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DELINKED FROM REALITY

by Philip Stevens

- Opponents of the current market-based system of drug development wish to replace IP rights with government-managed prizes as the main innovation incentive. This "de-linking" of the end price of drugs from R&D expenditures will make innovative medicines far cheaper, they argue. But the approach would do much unintended harm.
- Governments would have to replace private medical R&D expenditure (at least $141bn per year) with tax-funded spending and face significant additional costs of running a new bureaucratic apparatus. This would create economic distortions without guaranteed success.
- The true economic and social value of a new medicine ahead of its creation is hard to measure. Underfunding a prize will lead to less R&D and fewer new medicines; over-funding will bring waste and duplication.
- Handing significant control over global biomedical R&D flows to a centralised bureaucracy is a recipe for crony capitalism and the politicisation of drug development.
- The current market-based system already achieves many delinkage aims. Health insurance shields consumers from the full cost of medicines. Market competition drives innovation and puts downward pressure on prices even during time-limited period of market exclusivity, while driving competition between and within therapeutic classes. Mechanisms such as Product Development Partnerships direct R&D resources to areas that have received less attention, such as neglected tropical diseases.
- Governments have proven unwilling to commit the necessary public funds for domestic biomedical R&D, let alone internationally. A change is unlikely soon, certainly nowhere near the levels required to replace private investment.

DELINKED FROM REALITY

Replacing patents with prizes to spur drug development is the idea of the moment. But this so-called "delinkage" won't deliver the innovation and low-cost medicines claimed by its supporters, writes *Philip Stevens*

Should the market-based system of drug development, which relies on intellectual property as its primary incentive, be replaced by a system of government-funded prizes?

The answer is an emphatic "yes" according to proponents of the idea, who claim that the current patent-based system makes drugs too expensive, while failing to provide cures for those in need who may be unable to pay, such as people in developing countries.[1]

Under a prize system, the developers of new drugs would no longer receive the investment and legal certainty patents provide to drive R&D, but would be rewarded for the successful development of a new medicine by a cash prize, among other suggestions.

In return, companies would have to hand over their intellectual property to the government, allowing generic manufacturers to enter the market immediately. Subsequent competition between generic drug manufacturers, so the theory goes, would allow new drugs to be sold at their marginal cost of manufacture, enabling immediate access to all those in need.

Meanwhile, governments would control and plan what disease areas are rewarded by prizes, ensuring that funding is allocated to health priorities in a fair and transparent fashion.

"Delinking" the cost of R&D from the final price paid for a medicine, and making governments the funders and planners of drug development, sounds like a simple solution to the complex range of factors that are responsible for poor healthcare. But so far, no country has taken the plunge.

The reason for this hesitance could be that replacing patents with prizes would almost certainly do more harm than good, resulting in a politicized drug development system that misaligns incentives, raises costs and delivers fewer new drugs.

AN OLD DEBATE

Using prizes to encourage inventors to solve problems is not a new idea. The Longitude Prize, sponsored by the British government, was famously awarded in 1737 to John Harrison for his novel, clock-based solution for determining a ship's longitude. Prizes were also offered in Napoleonic France for a functional water turbine, and for a method of

preserving food for the army – the precursor of the now ubiquitous tin can.

Innovation prizes fell out of academic and political fashion for most of the twentieth century, as patents and other forms of intellectual property rights continued as the main driver of technological innovation (with the exception of the technologically backward Soviet Union). This move away from innovation prizes towards today's market-based system of innovation reward was hardly surprising given the deep structural problems with prizes, as documented by economic historian Zorina Khan in her 2015 analysis of dozens of 19th century innovation prizes administered in Britain, France and the United States[2].

Nevertheless, since the early 2000s there has been a resurgence of academic and political interest in replacing intellectual property rights with prizes, particularly within the field of drug development.

A QUESTIONABLE CURE

Proponents of prizes see two fundamental problems with the current system of drug development which they believe could be solved by government-funded prizes.

