to grant patents for knowledge made previously public. In practice this also comes at a certain cost for smaller institutions that cannot cover the costs of intellectual property protection on their own and are dependent on seeking for investors. Even though non-disclosure agreements can partly overcome the problem, it is quite difficult for poorer innovators to reach a good deal if they are not allowed to make their invention public, as trying to convince another investor is bound with risks of misappropriation.

On the other hand, the bar on what can count as novel or non-obvious cannot be lowered for the sake of researcher of institutions with fewer resources, as it will undermine the quality of patents, something that will come at the cost of the whole scientific community.

To say that the HIF would strengthen the divide between technology receivers and technology providers might be a quite strong claim, as empirical evidence would still be needed. This nevertheless does not prevent us from holding the claim that the HIF would be doing a far better job in alleviating this divide if the strict requirement of patenting is dropped when assessing the impact of a technology. This would foster grass-root innovation, which is a first step in closing up this huge divide. Sticking to the patent prerequisite makes the precursors of the HIF debtors to an explanation of why non-patented high impact innovations are being discriminated even when equally beneficial for public health.

*The HIF and Open Innovation*

Open innovation is not only scientific research minus patents, but a commitment of emphasising the public good nature of knowledge and freedom in science. Therefore the people that commit themselves to open innovation see themselves as part of a different community, as advocates of a movement. An example of this is the open and free software movement, one of its forerunners, Richard Stallman, stated that software should be free as in "free speech, not free beer,"[22] which means that the importance should be on freedom to operate, not on freedom of being sold. Open innovation is compatible with market models although the current patent system in itself might not be sufficient to make this way of doing science self-sustainable.

The HIF can play here a key role, if some slight changes are made, something that is of key interest for ensuring the right to share in the advancement of science and gaining support by the open innovation communities. An option lays not so much for "pure" open innovation, but for creative commons like enterprises or any community that relies on share-a-like licences, so-called "copyleft" clauses, that rely on intellectual property rights to keep others from misappropriating the developed content and, in some of their variations, even follow-up inventions. The

diseases or whether it's primary objective is to reduce the global burden of disease."

[21] The same point is also addressed by Syed [2009] concentrating on the issue of proving new medical uses of known compounds and stating the necessity of information and innovation being "publicly available in a valuable form" [idem, p. 10].

[22] Quoted by Lessing [2006].

community as a whole can have as a binding contract that any promising molecule has to be licensed only to companies that commit themselves to the HIF. Therefore, using licenses, a commons group can outsource clinical trials (at what level depends of the group) to a separate company that specializes in carrying those tests out, while having the certainty that it will not lose freedom-to-operate and while retaining the rights to use the subcomponents. The refined research and development on the drug itself can be made by one of the parties alone or as collaboration. The necessary incentive for the company undertaking the clinical trials is created by the HIF – we can even speculate that an especial new branch of companies might arise. How the reward given by the HIF will be shared among the commons community and the company carrying out the clinical trials is something those two parties can decide on their own. This strategy has the potential to also address the issue of public institution research and the harvests thereof.[23]

*Technology Producers vs. Technology Receivers*

Let us start with the claim, for the sake of the argument, that we could ensure access to medicines more efficiently if only one part of the world does the research and development for new medicines for all the diseases in the world. We could say that any attempt of building up capacities comes at the price of postponing access to medicines and thus affecting a higher priority, which is relieving people from the agonies of diseases. Public moral intuitions might very well favour prioritizing wide access to medicines over other projects.

Although we are very far away of securing access and availability of medicines for the vast majority of the world's population, our world is characterized by having this strong division of who is providing and who is only receiving objects of medical innovation.

Going back to the argument of efficiency, we will see that the right to share in the advancement of science, to take an example, goes into direct conflict with the main goal of ensuring access to medicines. Without resources for building up infrastructure and having the financial freedom to invest time in research, most people cannot secure the right to be able to share in scientific enterprises. Again, we might think that this is acceptable, since drastically more welfare is lost by health hazards. However this type of reasoning has a strong utilitarian foundation, maximizing QALY as a main goal, to speak in HIF terms, while relying strongly on the efficiency premise.

In order for the efficiency premise to hold, the part of the world that is providing medicines does have to take into account local varieties of the diseases and develop medicines that take into account physiological diversities and local environmental interactions[24] – we might expect too much of philanthropy if in times of scarce resources those communities that are not providing medicines are prioritized or given equal standing.

