From TRIPS to RIPS: A better Trade Framework to support Innovation in Medical Technologies

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Introduction

There is an almost unbounded interest in the development of new health care technologies that will prolong life or reduce suffering. The pace and direction of innovation will depend in part on the resources mobilized for research and development (R&D). National governments have a variety of policy instruments to lift and shape R&D expenditures. Public sector grants and contracts, tax incentives, government imposed research mandates, philanthropic efforts, and an expanding universe of intellectual property protection schemes are all important in raising levels of R&D investments. Each instrument has its own advantages and shortcomings. Most countries undertake a mixed strategy of public and private funding.

In recent years the framework for funding such R&D has become the subject of a multilateral, regional and bilateral trade negotiations. The most important discussions have concerned intellectual property rights, the systems of private rights in data and inventions that protect investment and create incentives to develop new commercially important products. The World Trade Organization (WTO) Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS) is the best known such agreement, but increasingly important are other multilateral agreements administered by

[1] Director, Consumer Project on Technology. This paper is based up collaboration with Tim Hubbard of the Welcome Trust/Sanger Institute, and has benefited from comments and suggestions by many public health experts, scientists, trade professionals, economists, pharmaceutical industry stakeholders, and others in several seminars. Notable was a September 2002, meeting organized by Aventis in Ottrott-le-Haut, France on "Pharma Scenarios for Sustainable Healthcare," where Tim Hubbard and James Love presented Radical IP Scenarios #1 and #2. The proposals were also discussed at the 2002 Trans Atlantic Consumer Dialogue meeting on intellectual property and health care, an October Buko/HAI meeting at Bad Boll Germany, the December 2002 MSF seminar on drugs for neglected diseases in Rio, a March 2003 conference in Stellenbosch, South Africa on Africa and the Human Genome, a March 2003 workshop on benefit sharing at University of Pennsylvania, an April workshop on TRIPS and public health in Sri Lanka, an April meeting on TRIPS and Public Goods at Duke University, and the April 29, 2003 CPTech, MSF, Oxfam, HAI workshop on a global framework for supporting health research and development (R&D) in areas of market and public policy failure, and at several other workshops and meetings. Many have offered thoughtful criticisms and suggestions, and none should be blamed for shortcomings of this paper.

the World Intellectual Property Organization (WIPO), and hundreds of bilateral and regional agreements on intellectual property norms and enforcement mechanisms, particularly those between the United States or Europe and smaller economies.

It is well known that patents and other forms of intellectual property protection have only limited efficacy in stimulating innovation in the health care field. Basic research, development of high-risk projects, and research on vaccines or neglected diseases are some well-known examples of areas where private market incentives are insufficient to secure adequate investment. There is also considerable evidence that systems of intellectual property protection are fraught with high costs in terms of administration and dispute resolution, and a number of well-known inefficiencies, such as anticompetitive barriers to follow-on innovators. Recently there is considerable interest in new collaborative open source development models, which in some cases work best with little or no intellectual property protection.

Intellectual property regimes that rely upon exclusive rights often lead to unacceptable barriers to access to treatments. This is problem in both rich and poor countries. For example, while developing countries struggle to pay for the least expensive HAART regimes to treat AIDS, there are also increasingly severe problems managing limited budgets for AIDS treatments in the United States and other wealthy countries, particularly with the introduction of products such as T-20, which are so expensive they threaten to exhaust limited public funding for indigent AIDS patients. Canada, France, Sweden and the UK are among the countries that see high fees for breast cancer screening patents as a barrier to deployment of these new technologies. The impact of high prices in the United States is a growing crisis for access among the uninsured, and in the United States, Europe and other OECD countries there are substantial controversies over which treatments will be reimbursed under public or private insurance schemes -- a rationing of the most expensive new medicines.