First, the intellectual property system's mechanism for encouraging innovation – granting patents and an attendant temporary period of market exclusivity to inventors – creates what economists call "deadweight losses." Put simply, patents theoretically enable their holders to exploit their market monopoly by inflating prices many multiples beyond the marginal cost of production. Under this view, this leads to significant welfare losses to society: patients who may be unable to pay are prevented from accessing the new medicine, while those who do have access are forced to spend money on expensive drugs rather than in the wider economy, creating economic distortions.

New taxes needed to replace private R&D investment

This analysis is problematic given the enormous social and economic value innovative medicines create in terms of increased productivity, averted hospitalization and increased longevity. But more to the point, an innovation system based on prizes could create just as many, if not more, deadweight losses.

THE TROUBLE WITH TAXES

Daniel Spulber is a Professor of International Business at the Kellogg School of Management, Northwestern University, and an award-winning expert on innovation policy.

"Most prize advocates assume free money. In fact, the government raises money for the prizes through taxation, which causes economic distortions that involve significant deadweight losses. The deadweight welfare losses resulting from a government prize system are likely to substantially exceed any such losses from competitive markets – replacing prices with prizes would lower social welfare," he cautions.[3]

Currently, the innovative pharmaceutical industry spends around US$141bn per year on R&D.[4] This is privately-raised capital which governments moving towards a delinkage drug development system would have to replace through taxation.

Crucially, the deadweight cost of this additional burden of taxation could exceed that of the patent system, especially if it is collected in the form of income or other labour taxes which are widely acknowledged to distort labour markets and interfere with job creation.[5] This may explain why no government, other than the former Soviet Union, has yet countenanced replacing intellectual property rights with prizes.

> "Most prize advocates assume free money. In fact, the government raises money for the prizes through taxation, which causes economic distortions"

BUREAUCRACY, NOT R&D

In addition, the bureaucratic apparatus required for the administration of a prize system would create its own costs which again would require additional taxes - and associated deadweight welfare losses.

Drug development prize committees would need to decide what kinds of discoveries should be eligible for prizes - and their market value - before any actual R&D begins. This kind of central planning would require prize agencies to avail themselves of technological expertise and foresight equal to the global pharmaceutical industry.

"Prize advocates tend to assume that the government would expend no resources in administering the prize system, including managing contests, selecting winners, and allocating inventions," says Prof Spulber.

"The government could not replace the entire patent system with contests and awards in every area of science and technology covered by the patent system without incurring astronomical administrative costs."[6]

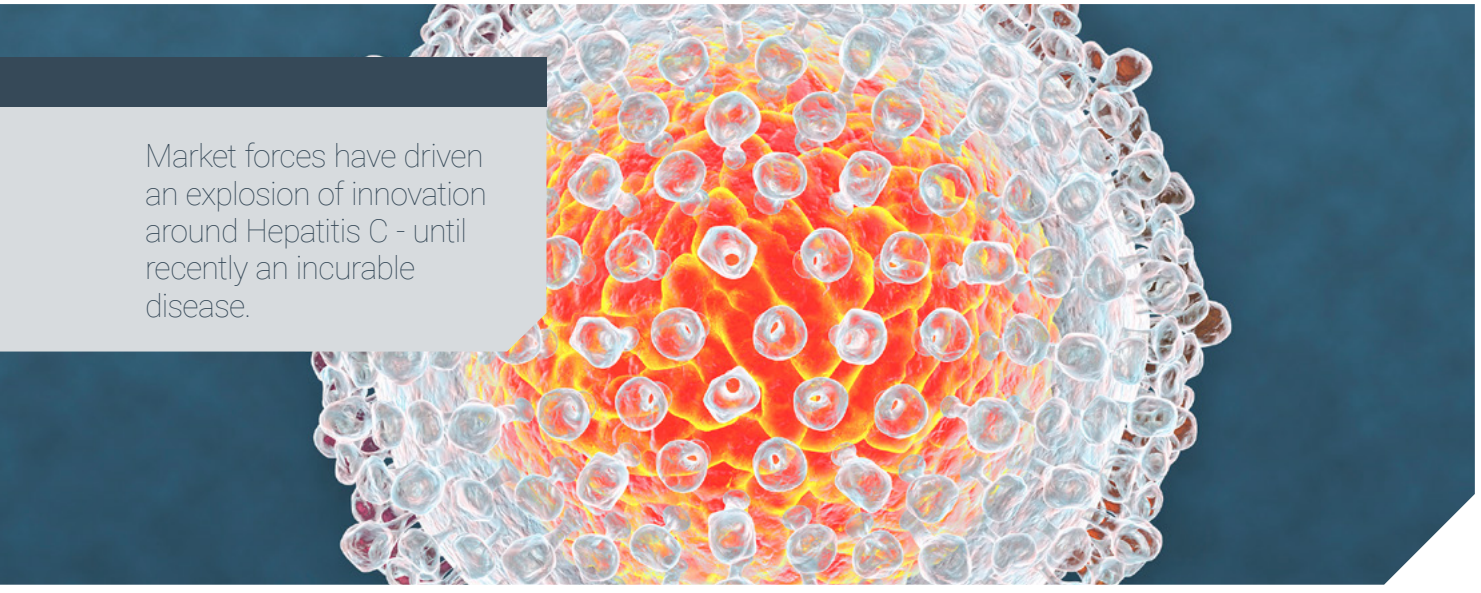
"None of these costs produce R&D, just pure losses," he adds.