Questioning the efficiency premise, we start to see the price of holding it, especially when we take into account the relatively low economic burden of fostering capacity-building compared to existing global inequalities. First-hand knowledge about local environments becomes extremely valuable, especially when one can identify new emerging strains of a disease or the development of resistance to drugs at an initial stage, allowing early action. Centralizing all innovation to some points in the world will have to deal with the extra costs of getting all this field information in due time. If doing the research needed to fulfil the human right to health is taken as a task for which only a particular group is made responsible, we still have to ask ourselves if other groups are willing to cooperate by sharing any (also not purely scientific) findings with this researching group. To take an example, we cannot expect that tiny shares of benefits will ensure the cooperation of indigenous communities in making public their traditional medicine. Experience has shown us that people are willing to forgo small benefits (or even endure penalties) by refusing to cooperate in endeavours they deem usurious.[25]

This *status quo* is also not a relation among equals, since societies with strict divisions of labour are prone to value one kind of work higher than the other, especially when some work is replaceable or a society can do both kinds of work, e.g. providing manufactured products and scientific innovations,

[23] There are also other prudential reasons for having more transparency in drug testing. Reichman [2009] offers extensive criticism on the conflict of interest that might arise when a pharmaceutical company has to perform clinical trials.

[24] Herewith I do not want to claim that local varieties play always a significant role, only that in some cases they have to be taken into account. In Timmermann and Belt [forthcoming] we elaborate upon the case of currently available vaccines against HPV and their lack of effectiveness towards the in developing countries widely propagated variant HPV 35.

[25] An interdisciplinary perspective on unwillingness to cooperate is offered by Ooms [2010], pp. 609-612.

while another society is only able to do one of those tasks. Even though recognition as equals, respecting human dignity at the same level, might be reachable, the desire to be recognized as a peer,[26] that is, as an irreplaceable member of a team, might remain unfulfilled.

Having developing countries as production sites for medicines, as might be incentivized by the HIF,[27] will most likely bring some innovation possibilities in the manufacturing process. However this type of innovation, although highly important, is much more constrained and does not receive a similar public appraisal as the identification of new cures.

*Conclusions*

Analysing the problems and consequences of the highly unequal distribution of IP rights on a pure rights-based perspective, without taking the magnitude of current public health inequalities into full account, might lead to some hesitation to support the HIF as it is. However advocating for a partial, but faster to implement solution like the HIF, will save lives until we can implement a system of incentives that is more in line with the right to share in the advancement of science. The urgency of public health needs and the irreversibility of damages caused by some diseases are good reasons to make some utilitarian concessions in order to alleviate this huge welfare burden.

The drafters of the HIF should do more work[28] in making its scheme attractive for consortia working under open innovation, since stimulating this kind of innovating could encounter much of its criticism.

Opponents of the HIF should not forget that the HIF could give thousands of researchers the opportunity to work in enterprises that are more committed to have a much wider impact on public health globally. Here we can reinterpret the way article 27.2 of the UDHR is traditionally understood: the right to ensure moral interest resulting from an invention does not only have to encompass *droits d'auteur* but also, maybe even more importantly, an ethical craving for one's own inventions having an increased role in alleviating the suffering of people all over the world.[29]

[26] Although in a different context, I take the concept of "recognition as a peer" from Fraser [1998].

[27] On this very issue, see Pogge and Hirsch-Allen [2011].

[28] A very brief statement is given in Anonymous [2010]

[29] During the review process of this paper, Thomas Pogge has brought to my attention that the work of Syed [2009] and Mendel and Hollis [2010] has convinced Incentives for Global Health to drop the strict patent requirement. This paper offers a series of additional arguments based on scientific participation to support this welcomed decision.

*Acknowledgements:*

I would like to thank Henk van den Belt and Osmat Jefferson for their valuable comments and suggestions, as well as the participants of the Bucharest Conference in Applied Ethics and the International Networking Conference on Ethical and Social Aspects of IPRs (Agrifood and Health), where I presented earlier versions of this paper, for the valuable discussion.

This article is the result of a research project of the Centre for Society and the Life Sciences in The Netherlands, funded by the Netherlands Genomics Initiative.

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