The Social Responsibility of Scientists

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In order to deal with the matter of the social responsibility of scientists it is necessary to consider the different discursive dimensions involved, not only in the paradigm of modern science, and in the abstract construction of Democracy, but also in other practical implications of a theoretical, economic, socio-political, public health and ethical nature which condition the development of bio-sciences in contemporary societies. For determining the limits of responsibility it is necessary to carry out a preliminary analysis, which relates the theory of responsibility to life's material conditions, to the legal and political regulation of these activities and the final aims that motivate technosciences. Only after having specified what the context of discovery and the context of the justification of present-day's biosciences constitute, it will be possible to outline where the scientists' responsibility lies. This paper has a more modest scope as, although the abovementioned co-ordinates are presupposed, here we will restrict ourselves to illustrate the difficulties, both theoretical and practical, that those carrying out the research find; those whose intention is at the same time to give an answer to society regarding the objects of knowledge and the means that science promises in the form of resources, in order to transform nature -more specifically, in order to meet health demands.

I. ON THE THEORETICAL CONTEXT OF RESPONSIBILITY

Points on the Responsibility of Scientists

After the bomb drop on Hiroshima and all the following discoveries made in molecular biology and genetics, the comfortable peace which reigned in the conscience of "natural" scientists disappeared; significant proof of this is R. Oppenheimer statement[1]: "the physicists have known sin and this is a knowledge which they cannot lose", as well as Paul Berg's subsequent initiative and his proposal for a moratorium on DNA research, which he presented to the scientific community and which was agreed upon in Asilomar (California, 1975). Along the lines of the new awareness of responsibility on the part of the scientific community, other later initiatives can also be reported, such as the proposal for an ethical evaluation of the Human Genome project -ELSI: *Ethical, Legal and Social Issues*- on the initiative of James Watson, as well as the general prohibition of human beings cloning. From this point of view, it can be affirmed that, within a wide sector of natural science researchers, there is a clear internal commitment to "responsibility", linked, in the majority of cases, to the carrying out of research activities. But as well as this, the scientific community has felt the external pressure in the form of a protest from a wide sector of public opinion, which has forced governments to take regulatory initiatives on the results of this particular professional activity. The full implications of bioscience in some of its applications is questioned by various social groups which demand the protection of the right to public health as it constitutes an important part of "human welfare"[2].

Which Responsibility does the Researcher have Insofar as the Result of His Research is Concerned?

Before answering this question, it is necessary to make some conceptual clarifications; firstly, "responsibility" is not the same as "obligation", but rather a particular part of it. Obligation might underlie certain behaviour. Responsibility goes further than that, it has an external reference[3]. In this sense, it can be affirmed that the researcher has the obligation to properly carry out his scientific activity, which would form a part of science's very *ethos.* At first sight, it might seem that there is no overlapping whatsoever between the two, if we leave internal morality aside; that is, loyalty to the mandates of science itself. For science, the only value is *knowledge*, its sole aim to achieve such knowledge; this affects the behavioural norms of the scientist themselves. Said differently, this attitude would coincide with territorial ethics, deontology, necessary in the world of science, whose principles - laxly expressed - are: to comply with the rules of the method and the proof, not to deceive by means of isolated conclusions or frivolous experiments, not to omit verification of their results, etc. In short, intellectual *rectitude* and *rigour*. From the point of view of internal ethics, these demands are no more than the imperative to be a good scientist rather than a bad one, and they establish no relationship between the

internal conduct desired from a scientist and the world outside.

The same could be said of personal virtues: dedication, perseverance, and the strength to overcome one's own prejudices: these are merely conditions for the work to be carried out successfully, although they might also be eloquent individual qualities. Lastly, the obligation of the researcher to communicate the bases of his findings and the results to the scientific community would seem to grant intrascientific morality something of a social and public dimension; but, in fact, given the increasing collective nature of scientific ventures, intercommunication[4] forms a part of the technical conditions in order to obtain good achievements in science; in this respect also scientific morality continues to be strictly "territorial" and the scientific collective is only obliged to comply with professional imperatives. Seen in this standard way, science would constitute a moral island, an affirmation which we are far from being able to sustain.

And that is because today, at least, a good scientist is subjected to responsibilities that exceed his professional work, because from his cognitive work applications with profound consequences for individual health and society as a whole are derived. Consequences that are already inscribed in the design of the very research to be carried out, as a part of the aims to be achieved, or as "undesired" consequences in the application foreseen; and this is because in biotechnology today -with the exception perhaps of astronomy- theoretical interest and practical interest combine indissolubly. This is especially relevant in the branches of natural science that affect health, reproduction and aesthetics in its three aspects: clinical, therapeutic and pharmacological. In the latter, the search for practical applied ends is imposed on the researcher in advance; for this reason, the scientist who manages to achieve the solution to the problem posed, almost automatically becomes an appendage of those who promote and profit from the solution discovered. In accordance with these real dynamics, it can be assumed that the responsible scientist could act in some "other" way, for example: refusing to be involved in certain areas of research, or keeping the results of his research secret. Both .. these options, if they were possible, would not only be useless -on account of the social conditions under which scientific research is carried out today- but furthermore the scientist who decided to exercise his responsibility negatively would fall into the violation of a positive obligation: that of using his research to serve ends which benefit and favour the health and life of living beings and of those yet to be born.