THE BENEFITS OF PATENT-BASED COMPETITION

Prof Spulber challenges the assumption made by advocates of government-run prizes that they would have minor deadweight costs compared to the "monopolies" created by the IP system. While patents may create temporary monopolies on specific inventions, in practice patent owners rarely have wider economic monopolies, because of market competition.

"There is extensive competition in the market for inventions, involving both rivalries from substitute and complementary technologies. There are over two million active patents, with more than a quarter of a million new patents every year. Patent owners face competition from past inventions and entry of new inventions," says Spulber.

"These market forces constrain the returns to inventors and innovators thus limiting deadweight welfare losses."



Market forces have driven an explosion of innovation around Hepatitis C - until recently an incurable disease.

Take Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients.

In 2013, a revolutionary new treatment named Solvadi was released that boosted cure rates to 90%. This was followed in 2014 by an improved treatment called Harvoni which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take account of the patient's liver and kidney status, co-infections, potential drug interactions, previous treatment failures and the genotype of HCV virus.[7]

"If you have to have Hepatitis C, now is the time to have it," says Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York told the Financial Times. "We have these marvellous drugs we can treat you with right now, without side effects," he adds. "And this time next year, we'll have another round of drugs available." [8]

Crucially, each of these companies does not have a monopoly on Hepatitis C treatment, despite their patents, but the prospect of decent returns entices new players to enter the market with new, improved products. Competition also forces prices down, limiting the deadweight losses of patents: Merck launched its Zepatier in the US at a 40% discount to rivals, for instance, with further discounts for insurers and government healthcare payers. [9]

LESS NOT MORE INNOVATION

Another accusation against the IP system is that it misdirects innovation. Because patent holders accrue rewards from innovating in areas where there is high consumer willingness to pay and high rates of return, focus will logically be on those areas. Diseases for which consumers are less able to pay, but still in significant need, get under-researched.

One example of this are "Neglected Tropical Diseases" such as schistosomiasis and Buruli ulcer which, despite afflicting millions of people in the poorest countries, have a dearth of viable treatments and cures.