Historically, governments have recognized these and other limitations, and complement the intellectual property approach with a variety of direct and indirect public subsidies to raise investment levels in health care R&D. The United States, for example, will spend more than $27 billion this year at the National Institutes of Health (NIH), and more through a variety of other agency efforts, and also subsidize R&D though income tax credits. Every OECD country and many developing countries have some public sector grant, tax or other subsidy programs to support health care R&D. In some areas, the US government simply mandates that private firms undertake R&D as a condition of doing business. Other national governments have their own mixed models of supporting R&D. For example, in the UK domestic prices of pharmaceutical drugs depend in part upon firm R&D expenditures, Canada linked NAFTA changes in its patent laws to a negotiated increases in levels of R&D that industry was obligated to undertake, and at the regional level, Brazil has imposed R&D mandates on private sector firms.

Despite the widely recognized importance of non-intellectual property factors in determining the levels of R&D and the rate of innovation in new treatments for disease, there has been little discussion of the trade related aspects of such programs. There are

notable exceptions, such as the G-8 discussions regarding funding R&D on drugs for neglected diseases, or the Blair/Clinton statement on the benefits of unencumbered access to human genome sequence. The G-8 discussions involved a handful of wealthy countries that were motivated to raise global levels of R&D on specific diseases, such as malaria or tuberculosis, that primarily afflict the poor, and for which the patent system does not provide sufficient incentives relative to the importance of these diseases from a public health perspective. The Blair/Clinton statement on the Human Genome Project (HGP) sought to address a different global IPR failure. The United States NIH, the UK Welcome Trust, and funding agencies in Japan, France and Germany agreed that donor and public sector funds would be used to sequence the human genome, and to place the results immediately in the public domain, without any IP claims. The no-IPR approach to the HGP was influenced by the growing interest in "open source" development models for software and medicines, that emphasized the benefits of increased access to information, and it also enjoyed substantial support within the pharmaceutical sector, due to concerns that broad gene patents would saddle researchers and firms with high royalties and deter development of new products. The Blair/Clinton statement strongly supported the principle of making raw research data freely available in order to maximize its use, as a way of obtaining the greatest medical benefits for humankind.

There are additionally a number of proposals for global agreements that would increase funding for vaccines, broaden the scientific commons,[2] or address other areas where there is a both a need and an opportunity for global cooperation on the development of public goods. However, none of these initiatives have the same level of multilateral, regional or bilateral attention that is now given to agreements on intellectual property rules.

We propose a new emphasis be placed on the development of formal global frameworks that consider jointly both the IP and the non-IP instruments for funding health care R&D. One fundamental rationale for any global framework is to address the free rider problem. There are global benefits to R&D, but local costs. The efforts to create more uniform IP regimes are efforts to share more broadly the costs of funding R&D, but there is clearly a need to expand the trade framework to address a broader range of funding instruments.

Even for a privatized research model, the IP regime by itself only addresses one aspect of financing R&D. In particular, the regulation of drug prices and the availability of social insurance to pay for medicines are two very important factors in determining the level of incentives for new drug development. Indeed, in recent years, the United States trade policy has placed increased emphasis the issue of drug pricing or the structure of social insurance reimbursement schemes, even though the US does not regulate drug prices or provide social insurance for drug purchases in its domestic market. The United States successfully demanded that Korea impose a seven country reference pricing system for minimum prices on innovative drugs, and the US trade officials have pressed Australia,

[2] John Barton, Science and Technology Diplomacy Initiative and the ICTSD-UNCTAD Project on IPRs and Sustainable Development , Policy Dialogue on a Proposal for an International Science and Technology Treaty, Room XXV, Palais des Nations, Geneva Friday, 11 April 2003.

Canada, France, Germany, New Zealand, Thailand and many other countries[3] to raise prices and extend reimbursement for new medicines. The US efforts to raise prices are bitterly resented by governments and patients, as higher prices inevitably reduce access to new treatments, and they do not recognize other ways that countries might support R&D, such as funding research that enters the public domain, or any number of public private partnerships to advance particular public health goals.

A Trade Framework that focuses on R&D

It is possible to craft a trade framework that recognizes the entire range of instruments that might be used to support health care R&D, and such a framework can be shaped to address public health goals. Iintellectual property agreements are often the product of lobbying by commercial interests. Pfizer, IBM and other intellectual property owner interests are widely credited with the design of the TRIPS agreement. But if one sought to design a trade framework that sought first and foremost to promote innovation and the advances of public health goals, it would be different. Intellectual property rights would be a means to an end, but not the only means. The protection of property rights would *not* be an end in itself, but one of *several* instruments to finance investments in innovation.

