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Alternative Incentive Models Delinking R&D Costs from Pharmaceutical Product Price

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The current incentive model based on the patent system is a failure in promoting pharmaceutical R&D addressing developing country health needs. It also blocks follow-on research and access to new pharmaceutical products to the impoverished lot, especially belonging to the developing countries. Thus it has become essential to think of an alternative incentive models delinking product price from the cost of R&D. An open access, collaborative research model, with prize fund incentive delinking costs of R&D from product price may be the appropriate incentive model for pharmaceutical R&D. It is also necessary to shift pharmaceutical R&D related issues from the trade fora to the human rights forum.

Keywords: Alternative incentive models, delinking R&D costs, open access, collaborative research model, prize fund incentive

The Commission on Intellectual Property Rights, Innovation and Public Health, in its Report in 2006, categorically stated that the current patent based incentive model of pharmaceutical R&D is a failure in addressing public health issues, especially in developing countries.[1] It failed, both in incentivizing investments in R&D on developing country specific health issues and in providing affordable access of the available R&D products to the poor people belonging to developing countries. It has also affected access to new pharmaceutical products to the uninsured and under-insured people belonging to developed countries. 'Public welfare' objective is totally absent in the practices of patent induced R&D activities of pharmaceutical industry both in the developing and developed countries.[2] Under the current, patent based incentive model, the incentive to invest in R&D activities is the monopoly profits the inventor/investor would earn, when he sells the products of such R&D at monopoly price. Thus, it addresses market demand rather than public health needs.

Apart from the deadweight loss due to monopoly pricing[3] and inadequate R&D activities addressing developing country health concerns, the other social costs incurred by the current patent based incentive model include the following: (i) it limits follow-on innovation, (ii) it does not incentivize investment in public good, such as basic research,[4] (iii) it promotes investment in R&D aimed at products having insignificant therapeutic benefits, (iv) it promotes research on commercially viable health issues rather than choosing a prioritized approach, and (v) reinvests only a negligible proportion of the turnover of global sale in to R&D.[5]

Most new drugs are not very important, because they do not offer significant improvements over existing medicines or are only simple reformulations of existing drugs, with only minor benefits in drug delivery.[6] According to the Food and Drug Administration, from 1993 to 2002, approximately 70 percent of all new drugs approved did not offer significant therapeutic benefits over existing medicines.[7] Apart from the fact that the me-too drugs have only very less social benefits, their development costs are very high due to the stringent clinical trial requirements for drugs having only small differences in efficacy when compared to the existing drugs.[6] In brief, the current patent system is a very expensive way to stimulate R&D. Consumers pay eight or nine dollars in higher prices to stimulate one dollar in R&D spending.[6] Global private sector investments in pharmaceutical R&D in 2005 were less than 9 per cent of global sales.[8]

The patent system relies too much on high drug prices to recoup its high R&D costs. High drug prices are always being justified in the name of high R&D

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costs.[9] Since the Kefauver hearings in 1959-1962, the industry's principal justification for its high prices on patented drugs has been the high cost of R&D, and it has sought further government protection from normal price competition in the form of increased patent term, data exclusivity etc., without good evidence that these measures increase innovation.[4] Industry leaders and lobbyists routinely warn (most often going to the extent of blackmailing) that lower prices will reduce funds for R&D and result in suffering and death that future medicines could reduce. In the study by DiMasi *et al*., it was stated that the fully capitalized total cost per approved new drug was US$ 802 million.[9] Since there is an appalling lack of transparency in the R&D system, one has to be highly sceptical in accepting the validity of such studies and figures explaining high R&D costs in the pharmaceutical sector. Instead, such studies and data are being accepted without dispute.[4] From the fact that pharmaceutical industry is one among the most profitable industries in the world, it becomes evident that under the pretext of recouping high R&D costs; –it is amassing huge profits at the costs of patients all over the world.