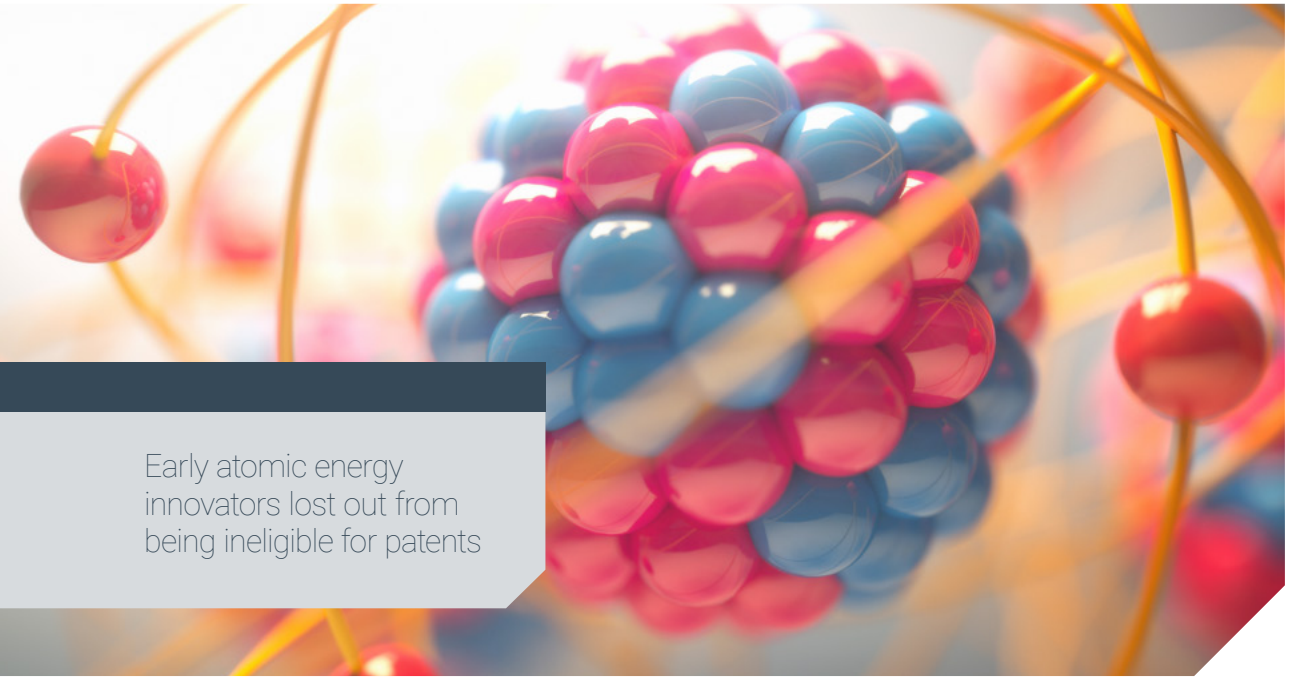
Governments, foundations and the private sector have responded by mobilizing unprecedented levels of resource and expertise to neglected tropical disease R&D, often through Product Development Partnerships (PDPs) between the private and public or non-profit sector. Many of these PDPs work within the existing international framework of intellectual property rights protection, for example granting royalty-free licenses for use in low-income countries, or agreeing to share IP amongst research partners in a way that promotes access to eventual products.[10]

HOW DO PLANNERS KNOW WHAT A DRUG IS WORTH?

A major - and as yet unresolved - problem with prizes is that governments find it very hard to determine accurately the true economic and social value of an invention. In the past, this failure has resulted in government prize committees undervaluing inventions.

"There is an inherent conservative bias in the prizes granted by administrative and quasi-judicial bodies. Munificence is a rare committee virtue," writes the Harvard economist FM Scherer.[11]

Under the US Atomic Energy Act of 1946, military uses of atomic energy were made ineligible for patent protection. Instead,



Early atomic energy innovators lost out from being ineligible for patents

monetary awards were disbursed to inventors by a specialist government committee. Prof Scherer observes that atomic energy innovators– including inventors of early methods of producing plutonium, and basic liquid rocket engines – were awarded sums far below what they could have earned had their inventions been patented.

Undervaluing a new medicine in a prize system matters for future innovation. In a situation where innovators know that their inventions are unlikely to be properly rewarded, they are less likely to invest in R&D and compete for the prize. With the current figures putting the cost of drug development at between $1.2bn and $2.6bn, innovators – and the venture capitalists on which many biopharmaceutical startups rely – need to be sure that the potential rewards are worth the risk of this capital. If there is a real prospect of under-reward, innovators could direct their capital away from medicines towards areas less prone to political risk.

Of course, the government planners could get it wrong the other way, and over-value the prize. In this case, this could lead to a duplication of R&D as multiple players compete for the same prize, all spending valuable capital on trying to create the same medicine – only one of which will eventually be rewarded, even if competitors have produced useful products. Given that a major motivation of prize advocates is to move away from the supposedly "wasteful" R&D that occurs under the patent system, it's not clear how prizes would be an improvement.