In the present-day context of discovery, it is not in any way strange for a researcher to suffer when he realises that society has undervalued the consequences of his research, especially when these are the consequences that determine his responsibility, not now as a specific researcher, but as a member of a social group, obliged to give its opinion on what is admissible and what is not. That is to say, regardless of the consequences that new discoveries might have insofar as biotechnological knowledge itself is concerned, the importance of such research in non-scientific circles, with repercussions throughout society as a whole, both on a symbolic and a material level.

What has been written up to this point regards some of the difficulties that "researchers' responsibility" present, and after such a brief introduction we could be tempted to leave things as they are and not probe the matter any further; however, this would be an irresponsible act. The question of the responsibility of scientists, in fact, is today a challenge that affects not only the internal conditions under which researchers carry out their work but also the external relationships that can be established between the aims and the means of biotechnologies, the principles of social organisation on the basis of which science, as a social undertaking, and very specially, affects the human beings who need the resources that biotechnology provides. For this reason, although dealing with this matter entails dangers, especially if one's intention is not to have the final word, we have to start to deal with the question of self-censorship of science, marked by responsibility, somewhere.

One way of clarifying this matter would be -along the lines of what has been pointed out above- to delve into the knowledge of the scientists' movement who, in Asilomar, put forth their demand for self-responsibility. By means of this analytical-sociological study, the key points regarding scientists' concerns could be clarified, as well as the reasons why they subsequently supported suspending the moratorium; also, by way of example, the complete sequence of the movement would help identify the type of "responsibility" they demand. However, in parallel with this task, it is necessary to become aware of some of the theoretical and practical difficulties that exist on the basis of the standard modern definition of science, in contrast to the characteristics of present-day's biosciences and the use which other corporate and economic authorities make of them. Only after such an analysis the conditions necessary to begin to talk of the "responsibility" of scientists can be specified.

The theoretical difficulties we refer to are fundamentally two: the first consists of the supposition that "science has no moral values", with the exception of the value of "truth" in itself and the search for such truth; the second derives from the unconditional acceptance of the assumed "right to the freedom of research", seen univocally as a *fundamental right.* Both assumptions are interrelated, although they are of a different nature; the postulate that "science leads to enhancement" can be looked at from two angles; a) on the one hand, it contains an imperative directed to the scientist: be objective, separate your values from the research you are carrying out, act as if you were an impartial and neutral observer, that is, be objective! This dimension has a clear methodological reach: it justifies the fact that for the scientist the only thing relevant is the *truth* of the object taken into consideration and that as an "object" of scientific knowledge it excludes all doubts of belief, but also establishes itself as an *a priori* to any attempt of regulation made outside the scientific community; b) the second meaning of the abovementioned postulate affects the *object* of knowledge itself: this is seen in itself as *neutral* when confronted with any value and as such science has to "see it". "Beyond the admonition to eliminate subjectivity in favour of values in the interest of objectivity, here a judgement is being made on the thing itself, the very nature of things is even on trial" (H. Jonas, 1997: 58). It is quite clear that this second implication of the postulate has an extremely important ontological and epistemological scope insofar as the self-legitimisation of modern science - to which undoubtedly the positivists of the Vienna Circle contributed decisively- is concerned, although today this thesis has been philosophically refuted by H. Jonas, among others[5].

Obviously, thus characterised, the two internal principles on which modern science is based, indifference to values, with the exception of the "truth" and the exclusive "freedom" the scientist has to determine, know and manipulate the object of his research, become an unquestionable dogmatic interpretation. From this theoretical interpretation, at least two important consequences relating to social responsibility follow: first, it allows scientists self-legitimisation and, secondly, it puts up a barrier, on which we can discuss but it still remains a powerful barrier, against public regulation of the right to the freedom of research which, as happens today, might also be a *patrimonial right*. H. Jonas refers to this aspect when he affirms that: "The freedom of research only becomes an ethical problem in the relationship between the inter-human and public commodity, with which it can come into conflict and this as much for the procedures of modern research as for its results." (Jonas, 1997: 63).

