

Premise

Recent discoveries in biotechnology have posed a series of legal questions which our current legislation is not always in a position to answer. As a result, our present-day society is not only questioning itself as to what kinds of genetic manipulation should be permitted and what kinds should be banned, but it also faces a question about the scope of application of our laws in general and the Spanish Penal Code in particular. The penal legislator is conscious that by criminalising certain forms of genetic manipulation he may be putting professionals in the field —doctors and biologists— at a disadvantage with respect to other scientists in Europe and America, where the same activities are «non-criminalised». In short, he may, by declaring certain activities to be crimes, paralyse research.

This paper presents a schematic overview of the problems posed to Spanish law by the task of regulating all matters connected to genetic manipulation, in its widest sense - which is exactly the sense in which the term is employed by the legislator. The paper then considers the response this legislation could offer to a hypothetical case of human cloning that had already occurred.

1. *Introduction to the legal aspects of the problem*

Historically, in what we may refer to as the development of the modern State, there have been few occasions on which a given scientific advance or discovery (in the traditional sense of the concept) has had such an immediate influence on the consolidated —and thus very often «conservative»— legal world, to the extent that we could say it transformed it. In the face of any problem posed by unprecedented events, the jurist tends to have recourse to the established principles and institutions for a complete response. He also tends to maintain this approach even when it is necessary to revise, reinterpret or extend either the principles or institutions. Only in a very limited number of extreme cases does the jurist abandon this traditional approach in favour of a another: when the implications of the problem, in terms of both potential and more than probable outcomes, are such that they practically shatter the established rules of the legal game.

Advances in genetics, in human genetics especially, and «genotechnologies» which have grown so rapidly in recent years, constitute one of these exceptional situations which may well shake, perhaps to the breaking point, several of the principles and institutions of the present-day legal world.

The numerous possibilities, indeed perhaps limitless possibilities, opened up by discoveries in genetics and, more especially, the level of information these have brought to light as to the biological essence of the human being, are going to produce, and to my understanding in a short period of time, important transformations in fundamental legal institutions. Until now, the problems faced have been merely hypothetical in nature, as is the question to be examined in this paper. However, the questions raised are uncomfortable ones which refuse to go away, and the answers to them will undoubtedly be the source of conflict. More seriously, they are questions which will not be answered through what we could refer to as «traditional» legal approaches and instruments. However, in certain areas, the problems are no longer hypothetical, they are very real in nature and present many pitfalls for the application of legislation.

So much so, that such «old» conflicts as those surrounding the use of assisted reproduction techniques now seem almost trivial in comparison with those likely to arise as a result of new knowledge about the human genome.

This is the case of the very idea of human responsibility¹ which, if things continue as at present, will be seriously affected once it becomes clear that the traditional vision of human responsibility cannot rely on our present laws for support, and this will happen even if we multiply our efforts to avoid the re-emergence of deterministic postulates. And more than this prospect, which is still relatively long term, there are also conflicts which loom closer on the horizon: the notion of privacy (and above all, the limits to the right to privacy)², the use of genetic information in the labour market (which could have highly negative effects for many people), the influence of that information on insurance contracts³, and even more so, the problem of storing and controlling all the information (a problem which is heightened by the fact that it is «living» information, in that its quality and accuracy will increase in line with continuing advances). Indeed, the use of genetic identification is well established for testing purposes in many different types of processes; it is frequently used in paternity cases and with very particular connotations in criminal cases (in which so-called «genetic fingerprints» have been used to secure convictions in high-profile and sensational cases).⁴

The most dramatic applications for «genotechnologies» of course lie in the production of biological weapons or weapons of mass destruction, and the creation of identical human beings through cloning or other procedures, with eugenic purposes. All these are likely to

1. For a detailed consideration of the problems posed for Criminal Law see, Peris Riera, Jaime M., «Orden biológico versus orden jurídico. El Derecho en el Tercer Milenio», Instituto de Derecho y Ética Industrial, CSIC, Madrid 1997, p. 35 and following.