High prices for new medicines have also led to increasing rationing of access, even in high-income countries.[10] The existence of high prices in the United States and other high-income countries is leading to enormous pressures on other countries to accept high prices, through such measures as new intellectual property norms, exercised both formally and informally.[6] The greatest flaw of the current system of financing R&D for new medicines is that it always attempts to tie the incentive for R&D to the price of products.[6] Therefore, the exclusive rights regime proves to be highly expensive and inefficient, resulting in high deadweight loss. These factors persuaded health activists to seek alternative incentive models delinking price of pharmaceutical products from the costs of medical R&D.

Alternative Incentive Models

A research model based on de-linking approach is different from the one based on patent monopoly, in that it eliminates monopoly on the final product of R&D and permits a much more decentralized system of manufacturing, distributing and marketing. Thus, it promotes competition, which results in considerable reduction of drug price, and induces R&D investment based upon public health priorities rather than market potential of the research outcome. Incentives are designed to reward investments in products that have the greatest impact on health outcomes. Thus, alternative incentive model of R&D covers basic research, and other product development activities irrespective of their commercial potential.[11]

The alternative incentive model delinking research costs from product price may have to make use of 'push'[12] and/or 'pull'[13] funding mechanisms. While push mechanisms aim at paying for the 'effort' on the part of researchers by financing the cost of that effort, pull mechanisms pay for 'results'.[14] A key advantage of pull mechanisms is that the funder can make use of the expertise of a large and diffuse set of researchers, rather than identifying and funding a handful with the greatest potential, especially when knowledge is spread throughout the world or experts are hard to identify.[14] The concept of delinkage was first mooted internationally by the WHO in the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.[15] This concept got included in the resolution WHA 63.28 of the World Health Assembly (WHA), which established in 2010, the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). The fundamental premise of the WHA resolution that established the CEWG is that the current incentive systems fail to generate enough R&D, in either the public or the private sector, to address need of the developing countries. The CEWG felt that the intellectual property system is based on a business model that allows developers of products to recoup the costs of R&D and to make profits through charging consumers on the basis of exclusivity conferred by intellectual property rights. Depending on the pricing policies of the originator in developing countries, this can result in the patient, or those purchasing on behalf of a patient such as a government or a health insurer, being unable to afford a life-saving treatment. Therefore, the CEWG Report, submitted in April 2012, suggested delinking R&D costs and the prices of the products for ensuring affordability and accessibility of pharmaceutical products.[16]

The CEWG considered a number of proposals suggesting other incentive models, including, Advanced Market Commitment (AMC), health impact fund, patent pools, orphan drug legislation, pooled funds, mile stone prizes and end prizes, priority review voucher, purchase or procurement

agreements, and open approaches to R&D.[17] After an assessment of all proposals, the CEWG identified those proposals which it thought could best promote health R&D relevant to the needs of developing countries. It concluded that open approach to R&D, together with the appropriate target funding such as mile stone prizes, is the best method to promote the delinkage of cost of R&D from product prices.[17] This approach, the CEWG felt, is capable of offering the most effective way to convert promising ideas into health technologies and products, without any concern about its commercial viability, and relatively low cost.[17] Such a model should not confine itself to the R&D related to Type II and Type III diseases alone. It has to have a wider coverage, and should be accepted as a universal model, replacing the patent monopoly in health related research and development. Open collaborative research through public-private participation, based on the philosophy of delinking the cost of R&D from the price of the pharmaceutical product appears to be a good alternative to the current incentive model.[18]

While the TRIPS Agreement mandates patent protection for inventions, it does not preclude government intervention, facilitating availability of R&D funding. Similarly, a government or foundation, whether public or private, may establish a prize fund under which persons, including private corporations, submitting award claims must agree that their research efforts will not be patented. The TRIPS Agreement does not mandate that persons pursuing prizes may not agree to forgo patenting. In this sense, the TRIPS Agreement provides space for innovation-incentive models that do not rely on the 20-year minimum patent term that must be available under domestic law.[19] But the ultimate question remains whether measures to implement the right to public health should be allowed to be tested against TRIPS mandates for their validity. In other words, should public health interests be subjected to trade/commercial interests?

