

Submission to the WHO Committee on Public Health, Innovation and Intellectual Property (Section 2)

The bottom line: Track2 is a powerful vehicle for implementing the mandate of WHA60.30.

Detailed Comment

WHA60:30 seeks an 'enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries'. Certain diseases disproportionately affect developing countries in part because these regions are underserved by pharmaceutical innovation: 79% of the global burden of disease (GBD) occurs in regions that account for under 8% of global pharmaceutical sales.¹

We also know that it is possible to reduce the global burden of disease through efforts that win the support of the private sector, governments and the general public. Our Track2 proposal does just that by translating the great need for effective medicines among the poor into effective market demand.

Despite the important incentives that patent rights provide for the development of new pharmaceutical products, the current pharmaceutical patent market system faces two related challenges, noted by the WHO IGWG:

Research Priorities. Remunerated through mark-ups on their patented products, innovators have reason to prioritize the search for medicines that suppress symptoms over vaccines and cures – though the latter innovations have greater potential for alleviating disease burdens. Moreover, such innovators have little or no commercial reason to tackle diseases that are heavily concentrated among the poor, since the poor cannot themselves afford remedies at monopoly prices.

Access. Even when effective new medicines exist (e.g., for HIV/Aids), the poor typically lack access to them because of unaffordably high prices during patent exclusivity and/or because of poorly developed health infrastructure in many poor countries.

Track2 aims to address these issues in a unified way: It creates a market for needs-based health research through rewarding innovators in proportion to health impact. By avoiding market exclusivity, it introduces new effective medicines priced near marginal cost of production. And it provides powerful incentives for those entitled to rewards on Track2 to collaborate toward improving health infrastructure in poor countries: to help ensure that medicines come with comprehensible instructions, are widely and cheaply available, are prescribed to those and only those who can benefit from them, and are actually used by such patients to best effect.

Summary of Track2

Track2 complements the existing patent regime with a practical, market-driven alternative that aligns industry interests with global public health needs. Our central idea is to create, in addition to monopoly patents, a second 'track' that rewards inventors willing to forgo market exclusivity in proportion to their invention's impact on the global burden of disease (GBD). Any inventor firm is free to choose either conventional patents or the new Track2. If it chooses the latter, its patented knowledge is treated as a public good, making the new medicine available for open manufacture, distribution and sale worldwide.

Track2 can be broken down into three components:

[1] Open Access

The fruits of any successful effort to develop (research, test, and obtain regulatory approval for) a new medicine, placed on Track2, are to be considered a public good. Patients worldwide would benefit from this freely available knowledge insofar as pharmaceutical manufacturers would use it and, in the context of a competitive market, offer the product at a price near marginal cost of production.

[2] Alternative Incentives

¹ "2004 Global Sales," *Parexel's Pharmaceutical R&D Sourcebook*, p6; WHO Department of Measurement and Health Information, 2004.

To ensure the Track2 innovator can recoup its R&D costs, we propose a reward based on the health benefit of the innovation – measured according to its impact on the GBD. There is no need to specify a specific reward; whatever works is rewarded according to how well it works in reducing the global burden of disease. In contrast to ‘push’ schemes and also to prizes, APCs and conventional AMCs, which all rely on government planners and experts to determine the direction of R&D, our plan is a ‘pull’ market solution that leaves it up to potential innovators to decide how they can make the most cost-effective contribution. This solution fits better with the spirit of private enterprise which increasingly pervades economic life worldwide. Moreover, it is more politically sustainable by generating industry support and assuring taxpayers that their money is used in the most cost-effective way.

In contrast to other currently popular pull schemes – advanced market commitments² - ours is a ‘comprehensive advanced market commitment’ (Hollis, 2007), also described as a ‘full pull’ plan (Pogge 2006, 2007), which promises to alleviate “the last mile problem”. Track2 would incentivise companies to forge and intensify relationships with an array of public health agents, including manufacturers, distributors, and health workers, involved in getting effective medicines to those who need them. It would be greatly to underestimate these powers of free enterprise to presume that pharmaceutical companies with stock market capitalizations in the hundreds of billions would not know how to build an effective disease reduction strategy around their medicines in the world’s more challenging environments.