2. See, Peris Riera, Jaime M., *op.cit.*, p. 71 and following.

3. For further information see, Peris Riera, Jaime M., *op.cit.*, p. 71 and following and quoted references.

4. Peris Riera, Jaime M., «La identificación genética y los derechos fundamentales», in: ARBOR, CSIC, December 1992, p. 45 and following.

become a reality in the near future, although recently they have been linked in the public mind, in my view unjustifiably, to the use of those same techniques for the creation of transgenic foodstuffs.

It is important to point out that in the face of this vast range of possibilities, our legal system remained silent until 1988, when the Spanish laws on assisted human reproduction and donation and use of human embryos and fetuses and their cells, tissues and organs were approved, (Law 35/1988 and Law 42/1988 respectively). These were followed in 1994 by the Law regulating the restricted use, voluntary donation and commercialisation of genetically modified organisms, so as to avoid risks to human health and the environment. All of this has been carried out, in my opinion, through defective legislation, which may undermine several fundamental principles of criminal law, in the new Spanish Penal Code of 1995 which includes a whole series of «offences related to genetic manipulation».

In general then, an effort was made to achieve national legislation on the subject, with a view to integration and harmonisation with the European system, bearing in mind that already in 1982 the Council of Europe had made a recommendation to the Council of Ministers that they should draw up a European agreement which would decide what the legitimate applications of the «genotechnologies» were. I believe that the Spanish measures, in addition to a number of other isolated but nonetheless serious problems, suffered from a lack of genuine society-wide debate which would have served to legitimise the legal measures, and this defect may mean that the legislation will fall short of some of the expectations it has raised, as has indeed become increasingly clear nowadays with the transgenic food controversy.

2. *The problem of the legal control of genetic manipulation*

Whereas a sizeable body of legal opinion recognises that the jurist must not only «rationalise» the present but must go further and «programme» the future⁵, nevertheless, the Law at present is caught up in a debate between two diametrically opposed approaches to new scientific developments: on one hand, there is the approach which feels Law should retire to the background, and on the other hand, there is that of a Law which is willing to play a central role.

The first position is the one adopted by Law in all those cases where, for any of a wide range of reasons and interests, a decision is made not to intervene; in other words, the Law does not take «its rightful place», thus giving rise to the customary «legal vacuum». These are cases in which the Law chooses «not to »programme» and in which science is forced to move in an area of «non-law», guided only by the criteria of the individual or by group conscience. The second option seems to appear when distrust or other interests demand intervention. This can be initiated discreetly by very subtle mechanisms, or more openly through the creation of special laws aimed

5. For full details see, Mantovani, F., «*Manipulaciones genéticas, bienes jurídicos amenazados, sistemas de control y técnicas de tutela*», translated by Jaime M. Peris Riera, in: *Revista de Derecho y Genoma Humano*, no. 1, July-December 1994.

at ensuring legislative control of these scientific activities⁶. In any case, as I shall try to clarify now, an approach which decides on «legal» regulation from the outset, or *a priori* regulation is not correct, and much less so, an approach which opts for criminal prohibitions.

Scientific activities, especially those concerned with such areas as genetic manipulation or biotechnologies in general, do not tend to pose an outright question or problem of licitness or illicitness. Instead, what tends to happen is that a question arises as to the limits of this licitness. The question is complex, since it is not a matter of simply enforcing prohibitions; rather, the aim is to regulate⁷ these activities «establishing their limits and penalising infringements with the aim of ensuring benefits and avoiding damage to mankind»⁸. Therefore, from the perspective of the Law, these new situations emerging from developments in genetic manipulation can be faced in either one of the two ways the legal system traditionally employs when faced with a new challenge: firstly, by adapting the existing legal mechanisms and rulings or secondly, by proceeding to establish regulations which will serve to channel or contain them. There is a mistaken school of thought which tends to consider it necessary to regulate the area exclusively for the protection of the welfare of those who are directly affected, the «patients» of the future, while forgetting, as pointed out by DONALDSON, that the legislation is necessary «both for the protection of the patients and the clinics which are responsible for the development of the new techniques».⁹

ROMEO CASABONA has recognised that from the point of view of the Law, the decisive issue is to find an answer to a preliminary question: «how should the Law intervene and with what effects and in which aspects?». To answer this question, he recommends we attempt to identify the interests that could be affected. At the same time we would have to pinpoint the limits of the area in need of regulation and, finally, we would have to determine exactly what should be banned and deemed punishable, how seriously and through which legal instruments.¹⁰

Authors such as ESER understand that the protection of the welfare of those affected, and the considered appreciation of the fundamental right to scientific and technological creativity, both require «a different body of rules adapted to the various degrees of protection needed»¹¹. A decision must

6. For further, more detailed information see, Vivant, M., «*La regulation juridique de l'activite scientifique*», en: *Sciences et democratie*, Presses universitaires de Strasbourg, 1993, p. 22 and following.