With Regard to the Freedom of Research and Its Conditions of Possibility

"Freedom of research" is one of the most important political and legal postulates of modern Western culture and from an early date it began to carry out a special function in relation to the general notion of "freedom". This meaning of "freedom" has not only been put above other supposedly more contingent meanings, but it is, moreover, the only one whose foundation would seem to be unconditional and, therefore, not limited by conflict with other rights. But if we look more closely into the question, we can see that there is a secret contradiction between the two halves of this affirmation. Because the special position the world has reached thanks to the freedom of research is to a large extent an external position of *power* and possession; i.e., acquired by the transformation of investigated knowledge into action, while the … unconditional nature of freedom of research has to base itself precisely on the fact that such activity, together with its internal objective, "*knowledge*", is strictly separate from the sphere of action. Thus, in theory, as we know and in relation with action, all liberties have limits insofar as *responsibility*, the *law* and other *social conditions* are concerned. In any case, up until the present day this right has been considered a supreme one in itself, an obligation even, and -except .. what is intimate and private .. - it knows no limits, as it is affirmed that [being] "inside a head can hurt no-one and the part of it that one has does not reduce the part of another, quite the opposite (…). Thus, neither does the process of its appropriation - …- interfere with any right of others; as such, within this enclave, freedom can be absolute." (Jonas, 1997: 65). Expressed in other words, the untouchability of the right to freedom of investigation is consolidated in the formal supposition that research as such, be it neutral and enhancing, poses neither moral nor social problems.

When we confront this traditional concept with the reality of present-day scientific ventures, the perception is that there is no correspondence; that perhaps it could have been true when the contemplative aspect of science was clearly separate from the applied aspect, as could have happened in pre-modern times, when theory made no in-roads into the practical spheres of daily life. At that time, knowledge could be contemplated as a private possession of those who

owned it, an internal possession which could do no harm to the others' well being and a knowledge aimed at understanding things, not changing them. Then, the diffusion of such knowledge was considered dangerous sometimes by the Church and the authorities for the *well-being of society as a whole*; but those in power had the coercive words and the means to refute any danger and, furthermore, in the event that new ideas were spread among the general public, all they had was a power to convince people; but they were of no use insofar as the manipulation of nature's objects and beings were concerned.

All of this legacy regarding the classical contemplative tradition fell apart with the growth of natural sciences at the beginning of the Modern Age (16th-17th Centuries). Their arrival heralded a radical change in the relationship between theory and practice, aimed at bringing the two ever closer together. Even so, the fiction surrounding "pure theory" and its essential "innocence" has survived. Under the generalised slogan of freedom of thought, word, movement, etc., scientific research could also have had the right to demand unlimited freedom for itself, but in a strange polyphony with the promise of a palpable and beneficial result for everyone, which contradicts the affirmation of its theoretic insularity. The promise of utility implicit in the model would have been complied with on a large scale only after the Industrial Revolution in the 19th Century and at present it places the emphasis in favour of science because of the practical benefits that can be achieved.

From the middle of the 19th Century, and ever-faster in the 20th, we witnessed a more and more irresistible transformation from the theory, however "pure" it might have been, to the common field of practice in the form of scientific technique. In the end of it all, the premonitory mandate of F. Bacon (1561-1626), urging the achievement of *power* over nature through research and the elevation of the material state of the human being through such research has become an active truth beyond all expectation. Therefore, in order to come closer to the conditions which can make the external responsibility of scientists possible it is necessary to look at the material transformations brought about in theory and in practice, which have a notable impact on research conditions, and at the reasons why the old interpretation which clearly distinguished between "pure theory" and "applied theory" constitutes today a justification for omitting true responsibility. At present, therefore, no branch of bioscience whose discoveries can be used in a technical way exists. And this condition, insofar as the researcher is concerned, makes it impossible for him to determine the object and carry out his research unconditionally, and not only because he needs materials, facilities, equipment, all in all, resources without which he cannot even begin a research project.

For all these reasons, it is said that science has undergone a process of change which allows it to be characterised by the following features: 1) At present, science depends to a large extent on the intellectual *feedback* which precisely provides it with its technical application. 2) From this, it receives its mandates: what direction to look in, what problems to solve. 3) In order to solve such problems and, in general, in order to develop, it uses an advanced technique: its material instruments are ever more demanding. In this sense, even the purest science participates in the benefits of the technique, in the same way that the technique participates in the benefits of science. 4) The costs of this material equipment and of its handling have to been provided from outside: the pure economy of the thing demands the collaboration of public funding or other financial sponsorship and as such, foundation of the approved project, even if it is not linked to any compensation whatsoever, is naturally produced in the expectation of some later benefit in the practical field. This is where mutual-understanding reigns: the value of the expected use openly asserts itself with the request for subsidies as the foundation of its recommendation, or specifies itself directly as the aim of its offer.

In short, we have reached a point where the tasks of science are determined more and more by external interests instead of by the logic of science itself or by the free curiosity of the researcher. This does not mean that the intention is either to underestimate those interests or the fact that science serves them and has thus become in part a public-social venture. But it has to be said that, with this role (without which there would be no advanced natural science, but neither would there be the type of society that enjoys its fruits) the excuse of the pure and "unselfish" theory disappears and science fully enters into the realms of social action, where everyone has to be responsible for his/her actions. Add to this the ever-present experience that the potentialities of the scientific discovery use are irresistible in the market of *profit* and *power* - what biotechnology shows can be done is *done*, with or without prior consent in this respect- and it will be sufficiently clear that no insularity of theory can now protect the theorist from being responsible for the huge and incalculable consequences. Meanwhile, technically speaking, it continues to be true that someone can be a good scientist without being a good person;

it is not true any more that being a "good person" begins outside the scientific activity: the activity itself provokes moral questions even within that sacred circle. (Jonas, 1997: 69).