In contrast to other incentive mechanisms currently proposed, Track2 addresses three key problems in a unified and efficient way: the problem of neglected diseases concentrated among the poor, the problem of high prices of recently introduced medicines, and the problem of poor health infrastructure among poor populations. This mechanism aligns the commercial interests of Track2 innovators with the interests of patients: both seek new medicines that maximally reduce the GBD. It also aligns the interests of Track2 innovators and generic producers (which the patent system brings into costly opposition in myriad jurisdictions) by incentivizing the former to share their expertise with the latter for the sake of ensuring a large and cheap global supply of their proprietary medicines.

[3] Funding

The incentives of Track2 materialize only insofar as the rewards are certain. Ideally, countries would make a treaty-based open-ended commitment to reward Track2 reductions of the GBD at a fixed rate. This commitment could be allocated among countries in proportion to their gross national incomes (GNIs) – with some progressivity perhaps according to per capita GNI so as to exempt the very poorest countries. This allocation should be enshrined in a solid international treaty and firmly built into the global trade and health regimes so as to provide maximum assurance to potential innovators.

Relationship to WHA 60.30

The Track2 amendment would help implement the mandate of WHA60.30 in the following ways:

(1) *‘Addressing the linkage between the cost of research and development and the price of medicines, vaccines, diagnostic kits and other health-care products’ (p.2).*

With open manufacture and sale, interventions registered under Track2 would be priced near marginal cost of production and hence be much more affordable to poorer patients in developing countries.

(2) *‘To encourage the development of proposals for health-needs driven research’ (p.2)*

Built into the Track2 reward scheme is a link between health impact and rate of return. Many currently neglected diseases concentrated among the poor would become lucrative targets for R&D efforts.

(3) *‘To encourage...a method for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionately affect developing countries’.*

Track2 meets both concerns in parallel. The reward is measured with as much specificity as possible – taking into account the complex causal relations between different interventions and diseases (see below). In addition, companies entitled to rewards under the proposed scheme would

² For more on AMCs see [Framework Document: Pilot AMC for Pneumococcal Vaccines](#).

have incentives to collaborate toward improving health infrastructure in developing countries, so as to ensure that their Track2 medicines make the largest possible contribution to reducing the GBD.

(4) *‘Addressing diseases that disproportionately affect developing countries’*

Track2 would make the greatest difference to diseases that are severe, widespread and concentrated among the poor – diseases that WHA60.30 notes that pharmaceutical innovators cannot profitably address under the current scheme. It would open up new markets for these firms, without threatening their opportunities to profit from the development of new medicines intended for conventional (‘Track1’) patenting.

(5) *‘To support countries that intend to make use of the flexibilities contained in the TRIPS Agreement and other international agreements to promote access to pharmaceutical products’.*

Track2 can be implemented without violating the TRIPS agreement, because it is an optional system. Innovators have a choice between exclusive exploitation of the innovation under the usual patent system, or submitting their product for Track2 rewards while forgoing their entitlement to exclude others from the use of the patented innovations. This would not in any way affect national and international commitments regarding patent rights, because any firm’s decision to forgo or to waive some of its patentable claims would be voluntary. And Track2 would very likely reduce the need for compulsory licenses insofar as innovators would often prefer to register a new medicine of great relevance to poor populations on Track2, especially when they can thereby avoid the cumbersome efforts of obtaining, renewing, defending, policing, and enforcing exclusionary patents in a large number of national jurisdictions.³

Proof of Concept

However compelling may be its central idea, Track2 requires various complex specifications to demonstrate its practicability. It requires, for instance, an appropriate metric for the GBD, sufficient data to assess the GBD *ex post* and to make plausible baseline GBD projections some years into the future, rules for allocating any specific GBD reduction among contributing pharmaceutical innovators, and adequate mechanisms for curbing corruption and gaming. Our research team is focused on showing how such technical issues can be resolved.

[1] Appropriate Metric for the GBD

Recent developments in the study of population health make operation of a scheme like Track2 more feasible. The WHO-sponsored GBD studies of 1990 and 2001 provide reasonably comprehensive assessments of the worldwide burden of over 100 diseases. We intend to use a modified version of the Quality Adjusted Life Year (QALY) metric to evaluate the incremental QALY impact of a given intervention rewardable under Track2.

