Roberto Bin
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Biotech Innovations and Fundamental Rights

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Preface

Biotechnology is a recognized research area that has increasingly advanced into new technologies and modern practices raising several legal, ethical and regulatory issues. In particular, the revolutionary speed of biotech innovations has had a significant impact on the protection of the rights of the individual. Fundamental rights provide a framework within which the justification of limitations and restrictions to biotechnology innovations and research results have to be assessed. The legal regulation of scientific research and scientific investigations impact more and more directly on the freedom of research and therapies as well as on the broad diffusion of knowledge. Closely related is also the much debated question of the technological manipulation of life and the boundary of scientific knowledge with regard to the topical question of genetic invention patents and their effects on access to scientific information and health care opportunities.

Today, interests antagonistic to freedom of scientific research and acces to scientific knowledge are emerging distinctly requiring a careful balance between public and private domain.

A few questions may arise in this regard: how do technology and science affect law and vice versa? Do new biotech innovations affect constitutional rights? How does the protection of genetic inventions change the conditions of access to knowledge? What are the public interests considered to be so deserving of protection that they effectively counter-limit rights already embedded with the architecture of many constitutional systems?

Within this framework the book puts forward a critical analysis of the problems concerning the protection of fundamental rights in the field of biotechnologies with a multidisciplinary and comparative approach. Drawing on expertise from different disciplines, the volume comprises invited papers and plenary presentations given at the conference entitled "Biotech Innovations & Fundamental Rights" that took place on January 20-21 2011 at the Department of Juridical Sciences of the University of Ferrara. Each contribution covers a different aspect of the legal and scientific issues involved in regulation of biotechnology. In particular the focus of attention has been given to genetic research, genetic data, freedom of scientific research in genetics and biotech patents.

The contributions included in this book present a broad spectrum of different research approaches to the issues raised by biotech innovations. In particular the book aims to highlight challenges, opportunities and contradictions regarding the revolu-

tionary technological developments in the life sciences and their consequences for the constitutional protection of individual and collective rights.

We would also like to take this opportunity to thank the panel moderators (professors Carlo Casonato, Antonio D'Aloia and Davide Sarti) for their active and productive contribution.

Roberto Bin
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Part I

Biotech Patents

Introduction

Paolo Veronesi

The issue of biotechnological innovation in many respects represents a substantial challenge to law. Genetic information has both significant margins of "utility" and, conversely, major danger areas. It is a very delicate terrain, involving not only the freedom of scientific research and its practical applications, but also the protection of individual rights. It entails factual consequences that may potentially result in the violation of rights, and imposes the necessity of striking a balance between opposing interests.

Whose right is it to settle the boundary lines between these two interacting domains? There is no doubt that the function of drawing the line between legal and illegal is the responsibility of the law, which must provide the appropriate safeguards and precautions. However, there are no certain answers to questions raising moral issues, since the principles governing what is ethical and what is unethical are not always clear. It is a question of implementing the right approach within the field, along with the necessary legal instruments to regulate the actual use of genetic information, thus avoiding misuses: abnormal and arbitrary uses or procedures adversely affecting the rights of others.

Even just thinking about the above scenario, it is clear that the issue of biotech innovations presents a deep and unexpected analogy with the more intimate nature of law and, in particular, with certain aspects of constitutional law.

We are required to consider genetic information and DNA-based inventions not only as an important subject of legal regulation. The similarities between the nature of genetic information and the legal realm are far more profound and pervasive: accordingly, we believe it is desirable to emphasize and highlight these critical analogies.

Within this perspective, genetic information may be viewed as a "sign", in the semiological sense of the word: it is no mere chance that the expression "read the genetic code" is often used in common parlance, thereby emphasizing the need to give it a "meaning" (also predictive) starting from a biological viewpoint. As a "sign", genetic information belongs to the same broad semiological framework as law. The law, too, must be interpreted by signs. At the same time, lawyers, judges, and legislators are always called upon to interpret and properly translate signs of different kinds: the different subject matters or "life events" involved, but also the words used in the applicable legal sources. The law actually and specifically enacted or

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adopted for the government of organized society cannot, by definition, avoid comparison with concrete and specific cases. Very often normative texts may have an entirely different meaning from those originally identified or abstractly conceived. This happens because of their interaction with the "environment" within which they operate.

The "fact" is never irrelevant in the identification and interpretation of law. The correct "pre-understanding of the case" allows the interpreter to determine the applicable law, which is to better identify and attribute a precise meaning to the abstract legal rules governing the matter at hand.

Thus, the law distilled from this process, applied to the fact that causes the problem, gives to the fact a better defined physiognomy and a more precise legal meaning. This is a typical case of the "hermeneutic circle".

Something very similar occurs in genetics. More precisely, the reading of genetic information can rarely predetermine with certainty the diseases that will affect a person's health.

In addition, it is often the case that some genetic sequences are already readable, although still incomprehensible. It is rather like picking up a book written in an unknown language, even if the letters that are used are familiar. In any case, biological information interacts in a significant, albeit not crucial, way with the environment and with the individual's will, including the behaviour adopted or avoided that might, for example, favour or inhibit the emergence of some pathologies. In so-called complex illnesses, for instance, the genetic component of the disease is far from fundamental, since it is distributed among the many genes spread throughout the genome. In such matters, the environment and context in which the person leads his/her life becomes a determining factor. But it is a problem that in practice concerns the situation in which each of us lives, even if to different extents. By contrast, the case of "non complex illnesses" is different, for they appear incurable at the time and are deterministically derived from a single gene: they are nonetheless situations that, fortunately, involve a smaller number of people. Even taking account of the necessary distinctions, such relationships appear rather similar to those that positive law establishes with the concrete cases that require its application, as evoked above when referring to the image of the circle.

Already in this sense, we can perceive some perhaps daring but certainly meaningful similarities between the intimate workings of a legal system and major aspects of genetics. This also holds as regards constitutional law. As Guido Barbujani affirms, science teaches us that, over all else, genes establish the extreme limits of what we are and could be, defining a rather ample space of possibilities. Where we actually position ourselves within this space, in the different phases of our lives, will depend on the different conditions in which we develop and in which we choose to set ourselves. As previously mentioned, it is proven that a genetic predisposition to the majority of diseases hardly ever implies the absolute certainty of their future emergence. A further example is the so called "aggression gene", whose presence in an individual's biological make up in no way means that he will inevitably becomes a delinquent. The same caution is also required in interpreting constitutional law and fundamental legal principles in general. *Mutatis mutandis*, in fact, the norms

and principles of the Constitution, in all their various combinations, rarely wholly foreseeable in the abstract, permit their application to highly diverse disciplines. This does not mean, however, that everything is permitted. Constitution law, in fact, draws the lines that cannot be passed, regardless of interpretative approach and context. On coming up against changing social conscience and positive law, scientific discoveries and technological innovations, such "barriers" are prone to evolve, over and above any timely modification of the constitutional text. This can occur because law is not merely a fixed and formal entity, whose meaning is unalterably crystallised in the moment when the text of a law is conceived and approved. It is, rather, in perennial flux, determined by the often unforeseeable questions that challenge the norms contained in law over time. New cases may highlight hitherto unperceived subtleties, while unexpected juridical consequences can arise from the continual interplay among the numerous and not always coherent principles (even constitutional ones) that call for application in the concrete reality on which they converge.