In this new constellation, where technoscience, its benefits and the new forms of life of individuals converge, we have to situate the matter of the scientists' responsibility, because from the impact of biotechnologies comes profound consequences for the real world, for human action and for the well-being of all of us; it is due to the far-reaching effects of the impact of biosciences in society that moral responsibility and legal limitations are called for. Above all because to continue maintaining the legal-political fiction of the existence of a right to an unconditional "freedom of research" is equal to conceal a social privilege capable of providing a power which transcends the private individual who professes to hold it; and this in order to hide the fact that such power serves powerful interests, from which the researcher himself cannot stand back, even if he wants to, in the name of a specific individual or social group in need, or in favour of common well-being. These facts cannot ask .. us the justification of what occurs, nor do they lead us to label all scientists irresponsible by affirming that if "the applications of their discoveries have nothing to do with their activity, then neither would they be responsible if they were used abusively". If carrying out scientific activity becomes an intervention in the social world, then it falls under the predominance of the law, the social and moral assessment which all external interventions in a common social system are subjected to; and in this process, it is interesting to look at the internal and external dimension of scientists' work because their work implies moral and legal questions which break down science's territorial barriers and have to be put before the general court of what is moral and what is legal; because in the face of the scope of the social problems generated, even the unquestioned freedom of research has to be subjected to public authority, in favour of the most disadvantaged sectors of society or of an adequate definition of what might be world "public well-being".

II. THE RESPONSIBILITY OF SCIENTISTS WHEN CONFRONTED WITH A PRACTICAL CASE: STAVUDINE AND HIV-AIDS[6]

1. The Research on the Retroviral Stavudine

The research team led by Drs. William Prusoff and Tai-Shum demonstrated in 1988 at Yale University's Medical School the properties of stavudine in treating HIV-aids. The base molecule on which they carried out the research had been synthesised in 1986 by Dr. Jerome Horowitz of the *Michigan Cancer Foundation*, and to carry out the research they had received public funding from the *National Cancer Institute*.

Stavudine and the four other antiretroviral of the nucleoside inhibitor family[7] were all invented in the United States with public funding. For the other new antiretrovirals (protease inhibitors and non-nucleosides) state funding backed up the research or the trial periods at some time or another. But it was private funds that gave the fundamental help. Dr. Prusoff recognises: "The contribution of private funding has not exceeded a quarter of the total of my resources in the thirteen years that I have led the research. But I have recommended that a license for stavudine be granted to Bristol-Myers Squibb [hereafter BMS], because our department had received an important grant from this company for many years to make anti-cancer medicines; I had a small part of that grant to do antiretroviral work. In exchange, BMS reserved the purchase right to any compound we produced. That is what happened with stavudine".

Since stavudine[8] was first marketed in 1994, it has earned Yale at least $261m (292 million euros) between 1994-2000. Making up for 90% of the University's royalty income, this medicine has meant that its intellectual property earnings are among the highest of any American university. Universities are in fact the owners of their inventions[9], even though at Yale, as at all other public centres, 80% of biomedical research funding comes from public via the *National Institutes of Health* (NIH).

But patenting an invention means nothing if the invention is not put on the market. In 1988, two years after filing its patent[10], the University granted pharmaceuticals giant Bristol-Myers Squibb (BMS) exclusive rights to exploit its invention. Thanks to this "exclusive license" BMS had a monopoly in all the countries where the University filed its patent: the United States, Europe, Canada, Australia, South Africa,... which means that the company was free to set prices as it wants: in certain circumstances it sold a 40mg tablet at an average of $4.28[11] (the recommended dose is two tablets a day).

Under the trade name Zerit®, stavudine has had a spectacular career. The cornerstone of tritherapy since 1998, it has become the most prescribed antiretroviral in the world. In two and a half years (from 1998 to the first half of 2000), BMS sold more than $2.3b worth, mainly in Western Europe and

United States. In South Africa, the country most affected by the HIV-aids pandemic[12], sales have been insignificant ($600,000 in 1998); most of the affected, in fact, cannot afford Zerit®, sold at $2.23 a dose

Yale in fact gives its inventors 30% of the fees it receives. Dr. Prusoff calculates that "in the last few years my share doesn't reach half the total, $5.5m or $6m a year". What is the receiving of such amounts based on? Has he not been doing his job as an investigator? "I am not a businessman, I admit, but why should universities let the pharmaceutical companies line their pockets with our inventions?". It is surprising that such a highly qualified person could be so naive, unaware of the economic intrigues that surround research.

2. Relations between Yale University and Bristol-Myers Squibb

The career of stavudine, as a medicine used in treating HIV-aids, is in this case exemplary. The molecule, which arose from university research, has been attributed exclusively to BMS, which has prevented it from being marketed in the countries most affected by the HIV-aids pandemic.