7. The «regulating» tendency is the more numerous; the final objective is some class of legislative clarification rather than direct penal prohibition. Thus, for example, the irresponsibility involved in «allowing people to go about reproducing humans in a complete legal darkness» (Cusine, D., «*Experimentation: some legal aspects*», in: *Experiments on embryos*, edited by Dyson & Harris, New York 1991, p. 123).

8. Mantovani, F., «*Manipulaciones genéticas, bienes juridicos amenazados, sistemas de control y técnicas de tutela*», cit., p. 18.

9. Donaldson, M., «*The control of reproductive research*», in: *Reproductive medicine and the law*, edited by Templeton & Cusine, New York 1990, p. 160.

10. Romeo Casabona, C.M., «*Límites penales de la manipulación genética*». In: *El Derecho ante el Proyecto Genoma Humano*, Fundación BBV (in preparation), p. 1 of the original typescript.

11. Eser, A., «*La moderna medicina de la reproducción e ingeniería genética. Aspectos legales y sociopolíticos desde el punto de vista alemán*». In: *Ingeniería genética y reproducción asistida*, Ed. Marino Barbero, Madrid 1989, p. 297.

be taken beforehand as to whether the so-called «extrapenal control systems» are sufficient, and they must be studied so as to determine the exact role they could play in this area.

Depending on the objectives of the protection and the type of risk being faced, a number of different types of regulation of varying intensity and application might be needed. In a well-known graded formula, ESER¹² also offers us the following possibilities which, taken together, seek to provide a response to the real needs, while at the same time aiming to avoid extreme reactions due to the fear brought about by disinformation:

a) Scientists can begin by employing certain deontological self-regulatory mechanisms. These would be mechanisms of professional self-discipline and control. Scientists and technologists would take multiple decisions covering a wide spectrum of responsibilities ranging «from an appropriately critical approach to the work carried out by other members of the scientific community, to involvement in serious social questions, and including the honest recognition of the limits of certainty in their own results and criteria, generosity in the exchange of opinions, and measured, honest communication whether in the form of support or denounce».¹³

Despite the importance of these measures in everyday professional conduct and despite the fact that several authors have pointed out how closely the history of many human failures has been bound up with a lack of attention to professional ethical codes and conscience¹⁴, I nevertheless incline more in favour of the view that sees traditional medical ethical codes (the Hippocratic Oath, the Physician's Oath of Geneva) and genuine medical ethics as insufficient to cope with the progress taking place at present in a range of medical fields¹⁵. The issues to be faced up to are so conflictive that, as has been said, the «self-regulatory decisions» cannot be left in the hands of the practitioner, either on an individual basis (personal ethics) or through professional groups in which he or she finds himself (deontological codes).¹⁶

Measures such as those taken by the Ethics Committees can be effective in providing a measure of guarantee, and in controlling the profession's self-protection instinct and its tendency to tolerate elitist immunity. However, under no circumstances should the State ever renounce its duty to intervene, since it is not the role of the Ethics Committees to delimit the scope of the law and to fix the limits of licitness in biomedicine which, when necessary (and in many areas it is necessary), must be done by the State. The role of the Ethics Committees is to supervise the profession and ensure that the respective legal rulings are obeyed.¹⁷

12. Eser, A., «*Genética humana desde la perspectiva del Derecho alemán*», in: *Anuario de Derecho Penal y C.P.*, 1985, p. 363.

13. Martín-Municio Aguado, A., «*Biología, progreso y ley*». In: *Ingeniería genética y reproducción asistida*, ed. Marino Barbero, Madrid 1989, p. 9.

