

The CP Tech proposal has in my view several merits and some important shortcomings.

The main merit is that it provides a concrete suggestion for obviating to the failures of the current system in raising funding and above all in allocating resources to research towards neglected diseases and – more generally – health care for the poor. The proposal starts from the premise that the current system – which is largely, although not exclusively, based on intellectual property rights – has substantially failed in these respects. This in my view correct.

The patent system has worked so far in a relatively efficient way in the field of biomedical research, contributing to promote and sustain innovation. It is therefore a legitimate question whether it is wise to “fix something that is not broken”. However, it has to be remembered that some of the negative effects of the patent system – particularly those linked to resulting high prices of drugs and difficult access to those drugs by less affluent people in rich countries - have been partly counterveiled by a host of different mechanisms, including price controls in most countries, insurance schemes, etc.. Moreover, the Intellectual Property Rights regimes in biomedical research have been relatively lenient and balanced. For example, in most European countries including Germany, Switzerland, France, Italy, Sweden, etc., product patents have been introduced in the 1960- end of the 1970s. It is also important to consider that biomedical research has been critically supported by public funding and by a regime of open circulation of scientific knowledge. More generally, innovation in the pharmaceutical and biomedical field has resulted from a highly complex and variegated system which includes a large variety of agents and networks of relationships among them, ranging from large pharmaceutical corporations, biotechnology companies, academic research, non-profit institutions, etc.. Finally, monopoly power resulting from patents has often been temporary and short-lived, thanks also to quick “inventing-around” activities by competitors. Indeed, the pharmaceutical industry has been unusually highly competitive as compared to other R&D and marketing-intensive sectors.

In more recent times, several factors have tilted the delicate balance inherent in patenting regimes legislation towards a much more aggressive stance. Market structure in pharmaceuticals is becoming much more concentrated than it traditionally used to be. Furthermore, the issue of access to drugs by poor people in both the North of the world and quite obviously in the South has reached extreme levels of economic inefficiency and moral unacceptability. At least, from these perspectives, the current system is actually “broken” and needs certainly profound changes. It is also worth noting that the pharmaceutical industry itself is undergoing deep and painful transformations. According to various analysts, the traditional business model that has characterized the industry since the end of World War II is no longer viable. While I personally do not entirely subscribe to this view, still there is room for more than legitimate doubt in believing that a further strengthening of the IPRs regimes is the appropriate answer to the problems that characterize the current system.

Thus, a proposal that seeks to suggest alternatives has to be welcomed and deserves attention and discussion.

The second main merit of the proposal is that it does not suggest one specific and rigid mechanism to support biomedical R&D, but it rather invokes flexibility and encourages experimentation with alternative schemes. Such possible alternative mechanisms are indeed poorly understood and – although historical experiences exist in using some of them – poorly experimented with, at least as compared to the patent system. Thus, some degree of experimentation in this domain is a valuable objective.

The third main merit is that the proposal highlights the global nature of the problem and suggests a framework where attempts at solving the current failures of the system are indeed placed in the global arena.

The fourth main merit is that the proposed Treaty emphasizes the value of open access to knowledge and to its circulation, at times when this principle is increasingly challenged.

The shortcomings of this proposal fall mainly in two categories. First, there is an issue of political feasibility. In this respect, there are many reasons for remaining highly skeptical in this respect. Yet, even if the proposal only served the purpose to focus attention and awareness on new opportunities, a valuable goal would have been already achieved. In any case, I won't comment on this aspect.

Second, the proposal lacks of clarity in many fundamental respects. As Professor Rochelle Dreyfuss noted, the main issue concerns how the co-existence of the patent system with alternative mechanisms for funding medical R&D is going to be dealt with. My understanding of the proposed Treaty is indeed that it does not suggest to abolish the patent system, but to complement it with alternatives schemes, which ought to soften some of the main drawbacks associated to excessive patent protection. In this respect, the objection raised by DiMasi and Grabowski – that substituting the patent system with some kind of central planning would be extremely dangerous – is very serious and important but not entirely compelling in my view. In fact, the patent system and other mechanisms are envisaged to co-exist (and perhaps to compete). And even today, the patent system is certainly not the only mechanism supporting R&D in pharmaceuticals as well as in other industries. Nor any kind of publicly supported scheme must necessarily be managed in a Soviet style. The question might therefore be what kind of changes are needed and how revolutionary they ought to be. As I said before, experimentation might be useful here, absent any obvious optimal solution.. However, the proposal says little about these problems. Probably, the discussion and the design of such schemes, let alone their practical implementation is thought to be left to the negotiations among the participants. Yet, this is a critical point which ought to be clarified.