It could have been called the "Stavudine Building". The new building is near the *Medical School*, not far from the neo-gothic medieval-style colleges and libraries of Yale University in New Haven (Connecticut). Neither public subsidies nor enrolment fees have helped to build it. Half of the $176m used in this new building for research costs came from royalties on an Aids drug discovered and patented by the University.

Every year the New York Company sponsors the BMS symposium and the *Graduate Student Research Symposium* at Yale, which helps graduates in biomedical sciences to meet prospective employers. Certain senior BMS executives have held responsible positions at Yale and, as Jonathan Soderstrom, director of the *Office for Cooperative Research* and manager of Yale's patents and licenses, has said, the company has funded several research programmes in Alzheimer's disease, cancer, Aids and others.

The relations between the research centre and BMS are not limited to what we have mentioned above, as Dr. Prusoff states: "It is true that companies exaggerate the prices! But we depend on them. They perform an invaluable service: Yale does not have the technical or financial means to produce the compound; before the drug can be given to patients it needs to be approved by the *Food and Drug Administration* (FDA), which requires it be tested on human beings at costs that are extremely expensive; often drugs turn out to be toxic and millions of dollars have been invested and lost. Considering the risks, from the concept to the marketplace it costs between $500m and $800m."

Dr. Prusoff has been asked by the *New York Times* how they obtain these figures but admits that nobody knows where they come from: "*I hear them quoted all the time.*"[13]. In fact, they are provided by the *Pharmaceutical Research and Manufacturers of America* (PhRMA), the pharmaceutical companies lobby and *Tufts Center of Study of Drug Development*, a centre 65% funded by the drugs industry; according to both up until December 2001 the average cost of developing a new drug was $500m, but then the *Tufts Center* reassessed it at $802m. But this study only looks into a small part of the research process, that regarding what has been discovered and developed without state aid. And, furthermore, they add that half of that amount is at least virtual, it is the "opportunity cost", compensation to the private industry for the money it would have earned if invested on the stock market.

Exaggerated assessments of the risks and compensation, disregard for the tax benefits. However, in 2001, the independent organisation *Public Citizen*[14], calculated, on the same bases, the maximum cost of marketing a completely new product for the private sector to be $110m. How can we know how much is public and how much is private contribution? It is totally opaque. When the private sector invests $1000 in a new drug it puts the final cost to $2000 in order to cover the risks and the compensation. Els Torreele, a researcher in biotechnology and promoter of the MSF campaign on diseases overcome in the Northern Hemisphere, states: "When, however, the public sector invests $1000 in a drug, its final contribution will still be $1000 because it is a subsidy and not an investment. As such, the public contribution to research is widely underestimated. Worse still, the private sector has become accustomed to including public money in its own calculations in order to define the cost and price of a drug. The result is that the taxpayer pays for the same drug twice."

3. Commercialisation of Stavudine and the Exclusion of HIV-affected Patients Unable to Afford it

On January 15, 2002, Pfizer, the pharmaceutical industry world leader, agreed to hand over its accounts information essential for verifying the prices of the drugs to the feared US Accounts Office (GAO).

Another ten companies have done the same. In order to obtain this documentation, a formal writ from the GAO was necessary. In September 2001 the American authorities had forced Bayer to reduce the price of the treatment against anthrax. In fact, in the United States, as it is happening in Europe, alarm is growing over the excessive increase in the pharmaceutical industry's profit, between 15 and 20% of turnover. In rich countries, decisions on the production and pricing policies of laboratories involve some degree of blackmail and in poor countries the same decisions prevent the greatest number of people in need of health care the access to it; this is exemplified by the case of stavudine in South Africa.

Throughout 2001 Zerit® was at the heart of the battle to give the very poor access to medical treatment. The South African branch of *Médicins sans Frontières* (MSF) started the ball rolling. In February 2001 Dr. Eric Goemaere, in the name of MSF, contacted Jonathan Soderstrom. MSF asked the University for "authorisation to import [into South Africa] a generic version of stavudine in order to provide treatment free of charge to people with HIV/Aids. In his letter he also mentioned that if authorised to manufacture the stavudine generic drug, the Indian laboratory *Cipla Ltd*. would promise to do it "thirty-four times cheaper" than the Zerit® version."

Mr. Soderstrom, representing Yale, sent the letter on to the management of BMS who sent it back to Yale. At the end of February (2001), thirty-nine American pharmaceutical companies took the South African government to court for authorising the production of the generic drug alleging the need for "compulsory licenses" which the World Trade Organisation (WTO) authorises for granting patents in health emergencies. When all of this came to light, the Yale campus rallied and a law student, Amy Kapczynski, backed by the *Graduate, Employees and Students Organization* (GESO), circulated a petition in support of MSF's urgent request to manufacture the generic drug.

The petition was signed by 600 students, technicians and researchers, among whom was Dr. William Prusoff, 81, the "father" of stavudine who, furthermore, stated publicly: "Nobody should die for economic reasons, because they cannot afford the drug. And I would be very happy not to receive any more royalties if it meant that Aids was completely eradicated."