14. Mantovani, F., «*Il delitti contro l'essere umano*», in: *Studi in onore di Giuliano Vassalli*, vol. I, p. 452.

15. Koch, H.G., «*Ética médica y Derecho médico: una propuesta de teoría armonizadora*». En: *Eguzkilore*, n.º 5, extraordinario, 1992, p. 113.

16. Romeo Casabona, C.M., «*Límites penales de la manipulación genética*», cit., p. 4 of the original typescript.

17. For a similar view see, Mantovani, F., «*Il delitti contro l'essere umano*», cit., p. 451 and 452; Romeo Casabona, C.M., «*Límites penales de la manipulación genética*», cit., p. 4.

These systems of ethical self-regulation can, therefore, only play a complementary role or that of guarantor, but they can never be construed as the source of licitness in such areas as biomedicine, which have such a direct effect on the profession.

b) A system of procedural administrative guarantees. This is a frequently employed measure, which was also initially adopted by the Spanish legal system to respond to such questions as we are now concerned with. This system is by no means unusual, given that the intervention of public powers in health-related issues is accepted in the developed societies. Since many of the most complex biomedical activities are regulated, there is all the more reason why these regulations should be extended to cover genetic manipulation in the widest sense of the term, whether applied to humans or to animals and plants. These systems, with their corresponding penalties, are recognised as being highly adequate by legal doctrine in that they provide for adequate control over the large-scale economic interests which in general tend to underlie these biomedical issues. This level of intervention is seen as fundamentally justified on the basis of its usefulness «as a preventive measure against potential dangers deriving from these activities».¹⁸

c) Criminal Law, with its corresponding prohibitions, should only be turned to as a last resort (and even then it is recommended that Private laws be created or strengthened when found to be effective). The needs for protection, penalisation and the nature of penalisation would have to be verified in each individual case.¹⁹

In conclusion, I would agree with ROMEO CASABONA that if this tiered system for legal intervention has proven adequate and suited to other spheres of human behaviour, then it is especially apt and indeed ideal for the field of biotechnology and biomedical science in general, since it allows for a flexible system of regulations which can be adapted so as to favour the greatest possible freedom for researchers and at the same time to pre-empt the undesirable consequences for society.²⁰

3. *General outline of legislation which conditions subsequent penal rulings*

Until just four years ago, Spanish Law was substantially different to that of other European countries. This was so, largely because until then the legislator, when setting out to regulate research activities in the fields of human, animal or plant genetics, had generally considered sufficient to create a set of specific laws on genetic techniques so as to establish the limits of licitness and make provision for administrative penalties for infringements.

It would seem that he bore in mind the tiered or graded formula for intervention which we have just mentioned, and drew especially on the system of procedural administrative guarantees. Furthermore, in these laws, unlike the approach adopted by legislators in other European countries, no forms of conduct, no matter how extreme, were criminalised.

18. Romeo Casabona, C.M., *op. cit.*, loc. cit.; Mantovani, F., *op. cit.*, loc. cit.

19. Eser, A., «*La moderna medicina de la reproducción e ingeniería genética*», *cit.*, p. 297.

20. Romeo Casabona, C.M., «*Límites penales de la manipulación genética*», *cit.*, p. 3 of the original typescript.

The general laws related to these matters can be outlined schematically as follows:

a) To the fore, we have a number of constitutional provisions, closely related to research techniques in human, animal and plant genetics. Primarily, the Carta Magna's recognition of the fundamental right to scientific production and creation (art. 20.1.b), although this is limited by article 20.4, which refers to «respect for the rights recognised in this Constitution, in the precepts established in the laws which are based on it and, especially, in the right to honour, privacy, one's own image and the protection of youth and children».

b) On the level of specific legislation, there are three laws which set down guidelines as to possible conduct, establishing the penalties for activities which infringe the limit of the permissible:

— Law 35/1988, of November 22, on techniques of assisted human reproduction.

— Law 42/1988, of December 28, on the donation and use of human embryos and foetuses and their cells, tissues and organs.

— Law 15/1994, of June 3, which established the law and jurisdiction of restricted use, voluntary donation and commercialisation of genetically modified organisms, with a view to preventing risks to human health and the environment.