Open Innovation Model

The 'open innovation' approach was originally pioneered by Henry Chesbrough, a professor from the USA.[17] This approach expects a company to open itself by entertaining external partners in order to better reach its innovation objectives. This is in contrast to the previous 'closed' models where R&D was essentially in-house. The open innovation approach facilitates collaborative research which is highly important to solve complex technological problems and to address current difficulties in the development of new treatments. But this approach neither addressed access issues nor did it consider the delinking model.

An open innovation approach, based on a delinking model is, therefore, the ideal one in addressing issues of public health access, especially of developing countries. The Open Source Drug Discovery (OSDD) initiative, designed by the Council of Scientific and Industrial Research (CSIR) Team India consortium with global partnerships, is an idea based upon the successful example of open source software development. OSDD has chosen tuberculosis as its first target disease and plans to expand into malaria. OSDD borrowed two components from software development: (i) collaboration and (ii) an open approach to intellectual property.

OSDD proposes a collaborative research approach, bringing the best minds to drug discovery through open innovation and best partners with experience of drug development through product development partnerships. OSDD is an open innovation platform, where all the projects and the research results are reported on the web based platform Sysborg 2.0. It covers all stages of drug discovery from early-stage discovery up to lead identification. In the clinical development stage it enters into partnership with other public funded organizations. The new drug which comes out of the drug discovery process is made available as a 'generic' molecule, free of intellectual property constraints for the industry to manufacture and distribute anywhere in the world, and this ensures affordable access to the drug.[20] But OSDD does not entirely rule out the use of patents in specified situations, like for example, for ensuring attribution.[21] Thus, IP may play a limited role but within the premises of affordability and accessibility.

The collaboration of the research community is based on some basic rules, laid out in the OSDD licence which all community members sign in when they join the Sysborg portal. OSDD licence treats the entire information available on the portal as 'protected collective information'. It mandates common ownership of the data and research results, sharing of such data, and contributing back improvements to the protected collective information. Such Protected Collective Information is held on behalf of OSDD community by CSIR as a

trustee holder with legal powers and authority for legal action. OSDD also makes available the molecules, which results from the drug discovery, without IP encumbrances.

Prize Fund Alternative

The prize fund alternative envisages an R&D model, which replaces incentive in the form of product monopoly with prizes. Prizes are rewards for successful completion of a specified set of R&D objectives. Two kinds of prize fund models commonly resorted to are mile stone prizes and end prizes. While the former model is meant for reaching specified milestones in the R&D process, the latter is meant for reaching a specified endpoint such as a new diagnostic, vaccine or medicine with a specifically targeted result in terms of performance, cost, efficacy and/or other important characteristics. Small companies which suffer from paucity of funds might be more attracted to milestone payments whereas, an end prize will attract companies that are capable of mobilizing funds and are less concerned about accepting the risk of failure.

The CEWG is of the view that prizes can be offered in two main circumstances, both of which may apply in the area of neglected diseases: (i) where there is no incentive for R&D because the potential market is too insufficient to stimulate needed innovations and (ii) where the R&D process has encountered a technological obstacle that needs a new approach.[17] But it is felt that this system need not be confined to R&D activities addressing developing country health concerns. For example, the United States' Bill 'Medical Innovation Prize Fund Act',[22] was meant for providing incentive to research and development generally, of new medicines and to enhance access to such medicines by allowing any person, in accordance with the FDA requirements, to manufacture, distribute or sell an approved medicine.[23] It also contemplated elimination of exclusive rights to market drugs and biological products and proposed to replace patents with Medical Innovation Prize Fund (MIPF).[24] Thus, it goes much beyond the recommendations of the CEWG.

The anticipated benefits of prize fund mechanism are manifold; by placing the invention in the public domain it encourages competition and thereby reduces the price of the pharmaceutical products and promotes follow-on research. It also incentivizes investment in research and development, related to innovations that have less market/commercial benefits like orphan illness, neglected diseases, global infectious diseases, etc. In other words, by delinking the price of pharmaceutical products from the cost of innovation it absolutely changes the 'incentive' concept. Prize fund mechanism is also capable of inducing collaborative research with an open approach.