Like most of the Yale Medical School's researchers, Dr. Prusoff plays down the importance of his research and his capacity to influence the private company that exploits his discovery. "I can always give the company my opinion, but I can't promise they'll take any notice." he has said. It is clear that he does not oppose the students' initiative: even before they sent their petition to Mr. Soderstrom, BMS gave way. On March 14, the New York-based Company announced a huge reduction in prices in South Africa and promised not to go ahead and prosecute any generics manufacturer.

However, the outcome did not satisfy Yale's appetite: the University has not given up its stavudine patent in South Africa or broken its agreement with BMS. As Dr. E. Goemaere of MSF said: "In South Africa we use stavudine from BMS because, thanks to Amy Kapczynski, among others, the prices have come down." *Aspen Pharmacare*, a South African generics manufacturer, wanted to make a copy. "But no agreement has been signed between Aspen and BMS and, after the debate, Aspen is satisfied that BMS is not taking the South African government to court," continued Dr. Goemaere. "The South African company has obtained no information on the molecule, no technology transfer. Unlike other times, BMS has only eased off the pressure, obtaining counter-benefits, as this dramatic drop in prices has discouraged competition and prevented since then the emergence of generic products."

This manner of solving the stavudine problem has been commented on by Amy Kapczynski: "The decision-making always takes place in the United States. From the result it is clear that the battle has not been won. Those in need of treatment should join together to demand responsibility, because they are not oblivious to the decision-making. Everything would have been different if Yale had given up their local patent. Then something really might have happened. But for Yale, to give up the patent and break the contract is touching on a delicate subject: that which involves the relationship between the University and the companies."

On this point, as on the remaining ones, BMS has refused to comment. And Yale's representative, Mr. Soderstrom, stated: "There have never been any differences between BMS and ourselves. Our common concern was to find the right answer [to MSF's lawsuit]. At Yale we could not act unilaterally. We had a license agreement and we've had different research programmes over the years with BMS."

Apart from the small group of GESO activists, Yale seems resigned to the answer when the question is: "Why didn't they grant BMS a more restrictive, non-exclusive license which would have allowed the University a means of pressure in favour of the public interest?" Mr. Soderstrom replies, "no company

would have agreed upon it. It's an exclusive licence or none at all! Given the time and the money necessary to carry out the clinical trials and develop the drug, it is difficult to conceive a company working with us if it isn't able to safeguard its investment." The medical adviser to the MSF New York office, Anne-Valérie Kaninda, has another explanation: "The exclusive license prolongs the monopoly chain that begins with the patent. It's this monopoly that drives up the prices."

Any attack, no matter how small, on this "monopoly chain" is also considered by the industry as an attack on the freedom of research. When the World Trade Organisation (WTO) met in Doha in November 2000, it decided to relax the rules on the patents granting for poor countries, an initiative which immediately caused uproar: "Without patents profits aren't possible and research suffers", Daniel Vasella, spokesman for Novartis AG[15] declared. But how can you explain that the large drugs manufacturers, all of which are making record profits, invest three times as much in marketing and administration as in research and development?"[16].

The laboratories use, as we have seen, the exorbitant costs of phase III trials, those carried out on sick volunteers on a large scale, as justification for their pricing policy. But how much have the stavudine trials really cost in phase III? Dr. Prusoff wrote in the *New York Times* of the incredible figures of "more than 13,000 patients infected with HIV" tested by BMS in phase III trials.

Eight months later, this very researcher admitted to Philippe Demenet that this figure had undoubtedly been inflated by someone, probably from BMS. On the other hand, an expert in the development of antiretrovirals puts the average number of patients tested in phase III at 3000, at a cost of $25,000 to $30,000 per patient per year. "Bearing in mind the insurance premiums, the transport of blood samples, the collection and processing of data, the monitoring of thousands of patients who have been give the drug on compassionate grounds, the toxicological studies, pharmaceutical development. That's not far off $500m."

James Love, director of the *Consumer Project on Technology*, has repeated the calculations for stavudine, based on the information published by the FDA (822 patients tested) at an average of $10,000 per patient per year; a calculation he affirms that "is notably higher than the usual sector average." In total, with regard to the risks, he adds, "they are nowhere near as risky as 70% of the phase III drugs are approved," and regarding the compensation, he goes on to say, "the capital cost was quite small since the study only lasted two years." He came to the conclusion that the development of stavudine cannot have cost BMS more than $15m.

What of the truth? It lies in the pharmaceutical companies' accounts, which they obstinately refuse to open, alleging commercial secrecy. When, in Pretoria, the South African judge wanted precise information on the pricing policy for antiretrovirals, the thirty-nine manufacturers preferred to withdraw their suit.

BY WAY OF CONCLUSION

The analysis of the process of invention, funding, obtaining the patent and the commercialisation of stavudine exemplifies the background against which the matter of the social responsibility of scientists must be set. Dr. Prusoff, distinguished scientist, the "father" of the retroviral, illustrates the role of a scientist who acts in accordance with deontological principles and who has good intentions insofar as what can be defined as the "right to health" is concerned; however, from his public declarations and activities, sadly, we cannot affirm anything else regarding his social responsibility, because such responsibility surpasses the scope of one or another declaration.

