How much will the vaccine cost (if ever discovered....)

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1 Pricing the vaccine

At the end of February 2020, when the Covid-19 pandemic was beginning to spread in Europe and North America, Alex M. Azar, the Trump administration's Secretary of Health and Human Services, had an official hearing before the US Congress to discuss the public health policies that the administration intended to adopt and their impact on the US budget. During the hearing, Secretary Azar, after declaring that a vaccine against covid-19 could be ready for testing in 3 months (a statement that proved grossly overoptimistic), also made an interesting statement on its likely price: "We would want to ensure that we work to make it affordable, but we can't control that price because we need the private sector to invest". Faced with this statement, 45 members of Congress sent a letter to President Trump the next day asking that the Department of Health not grant any exclusive license for a coronavirus vaccine or cure to a private enterprise if the research leading to these treatments was partly financed by public funds. More generally, the letter argues that granting monopoly rights on these pharmaceutical discoveries could result in excessively high sales prices, with strongly negative consequences on public health and on the budgets of households and government. If these excessive prices were actually charged—the petitioners argued—the government should intervene and take all necessary measures to ensure that treatments and vaccines be available for all at affordable prices.

Secretary Azar on the one hand and the signatories of the letter on the other pose a fundamental question: in a capitalistic market system, companies are free to invest resources in research and innovation if and where they expect high returns on these investments. Therefore, as Secretary Azar claims, if we want pharmaceutical and biotech companies to invest in the search for covid-19 vaccines and treatments, we must offer them the prospect of high returns, that is, we must give them the opportunity to sell medicines and vaccines at prices substantially higher than production costs.

Our economic systems have created and developed a special tool to guarantee these high returns for innovators: patents. Patents "reward" innovators with

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monopoly rights for a given number of years (normally 20). But this monopoly right—argue the 45 signatories of the letter—will inevitably result in high prices, reduced quantities and a redistribution of well-being to the detriment of the consumer and in favour of the producer. At this point, however, Azar would probably rebut that it is true that the monopoly power granted by patents reduces the well-being of consumers of the new medicine compared to a hypothetical situation in which this medicine was sold under a competitive regime. But, without a patent, this medicine would probably not exist at all because no company would invest in an innovation that competitors could easily imitate. Therefore, Azar would argue, the real comparison we have to make is not between a vaccine or treatment sold at either monopoly or competitive price, but between a vaccine sold at monopoly price and no vaccine at all. Monopoly and high prices would therefore be a sort of inevitable lesser evil, a price that society must pay for the treatments and vaccines that otherwise would not be invented by profit seeking firms.

Who is right? Azar or the signatories of the letter? In my opinion, the signatories of the letter, for at least two orders of reasons. First, Azar raises a real problem, that is how to encourage the production of innovations by private companies in a market economy, but assumes that patents are the best solution to this problem, while I think they are not. Secondly, it takes for granted that the market is the economically and socially best way to solve a problem such as finding cures and vaccines that block or at least reduce the effects of a pandemic such as that caused by covid-19.

2 Patents

The fifteenth century saw an imposing migratory wave from Byzantium to Europe and, in particular, to Venice. Migrants included a large number of craftsmen, engineers and artists. With the aim of promoting and encouraging the stay in Venice of persons of talent capable of promoting and increasing the power and well-being of the city, the Senate of Venice promulgated in 1474 the first statute on patents. It was established that craftsmen, engineers and artists who established their residence in Venice for a sufficiently long period of time and invented something useful and new would be granted the right to be the only one to commercially exploit the work of their talent for 10 years. In exchange, the inventor was committed to reveal the technical details of his invention before he could leave the city.

The Venetian statute allows us to immediately grasp the meaning of patents as a social institution: the right to commercial exploitation of a discovery in exchange for a commitment to make it public. But since the industrial revolution and especially in recent decades patents have profoundly changed their nature, becoming intellectual property rights.

Does it make sense to confer property rights, albeit of limited duration (but 20 years is a very long time in the life of an innovation), on innovations, that is, on new knowledge? The answer, in my opinion, is no. Property confers a right of exclusion: if I own, for instance, a parcel of farming land, nobody can use it without my permission. This right of exclusion, economists say, serves to avoid problems of over-exploitation of the resource that would occur if the resource were accessible to

all (Hardin 1968). The solution is to confer a monopoly of exploitation on a single subject. Moreover, ownership can be transferred in a market and if the latter works properly the parcel of farming land will go to the best user, i.e. to the farmer who can maximize its yield (Coase 1960).

But if we consider knowledge rather than land or other material resources this line of reasoning does not stand up. Knowledge is not an exhaustible resource such as agricultural land or fish in the sea and therefore it is not subject to any risk of over-exploitation. Quite on the contrary, knowledge typically progresses in a cumulative way and therefore, contrary to exhaustible physical resources, if we want to maximize the growth of knowledge we should maximize its diffusion.