Briefly, some basic similarities exist between the workings of a constitutional juridical system and some of the processes triggered by the knowledge of genetic heritage. Such similarities probably merit reflection and consideration, in the event that they may turn out to be useful.

Further confirmation of this is the fact that the practical problems and risks involved in the applications of genetic science are often analogous, even though in a different guise, to those that have already arisen in traditional juridical experience, on contact with the most simple situations. This is not to deny that new biotech applications can often assume an original character, especially in terms of the risk of abuse. It is nonetheless our view that arguments against an uncritical acceptance of so-called "genetic exceptionalism" have some sound points in their favour. Thus, while never forgetting the new perspective linked to the issues posed by biotech innovations, it can certainly be helpful to link the solutions of the problems they generate over time to some reference point provided by tradition, by all means adapting them to the new situation. It has to be said that it is an approach that law adopts when confronting any form of new phenomenon, as well as "great reforms". We think here, for example, of the issues linked to the use of DNA databanks in forensics, clearly bringing into play problems of personal freedom, privacy and the subjective limits of those whose genetic sequence is stored. Such problems are not wholly dissimilar from those emerging in previously experienced, more traditional contexts. Or, again, consider the vast issue of biobanks, with all the questions arising in terms of consent, donor traceability, data access and the right not to know. Furthermore, the risk of discrimination of individuals and groups based on genetics constitutes a typical ground of commitment for law, and constitutional law in particular, involving the great issue of applications of the principle of equality.

A number of other serious concerns have been raised by policy makers, scholars and researchers in relation to genetic invention patents. Biotech patents (including genes, cell lines and living processes) may be more problematic than patents in other fields (See Plomer A, Taymor KS, Scott CT. Challenges to human embryonic stem cell patents. Cell Stem Cell. 2008 Jan 10;2(1): 13-7). Especially in genetics, patents

can have the adverse effect of restricting access to research, scientific information and health care opportunities. Some scholars have also speculated that biotechnology patents can hamper biomedical research because of their "anticommons" effect (See Michael A. Heller and Rebecca S. Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698 (1998)). In opposition to these arguments, we can observe that some empirical studies exclude a negative impact of patents in genomics (see generally Joseph Straus et al., Genetic Inventions and Patent Law, An Empirical Survey of Selected German R&D Institutions, Munich, 2004). However, apart from complex ethical, economical and juridical implications arising from these kinds of patents, it is clear there are many unanswered questions concerning health, environment, scientific research and access to knowledge. In fact, the patenting of living organisms and genetic materials involves an unexpected reversal of values, opening the frontier to some form of "commodification of life".

Almost all contemporary democratic Constitutions contain a series of principles that must per force be applied also in all the said circumstance. Take, for example, the aforementioned principle of equality both in its central meaning, and in the various ideas of "reasonableness" descending from it. The use of genetic information must never give rise to discrimination, nor go against the idea of the equal social rights of individuals, with all the effects that may be implied on the tenets underpinning the welfare state, which will undoubtedly have to be adapted. It is within this context, in fact, that some possible and dangerous applications linked to the knowledge of the genetic patrimony must be confronted. It is sufficient to contemplate the risk of discrimination in the world of work and insurance sector, instances in which the individual must not be abandoned to the whims of large industrial and insurance companies, unless one wishes to see the reestablishment of very ancient power relationships.

A further confirmation of the unexpected consonance between "the world of law" and some aspects of genetics can be perceived in the significant fact that the very principle of equality, one of the most important artificial creations of constitutional law, now finds justification precisely in the outcomes of biological research and biotech innovations. Briefly, genetics has highlighted starkly how the idea of the existence of different races with different characteristics constitutes an actual "invention" (see generally G. Babujani, L'invenzione delle razze. Capire la biodiversità umana, Milano, 2006). Thus, juridical process and genetic analysis are again shown to be deeply and inextricably interrelated.

But genetics also appears to open a new chapter concerning the relationship between the law and the human body, and thus the interrelation between power, in its broadest sense, and the body, a problem that lies at the very core of fundamental rights, starting from so-called *habeas corpus*. We may think of the problems connected to the collection of biological samples from which to obtain the desired information, and of the numerous issues inherent in their conservation and management. Within this perspective, it is important to recognise how genetics highlights the existence of apparently invisible relationships among the bodies that are present in the same group of origin. For example, the management of information obtained

from an individual's genetic information may eventually involve not only the person him/herself, but may also affect all members of his/her biological family. Therefore, a refusal to allow the transmission of one's own genetic data could end up leading to repercussions for one's own family nucleus, whether negative, or positive (for example, protecting the identity of the family of a suspected criminal). Even if in a wholly novel way, such considerations also re-frame the entire question of relationships between individuals and the group, one of the typical problems of constitutional law. Therefore, to resolve the many applicative issues connected with information management, it is no futile task to dwell upon the centrality of the individual in his/her social grouping, also with a view to ascribing a correct value to the network of social duties expected of him/her (one may consider the all-inclusiveness of art. 2 of the Italian Constitution).

However, the outcomes of genetic research impact on the law-body relationship also in another very different sense. Genetic science overpasses actual bodily confines, arriving at the very origin of many of the body's manifestations and a greater possibility of predicting its future destiny, albeit with the previously described significant limitations. These are challenges that cannot be simply rejected by law; on the contrary, it must accept and control them, adapting and remoulding its instruments in an effort to single out the positive effects of new approaches, while avoiding their more negative potential.

With the development of this intensely individualised outlook, there emerge other, very important analogies between the cognitive model defined by genetic information and the one increasingly pursued by the law. It is a parabola perceivable also in new ways of interpreting and applying both constitutional norms and, in turn, those approved by the general legislator.

Knowledge of the genetic matrix of a disease in fact allows, and will very soon allow in an increasingly targeted way, the maximum level of therapeutic personalization.For example, the expected progress in genetic medicine will offer the possibility of intervening on a patient's genetic patrimony, in order to treat a disease produced by the presence of a defective gene. In the same area, it also appears likely that sooner or later, the capacity will be developed to produce synthetically-based DNA (with single components referred to as *biobricks*) capable of selectively repairing the sick gene. While still at a very early stage, and so far tested through the creating of bacteria and viruses, it is a possibility that has potentially huge implications, both for good and for bad. Still with regard to personalization, we may contemplate the likelihood of a personalization of genetically-based drugs, and of transplant organs, created perhaps starting from biological material from the patient himself, and therefore at virtually zero risk of rejection, as is already happening in some forms of minor surgery. Such lines of research should be the focus of special interest, in view of their anticipated future developments.

On closer consideration, the convergence towards increasingly personalized therapeutic practices embodies a further and extreme application of a constitutional mainstay, i.e. the personalist principle, which in turn translates into a juridical form the Kantian maxim according to which the person must always be the end and never the means of human action. It is a principle that always leaves space for an inevitable

recalibration of the solutions offered by law in the light of individual needs. It is no coincidence if a shift towards a greater "personalization" of the solutions adopted from case to case is already increasingly practiced and recommended, and not only by constitutional law.