[2] Sufficient data to assess the GBD *ex post*

Although the GBD studies have facilitated better data collection, it is still the case that the best data come from countries with good vital registration systems for reporting and recording, among other things, each death and its cause. But such systems are often rudimentary or even absent in poor countries from which good data are especially needed for Track2. Fortunately, improved data are a crucial and cost-effective element of almost any health improvement initiative. The WHO’s new International Health Regulations already require improved disease surveillance worldwide, and economists hold that surveillance should be treated as a global public good. Implementation of our proposal would give poor countries incentives to build reliable vital registration systems, which could also be mandated by the above-mentioned treaty.

[3] Rules for allocating a specific GBD reduction amongst causes

The allocation rules for Track2 must be sensitive to the fact that GBD reduction is often over-determined; something that cannot be accommodated by the current GBD studies, which attribute all years of life lost to one disease (in accordance with International Classification of Disease guidelines) even in cases involving co-morbidity. To supplement the QALY metric, we are designing

³ These efforts may not be wholly avoidable in cases where an invention has other uses with great profit potential on Track1.

a Monte Carlo simulation model to estimate more accurately the mortality damage for the years of life lost according to a certain cause.⁴

[4] Rules for allocating a specific GBD reduction among innovators

The rules for allocating specific GBD reductions among contributing pharmaceutical innovators must also cope with cases where medicines patented by different firms address the same disease, either through alternative treatments or through joint treatments (“drug cocktails”). In such cases, public health by means of counterfactual analysis will be informative.⁵

Reward Scheme

In parallel to the measurement work, our team is developing several options for the reward mechanism for Track2, focusing on the type of data needed, the duration of the reward, and the timing of payments. Our team will provide a model for testing, but the beauty of Track2 lies in the fact that the implemented solution can be worked out *with* the firms in the relevant industries. Since these companies negotiate under a virtual veil of ignorance with respect to as yet uninvented medicines and their inventors, their collective interests will shape their negotiating strategy. They will want to design the allocation rules so as to maximize their collective harvest of rewards. In particular, they will want these rules to be clear and transparent so as to reduce uncertainty. They will want the incentives to be shaped so as to foster efficient collaboration and synergies among themselves. They will want to set up a cheap and reliable arbitration mechanism so as to reduce litigation expenses. There is then considerable harmony of interests not merely in the operation of Track2, but also in specifying its design — lending further support to our belief that its central idea is both feasible and politically realistic

Future Steps

The next stages of the project involve further development of robust allocation and monitoring instruments, as well as the design and execution of pilot projects to test specific aspects of Track2 in the field. We have received funding from the UK-based BUPA Foundation to support several additional researchers, including two economists and a public health expert, and are fortunate to enjoy substantial support and collaboration from leading academics in law, medicine, public health and economics. Incentives for Global Health, the non-profit organization founded to support our work in the US, is working to connect us with large investors, political leaders in several countries, representatives of the pharmaceutical industry, consultancy firms, governmental and intergovernmental agencies (NIH, WHO), and NGOs. Members of our team have speaking engagements at a number of universities and think-tanks in Europe, the US, South America, and China, and we recently organized a major conference in the U.K. to discuss the plan with leading academics.

The bottom line: Track2 is a powerful vehicle for implementing the mandate of WHA60.30.

⁴ For an example of Monte Carlo simulation models combined with a DALY/QALY metric, see the recent malaria studies carried out by the Global Forum for Health Research <http://www.globalforumhealth.org/filesupld/malaria1/malariachap2.pdf>

⁵ For discussion of causation in public health see Christopher J. L. Murray, and Alan D. Lopez, “On the Comparable Quantification of Health Risks: Lessons from the Global Burden of Disease Study,” *Epidemiology* 10 (September, 1999), pp. 594-605; Colin D. Mathers, Majid Ezzati, Alan D. Lopez, Christopher J. L. Murray, and Anthony Rodgers, “Causal Decomposition of Summary Measures of Population Health,” in Christopher J. L. Murray, Joshua A. Salomon, Colin D. Mathers, and Alan D. Lopez, eds., *Summary Measures of Population Health: Concepts, Ethics, Measurement and Applications* (Geneva: World Health Organization, 2002), pp. 273-290.