Moreover, knowledge is not only non-rival, but also infinitely expansible (Quah 2003) and cumulative. Thus the issue of allocating it to the most productive user is meaningless and counterproductive. In the short run it does not make sense to allocate to one individual or company a resource which is not scarce, but even more so, in the long run, we cannot know *ex ante* in which directions the future cumulative developments of this knowledge will take place and which agents are more likely to contribute to them. Thus, from this point of view, society maximizes the future growth of the stock of knowledge by making it public.

It is no coincidence that Western science and culture have been progressing for thousands of years thanks to the mechanism of publication and mutual sharing, that is, an institutional mechanism opposed to ownership, exclusion, monopoly. This is true of scientific knowledge but it is equally true of technological knowledge (assuming that the division still makes sense today).

Using the right of exclusion to guarantee the innovator's remuneration does not make sense, because it creates an artificial scarcity in a resource that is not scarce and that on the contrary tends to increase and improve as the number of those who share it grows. Secondly, ownership always creates a monopoly, with the associated social costs deriving from it. Now, if this monopoly concerns, for example, small or medium-sized agricultural land, such social costs will not be very significant because there will be some other similar and equally productive land. If instead the monopoly is given on an important discovery or innovation which is by definition unique and has no substitutes, the social cost deriving from the monopoly will be very high.

In this regard it can be argued that the pharmaceutical market is probably the one in which the social damage produced by a monopoly is the highest possible. I make this claim for two reasons. First, the pharmaceutical market does not exist, at least if we look for it from the demand side, but there are as many sub-markets as there are pathologies and these sub-markets are often totally separated. This generally does not occur in other markets that are indeed segmented but where usually there is cross competition between different segments. In the pharmaceutical sector it generally does not work like this: if I have to get vaccinated against covid-19 I need this particular vaccine and a vaccine against e.g. measles will be totally useless. Therefore in the pharmaceutical industry, especially for serious and important diseases and for truly effective medicines, monopoly power is much stronger than in other sectors because sub-markets are naturally impervious to competition from other sub-markets.

Secondly, the elasticity of demand for important medicines, life-saving or otherwise capable of curbing or treating diseases with a high individual and social impact, is certainly very low as there are no substitutes and the alternative to consumption may be a serious threat to life. In conclusion, the pharmaceutical sector is a true monopolist's heaven and a potential hell for the consumer. It is therefore truly surprising that in our economic systems there are on the one hand anti-trust laws and authorities that prohibit and punish monopolistic behaviour and on the other legislation protecting patents that create monopolies precisely where monopolies can be more harmful to the community.

Finally, this extreme protection of the interests of pharmaceutical companies does not seem to have even created the benefits in terms of innovation that its defenders hypothesize. According to many empirical studies, the sector's innovativeness rate is declining, and in many fields important to public health, investments and innovations have been scarce or non-existent for many years. For obvious reason, "Big Pharma" R&D effort have been more and more concentrated on "blockbuster" drugs for chronic disease: the perfect customer for a pharmaceutical company is wealthy, chronically ill, hypochondriac and a maniac pill-popper. Cancer, diabetes, cardiovascular diseases, and erectile dysfunctions are attracting most of the R&D investment. Infectious diseases and vaccines on the contrary attract little interest because they are for once-for-all uses only and if effective they tend to kill their own market. It is well known for instance that efforts to find a vaccine against SARS have been abandoned when the SARS pandemic slowed down, but, if pursued, could have put us in much better conditions for a vaccine against Covid-19. The team at Oxford University which is now in a leading position in the race for the latter vaccine has invested a lot in finding a vaccine for MERS, regardless the weak economic incentive offered by the limited spread of this epidemic. This point is very important and concerns again cumulative/sequential innovation: it may be the case that innovation A does not have a big enough market and incentives to produce it may be too weak. However innovation A may prove to be an essential step needed to produce innovation B which, on the contrary, may have a potential large market. Abandoning R&D in A may indeed be fully justified in term of market incentives but may cause a kind of adverse selection which may generate huge social costs in the long run.

3 Public-private

Azar's second mistake is that he overstates the centrality of private companies in pharmaceutical research, where on the contrary public funding always plays a fundamental role in the processes of discovery, development and pre-clinical and clinical tests of new medicines. For instance, Sampat (2009) has estimated that 7.7% of all approvals by the Food and Drug Administration (FDA) and 10.6% of NMEs are based on academic patents. Expanding on this analysis, Sampat and Lichtenberg (2011) explored the indirect contributions of public-sector funding to drug patents by characterizing the prior art referenced in these patents. Their studies show that, of 379 drugs approved in the period 1988–2007, 48% were associated with a patent that cited prior art generated in the public sector. Azoulay et al. (2019) find a strong

and highly significant multiplicative effect of NIH (National Institute for Health, the primary agency of the US government responsible for biomedical and public health research) funding for the private pharma industry. They estimate that each dollar spent by NIH in basic research generates \$2.43 of additional drug sales and that \$10 million increase in public funding generates 2.5 new patents. Galkina Cleary et al. (2018) found substantial US federal funding behind the development of all the 210 new molecular entities approved by FDA between 2010 and 2016, with a total government spending of more than \$100 billion. They also conclude that public sector investment for each first-in-class new molecular entity (i.e. a molecule that uses a new and unique mechanism of action for treating a medical condition) has been on average \$839 million and mostly concentrated in essential and more risky stages of basic research.