Let us consider the very high degree of personalization underpinning the idea of "informed consent" which, in the absence of clear normative instructions, the Italian Constitutional Court extrapolated by appropriately re-reading a series of specific constitutional norms. Thus, in sentence no. 438/2008 we read that "informed consent, intended as the expression of conscious acceptance of a medical treatment proposed by a doctor, represents an actual right of the person and derives from the principles expressed in art. 2 of the Italian Constitution, which protects and promotes his/her fundamental rights, and in articles 13 and 32 of the Italian Constitution, which establish, respectively, that 'personal freedom is inviolable', and that 'no one can be obliged to undergo a given medical treatment except by specific ruling of law"'. The Court arrives at its conclusion, moreover, also by examining the "numerous international norms" that "envisage the necessity of the patient's informed consent in the field of medical treatments". In a similar spirit, the principle was subsequently reiterated in sentence no. 253/2009. We are evidently dealing with an idea and a right that envisage the concrete possibility that different individuals may arrive at profoundly different, but personally sincere choices, while experiencing identical clinical conditions. The fallout of all this is particularly apparent when addressing the options for implementation in the field of end- of-life care, for example, the refusal of certain therapies or the selection of treatments that one intends to undergo, and all the ensuing implications. Against this backdrop, the model of so-called "medical paternalism" becomes increasingly irrelevant, resting as it does on the presupposition of the necessary dependence on expert technical choices, while the new outlook places centre stage the patient's informed will, that is to say his/her specific personality.

Within a similar framework, we can position the Italian constitutional jurisprudence that has demolished some fundamental passages of Italy's inflexible law on medically assisted procreation (n. 40/2004). This was possible precisely because of the law's excessive rigidity, which constituted an insurmountable obstacle to the adoption of reproductive technologies that were as far as possible tailored to the specific physiological needs of the women involved.The argumentation presented in sentence no. 151/2009 is of particular interest in this regard. The Court affirms that "the prohibition contained in comma 2 of art. 14, by excluding any possibility to create a number of embryos greater that that strictly necessary for a single, simultaneous implant, or, in any case, greater than three, imposes the necessity of multiplying the cycles of fertilisation ... since the three embryos produced in the event, are not always able to bring about a pregnancy. The possibilities of success vary, in fact, as a function of both the characteristics of the embryos, and the subjective condition of the women who choose to undergo the procedure of medically assisted procreation, in whom the passage of time gradually reduces the possibility of pregnancy. The legal limit under consideration has the effect, therefore, of favouring, on the one hand – by imposing the need for recourse to the repetition of the said cycles

of ovarian stimulation, should the first implant not produce any result – an increased risk of insurgence of pathologies arising from such hyperstimulation; on the other hand, in the hypothesis of a greater chance of successful fertilisation, it determines a different form of prejudice to the health of the woman and the foetus, in the form of multiple pregnancies, in respect of the prohibition of selective embryo reduction in the case of such pregnancies according to art. 14, comma 4, except for recourse to abortion. This derives from the fact that the legislative regulation does allow the doctor to make an evaluation, on the basis on most modern and accredited technical and scientific knowledge, of individual cases under treatment, and to ascertain from case to case the numerical limit of embryos for implant, deemed appropriate to ensure a serious attempt of assisted procreation, reducing to the theoretical minimum the risk to the health of the woman and the foetus". The Court points out, moreover, that throughout its provisions, it "has repeatedly emphasised the limits posed on legislative discretion by scientific and experimental acquisitions, which are in continual evolution and constitute the basis of medicine: thus, on questions of therapeutic practice, the basic rule must be the autonomy and responsibility of the doctor who, with the patient's consent, shall make the necessary professional choices (sentences no. 338 of 2003 and no. 282 of 2002)".

The principles referred to above, however, are part of an attitude that arrives from afar and has been implemented in numerous situations, including ones not linked to the biotech or new medical issues. We may consider, for example, the important question of personalization of punishments (sentence no. 253/2003), or the ways in which the same Court has chosen to formulate the right to health in art. 32 of the Italian Constitution, in order to allow a more flexible application of other long established principles and provisions that are apparently impermeable to change. It is what transpires from the constitutional jurisprudence that declared the constitutional illegitimacy of the norms of criminal law that punished abortion, even when pregnancy potentially endangered - precisely - the health of the woman (sentence no. 27/1975). There is also the sentence that declared unfounded the questions of legitimacy raised against law no. 164/1982, which allows the demolition and reconstruction of the sexual traits of persons, when such traits do not correspond to their innermost gender identity (sentence no. 161/1985). Or, again, we may reflect on the circumstances in which the Court recognizes the necessity that it should be up to judges, when evaluating the merits of concrete cases, to ponder their decisions in the light of each case's specific characteristics (the so called "delega di bilanciamento in concreto"). In some cases, however, this "special assignment" does not concern judges, but the experts appointed to answer upon specific aspects of problematic cases (for example, physicians), which will inevitably have effects on situations and their protagonists. It may also be borne in mind that the entire jurisprudence of the *western legal tradition* is based on this philosophy, as it increasingly comes to grips with issues of multiculturalism, variously adapting the concrete application of the repressive tools made available by the law, to deal with the specificities of the matter at hand, taking account of the cultural dimension in which the offender has acted.

An endless number of examples could probably be cited, but what really interests us is the general picture emerging from these examples. First of all, as is easily un-

derstood from these brief remarks, such developments open up, in all cases and all sectors, ample terrain for legislative or jurisprudential evaluations of equality, reasonableness, and discretion; that is to say, for re-adapting the forms of judgement that have long characterised jurisprudence throughout the world. There is more, however. These examples confirm how law is increasingly called upon to grapple with the distinctive physiognomies of single cases and the variables that each of them brings into play. The same is true, to the most extreme degree, as previously discussed, for medical applications of biotechnologies, in view of their structural originality. They tell us that such patterns, so similar in their essential traits, are part and parcel of the times in which we live, characterising them in a very deep sense. They constitute, in brief, the specific challenge of law in the post-modern era, as affirmed by Paolo Grossi. They are further confirmation, moreover, of our underlying argument, i.e. that the problems raised by new technologies often conceal, in diverse guises, substantially common outlines to the issues and approaches that law has for some time applied in far more traditional areas. They represent, therefore, experiences and profiles that, far from being abandoned, should be appropriately re-examined in the light of new developments.

In the meantime, however, all this is before our very eyes, and jurisprudence is already employing the approaches summarised above, while – on a series of issues that we may define as "topical" – parliamentary and political procedures paradoxically appear increasingly unreceptive to both scientific outcomes and the law of the most discerning courts. It certainly offers little encouragement, not only in matters by now considered traditional (such as assisted procreation or techniques for the termination of pregnancy), but, to an even greater extent, when we ponder the future regulation of highly complex and specialised issues, such as those relating to genetics. The tendency is particularly evident in the Italian politics, which are characterised by a high level of ideological instrumentation with regard to these themes. We have in mind, for example, the events centring upon the approval of the abovementioned law no. 40/2004, and the current discussion on the proposed law on the "biological will". Nonetheless, significant examples of similar attitudes are emerging in other contexts. An instance can be identified in the pronouncement of the US Supreme Court *Gonzales v. Carhart* of 18 April 2007, which approved the prohibition to employ a specific abortion technique, on the basis of highly questionable scientific data that are strictly functional to the so-called pro-life thesis. Or, again, consider the controversy that surrounded in the past in the United States, and that still goes on today in Italy, on the subject of embryonic stem cell research. Such crude ideological preclusions are impervious to the complexity of the matters at hand, the interests involved and the possible beneficial applications of biotechnological outcomes.