The basic differences between these laws lie in the various biological qualities of the object at the centre of the activity in question. The distinction in terms of the techniques employed is clear from the name of each of the laws.

The general system of infringements and penalties provided for in these laws was based on a common principle: all three set out a series of conducts which are prohibited, and breach of this prohibition will constitute a minor, serious or very serious infringement, according to the individual case. Similarly, the corresponding penalties are also set out. The specialised doctrine reacted favourably to these laws stating that they were in keeping with «the constitutional parameters which should guide them» and that they «limited the field of human genetics in a way accepted by the majority of our society».²¹

4. *The general response of Criminal Law*

For years, indeed dating from the origin of the techniques in question here, the Spanish legislator set out from the basis of total licitness. Later, in the aftermath of the 1988 regulations, he seems to have been satisfied with a protective barrier which was administrative in nature. Now however, since the Criminal law bill of 1992 appeared, the former view has faded away and been replaced by one which actively favours the criminalisation of certain types of conduct in the field of genetic manipulation.

Developments since 1992, including the consolidation of the 1992 bill —although with some limitations— in the Spanish Penal Code of 1995, would seem to bear out the views of

21. Valle Muñiz, J.M.-Gonzalez Gonzalez, M., «Utilización abusiva de técnicas genéticas y Derecho penal», in: Poder Judicial, n.º 26, 1992, p. 126 and following.

those who openly expressed their misgivings about the single administrative prohibition which they saw as insufficient and in need of a greater range and power: a level of punitive effect. Indeed, both the Penal Code bill of 1992 and that of 1994, which was to become the present Spanish Penal Code, made provision for «criminal offences».

What can now be referred to as our Criminal Law regulation of genetic manipulation (understood by the legislator in a very broad sense) contains a series of criminal offences which are relatively similar to those in national and international law in so far as the justification of their criminalisation is concerned. This is not the place to delve into further detail²², however, I must take the opportunity to point out that the Spanish legislator has decided to penalise the use of genetic engineering for the production of biological weapons or weapons of mass destruction (article 160), the fertilisation of human oocytes for any purpose other than human procreation, and cloning or the use of any procedure with eugenic purposes (article 161).

Nevertheless, this same Code (Volume V, Book II) also established generic criminalisation of all manipulation of human genes carried out for any purpose other than the «elimination and reduction of defects or serious illnesses» (article 159).

This approach, that of general criminalisation, which to my understanding sets out from a mistaken use of the term «genotype» is part of the trend to use «all-embracing and simplistic formulas» which by indiscriminate prohibition of all types of genetic experimentation or manipulation have once again converted Criminal Law into «the secular arm of an obscurantist and counterproductive persecution»²³. So that the reader may obtain some idea of the extent of the indiscriminate criminalisation that this allows, suffice to say that when it comes to penalising genetic manipulation, the fundamental distinction between somatic and germ cells is not taken into consideration, although the importance of this difference has been fully accepted by the international scientific community for a long time, because of the enormous differences in their consequences.

Furthermore, since this unfortunate measure prospered we now have, as mentioned earlier, a discrepancy within the legislative panorama affecting this area. Norms such as that governing assisted reproduction permit research and experimentation for purposes other than those mentioned (such as for example, basic research into the origin of human life (in its initial phases), cellular ageing, and cell division, meiosis, mitosis and cytokinesis); however it now turns out that the Spanish Penal Code would penalise these very same activities. This will oblige the person applying the Law to have recourse to serpentine interpretations of the legislation if he is to avoid absolutely incoherent consequences.

There are of course numerous reasons to roundly criticise any measures based on the indiscriminate criminalisation of fundamental research in Biology and Biomedical Science. And,

22. For a full consideration of all technical aspects of the criminalisation of these activities see, Peris Riera, Jaime Miguel, *«La regulación penal de la manipulación genética en España»*, ed. Civitas, Madrid 1995, and quoted references.

23. Soto Lamadrid, M.A., *«Biogenética, filiación y delito. La fecundación artificial y la experimentación genética ante el Derecho»*. Buenos Aires, 1990, p. 259.

while wishing to avoid technical details more suited perhaps to a purely legal study, nevertheless I feel it is worthwhile pointing out some of the more weighty reasons here.