Treaties or Trade Negotiations that address R&D

There are many treaties and trade discussions that have addressed R&D directly. For example:

- The Treaty of Europe includes provisions for public sector funding of R&D. There are measures to ensure that the least developed countries in Europe receive a relatively greater share of R&D investments in order to promote a more equal level of development. This is the type of operational mechanism to give effect to technology transfer and capacity building that was promised but never delivered in the TRIPS agreement.

- The Landmine Treaty requires support for R&D into humanitarian de-mining technologies.

- The Koyto Climate Treaty calls for R&D into energy efficient technologies.

- The G-8 has held discussions over the need to increase public sector support for funding R&D for vaccines and drugs for neglected diseases.

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[3] Often motivated by industry submissions to USTR. For example: *PhRMA "Special 301" Submission: Priority Watch List Countries. "*The Croatian sick fund disregards the considerable R&D costs associated with innovative medicines. Many innovative products that are still protected by patents in the U.S. or the EU are reimbursed in Croatia at levels that are not significantly different than the prices of local and Slovenian copies, therefore disregarding the high R&D costs of pharmaceutical innovation."

- The Human Genome Project (HGP) involved coordination between the United States and several governments, including for example the highly publicized Clinton/Blair announcement that the donor and government funded sequencing efforts would put data into the public domain in order to provide the research community with a global public good.

How might one frame a treaty or trade agreement to support R&D for health care research? If this framework would ever replace TRIPS, it would have to address the free rider problem. Everyone wants to enjoy the benefits of health care R&D, but no one wants to pay. The trade agreement would have to address this issue. But there are also many other topics to explore. Features of a treaty or trade agreement might include:

- Transparency of investment flows,
- Identification of areas of the greatest public health R&D needs,
- Mechanisms to ensure that there is access to new inventions,
- Technology transfer and capacity building in lesser developed countries,
- Greater efficiency in terms of the costs of acquiring R&D, and
- Avoidance of anti-competitive or unfair trade practices.

Proposal for a Trade Framework

The following is a proposal for a trade framework to support innovation in health care. It is designed to be an alternative to the WTO TRIPS accord, but it would easily work independent of or together with the TRIPS. It is designed to support the entire health care sector, but it could also be implemented in a much narrower way, for example to address only medicines for HIV or neglected diseases, databases and other public goods, or for a broader category of essential medicines.

The key features of this proposal are as follows:

1. Every country would have to take measures to ensure greater transparency of R&D investment flows and financing.
2. Every country would be expected to meet or exceed norms regarding aggregate funding of R&D. The funding could be supported through a variety of means, including purchase of commercial products from innovators, direct public funding, research mandates, or other mechanisms.
3. The measured contributions of support for investment would reflect social valuations that would differ from market transactions. A set of multipliers would increase the weights given to investments that were open, addressed public health priorities, or which transferred technology or built research capacity in developing countries.
4. The member countries would have flexibility to manage their own R&D investments. They could adopt strategies that were highly centralized or highly decentralized. They could cooperate with other countries in managing R&D funding or projects, or they could act entirely independent. They could

outsource R&D performance in foreign countries, or do everything domestically.

5. There would be experimentation and competition between countries to find the best implementation strategies. There would be coercion regarding the aggregate level of support for R&D, and global agreement on the rules for transparency and social weights, but considerable freedom to choose a particular national implementation strategy given those requirements and global values.
6. Nations could choose to have high levels of intellectual protection, or no intellectual property protection at all. Nations could choose an entirely proprietary research program, or a strategy that would put all research in the public domain, or any combination of strategies.
7. The trading system would have a tool other than intellectual property rights to address the aggregate level of funding R&D, and also to ensure that investment flows in R&D addressed social priorities, such as sufficient R&D in areas of the greatest public health need, the creation of public goods, or to help developing countries enhance their own levels of economic development.
8. One caveat would concern anti-competitive or unfair trade policies, in the context of a trade liberation agenda. One could imagine some constraints in national implementation strategies to address these issues.

The following further describes how such a trade framework would work, and provides a discussion of transition and implementation issues.