The Health Impact Fund (HIF) is also in effect a voluntary prize mechanism which would substitute for patent rewards in the products that it covers. The proposal is based on the premise that companies which register products with the HIF will be paid in proportion to the incremental private health impact. A standard measure of public health impact is quality adjusted life years (QALY) – number of healthy years extended in one's life. But the CEWG is not in favour of this model, mainly because of its high cost and practical difficulties of implementation.[17] There are other forms of prizes which do not substitute market incentive as such, but rather stimulate R&D by rewarding achievements.

R&D with delinkage can be implemented with or without intellectual property protections, as long as intellectual property rights are not implemented as the exclusive rights to make, sell or distribute products. Patents can be used to establish claims on rewards that are implemented, outside the system of time limited legal monopolies. But sharing of knowledge, materials and technologies can also be rewarded through open source dividend reward programs, creating different and competing incentives for researchers and research firms.[6]

Problems Faced by Alternative Incentive Models

The main problems confronted by the alternative models relate to financing, and administration of prize fund. Under the prize system, R&D funds, currently recovered from patients and taxpayers through high medicine prices, have to be replaced with public funding. Under the MIPF system it was envisaged to distribute 0.5% of the GDP of the previous year as prizes from the MIPF. Such prizes were expected to meet the goals of incentivizing R&D investments in new and significantly better medicines, to enhance access to medicines and to focus more resources in non-profitable areas such as global infectious diseases, 'orphan drugs' and neglected diseases.[25] In the case of OSDD, major funding comes from the Government

of India. Public-Private-Partnership is another mechanism used by OSDD. OSDD is a major opportunity for industries to discharge their corporate social responsibility by participating in research into neglected diseases. It is already working with SUN Microsystems, Hewlett-Packard (HP), Infosys Technologies Limited, Jubilant Chemsys and Premas Biotech on various projects ranging from portal design to lead optimization.[26] OSDD model is a viable option for developing countries to increase their capability to engage in drug discovery and research.[27] Governments may amass investment capital by collecting taxes, developing and selling assets, issuing debt or functioning as enterprises.

The Achilles' heel of any prize system, as rightly said by Marlynn Wei, is its administration, including the ability for the government to distribute prizes.[28] One fundamental problem of prize systems is determining how much to spend on the prize system overall and how to evaluate R&D outcomes and reward individual innovations. If the prize is too low, then it will be inadequate in stimulating R&D investment and if the prize is too high, it nullifies the benefits of prize system by encouraging resource duplication and favouritism.

For the purpose of measuring the value of innovation and setting appropriate prizes for innovation, the Medical Innovation Prize Fund Act, 2005 links size of the prize to its social value. This is achieved by awarding prizes based on a set of pre-determined criteria. Instead of specifying the amount, it sets the criteria by which the innovation will be judged. The following are the criteria: (i) number of patients, including non-US patients benefited by the innovation; (ii) incremental therapeutic benefits of the innovation; (iii) degree to which the innovation addresses health care needs, including global infectious diseases, orphan illnesses, and neglected diseases affecting the poor in developing countries; and (iv) improved efficiency of manufacturing processes for drugs or biological processes.[28,29] Prize payments are envisaged to be distributed from MIPF. The Act does not provide a formula as to how the Board will determine the amount of each prize payment.

The OSDD model uses another remarkable mechanism to evaluate research output. Credit points are assigned to contributors using micro-attribution system and algorithm and rewards are determined based on credit points.[26] Sharing of data among investigators reduces duplication of efforts while giving appropriate credits to the contributors. All data, methods, procedures, algorithms and scripts are available for use, reuse and modification for further activities within the purview of OSDD licence. The information available online on the OSDD portal is regarded as a 'Protected Collective Information' by the OSDD sign-in licence. Anyone is free to contribute to or use this community property if he/she is willing to comply with the obligation that all improvements and value additions are contributed back to the community. The collaborative approach facilitates integration of different facets, namely, computational biology, bioinformatics, systems biology, molecular biology, chemo-informatics, medicinal chemistry, experimental pharmacology of the drug discovery process without time delay, etc. Furthermore, this enables online review of work done. It also facilitates sharing the information on both successful and failed experiments among the members of the community so that other investigators can modify or improve them for achieving better results. This web-based collaborative model holds great promise for future global open innovative collaboration.[26] The highly transparent, open peer-review method of project approval, coordinated by CSIR is another hallmark of OSDD.