A second problem concerns the contribution of countries to medical R&D, which should come as a percentage of GDP. Di Masi and Grabowski are correct, in my opinion, in suggesting that fixing a percentage might not be a completely efficient way of deciding how much is to be spent – by each country – for medical R&D, since the optimal spending depends on a host of variables ranging from technological opportunities, to the medical needs of each country, etc.. However, absent any clear and obvious way to determine how the optimal expenditure should be, a rule of thumb looks as a simple and practical, albeit imperfect, alternative. Di Masi and Grabowski note that profit motivated decisions by firms could better reflect costs and opportunities of R&D investments. This is correct, but only to the extent that such decisions reflect only the private and not the social value of R&D. Moreover, targets expressed as fractions of GDP are ubiquitous in other economic domains – e.g. the Lisbon agenda in the European Union, public deficits, etc.. The logic of these targets is highly controversial, but they could be thought of as commitments meant – among other reasons – to provide credibility to announced strategies. It has also to be noted that – of course - the indicated fractions represent floors, not ceilings. So, each country would be obviously free to raise expenditure above the limits. However, it is often in the very nature of these targets that they tend to become “focal points” to which agents converge. This effect might actually produced unintended results, lowering expenditures in some cases.

Related to this point there is the question of the extent to which such a distribution of the contribution to expenditures might be considered fair, especially by those countries which now disproportionately contribute to medical R&D. In this respect, the proposal does not clarify how much the overall funding of medical R&D might be increased or decreased, also because - if I understand it well – all kind of medically – related expenditures including “*purchases of relevant medical products (to the degree that such expenditures induce investments in medical R&D)*” are considered as acceptable method of finance. Does this imply that e.g. purchases of high-priced patented drugs in the USA and Europe would be considered as fulfilling the obligation of the Treaty? Only to the extent that they stimulate R&D? How would that incentive be calculated? Note

also that this provision might have the perverse effect of discouraging any measures aiming at reducing the prices of drugs (like price controls, auction-based price fixing mechanisms, even the diffusion of generics, etc..).

In general, the whole proposal is quite vague in many fundamental aspects. As I mentioned earlier, this vagueness is not necessarily a drawback, to the extent that the definition of this issues has to be left to the negotiation among members. However, a considerable disagreement is likely to emerge among countries, raising serious concerns about the very political feasibility of this proposal.

As a final remark, the question has to be raised about alternative routes for securing sustainable funding to medical R&D and more broadly to design a system that is capable of generating high rates of innovation as well as fair and efficient access to drugs and treatments. There are a host of different issues at stake here.

One is certainly funding of R&D, i.e. providing resources to sustain research, especially in neglected areas. Another issue concerns incentives. (Funding and incentives are not the same thing: just think of an academic research team, fully motivated by non-profit motivations, but still constrained by lack of funding). A third issue regards the organization of the innovative process and its integration with the development, production and actual delivery of drugs.

The current, largely patent-based system provides a partial and imperfect solution to these problems: it creates incentives and funding at the same time for R&D. Insistence on a tight patenting regime by the pharmaceutical industry is partly – but not only - motivated by the fear that rising costs of R&D can no longer secure high rates of innovation and profitability. But if funding of R&D were the only problem, other mechanisms, including at a least partial socialization of clinical trials could be a (controversial, imperfect and difficult to implement, but worthwhile exploring) option.

Yet, the pharmaceutical industry in its golden age contributed to a further fundamental economic function, namely to integrate research, development, production and marketing of drugs. This business model is now under strain and the question is increasingly raised whether it is still viable. Vertical disintegration and specialization of the various stages of the process appears to be a significant trend in the industry, with increasing outsourcing of preclinical R&D, clinical trials, etc.. However, serious questions remain in my view about how the interfaces and the integration of all these different activities can be effectively and efficiently achieved and what a new system might look like.

The CPTech proposal deals only with the funding of R&D. I am not entirely sure that separating so bluntly R&D from everything else that is needed to deliver drugs to the public is conceptually and practically useful.

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