Transparency of Investment Flows

Public health authorities know very little about current investment flows on R&D. There are some data published by trade associations, such as the US based Pharmaceutics Research and Manufacturing Association (PhRMA) annual survey of R&D expenditures, information from company annual reports and SEC disclosure reports, and some independent data, such as information reported by the US Internal Revenue Service (IRS) in connection with the increasing R&D income tax credit, or disclosed to governments of Canada or the UK in connection with pharmaceutical pricing policies. But in general, little is systematically collected on core details of the global allocation of R&D funds. A treaty or trade framework for R&D that addressed norms for support for R&D would need to rely upon more information than what currently exists. A global effort to increase transparency of investment flows would benefit from a framework for disclosure and reporting of investment flows. Policy makers would benefit from information on the (a) stage of R&D, including each phase of clinical trials, (b) the disease or condition the R&D was directed at, (c) the sources of funds and (d) the intellectual property status, and in particular, to determine if the research project is proprietary or open.[4] The performers of the R&D would make these disclosures.

[4] Private corporations sometimes fund open projects, of non-profit educational institutions often seek patents and other intellectual property protections on government funded research.

Table 1
Disclosures of investment flows
(disclosure by performers)

Stage of R&D
- Basic research
- Clinical trials
- Phase I, II, III and IV

Disease or condition
- AIDS, malaria, cancer, diabetes, spinal injuries, etc…

Source of Funds
- Public
- Private
- Philanthropic

IP status
- Proprietary
- Open Source

Measurement of Contributions to R&D

Each country would report its contributions to R&D investments. This would involve two steps. The first is to identify the raw monetary value of the contribution. The second is to introduce weights to reflect social priorities.

The measurement of the raw monetary values would reflect the contributions in *dollar or euro* terms, of R&D supported by a particular country. These contributions would come from a variety of actions. Purchases of medicines from innovators would count, to the degree that a percent of the turnover was reinvested in R&D. Thus, for example, if Sales were *S*, and the reinvestment rate was *r*, the raw contribution from sales would be *Sr*. This would require reporting of both *S* and *r*. There would also be a variety of research that was funded by the government. In some cases, private firms are required by the government to fund or perform research. For purposes for this illustration, all government funded and mandated research would be identified as *M*.

Raw contributions
- Pharmaceutical Sales = S_i
- Re-Investment in R&D = r_i
- Mandated Research *(including public sector funded)* = M_i

Next, a system of multipliers gives greater weights to R&D investments that address social priorities. In particular, there are three areas where R&D investments would be given greater weights. Open research would be valued higher than proprietary research. Countries that place R&D into the public domain provide a global public good. And many researchers believe that research that is open and readily available for other researchers to explore and advance is more productive than research that is protected by

patents, secrecy or other measures. Second, there are clearly areas of research that are more important than others. For example, the development of a new innovative medicine for an untreated condition is a higher priority than one that simply expands the number of options within an existing class of therapies. We are certainly under investing in vaccines, diseases that primarily afflict the poor, or for emerging public health threats such as SARS. Third, there is a social value in giving effect to various global pronouncements in favor of technology transfer and capacity building in poorer countries. The full set of multipliers would be as follows:

Social Priority Multipliers
- Open Research = α_i
- Priority Research = β_i
- Technology transfer = λ_i

The raw contributions would be recalculated to reflect these social priorities. The adjusted contribution could be expressed as follows:

$$Adjusted\ Contribution_i = \sum_i \alpha_i\ \beta_i\ \lambda_i\ [\ M_i + \ S_i\ r_i\ ]$$

The sum of the adjusted contributions would have to met or exceed the minimum investment norms established by the trade agreement.

Simple Illustration of Adjusted Contributions

The weights would be uniform globally, and both controversial and interesting from public health, trade and social points of view. One can imagine countries with large prevalence of HIV or malaria arguing for high weights on those diseases, and developing countries in general pushing for a significant multiplier for technology transfer. There would be debates between commercial interests and the non-profit research community on the multiplier for openness. The following is a simple illustration of how such a system might work, with arbitrary values for $\alpha_{i,}$ $\beta_{i,}$ and λ_i.