Against this backdrop, the problem arises of understanding what type of law is likely to be produced by political bodies that are so closed to the biotech discoveries and, at the same time, so reluctant to apply to new situations, the same coordinates already tried and tested in the past and, still today, not wholly to be discounted. What law? This is, definitively, the interrogative posed by the various contributors to this volume, whose task it is to provide some difficult answers.

The Case against the Privatization of Knowledge: Some Thoughts on the Myriad Genetics Controversy

Giorgio Resta

Abstract In the current debate on intellectual property, the work of Karl Polanyi is frequently referred to by jurists, mainly in connection with the story of the 'old' and 'new' enclosures. In this paper I suggest that the critical account of the rise of the 'market economy' provided by Polanyi can shed some light on other important issues in intellectual property law. In particular, I advance the hypothesis that the paradigm of the 'double movement' might contribute to a better understanding of the contemporary movements of resistance against the increasing commodification of knowledge. Using the *Myriad Genetics* controversy as a paradigmatic example, I reflect on the importance of fundamental rights as an institutional safeguard against the expansionary tendency of intellectual property law and on the role of the judiciary as guarantor of social cohesion, endangered by the disruptive effects of market rationality.

Keywords Gene patents, fundamental rights, commodification of knowledge, enclosures.

1 Knowledge as a "Fictitious Commodity"

In the current debate on intellectual property, one of the most recurrent metaphors is that of the *enclosure*[1]. In the discourse of economic historians this expression refers to the fencing off of open lands, which took place in England from early Tudor times

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[1] See C. May, *The Global Political Economy of Intellectual Property Rights. The New Enclosures*, Oxon-New York, 2010, 12, 52; J. Boyle, *Public Domain. Enclosing the Commons of the Mind*, New Haven, 2008, 42 ss.; Id., *The Second Enclosure Movement and the Construction of the Public Domain*, in 66 *Law & Cont. Prob's* 33, 37 (2003); Id., *Fencing Off Ideas,* in *Daedalus* 13 (2002); Id., *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us*, in F. Scott Kieff, *Perspectives on Properties of the Human Genome Project*, San Diego, 2003, 97 ss.; N. Kranich, *Countering the Enclosure: Reclaiming the Knowledge Commons,* in C. Hess – E. Ostrom, Eds., *Understanding Knowledge as a Commons. From Theory to Practice*, Cambridge, 2007, 85 ss.; M. Cassier, *New 'Enclosures' and the Creation of New 'Common Rights' in the Genome and in Software*, in 15 *Contemporary European History* 255 (2006); H.

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up to the Industrial Revolution[2]. Today's jurists use the term *enclosure* to describe a different process underway in the field of intellectual property: the continual expansion of the sphere of exclusive rights and the shrinking spaces of free access to immaterial resources. In analogy to the events of other historical periods involving the regulation of access and enjoyment of land, we today find ourselves confronted with a new "enclosure movement", this time involving intangible *commons*[3].

Based on the premise that the knowledge economy extols the economic value of information and requires a "high" level of protection (cfr. Directive 2004/48/CE, *whereas clause* n. 10; Directive 2001/29/CE, *whereas clauses* 4 and 9)[4], most western legal systems have pursued over the past twenty years a clear strategy of vertical and horizontal expansion of exclusive rights[5]. It is not easy to understand whether this institutional tendency constitutes a rational response to the evolving social and technological context, or whether it represents one of the many examples of "capture" of the regulator by a few, powerful economic actors who are able to wield influence over the marketplace of national and international legislation[6]. What is certain is that the dividing line between 'public' and 'private' in the production and distribution of knowledge has become increasingly finer, with a clear tendency towards the strengthening of the "private" to the detriment of the "public"[7]. Against this background, knowledge is increasingly assuming the characteristics of a "fictitious commodity".

This expression was used by Karl Polanyi to define those entities, like land, labour and money that, while not having the features of commodity (that is to say, being neither things *produced* by man, as in the case of land, nor *produced for sale*, as in the case of labour), are nonetheless acquired and regulated as such within the framework of the modern capitalist system[8]. In the course of history, the "fiction" whereby the human person, land and money have come to assume the status of commodity, has been vested with extraordinary value. It is only thanks to this fiction that it has been possible to organise the labour, land and money markets, which have in turn become the central pillars of the model, emerging in the nineteenth century, of

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Travis, *Pirates of the Information Infrastructure: Blackstonian Copyright and the First Amendment*, in 15 *Berkeley Tech. L.J.* 777, 785, 827 (2000).

[2] See J. A. Yelling, *Common Field and Enclosure in England 1450-1850*, Hamden, 1977; R. Kain – J. Chapman – R. Oliver, *The Enclosure Maps of England and Wales*. 1595-1918, Cambridge, 2004.

[3] The best description of this phenomenon is given by J. Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, cit., 33 ss.

[4] See A. Peukert, *Güterzuordnung und Freiheitsschutz*, in R.M. Hilty – T. Jaeger – V. Kitz, Eds., *Geistiges Eigentum. Herausforderung Durchsetzung*, Berlin - Heidelberg, 2008, 47 ss.

[5] For a more detailed discussion, refer to G. Resta, *Nuovi beni immateriali e* numerus clausus *dei diritti esclusivi,* in G. Resta, Ed., *Diritti esclusivi e nuovi beni immateriali*, Torino, 2010, 3 ss., 15.

[6] S. Levmore, *Property's Uneasy Path and Expanding Future*, in 70 *U. Chicago L. Rev.* 181, 190-194 (2003); J. Lapousterle, *L'influence des groupes de pression sur l'élaboration des normes. Illustration à partir du droit de la propriété littéraire et artistique*, Paris, 2009; P. Drahos – J. Braithwaite, *Information Feudalism. Who Owns the Knowledge Economy?*, London, 2002, 14.

[7] C. May, *The Global Political Economy of Intellectual Property Rights*, cit., 69.

[8] K. Polanyi, *The Livelihood of Man,* edited by H.W. Pearson, New York, 1977, 10; Id., *La mentalité de marché est obsolète!*, in *Essais de Karl Polanyi*, Paris, 2008, 505 ss., 507.

the self-regulating market[9]. Such equivalence was, therefore, the cornerstone of the autonomization of the economic system, unknown until then in the history of social organisation[10], and of the inversion of the relationship between economy and society: no longer was the economy *embedded* in social institutions, but social relations were embedded in the economic system[11].