THE REAL RISK OF EXPROPRIATION

Innovation could also suffer if a centrally-planned drug development system based around prizes led to the expropriation or significant under-reward by governments of valuable knowledge and inventions.

While at first glance this may seem improbable, the dynamics of intellectual property, drug development and prizes should at least give innovators pause for thought.

In a prize system, innovators hold few cards. Their R&D costs are already sunk at the time of prize disbursement, and to qualify for the prize, details of the invention would have to be disclosed to the government at a level of detail far beyond that currently required by the patent system. It could be tempting for cash-strapped or populist governments to co-opt the invention and direct the prize funding towards spending priorities more politically rewarding than handing a large lump sum over to pharmaceutical companies.

Such a contingency is not so outlandish when considered against efforts by a few middle-income countries to compulsory license patents over the past twenty years, including Brazil, India and Thailand.

Some prize advocates have suggested the problems of under-valuation and expropriation could be avoided by allocating a fixed amount to prize agencies and legally requiring them to disburse all their monies according to pre-set rules and criteria.[12] But this does not prevent governments from under-funding the prize committee in the first place. And given the poor track record of government funded R&D, the problem of under-rewarding invention is likely to be a fatal flaw in a prize system that could seriously disrupt innovation. In turn, that would hurt society as fewer new medicines would be developed.

> “A major - and as yet unresolved - problem with innovation prizes is that governments find it very hard to determine accurately the true economic and social value of an invention.”

PRIZES: THE POLITICISATION OF R&D

Opponents of the market-based system of drug development decry funds spent by the pharmaceutical industry on lobbying governments to ensure a favourable policy regime. But a prize system would hand significant new discretionary powers to government officials, who would be the ultimate arbiters of whether a new medicine

wins a prize. This would create major new incentives for rent-seeking and crony capitalism and result in the wholesale politicization of drug development.

According to economic historian Zorina Khan, some of the earliest (and most famous) prizes were tainted by politics. John Harrison, a poor, uneducated clockmaker, is credited as the inventor of the method of determining a ship's longitude at sea, yet the Longitude prize was never officially won and it took him 47 years to receive compensation for his invention - which came eventually from a different source. His lack of social standing, difficulties in dealing with the prize board and political interference from better connected competitors may have been responsible for his maltreatment, according to Dr Khan. In fact, Dr Khan's statistical analysis of dozens of prizes granted to British inventors in the 19th century shows that those with an elite, Oxbridge education were twice as likely to win awards. Technical qualifications or accomplishments had little bearing on the likelihood of prize success.

Under a prize-based system, there is a risk that political factors could influence decision-making, rather than clinical demand. Political connections and lobbying could both play a role in securing a prize, while elected officials may attempt to influence R&D spending by government agencies.

Patents, on the other hand, are far less arbitrary form of innovation incentive. Government merely sets the framework of patent law, under which all companies compete.

INVESTING IN HEALTH COVERAGE SOLVES THE PROBLEM

If prizes can outperform the intellectual property system in delivering innovative

John Harrison's lack of social standing may explain why it took him 47 years to receive compensation for his prize-winning Longitude idea

medicines across all disease areas with minimal deadweight costs to the wider economy, as its proponents claim, the question is why no country has yet made the switch.

"The obvious answer is that the benefits from eliminating drug patents would be much smaller than predicted by the prize literature, and there might not be any benefits at all", argues Benjamin Roin of the MIT Sloan School of Management.[13]

Prof Roin points out that patents are frequently mischaracterized as giving the right to monopoly profits, effectively forcing consumers to pay the full monopoly price of medicines. In fact, patents grant no such right, merely giving the right to exclude others from copying a patented product.

Consumers almost never pay the full monopoly price of a patented medicine due to various government interventions into the market for medicines, most notably national health insurance schemes. Health insurance coverage, whether publically or privately funded, means that patented medicines are made available to end consumers at minimal cost, while payers and innovators negotiate to reach mutually acceptable pricing that balances accessibility with rewarding the value of innovation.