In this example, a country will compare the contributions it is credited with through two different strategies. The first is to buy medicines at willing buyer/willing seller prices from patent owners who have exclusive rights. The second is a public sector investment in an open source effort to develop a vaccine for HIV, with one half of the investment performed by researchers in Africa, Asian and Latin American counties.

Possible values

For purposes of this illustration, suppose the evidence based reinvestment rate for R&D was 10 percent of turnover from pharmaceutical sales, and we assigned a weight of 2 for each of the three social multipliers.

$$r = .1$$

Social multipliers:

$$\alpha_{i,} = \beta_{i,} = \lambda_i = 2$$

A purchase of $100 million of pharmaceuticals from the innovator would count toward the required expenditures as follows:

$100 million pharmaceutical sales x .1 = $10 million

Next consider an alternative expenditure of $10 million on open source research on a HIV vaccine. In this case the investment is funded in a developed economy, but half of the expenditures are performed by researchers in developing countries, and qualify for the technology transfer multiplier.

Performed in developed economy

$5 million x 2 x 2 = $20 million.

Performed in developing economy

$5 million x 2 x 2 x 2 = $40 million.

In this example, $100 million on purchases of pharmaceutical drugs from innovators would count as $10 million toward the required minimum expenditure, while $10 million in open source research on a HIV vaccine that was performed half in developing economies would count as $60 million. In other words, the $10 million in open source HIV vaccine research would be equivalent to $600 million in purchasers of medicines from innovators.

Norms for Aggregate R&D levels

The norms for investment would be related to both the global targets for funding innovation and the fiscal capacity of a particular country to support health care R&D. At the global level, the norm could be set higher in order to increase the rate of innovation. At the local level, rich countries would be expected to invest more, in absolute terms, and less would be expected from poorer countries.

Without more data, particularly regarding public expenditures on health care R&D, it is not obvious what the norms should be, or how they might vary by the income of countries. However, one can make some assessments by looking at data of expenditures on pharmaceutical products. Given the fact that most countries have modest budgets for public sector R&D, and that the TRIPS itself only focuses on the private sector sales of pharmaceuticals, this is a useful place to start. Table 2 reports 2002 retail pharmaceutical sales for 20 countries. There are huge differences in per capita expenditures, ranging from $3 in India to $544 for the United States. However, as a percentage of GDP, the range is much narrower, ranging from .5 to 1.5 percent, with most countries fairly close to 1 percent, regardless of income. India, Thailand and the UK are both at .7 percent of GDP. Brazil, Germany and Australia and New Zealand (combined) are at .8 percent. Mexico, Spain, France and Japan are at 1.1 percent. The Philippines is at 1.4 percent, second only to the US at 1.5 percent.

Table 2
2002 National Expenditures on Retail Pharmacy Sales
USD per capita and as percent of GDP

Country	***per capita expenditures***	***percent of GDP***
France	$243	1.1%
Germany	$207	0.8%
Italy	$178	0.9%
Spain	$160	1.1%
UK	$177	0.7%
Canada	$219	1.0%
USA	$544	1.5%
NZ and Australia	$138	0.8%
Japan	$368	1.1%
Argentina	$34	0.5%
Brazil	$23	0.8%
Mexico	$59	1.1%
China	$5	0.6%
India	$3	0.7%
Malaysia	$18	0.5%
Philippines	$12	1.4%
S Korea	$64	0.7%
Thailand	$13	0.7%

Looking at 1999 US income tax returns, pharmaceutical companies appeared to have invested 8.8 percent in the development of new products.[5] Adjusting this upwards by 20 percent to include R&D on existing products gives a reinvestment rate in R&D of 11 percent of turnover. If one took 1 percent as an average rate of expenditures on pharmaceuticals (looking only for the moment at retail pharmacy sales), and using the US reinvestment rate as typical for markets dominated by large multinational firms, then an average level of support for R&D might be 11 basis points of GDP. If one included non-pharmacy sales and public sector R&D, the norms would be higher. Somewhere

[5] James Love, What do US IRS tax returns tell us about R&D investments?, Van ontwikkelen tot slikken, Pharma Selecta congres, Utrecht, the Netherlands, January 16, 2003.

between 10 and 15 basis points would be a first approximation for a reasonable norm. It is not obvious if norms based upon a percentage of GDP should be the same for all countries, or higher for wealthy countries. In practice, policy makers could set the norms at any level that reflected a consensus target for R&D.