The example of the "stavudine case" could be extended to other drugs and procedures with the same result: the reality does not change with well-intentioned speeches and, undoubtedly, we are left in the dark when it comes to demanding responsibility from any of those involved. This is why we consider that, in the face of the social reality in which biotechnological research is carried out, the traditional distinction between "pure science" and "applied science" is impossible to sustain; regardless of how they might have been related in the past, at present both overlap into the investigative process and from the coming together of the two it is no longer possible to sustain that an unconditional right to the freedom of research exists. It is not a question of abolishing this fundamental right which has contributed to such a large extent to the freedom of individuals and peoples but rather to resituate it in its doctrinal nature in a way that justifies its limitation in the cases in which it is transformed into a patrimonial right; it is then that it should be limited to the benefit of the right to health. It should be understood, however, that the material protection of this right depends not only on such discursive dimension but that economic and political reasons are the ones that complementarily back up the discourse in order to make the right to health a

disposition only within the rich who can pay for it. As H. Jonas points out, research, and health, has become a market commodity and is fully in the hands of state inspection, which will be all the less reliable the more it is extended from the initial state of research to its industrial exploitation. (H. Jonas, 1997:73).

KEYWORDS Responsibility. Health Protection Right. Patents. Estaduvine. Patrimonial Rights. Context of the Discover

ABSTRACT This description leads to the analysis of the paradox - and the unfairness - that combines two factors: the right for health is recognised a an universal right, but in the practice it is useless in front of the patent right, which is recognised as a right of the patrimony. This is to say that the interaction between research and the economic system (public funds for research, patent obtention and commercialisation of medicine) denies the satisfaction of this so-called right for health. And, this paradox - which resolution claims *responsibility* - does not only have evident and negative consequences among the population of the south affected by AIDS. It also illustrates what can happen to the countries of the north if National Health Systems cannot support the high costs of medicine in a close future.

NOTES

1. Robert Oppenheimer was the person in charge of the *Manhattan* project, which involved the construction of the very first atomic bombs
2. To this end, we can mention the initiatives of pressure groups against AIDS and the emblematic *Act Up*, the creation of hospital and state bioethical commissions, See A. Cambrón "Funciones y limitaciones de las comisiones Nacionales de Bioética", in M. Casado (coord.). *Bioética, Derecho y Sociedad*. Trotta. Madrid, 1998. And A. Cambrón, " El Proyecto Genoma Humano y el derecho a la propiedad intelectual", in *Revista Derecho y Genoma Humano*. No. 13. July-December, 2000 (p.79-102).
3. H. Jonas. *Technik, Medizin und Ethik. Zur Praxis des Prinzips Verantwortung*. Spanish translation by Carlos Fortea Gil. Paidos. Barcelona, 1997 (p. 55).
4. However, if we look at things from a more theoretical angle, it seems that this maxim has not always been complied with, as "trafficking in secrets" within scientific circles reflects; it is not a question of obtaining the materials, reagents, cells, etc. of others but of obtaining "information" which gives power. In this sense, the scientists involved in the Human Genome project very much regret the fact that their private competitor, the company Celera Genomics exploited their information to extenuation. But this does not mean that Craig Venter, up until a few months ago the company chairman, sneaked into the state laboratories one night and stole a box full of cells or chromosomes. Venter only took advantage of the research carried out in the public project. The two scientists who discovered the double helix of DNA in 1953, Francis Crick and James Watson, also borrowed certain crucial information from a competitor, the crystallographer Rosalind Franklin. This is what Watson and Crick themselves had to say, in their original article (*Nature*, 25 April 1953): "We have also been stimulated by a knowledge of the general nature of the unpublished experimental results and ideas of Dr. M.H.F. Wilkins, Dr. R.E. Franklin and their co-workers at King´s College, London." Notes taken from J. Sampedro's article, "El precio de una idea" ("The price of an idea"), *El País*, 8 August, 2002.
5. H. Jonas. *Das Prinzip Verantwortung*. (1979). Spanish translation by J. Mª. Fernández Retenaga. Ed. Herder. Barcelona, 1995
6. The information used in this section has been obtained from different articles published in the publication *Le Monde Diplomatique:*
   S. George. "Sommet de l´OMC à Seattle. Le commerce avat les lbertés", nº.548, Novembre 1999, p.1-16.
   M. Bulard. La nécessaire définition d´un bien publique mondial», nº.550, Janvier, 2000, p. 8-9.
   D. Frommel. «Le sud ravagé par la pandemie. Contre le sida», nº. 561,Décembre, 2000, p. 8-9.
   Ph. Demenet. «Contre l´apartheid médical. Stratégies mondiales pour la santé», nº. 564, Mars, 2001, p.26-7.
   Ph. Demenet. «Le scandale stavudine. Ces profiteurs du sida», nº 575, Février, 2002, p. 10-11.
   Ph. Rivière. «Vivre à Soweto avec le sida», nº. 581, Août, 2002, p.12-13.
7. Zidovudine or AZT, didanosine or ddl, zalcitabine or ddC and lamiduvine or 3TC
8. Also called d4t, stavudine is a nucleoside reverse transcriptase inhibitor of the AZT family.
9. Since the *Bayh-Dole* Act passed in 1980.
10. The patent was registered in 1990.
11. $4.56 in the United States, but $3.68 in France (4.12 euros), where prices are negotiated, to the detriment of pharmaceutical multinationals.
12. 4.7 million South Africans are infected with HIV and 250,000 die every year. Aids is responsible for 40% of deaths in the 15-49 age group.
13. *New York Times*, 19 March 2001.
14. A non-governmental consumer protection and lobbying organisation founded by Ralph Nader.
15. *The Wall Street Journal*, New York, November 14, 2001.
16. In Decenber 2001, two researchers at the University of Boston's *School of Public Health*, Alan Sager and Deborath Socolar, published a comparative study of changing manpower levels. The American pharmaceutical industry employs almost twice as many people (81% more) in marketing as in research. And the gap has widened considerably in the last five years. For its part, in 2000, BMS spent $3.86bn on marketing and administration compared with $1.93bn on research and development.