Close scrutiny of our surrounding reality seems to endorse the hypothesis that today, knowledge is not just one of the principle factors of production, but it is also increasingly and irreversibly drawn towards the sphere of commodities[12]. Obviously, there are aspects of the regulation of knowledge that justify its equivalency with the category of commodity in the strict sense: any time it is actively produced for sale in a labour process (like software, for example), this characteristic would be difficult to deny. However, there are many cases in which knowledge is either not produced for sale, but as a use value, or it is not produced at all, because it already exists in nature prior to assuming a form of an exchange value[13]. In these hypotheses, the application of a legal regime, predicated on commercialization and trade, certainly leads knowledge to be counted as a fictitious commodity.

Careful analysis of the institutional processes underway shows how their main effect is to cut away more and more of the collective store of knowledge, subjecting it to a logic of exclusive appropriation and market exploitation. This is particularly evident when we test the hypothesis that basic knowledge, traditionally produced for collective fruition, is today invested by a process of increasing *commodification*[14], emblematically inaugurated by the Bay-Dohle Act, and other legal provisions whose goal is to increase patenting by public university institutions, as well as the transfer of technology into private hands[15]. The same can be said, however, of many other widely studied hypotheses, such as the introduction of exclusive rights

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[9] K. Polanyi, *La grande trasformazione. Le origini economiche e politiche della nostra epoca*, Torino, 1974, 94, 168.

[10] See K. Polanyi, *The Economy as Instituted Process*, in K. Polanyi – C.M. Arensberg – A. W. Pearson, *Trade and Market in the Early Empires. Economies in History and Theory*, New York, 1957, 243 ss., 250.

[11] K. Polanyi, *La grande trasformazione*, cit., 74; for a close analysis of this interpretative perspective see, now, M. Cangiani, *Karl Polanyi's Institutional Theory: Market Society and Its 'Disembedded' Economy*, in 45 *J. Econ. Issues* 177 (2011).

[12] See B. Jessop, *Knowledge as a Fictitious Commodity: Insights and Limits of a Polanyian Perspective,* in A. Buğra – K. Ağartan, Eds., *Reading Karl Polanyi for the Twenty-First Century. Market Economy as a Political Project,* New York, 2007, 115 ss.; C. May, *The Global Political Economy of Intellectual Property Rights*, cit., 22-48; and T. MacNeill, *The End of Transformation? Culture as the Final Fictitious Commodity,* in 12 *Problématique. Journal of Political Studies* 17, 25 (2009).

[13] On such distinctions, see B. Jessop, *Knowledge as a Fictitious Commodity: Insights and Limits of a Polanyian Perspective*, cit., 118.

[14] See G. Irzik, *Commercialization of Science in a Neoliberal World*, in A. Buğra – K. Ağartan, Eds., *Reading Karl Polanyi for the Twenty-First Century. Market Economy as a Political Project*, cit., 135 ss.

[15] See A. Rai – R. Eisenberg, *Bayh-Dole Reform And The Progress of Biomedicine*, in 66 *Law & Cont. Probs.* 289 (2003); B. Williams-Jones – V. Ozdemir, *Enclosing the 'Knowledge Commons': Patenting Genes for Disease Risk and Drug Response at the University – Industry Interface*, in C. Lenk – N. Hoppe – R. Andorno, *Ethics and Law of Intellectual Property. Current Problems in Politics, Science and Technology*, Aldershot, 2007, 137; R. Caso, Ed., *Ricerca scientifica pubblica, trasferimento tecnologico e proprietà intellettuale*, Bologna, 2005.

on non-creative collections of data[16], or – an issue later explored in some depth – the patenting of human DNA sequences[17]. While the methods employed are diverse, the overall trend in all these sectors is the same: through various conscious institutional choices, new *property rights* have been introduced with regard to goods previously subject to a regime of free access, or market-inalienability. That this has been possible is largely due to a process of cultural legitimation, rooted in the conception that sees knowledge as a commodity.

As a result, knowledge is created on the basis of this fiction, one that has historically accounted for the development of land, labour and money markets.

2 Intellectual Property: Techniques and Ideologies

One may wonder why it is useful to refer to categories that are not strictly legal, like that of the "enclosure", or "fictitious commodity", to better understand the regulation of intellectual property and its more recent evolution.

Such a question may solicit different answers, according to the particular methodological approach adopted by the interpreter. With the perspective presented here, I believe there is a major advantage in cognitive terms to be gained from the use of this kind of argumentative model. It is that of delineating a critical framework that differs from the one offered by the mainstream literature, one that is able to provide insight on the real nature of the interests involved in the choices that jurists tend to describe as "merely technical"[18]. The positivistic orientation of our legal culture prevents us from exactly grasping the extraordinary role that ideology has always played, and continues to play, in the area of immaterial assets[19]. From the very outset it has served as a crucial instrument of legitimation and consolidation of exclusive rights, first discredited by the breakdown of the system of *Ancien Régime* privileges[20], and today threatened by the rapid pace of technological progress, which,

[16] On this topic, see, among many others, J.H. Reichman – P.F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, in 66 *Law & Cont. Prob's* 314, 361-461 (2003). A further particularly relevant issue is that of geospatial data and public sector information: see M. van Eechoud, *The Commercialization of Public Sector Information. Delineating the Issue*, in P.B. Hugenholtz – L. Guibault, *The Future of the Public Domain*, The Hague, 2006, 279; P. Weiss, *Borders in Cyberspace: Conflicting Government Information Policies and their Economic Impacts*, in *Open Access and the Public Domain in Digital Data and Information for Science: Proceedings of an International Symposium*, Washington, D.C, 2004, 69 ss.

[17] See *infra*, parr. 4-5.

[18] See, in general Du. Kennedy, *The Political Stakes in "Merely Technical" Issues of Contract Law*, in 1 *Eur. R. Priv. L.* 7 (2001); with specific reference to the debate on methods of comparative law, see Dav. Kennedy, *The Politics and Methods of Comparative Law*, in P. Legrand – R. Munday, Eds., *Comparative Legal Studies: Traditions and Transitions*, Cambridge, 2003, 345 ss.

[19] See A. Kapczynski, *Access to Knowledge: A Conceptual Genealogy*, in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property*, New York, 2010, 17 ss., 26 ss.; also J. Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, cit., 51 ss.

[20] See V. Jänich, *Geistiges Eigentum – eine Komplementärerscheinung zum Sacheigentum?*, Tübingen, 2002, 183.

while increasing the economic value of information, also favours opportunities of its abusive exploitation[21].

At the time of the Industrial Revolution, free-trade doctrines fused with the new conditions that arose from developments linked to the advent of large machines[22]. Now, as then, the ideological apparatus superimposes on the technological substrate to fuel the impetus towards a *commodification* of knowledge[23]. It is important, therefore, to identify the conceptual mainstays of the policy of "high level of protection" and the steady expansion of intellectual property rights.