Suppose Brazil was seeking to meet a norm of 10 basis points of GDP to support R&D, and total expenditures on medicines were equal to retail pharmacy sales[6] -- .8 percent of GDP. The measured contribution from pharmacy sales would be .8 x .11 = 8.8 basis points. Brazil would be 1.2 basis points below the norm. It could make that up in a variety of ways. It could adopt policies that would increase outlays on medicines, by increasing prices or quantities. Or it could use public funds or investment mandates to fund research projects, including those that would benefit from the multipliers. For example, based upon 2002 data, Brazil could increase expenditures on medicines by $573 million, or alternatively, Brazil could invest a smaller amount in public sector or mandated research projects. For example, using the illustrative weights of $\alpha_{i,} = \beta_i = 2$, an investment of 16 million in open source projects on priority diseases would also be sufficient to met the overall investment norm. In effect, Brazil could choose between spending $573 million more for medicines, or investing $16 million in the open source vaccine project, or some number of other alternatives.

Global Strategy for Implementation

The WTO TRIPS agreement now sets a global standard for the protection of intellectual property. In the absence of any new agreement, it places significant burdens on consumers to pay for R&D. The development of a new framework for funding R&D could be offered as a substitute for TRIPS. It would not have to replace TRIPS entirely, or for every country.

One plausible strategy would be to first develop the new framework as a soft norm, a best practices approach, and then to later propose, in the context of a new WTO round of negotiations, that countries that met or exceeded the best practices norms be exempt from TRIPS requirements, in the areas covered by the best practices agreement.

The discussion above describes an agreement that would apply to all pharmaceuticals. It could also be extended to a larger universe of health care technologies, or a smaller set. The agreement could cover only medicines to treat HIV, a category of selected diseases, or only public goods. There are obvious advantages to framing the agreement larger rather than smaller. Each country's profile of disease prevalence differs, and the ability to use the multiplier to redirect investments is potentially a major benefit.

In discussions of this framework, some have expressed concerns that there is considerable opposition to measures that might be construed as a global tax, particularly from the US government. The framework described above would different significantly from a tax for the following reasons:

[6] They are of course higher, but this example illustrates the alternative strategies available to a country to meet norms.

1. The investments would be managed by the country itself, and there would be no requirement to give funds for R&D to a global body.
2. If presented as an alternative to TRIPS compliance, it would merely be an additional choice. The TRIPS is already a coercive agreement that imposes costs of governments and consumers.

Local Strategies for Implementation

As noted above, countries would have considerable freedom in choosing strategies to implement R&D funding strategies. They would clearly be influenced by the overall funding requirements and the choice of the social weights for $\alpha, \beta,$ *and* λ. However, within this framework, a number of strategies would be possible. Several models for implementation have been discussed. Here are a few variations.

1. Traditional IPR regimes. There are those that argue that the existing IPR system works well, and that when combined with sufficient social insurance for medicines, there will be adequate access to medicines and sufficient incentives for investment in new products.
2. Open Source development models. There is a view that new open source development models are more efficient that proprietary models. Parties involved in the Human Genome Project have developed new peer review processes that they believe could be used to evaluate drug development. In any case, open source projects have proved successful for the creation of databases and other important research and development activities.
3. Expanded role in government drug development. Some advocate[7] a greatly expanded role of the government in drug development.
4. Prize models. There has been a renewed interest in prize models to fund R&D. New products would be rewarded with large upfront rewards, based upon objective public health criteria, and post product entry, generic competition would drive prices toward marginal costs.
5. IPR Liability models. These proposals would replace the exclusive rights model with one based upon a liability rule. Everyone would be allowed to use everyone else's inventions and data, subject to compensation.
6. Research Mandates. The US, Canada, UK, Argentina, Brazil, India and other countries have experimented with various strong government mandates to invest in R&D.

The new trade framework would allow these and other approaches or combinations. There would be a competition of business models. The trade framework would ensure that countries funded R&D in sufficient levels, but would allow dynamic experimentation in business models.