"The structure of these policy interventions is eerily similar to many of the proposals for replacing drug patents with prizes, which often involve consumers purchasing drugs at their generic price and governments paying a reward to pharmaceutical companies based on the sales of their drugs," Roin argues.[14]

What of lower and middle-income countries, where public health coverage is often minimal and most health spending comes from people's pockets? Here, the real problem is not so much drug pricing, but a lack of coverage. In a survey of 33 low-income countries, it was found that out-of-pocket payments represent more than half of total health expenditures.[15]

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As a result, most people struggle to afford even cheap essential medicines that have been off-patent for decades, let alone far more expensive physician fees and hospital costs. Improving health coverage and health systems is the answer to better healthcare in these countries, rather than prizes for innovation.

MANAGING DELINKAGE INTERNATIONALLY

A drug development system in which prizes replaced intellectual property would have very limited impact if only one country chose to adopt it. Companies would be discouraged from investing and launching new medicines in that country, focusing their efforts elsewhere – most likely countries that retained robust standards of IP protection.

This explains why proponents of a prize-based delinkage system are also pushing for a global and legally-binding Medical R&D Treaty (MRDT). In its most complete form, such a treaty would place R&D spending obligations on all countries, and centrally direct public funding towards disease areas the treaty secretariat considers a priority. Under such a treaty, intellectual property rights would gradually be replaced by delinkage mechanisms such as prizes.

Various efforts have been made to promote this treaty at the World Health Organization over the years, without success. Perhaps this is because the idea, while appearing simple on the surface, would give rise to all manner of complexities and perverse incentives.

In his analysis of the feasibility of a global medical R&D treaty, Oxford University’s Andrew Farlow raises several pertinent questions.

How would it be possible to compel countries to meet their R&D funding obligations and prevent free-riding, particularly in the face

of historic government underspending on R&D? How would the treaty secretariat be able to properly value medical inventions, and accurately measure R&D spending flows? How could politics be removed from the determination of R&D spending priorities, and how could countries be prevented from gaming the system? These are complex issues which an R&D treaty would struggle to overcome.

The track record is not promising. As part of the WHO's push to boost spending in global health R&D, WHO member states in 2013 agreed to establish a Global Observatory on R&D to monitor spending and set priorities, and also to undertake a number of global health R&D demonstration projects. At the World Health Assembly in Geneva in May 2017, Marie-Paule Kieny, WHO assistant director-general for Health Systems and Innovation, remarked on the chronic under-funding of this "critically important" agenda, noting that one of the demonstration projects (on a nano-based malaria drug delivery system) is being cancelled unfinished due to a lack of funding.[16]

According to the WHO, US$85m was needed between 2014-17 to complete these projects, yet by the end of 2016 only US$11m had been committed by only 10 WHO member states, leaving a shortfall of US$73m.[17]

If WHO Members cannot agree amongst themselves to provide the relatively small amounts of funding for this modest agenda, it seems unlikely that they will stump up the hundreds of billions of dollars required to implement delinkage.

BOTTOM UP, NOT TOP DOWN

In the end, focusing on a global R&D treaty and replacing intellectual property rights with prizes would be a major distraction from more practical activities that could deliver results now. "There are plenty of current innovations, medical and otherwise, that are woefully underused, a situation which will not be resolved by a medical R&D Treaty", says Farlow.

"There are multiple ways to achieve impact with global health innovations, without complicating, distracting and delaying us from this goal."

"Given all the recent initiatives to invest in global health, the real challenge is to turn all of that investment and activity into things that will improve the lives of the poor immediately. We

WHO member states have failed to honour very modest commitments to global health R&D

should favour the simple, direct, and immediate over the grandiose and bureaucratic, as typified by the MRDT," he writes.[18]

Member States of the World Health Organization are currently struggling to properly finance modest R&D demonstration projects and a Global Observatory to track R&D flows. It is unlikely that they will reach consensus on the endlessly complex and continually evolving field of biomedical R&D without handing an enormous amount of discretionary power to a new centralised global R&D body.