Laying aside the specifics of individual legal traditions, the argument generally hinges on the idea of the natural inefficiency of regimes of free access to information and recourse to the system of time-restricted exclusive rights, as the necessary drivers of innovation[24].This outlook, matured within the Anglo-American setting and embraced by a very large number of supranational institutions, has a dual theoretical foundation[25]. On the one hand, it rests on the postulates of information economics and, on the other, on the Hayekian thesis of the superiority of private ownership regimes over the various forms of public regulation. The point of intersection between the two theoretical models is represented by the paradigm of the tragedy of the *commons*, so vividly described in the pages of the biologist Garrett Hardin, and adapted to the specific characteristic of the assets in question[26]. In the field of tangible goods the "tragedy" takes the form of overexploitation leading to the complete consumption of resources. In the area of intangibles, in view of the non-excludability and non-rivalry of information, it stems from an insufficient production of such assets[27]. Obviously, it would be easy to object that the problem of sub-optimal levels of information production could be solved by institutional solutions different from the constitution of monopoly rights: for example, through a publicly funded system of rewards, prizes, subsidization, etc.[28] However, it is precisely to side-step such objections that the dominant perspective borrows from the classic theory of property rights[29] and, extolling the "virtues of decentralization",

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[21] J. Boyle, *The Public Domain*, cit., 54 ss.

[22] See K. Polanyi, *La grande trasformazione,* cit., 141-164; Id., *The machine and the discovery of society*, manuscript of 24 April 1957, now published in the French translation in *Essais de Karl Polanyi*, cit., 547; on the point G. Dale, *Karl Polanyi*, cit., 52-58.

[23] See C. May, The Global Political Economy of Intellectual Property Rights, cit., 11 ss.; T. MacNeill, *The End of Transformation? Culture as the Final Fictitious Commodity*, cit., 28.

[24] For a description of the theoretical models of reference, see. P. Menell – S. Scotchmer, *Intellectual Property*, in A. Mitchell Polinksy – S. Shavell, *Handbook of Law & Economics*, II, Amsterdam, 2007, 1475 ss., 1482; W. Gordon, *Intellectual Property*, in P. Cane – M. Tushnet, *The Oxford Handbook of Legal Studies*, Oxford, 2003, 617 ss., 638.

[25] See on this point the lucid analysis of A. Kapczynski, *Access to Knowledge: A Conceptual Genealogy*, cit., 26 ss.

[26] G. Hardin, *The Tragedy of the Commons*, in 162 *Science* 1243 (1968).

[27] R. Cooter – T. Ulen, *Law & Economics*, III ed., Reading-Menlo Park, 2000 ss., 126.

[28] P. Menell – S. Scotchmer, *Intellectual Property*, cit., 1530 ss.

[29] See U. Mattei, *Basic Principles of Property Law. A Comparative Legal and Economic Introduction*, Westport-London, 2000, 1 ss.

leans towards the superiority of a system of innovation stimuli centred on private initiative, rather than mechanisms of centralised planning and public regulation[30].

If this is the theoretical model underpinning the politics of "high protection" of intellectual property rights, it is easy to understand how the comparison with the first enclosure movement is essentially functional to the purpose of "ideological criticism"[31]. In the works of authors who, like Boyle, have insisted most on the analogy, the reference to the privatisation of common lands appears fundamental to underscoring two critical elements of the exclusivist model.

The first is that of the social and redistributive impact of the privatisation of knowledge[32]. Here, the allusion to the enclosures experience can be particularly elucidating. While the traditional literature has mainly stressed the pro-competitive effect of enclosures, which – it maintains – favoured the rationalization of land-use and represented an essential premise of the subsequent industrial development[33], the research performed by Polanyi and other economic historians have yielded a far more detailed, and less apologetic picture of the phenomenon[34]. In particular, their studies recall how the mutation in the land ownership regime, so brightly described in terms of its improving side-effects, caused in reality a violent uprooting of large segments of the population from their homelands, the upheaval of the social fabric and a far reaching cultural impoverishment, that no level of industrial development was ever able to cancel out[35]. What was defined by many as "progress", for others was an immense calamity, a real "revolution of the rich against the poor"[36]. As was the case in the field of material goods, the process of 'privatization' of immaterial resources is today justified according to the "neutral" paradigm of rational choice, but it presents many serious social and redistributive implications which, as emblematically shown by the issue of access to patented antiretroviral drugs, must be neither undervalued, nor underplayed[37].

The second critical element has to do with the issue of allocative efficiency, and particularly involves the transposability of the "tragedy of the commons" model to the intangibles sector[38]. Even leaving aside the criticism previously lodged against

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[30] P. Menell – S. Scotchmer, *Intellectual Property*, cit., 1477; J. Boyle, *Public Domain*, cit., 2.

[31] As lucidly emerges from the pages of J. Boyle, *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us*, cit., 106 ss., spec. 113 ss.

[32] See, again, J. Boyle, *Enclosing the Genome: What Squabbles over Genetic Patents Could Teach Us*, cit., 113.

[33] For a discussion of the benefits in terms of efficiency related to the enclosure movement, see, D.N. McCloskey, *The Enclosure of Open Fields: Preface to a Study of Its Impact on the Efficiency of English Agriculture in the Eighteenth Century*, in 132 *J. Econ. History* 15 (1972).

[34] See K. Polanyi, *La grande trasformazione*, cit., *passim*; see, also, R.C. Allen, *Enclosure and the Yeoman,* New York, 1992; Id., *The Efficiency and Distributional Consequences of Eighteenth Century Enclosures*, in 92 *Econ. J.* 937 (1982).

[35] K. Polanyi, *La grande trasformazione*, cit., 45-56.

[36] K. Polanyi, *La grande trasformazione*, cit., 47.

[37] For a critical view on intellectual property 'politics' over the past decades, see, in particular, P. Drahos, *"IP World" – Made by TNC Inc.,* in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property,* cit., 197 ss., spec. 205 ss.

[38] J. Boyle, *Public Domain*, cit., 47 ss.

this paradigm in the field of material resources (e.g. the studies of Carol Rose and Elinor Ostrom)[39], it must be borne in mind that, when the resources in question are not of a material character, but are intangible, it has yet to be demonstrated that a regime of free access necessarily leads to "tragic" outcomes. In particular, the problem of the production of a sub-optimal amount of information appears somewhat overestimated, since in many sectors reputational factors and informal social rules often constitute incentives to innovation no less efficient than the promise of a monopoly on exploitation[40]. The intrinsic limitation of the "economistic" approach is that of elevating the paradigm of rational choice to the status of ordering criterion, thus taking insufficient account of non-utilitarian models of behaviour, such as those based on reciprocity and redistribution[41]. Additionally, considerations in terms of efficiency lead us to voice serious concerns as to the risks deriving from the introduction of excessively high barriers to information access. Because knowledge is never just the output, but is also the input of all production processes, recourse to the strategy of monopoly becomes highly problematic. If not adequately controlled, it risks endangering the possibility of future development and innovation, neutralizing the benefits drawn from technological progress and the growing opportunities of information sharing[42]. This radically turns the tables on the scenario evoked by Hardin: no longer the tragedy of the *commons* caused by the granting of property rights, but the tragedy of the *anti-commons*, as the counterproductive effect of an excessive proliferation of monopoly rights[43]. New property rights are created as instruments of development and economic growth, but due to a curious phenomenon of heterogenesis of ends, we find ourselves in the middle of a gridlock economy[44].