Firstly, because the Constitution establishes the right to scientific and technical production, and this right is incompatible with the indiscriminate restriction mentioned above. Like all rights, it can of course be limited because it is not an absolute principle, but were it to be limited, the basic rules of the principle of proportionality would have to be respected. Secondly, a point accepted even by those who are in favour of criminalisation is that the rational principle *leges non sunt multiplicandae sine necessitate* should also apply in the specific context of biomedical research, and efforts should be made to avoid a rampant proliferation of criminal legislation.²⁴

On a more general level, one of the basic principles of contemporary Criminal Law should also be borne in mind, which is, that the adoption of any penal measure implies an encroachment into the sphere of individual freedom and precisely for this reason, it can only be legitimate when it is carried out to protect other goods or interests: In other words, it draws its justification from a situation in which this level of protection is necessary, adequate and proportional. This principle of minimum intervention also involves a criteria of «economy» which is highly important since failure to comply with it gives rise to negative effects, including «prejudice to the people who are unnecessarily criminalised, and prejudice to social harmony which is damaged when conflicts which do not require a penal solution are given one».²⁵

Finally, we must remember that the near missionary zeal of the legislator to «educate» the citizenry through the legal code is not seen as positive by many important sectors of doctrine. Penalisation is not the best means to bring about a change of values in society since the State «lacks legitimacy to promote (anything) through Criminal Law, reinforcing already existing educational processes».²⁶

5. *Cloning from the perspective of Criminal law*

Article 161 of the present Spanish Penal Code makes provision for prison sentences of between one and five years and disqualification from public office or employment for between six and ten years for offenders found guilty of «fertilising human oocytes for any purpose other than human procreation». In this same rule provision is made for the same punishment for «the creation of identical human beings by cloning or other procedures with eugenic aims».

We must now relate some of the points made earlier with the provisions of this article, since these activities which have now been criminalised were also seen as very serious offences in sub-sections a), k) and l) of section 2.B of article 20 of Law 35/1998, on assisted reproduction. However, these sub-sections were eliminated from additional clause no. 3 of the new Spanish Penal Code so as to

24. Mantovani, Ferrando, *«I delitti contro l'essere umano»*, cit., p. 453 and 454.

25. Consejo General del Poder Judicial, *Anteproyecto del Código Penal de 1992 e informe y votos agregados del Consejo General del Poder Judicial*, Cuadernos del CGPJ, n.º 11, Madrid 1992, pp. 165 and 166.

26. Silva Sanchez, Jesus M., *«Aproximación al Derecho Penal contemporáneo»*, ed., Bosch, Barcelona 1992, p. 303.

avoid duplicating the regulations. We can therefore, say that these activities have been prohibited in our country since 1988, but whereas until 1995 they were punishable by administrative penalty, in May 1996 with the advent of the 1995 Penal Code they became punishable by criminal penalties. The legislator limited himself to a reworking of the content of sub-sections k) and l) in the second section of this article, and technically the result was short of satisfactory.

By criminalising these areas, the Code has pleased those who hold that manipulation of the human genome for purposes other than the purely therapeutic or diagnostic is deserving of penal punishment. Indeed, this penalisation had been recommended, both at the international level, through the resolutions adopted by the Fourteenth Congress of International Criminal Law Association, and in Spain, through the provisions set out by the so-called «Informe Palacios» (Palacios Report).

What is true however, is, as pointed out earlier, that the Spanish legislator had taken no action in Laws 35 and 42 of 1988, in which provision was made only for non-criminal infringements and administrative sanctions. Action was taken later, in 1995, protecting such general concepts as the inalterability and intangibility of the human gene, and the individual identity and unrepeatability of every human being. Due to the nature of these concepts, the criminal law provisions are also framed in terms of abstract risks. To my understanding, the very structure and existence of these provisions rendered it unnecessary to include the specific regulation of genetic manipulation in the strict sense. However the Code does include it. It is unnecessary, since as we have seen, its wide-sweeping typification could limit scientific research and experimentation and the risks it strives to avoid are already covered elsewhere.