Also in the case of covid-19, the governments of many countries have already invested large amounts and research centres and public hospitals will have a fundamental role in basic research, development and testing. It is therefore not clear why knowledge generated with the taxpayer's essential contribution must be entirely appropriated by private companies. In this way, the taxpayer pays the research twice, financing it and then paying the resulting medicine at a monopoly price.

More broadly, the current pandemic raises the fundamental question of why major health problems that generate huge social costs and have gigantic impacts on public finances should not be tackled with large public programs that produce collective knowledge and innovations to be put at the service of collective well-being. Programs for the exploration of the outer space or the investigation of the inner structure of the atom have been managed by public agencies like NASA or CERN, why should not we promote similar programs to treat covid-19 and other important diseases with a strong social impact? These large projects can and must involve private actors, both because they have fundamental knowledge and because it is good to promote a plurality of approaches. But private actors must be "subcontractors" of the public project and remunerated as such, unlike what happens now, where we have public projects at the service of private companies (see Florio (2020) for an articulated proposal of a European research infrastructure). Notice that the recently developed "EU strategy for Covid-19 vaccines",¹ although very important and generously funded, does not go into this direction as it is based on two pillar: using regulatory flexibility to speed up testing and approval of vaccines and, especially, securing mass production of the vaccine once approved. The latter aim will be pursued by recurring to Advance Purchase Agreements with pharmaceutical companies, but no mention is made to possible interventions on the patent protection of the vaccine.

¹ https://ec.europa.eu/info/sites/info/files/communication-eu-strategy-vaccines-covid19_en.pdf

4 Are there alternatives?

Back in 1958 Fritz Machlup expressed in the clearest way how the patent system, far from being a socially efficient institution, has however consolidated because of path dependency, vested interests and lack of viable alternatives:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it. (Machlup 1958, p.80)

In addition to the theoretical arguments that I briefly summarized in the first section of the paper, there is a vast more empirically oriented literature criticising various aspects of the current patent system and how such aspects are the product of an evolution of the system which has pushed a delicate balance more and more towards the interests of the producers/innovators and towards a legal framework which more and more espouses the view of patents as property rights with the kind of “sacred aura” that property enjoys in our legal systems. I cannot summarize this vast literature in this short note but, among the many publications, the reader can refer for instance to Bessen and Meurer (2008), Hall and Ziedonis (2001), Dosi and Marengo (2006), Moser (2013).

Roughly speaking these criticisms focus on the following themes: (1) the role of patents in the appropriability of the benefits of innovation is overstated because lead time, learning curve, complementary assets are often more important and because imitation is often very costly and difficult (Teece 1986; Levin et al. 1987); (2) patents are more and more used not for their original aim of incentivizing innovations but for strategic purposes, e.g. as means for entry deterrence, for blocking rivals’ innovations, for infringement and counter infringement suits against rivals, as ‘bargaining chips’ in the exchanges of technology among firms and to signal to financial markets likely streams of future profits (Jaffe 2000; Hall and Ziedonis 2001; Winter 2002); (3) the patent system has huge administrative and transaction costs. In many industries the expected costs of patent litigations exceed the profits derived from patents. This means that in these industries patents likely provide a net disincentive for innovation (Bessen and Meurer 2008); (4) in cumulative (or sequential) and complex (i.e. products and technologies which combine a large number of interacting bodies of knowledge and components) technologies strong patents can actually prevent innovations because additional progress is often stopped by lots of pending patent (Bessen and Maskin 2009; Marengo et al. 2012).

Are there alternatives to the current patent system? In principle the solution would be to give incentives to innovation but without monopoly rights. Extending and institutionalizing compulsory licensing, which already exists in most patent laws and in the TRIPS agreement in case of national emergency, could be a relatively easy way to strike a more equitable balance. For instance, the patent office could still grant patents, but would also issue unlimited licences and levy a

(decreasing) tax on the licensees' sales which would be transferred to the patent holder and reward the innovative effort. Alternatively, licenses could be allocated on a continuous auction market where also licensees could issue and sell additional licenses. In this way a stream of profit could flow to the innovator but the price of the drug would quickly decrease towards marginal cost.

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