Such a top down body will be open to politicization and rent-seeking, and by replacing patents with prizes and other delinkage mechanisms, it would destroy many of the incentives that have been responsible for the vast panoply of medicines and treatments upon which physicians and patients can draw today.

The planners in this body would need all the knowledge of the entrepreneurs and managers currently engaged in biopharmaceutical innovation, as well as having the capacity to accurately estimate market prices for all new required medicines. Get this wrong and private sector investors will walk away from pharmaceutical R&D and commit their capital to politically safer but less socially useful areas.

No country has yet taken this leap into the unknown, not least because health insurance and other forms of medical coverage already insulate patients from the cost of medicines – and indeed all healthcare.

The current market-based system of drug development allows for experimentation and competition within and between therapeutic classes. Crucially, it allows for serendipitous discoveries, such as new uses for existing drugs. Thousands of promising leads enter the drug development pathway, but only a few make it through the rigorous process of clinical trials. The cost of failures and the risk is borne almost entirely by the private sector at no cost to taxpayers.

"There is nothing wrong with awarding prizes. But replacing markets for medicines with government prizes would destroy one of the most innovative areas in the economy, and stop the endless source of life-saving medicines", says Prof Spulber.

WHO member states should beware of throwing the baby out with the bathwater.

About The Author

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What lessons can be drawn from the XPrize?

One of the more high-profile innovation prizes of the last twenty years has been the various X-Prizes, which aim to mobilise private sector resources into under-researched areas that could benefit all of humanity, from cheap space flight to energy-efficient water production technologies.

What lessons does the XPrize model hold for governments wishing to replace intellectual property rights with prizes as the major incentive for drug development?

The first XPrize - the Ansari XPrize - offered a prize of $10m for the first privately financed team that could build and fly a three-passenger vehicle 100 kilometres into space twice within two weeks.

The prize was won in 2004 by the makers of SpaceShipOne and overall, the prize mobilised $100m of R&D by 26 teams. SpaceShipOne provided a basis for future design of private space crafts, including those of Virgin Galactic.

A defining feature of the XPrize is that it provides rewards for achieving clearly delineated milestones and outcomes, a model that is attractive to proponents of medical innovation prizes.

But as a way of incentivising commercial R&D, the XPrize experience offers some cautionary lessons that underscore the importance of the intellectual property systems.

In this context, the Google Lunar XPrize (GLXP), announced in 2007, is instructive. The GLXP will award $20m to the first team to land a rover on the moon that travels more than 500m transmitting high definition video and pictures.

The prize has mobilised new sources of capital and intellectual capacity, with five teams from around the world currently vying for the prize.

But the cash prize is not what motivates most of these entrants, according to Georgia Tech's Luciano Kay, who studies the economics of innovation prizes. Many entrants care more about enhancing their public reputation, or gaining access to commercial networks to find new opportunities for their products. This is particularly valuable for fledgling companies trying to enter a market.

"Non-monetary incentives (e.g. prestige, visibility, opportunities to accomplish other goals) and the market value of the prize technologies strongly influence decisions on whether to enter a competition," writes Prof Kay in his 2012 book, "Technological Innovation and Prize Incentives: The Google Lunar X Prize and Other Aerospace Competitions".

As such, is it questionable as to whether the XPrize or a variant could replace patents as a means of motivating large-scale commercial R&D. Prof Kay observes that Boeing, Lockheed Martin and other established space exploration companies have not entered the GLXP competition, because they do not see it as a viable commercial opportunity. The XPrize is a discrete, one-off competition, and as such, does not represent a sustainable business model over time, especially given the enormous fixed-costs and overheads borne by large R&D companies, who are able to underwrite these costs from revenue derived from existing patents, licenses, research grants and so on.

If winner-takes-all prizes were to replace patents, therefore, they would have to become progressively more valuable - valuable enough to cover all the research expenditures of those hoping to win.

While the XPrize has encouraged new and unexpected organisations to get involved in R&D, it is traditional incentives such as patents that underpin much of their work. "Modern technology prizes (which systematically offer cash rewards equal to or below expected R&D costs) complement and do not replace patents and other traditional incentive mechanisms such as contracts and research grants", writes Prof Kay.

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