3 Commodification and Its Discontents: the "Double Movement" Paradigm

The complexity and importance of the issues at stake in the intellectual property arena should encourage us to read the operational reality through lenses other than those prescribed by the Chicago laboratory. In particular, having abandoned the postulate of the 'naturality' of monopoly ownership models, one must reflect very care-

[39] C. Rose, *The Comedy of the Commons: Custom, Commerce and Inherently Public Property*, in 53 *U. Chicago L. Rev.* 711 (1986); E. Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action,* Cambridge, 1990.

[40] J. Boyle, *Public Domain*, cit., 3 ss.

[41] See K. Polanyi, *The Economy as Instituted Process*, cit., 243 ss.; and, albeit from a different perspective, D.C. North, *Markets and Other Allocation Systems in History: The Challenge of Karl Polanyi*, in 6 *J. Eur. Econ. History* 703 (1977).

[42] J. Boyle, *Public Domain. Enclosing the Commons of the Mind*, cit., 48 ss.; M. Boldrin – D.K. Levine, *Against Intellectual Monopoly*, Cambridge, 2008, 68 ss., 184 ss., 243.

[43] M.A. Heller – R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, in 280 *Science* 698 (1998).

[44] M. Heller, *The Gridlock Economy. How Too Much Ownership Wrecks Markets, Stops Innovation, and Costs Lives*, New York, 2008, *passim*.

fully on the implications of the institutional choices adopted by bodies responsible for creating and regulating knowledge markets. Who wins and who loses in this process? Above all: what are its long-term consequences?

For a critical exploration of these interrogatives, it can be useful to go back to Polanyi's analysis, this time going beyond the 'first part', usually the main focus of intellectual property scholars[45].

The Great Transformation does not limit itself to describing the genesis and affirmation of the self-regulated market model, as a parable that takes in also the enclosure movement experience.The entire 'second part' of the book is devoted to an analysis of the complex processes of adaptation and reaction, triggered by the reversal in the relationships between economy and other social institutions[46]. As we know, Polanyi's central thesis is that the utopia of a society organised and governed entirely by the logic of the market, in which land, labour and money are fictitiously treated as commodities, is in the long term unsustainable for any community. According to the interpretation advanced by the Hungarian author, this gives rise to a series of apparently heterogeneous responses – e.g. the introduction of factory laws, worker protection statutes, the application of import tariffs, the regulation of the monetary system. However, when taken together, they are seen as the expression of a more generalised counter-movement, through which society defends itself against the destructive tendencies of the market[47]. In Polanyi's analysis, the counter-movement was neither politically univocal nor internally coherent; neither did it merely serve to add "a few drops of social oil" (to use the words of Gierke) to the market's self-regulating mechanism. On the contrary, it was destined to fuel further tension and greater contradictions, culminating in the implosion of the *laissez faire* model as conceived in the nineteenth century[48].

Although formulated in relation to a specific phase of capitalism, and not uncontroversial[49], Polanyi's reflection still seems to offer several interpretative keys useful for understanding many of the processes underway in contemporary society. In particular, the "double movement" paradigm has been cited by many authors – including Habermas[50] – to elucidate the dynamics of market globalization, and to reconsider the overall effects of the Neo-liberal reforms undertaken in last thirty years[51]. If properly historicised and taken merely as a theoretical framework of

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[45] See, for example, J. Boyle, *The Second Enclosure Movement and the Construction of the Public Domain*, cit., 33 ss.

[46] K. Polanyi, *La grande trasformazione*, cit., 167-278.

[47] K. Polanyi, *La grande trasformazione*, cit., 98.

[48] On Polanyi's thesis of 'double movement', see M. Cangiani, *Economia e democrazia. Saggio su Karl Polanyi*, Padova, 1998, 58 ss.; G. Berthoud, *Repenser le 'double mouvement'*, in M. Servet – J. Macourant – A. Tiran, Eds., *La modernité de Karl Polanyi*, Paris, 1998, 363 ss.

[49] On this, see G. Dale, *Karl Polanyi. The Limits of the Market*, Cambridge, 2010, 72-88.

[50] J. Habermas, *The Postnational Constellation and the Future of Democracy*, in Id., *The Postnational Constellation. Politcal Essays*, translated by M. Pensky, Cambridge, 2001, 58 ss., 84-85.

[51] See for example, A. Buğra, *Polanyi's Concept of Double Movement and Politics in the Contemporary Market Society*, in A. Buğra – K. Ağartan, Eds., *Reading Karl Polanyi for the Twenty-First Century,* cit., 173 ss.; M. Bienefeld, *Suppressing the Double Movement to Secure the Dictatorship of Finance*, ivi, 13 ss.; F. Block, *Polanyi's Double Movement and the Reconstruction of Critical Theory*, in 38 *Rev. Inter-*

reference (rather than as a predictive model), the bipolar model reconstructed by Polanyi can be usefully employed in a non-orthodox re-reading of some of the developments arising in the field of intellectual property, at least starting from the TRIPs agreements[52].

So far, we have spoken of the process of expansion of monopoly rights as the salient feature of contemporary cognitive capitalism. It is, however, only part of the story and does not address exhaustively all of the relevant phenomena arising in the intellectual property domain. While it is true that access to knowledge accounts for some of the essential nodes of the current 'ownership issue'[53], it is not surprising that precisely such questions have become the gathering focus first of critical analysis, then of phenomena of individual dissent, and finally of organised mobilisations of opinion. The latter proclaim the need for a reorganisation of innovation stimulating regimes in terms of the category of non-appropriable common goods and cooperative models of interaction (such as those based on the logic of open access)[54]. One of the best known among such movements is A2K, an acronym that stands for "access to knowledge"[55]. It includes among its ideal members lawyers, NGO representatives, activists and political leaders from different parts of the world, particularly the developing countries. They are engaged in opposing the 'neo-protectionist' rationales and in the effort to set up a different 'ecology' of information[56].

The project for the regulation of knowledge as a "commons"[57] has not only become an established figure in public debate, but it has also attained its first operative successes in the form of several important legal provisions and planning documents adopted by institutions responsible for regulating intellectual property and human rights. They include, among others, the 2001 Doha Declaration and the 2003 De-

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ventions économiques [En ligne], 38 (2008); B.J. Silver – G. Arrighi, *Polanyi's "Double Movement": The* Belle Époques *of British and U.S. Hegemony Compared*, in 31 *Politics & Society* 325 (2003).

[52] On TRIPS as a watershed in the evolution of the intellectual property experience, see L. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, in 29 *Yale J. Int. L.* 1 (2004); G. Krikorian, *Free-Trade Agreements and Neoliberalism: How to Derail the Political Rationales that Impose Strong Intellectual Property Protection*, in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property*, cit., 293 ss.

[53] See, in general, S. Rodotà, *Proprietà: una parola controversa*, in *ParoleChiave*, 2003, 1 ss.

[54] See N. Kranich, *Countering the Enclosure: Reclaiming the Knowledge Commons*, cit., 94 ss.; P. Levine, *Collective Action, Civic Engagement, and the Knowledge Commons*, in C. Hess – E. Ostrom, *Understanding Knowledge as a Commons*, cit., 247 ss.; P. Suber, *Creating and Intellectual Commons through Open Access*, ivi, 171 ss.

[55] A. Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, in 117 *Yale L. J.* 804 (2008).