[7] Dean Baker Proposal. David Kessler speech.

Appendix
Radical IP Scenario #1.

In September 2002, Aventis held a meeting in Ottrott-le-Haut, France to discuss various scenarios for the pharmaceutical sector. One was Radical IP Scenario #1 (RIPS #1). RIPS # 1 was proposed by Tim Hubbard from the Welcome Trust, and James Love from CPTech.[8] It included the new trade framework described above to replace TRIPS as the solution to the global free rider problem. Then it recommended a particular country implementation strategy, using the US as its test case.

The US would be unlikely to be constrained by the multipliers described above, because it is already far above average in terms of funding R&D. The US currently spends more than $100 per capital in public sector health R&D, and spends nearly 2 percent of GDP on pharmaceutical sales, making it an outlier in both public and private spending. The treaty was mostly important for guaranteeing that the rest of the world would not free ride on the considerable US willingness to pay for R&D, should countries be allowed to ignore the TRIPS framework for medicines.

The themes and assumptions for the Ottrott-le-Haut proposal were as follows:

Current Pharmaceutical Market

- High fixed cost low marginal cost goods
- Major efficiency and ethical concerns over access
- Innovation is decentralized and highly competitive
- Marketing is dominated by handful of large firms
    - Marketing costs are huge and inefficient
    - Much non-price competition
    - Corruption of evidence base
- Very inefficient private R&D agenda
    - Excessive investment in me-too products
    - Too little investment in innovative or priority products
- An inefficient IP system
    - Costly to administer
    - Used to achieve anticompetitive ends

RIPS # was a no intellectual property rights scenario. The business model for drug development would not depend upon a post development marketing monopoly, or indeed on any monopoly.

[8] While this scenario benefited considerably from the thoughtful criticisms of Aventis, it in no way has been endorsed by Aventis.

Updating slightly the assumptions from the Ottrott-le-Haut exercise,[9] the stylized facts were assumed to be:

US market:

Sales = $200+ billion

R&D at 10 to 15 percent reinvestment rate = $20 to $30 billion

Elimination of IP leads to declines in prices and outlays,

Outlays if every product is sold as generic = less than $50 billion

Savings at least = $200 - $50 = $150 billion before funding R&D

The challenge was to replace the $20 to $30 billion in IP driven R&D expenditures, using the $150 billion in reduced outlays from using generic drugs. Obvious, the savings were huge relative to assumed R&D outlays, so it was mostly a problem of creating a management system that would be efficient.

RIPS # 1 proposed funding for R&D from mandatory employer contributions -- $100 to $200 per dependent in our exercise. In return for making these contributions, the employer benefited from lower outlays on pharmaceutical drugs, as every drug would be marketed as a generic drug, driving prices closer to marginal costs. At $200 per dependent, there would be a considerable increase in total R&D outlays.[10]

The next step was to identify who would manage the money. We proposed a system of licensed intermediators that would act as investors in R&D. The government role would be primarily to ensure transparency and accountability. We proposed the intermediators compete for allocations of R&D funding. The competition could take place in different ways. Among the models discussed were:

1. Committees of experts could allocate funds based upon objective measures of R&D outcomes.

[9] The stylized assumptions in Ottrott-le-Haut were:
US market: Sales = $178 billion, R&D at 15 percent reinvestment rate = $27 billion
Elimination of IP leads to declines in prices and outlays,
No IP outlays = $45 billion, Savings = $178 - $45 = $134 billion.

[10] Even higher per capita outlays on R&D were feasible, and still far cheaper that supporting the current IP system, given the current outlays of $660 per capita for medicine.

2. Intermediators would directly solicit funds from employers, just as pension fund managers. Small employers could job larger investor groups that could afford to conduct due diligence.
3. Combinations of (1) and (2).

Intermediators would be free to adopt any number of different strategies to achieve R&D objectives. They could have open source development models, contract research, grants, prizes, and other mechanisms. Competition for allocations was designed to ensure that the business models that were empirically successful would be rewarded, and the ones that were not would fail.

Key features of this approach were the high values we placed upon decentralization and competition.