REFERENCES

Benkimoun, P.: *Mors sans ordonnance*. Hachette. Paris (2002).

Bulard, M.: «La nécessaire définition d´un bien public mondial. Les firmes pharmaceutiques organisent l´apartheid sanitaire», Le Monde Diplomatique, nº. 550, pp 8-9 (Janvier 2000).

Callaham, D.: «Ethical Responsibility in Science in the Face of Uncertain Consequences», en M. Lappé- R. S. Morrison (Eds.). *Ethical & Scientific Issues Posed by Human Uses of Molecular Genetics.* Academy of Sciences. New York, p. 1-12 (1976).

Cambrón Infante, A.: "Funciones y limitaciones de las comisiones Nacionales de Bioética", en M. Casado. Bioética, Derecho y Sociedad. Edt. Trotta. Madrid (1998).

Cambrón Infante, A.: "El proyecto Genoma Humano y el derecho a la propiedad intelectual", en *Revista de Derecho y Genoma Humano.* Nº. 13. (Julio-Diciembre, 2000).

Davis, Ann: "Postmarketing by Markers of Alzheimer´s Pill Raises Questions About the Uses of Research", en *The Wall Street Journal Europe* (7-01-2002).
Demenet, Philippe: "Contre l´apartheid médical. Stratégies mondiales pour la santé populaire", en *Le Monde Diplomatique*, nº. 564, Mars, pp.26-27 (2001).
Dement, Philippe: «Le scandale stavudine. Ces profiteurs du sida», en *Le Monde Diplomatique*, nº. 575, Février, pp. 1 et 22-23 (2002).
Frommel, Dominique: «Le sud ravagé par la pandemie. Contre le sida, l´arme du debat», en *Le Monde Diplomatique*, nº. 561, Décembre, pp. 8-9 (2000).
George, Susan: «Sommet de l´OMC à Seatle. Le commerce avant les libertés», en *Le Monde Diplomatique*, nº. 548, Novembre, pp. 1 et 16 (1999).
Independing Catastrophe Revisited. Documento de 36 páginas editado por LoveLife. Henry J. Kaiser Family Foundation. Johannesburg, 2001.
ISDB: "Declaration on Therapeutic Advance in the Use of Medicines", en Revue Prescrire. Paris (15 et 16 Novembre, 2001).
Jonas, H.: El principio de responsabilidad. Ensayo de una ética para la civilización tecnológica. (1979). Trad. cast. de J. M. Fernández Retenaga. Edt. Herder. Barcelona (1995).
Jonas, H.: Técnica, medicina y ética. La práctica del principio de responsabilidad. Trad. cast. C. Fortea Gil. Edt. Paidos. Barcelona (1997).
Loup Motchane, J.: "Droits de brevets ou droit à la santé?, en *Le Monde Diplomatique*, nº. 580, Juillet, pp.10-11 (2002).
Love Life: http://www.lovelife.org.za/
New England Journal of Medicine, vol. 345, nº. 11, pp. 825-827 (13-09-2001).
ONUSIDA, Genève: http://www.unaids.org/
Pollard, Stephen, Big Pharmaceuticals Take the Gloves off", in *The Wall Street Journal Europe* (17 December 2001).
Rapport mondial sur le développement humanin. Programme des Nations Unies pour le développement. De Boeck Université. Bruxelles (2000).
Rivière, Philippe, «Vivre à Soweto avec le sida», en *Le Monde Diplomatique*, nº. 581, pp.12-13 (Août, 2002).
Sen, Amartya, «Santé et développement». Alocución pronunciada en la 52ª Asamblea Mundial de la Salud. Genève (mayo de 2000).
The Wall Street Journal. New York (14-11-2001 and 7-01-2002).

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