Genomics research has been another major area for commons-based initiatives. The most prominent of such efforts is the Human Genome Project (HGP), a publicly funded, international research project that committed itself to releasing its data and not claiming patent rights in the mapped genome.[30] Many of the follow-on projects which seek to functionally specify genomic sequences and create maps useful for applied research have also adopted commons-based structures.[31] Biomedical research institutions in the public sector, of late, are increasingly adopting commons-based strategies to promote production and access to information.[30]

But drug discovery and development models, based on an open access approach with prize funds incentives, are also confronted with other serious practical issues. One such issue is one of the ability of open source collaborations in organizing clinical trials.[32] Since 75 per cent of the cost of new drugs takes place after clinical trials begin, it is one of the most important challenges faced by OSDD. Given the fact that public sector research, including research done at universities, is a central contributor to R&D,

particularly in pharmaceutical industry, financing drug discovery may be possibility.[30] However, drug development financing is major challenge in the likely absence of deep investments by pharmaceutical companies in the backdrop of lack of market exclusivity.[33] Even if the development costs are somehow managed, the extensive regulatory processes still require significant source of sustainable financing.[33]

Is it possible for governments to risk tax payer money to a large outgoing expense that almost certainly will not, in most cases, yield end products? What are the chances for public-private-partnership model solving the issue? To what extent will governments, philanthropic organizations/consortium or public-private-partnerships be able to provide sustainable funding to open source drug discovery and development? Is it true that open source drug development will always result in lower cost drugs? Increased competition *per se* does not guarantee that open source developed drugs will be cheap.[33] Unless properly regulated, there is a chance that high competition encouraged by open source drug licensing may be counterproductive and may lead to crash down of generic pharmaceutical industry. These issues need to be tackled at the appropriate stages by strategic approaches. Still it is highly essential that public health issue is not left to the mercy of big pharmaceutical companies to decide. The national governments and the international human rights bodies need to play a big role in addressing these issues and promoting alternative models to solve problems of access to public health.

Future of an Alternative Business Model

The current incentive model based on intellectual property rights are being governed internationally by global trade agreements (such as the TRIPS Agreement and bilateral or regional trade agreements), the major concern of which is ensuring commercial interests of the Big Pharma. History reveals that such international arrangements are glaringly indifferent to global public health. Without a more fundamental reform in the international norms, poor people in developing countries will not be allowed to use existing flexibilities in trade agreements and their specific health concerns will not be adequately addressed. Therefore, more radical reforms may be needed for a sustainable solution to the global problem of access. It requires global acceptance of alternative models for incentivizing pharmaceutical R&D. Thus, globalization of the delinkage approach needs to eventually replace trade agreements with new norms that focus on universal access to public health. With this objective, the CEWG was asked to consider a proposal for a biomedical R&D treaty. The CEWG accepted this proposal and stressed the need for 'a coherent global framework' for promoting, implementing and monitoring appropriate funding and incentive mechanisms. This recommendation became controversial because it was seen as a step towards implementing delinkage approaches globally.

Marlynn Wei suggests that a mandatory system based on the delinking model may be both politically impossible to implement and risky.[28] Still she admitted that it would be desirable than the patent system. Narrowing the prize system to a particular area of R&D, as in the case of neglected diseases, will help to find a solution for a particular set of diseases or medicines. However, this will not solve the larger problem of universal access to public health and deny access to pharmaceutical products falling within other types of diseases to the less affordable lot, belonging to developed and developing countries.

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