[56] For the necessary references, see, in particular, Y. Benkler, *The Idea of Access to Knowledge and the Information Commons: Long-Term Trends and Basic Elements*, in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property,* cit., 217 ss.; G. Krikorian, *Access to Knowledge as a Field of Activism*, ivi, 57 ss.; A. Abdel Latif, *The Emergence of the A2K Movement: Reminiscences and Reflections of a Developing-Country Delegate*, ivi, 99 ss.

[57] See C. Hess – E. Ostrom, Eds., *Understanding Knowledge as a Commons*, cit.; J. Boyle, *Public Domain*, cit., 230 ss.

cision of the General Council (WTO) on access to patented medicines[58]; or again, the establishment in 2007 of the WIPO Development Agenda, supported by a broad coalition of developing countries[59]. In addition, a similar legislative policy seems to have informed the position adopted by the European Parliament during discussions on the directive proposal (then rejected) on software patenting[60].

Could we be witnessing the first signs of a self-defence strategy of society against the dangers brought by market universalisation? Answering this question is certainly not easy. On the other hand, neither is it indispensable, at least if we do not consider the double-movement paradigm as a predictive model of behaviour. It appears more useful to reflect upon the forms that such social protectionism might assume, and on the outcomes it may achieve for the overhauling of the system of knowledge regulation.

In this essay, I confine myself to addressing the first of these two points. The main question lies in identifying the institutional circuits through which the collective claim to protection may more easily find acceptance and effective representation. The most obvious hypothesis is that of the political process and, at least within democratic systems, parliamentary initiatives[61]. From a retrospective viewpoint, this has been the most commonly chosen and, not infrequently, most successful route. However, it would be short-sighted to ignore the objective hurdles encountered by such strategies in the current institutional framework, characterised as it is by a strong decentralisation of legislative sources[62], the constant pressure of regulatory competition[63],and the pace of technological change. Finally, there is the deep asymmetry in capacities of political influence, in all sectors (like that of intellectual property) where a few 'repeat players', endowed with strong economic power and homogeneous interests, compete with a large but disorganised body of potential counter-interests[64]. In this context, an important, although rarely considered, alternative is that of the court system. Especially where it is possible to configure the said opposing interests in terms of constitutional rights, the court system can offer an efficient channel of representation of non-proprietary interests, in conjunction with, or in substitution of the ordinary political process.

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[58] On this theme see S. Shashikant, *The Doha Declaration on TRIPS and Public Health: An Impetus for Access to Medicines*, in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property*, cit., 141 ss.

[59] In this respect, see V. Muñoz Tellez – S. Musungu, *A2K at WIPO: The Development Agenda and the Debate on the Proposed Broadcasting Treaty*, in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property*, cit., 175 ss.

[60] See P. Aigrin, *An Uncertain Victory: The 2005 Rejection of Software Patents by the European Parliament,* in G. Krikorian – A. Kapczynski, Eds., *Access to Knowledge in the Age of Intellectual Property,* cit., 161 ss.

[61] See for example, F. Block, *Polanyi's Double Movement and the Reconstruction of Critical Theory*, cit., 5-6.

[62] See U. Breccia, *Immagini della giuridicità contemporanea tra disordine delle fonti e ritorno al diritto*, in *Riv. crit. dir. priv.*, 2006, 361; N. Lipari, *Le fonti del diritto*, Milano, 2008.

[63] See A. Zoppini, Ed., *La concorrenza tra ordinamenti giuridici*, Roma-Bari, 2004.

[64] S. Levmore, *Property's Uneasy Path and Expanding Future*, cit., 190-194.

4 Is the Human Genome Patentable? The Myriad Genetics Controversy

To illustrate this phenomenon, few episodes are as instructive as the one that recently took place before the US Federal Courts, scene of a head-on challenge of one of the determining precepts of contemporary proprietary theology: the principle of patentability of human DNA sequences[65]. On 29 March 2010, the U.S. District Court for the Southern District of New York issued a decision which, if it holds up on appeal, is destined to alter profoundly the institutional infrastructure of biotech research, above all (but not exclusively) in the US context[66]. The decision passed in the controversy *Association of Molecular Pathology v. USPTO*[67], has concretely invalidated 7 of the 23 patents granted to the company Myriad Genetics in relation to the sequences of tumour-suppressor genes BRCA1 and BRCA2 (whose mutations are responsible for the predisposition to breast and ovarian cancers) and respective diagnostic tests.

The Myriad Genetics controversy is well known and has already received detailed coverage. However, to better understand the important ramifications of the decision in question, it is useful to recall some of the actual premises from which the dispute arose. The following account is based on some detailed studies recently published, as well as on the summary of the facts provided by the U.S. District Court's decision[68].

Myriad Genetics was set up in 1991 by the geneticist Mark Skolnick and Prof. Walter Gilbert, Nobel Prize winner for chemistry for his work on the sequencing of nucleic acid. At that time, Skolnick was the head of one of the most important international research groups engaged in the identification of the genes involved in the insurgence of breast cancer. His group, with the collaboration of some researchers of the National Institute of Health, had undertaken a large-scale study on the genetic profile of the Mormon community. Fundamental to the study was the availability of a database compiled by Skolnick in the 1970s at the Center for Cancer Genetics Epidemiology of the University of Utah, which contained information on many families

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[65] The principle is assimilated in numerous legal systems and supported by the TRIPS agreements: see G. Van Overwalle, *Biotechnology and Patents: Global Standards, European Approaches and National Accents*, in D. Wüger – T. Cottier, *Genetic Engineering and the World Trade System*, Cambridge, 1998, 91 ss.; C.A. Fowler, *Ending Genetic Monopolies: How the TRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide*, in 25 *Am. U. Int'L L. Rev.* 1073 (2010); L. Andrews, *Genes and patent policy: rethinking intellectual property rights*, in 3 *Nature Genetics* 803 (2002).

[66] See, on the point under consideration, M. Cho, *Patently unpatentable: implications of the Myriad court decision on genetic diagnostics*, in 28 *Trends in Biotechnology* 548 (2010); M. Yoon, *Gene Patenting Debate: The Meaning of* Myriad, in 9 *J. Marshall Rev. Int. Prop. L.* 953 (2010).

[67] *Association for Molecular Pathology v. United States Patent and Trademark Office*, No. 09 Civ. 4515 (S.D.N.Y., Mar. 29, 2010).

[68] See R. Gold – J. Carbone, *Myriad Genetics. In the Eye of the Policy Storm*, in 12 *Genetics in Medicine* 39 (2010); B. Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, in 10 *Health L. J.* 123 (2002).

and descendants of the original 10.000 Utah settlers[69]. This database was crossed with the Utah cancer register, thus creating a sample of 40,000 highly representative genetic profiles, which became the focus of Skolnick's subsequent research. This was the background against which Myriad was founded: the company came into being as a spin off of the abovementioned Center in order to attract the risk capital required for completing such research[70]. Myriad had already received notable amounts of public funding specifically granted for research on the gene BRCA1 from the National Institute of Health (between 2 and 5 million dollars, equal to a third of the funds necessary for the completion of research)[71] and from the National Cancer Institute of Canada, but they were evidently insufficient to achieve the targets set. An arrangement was soon reached with the drug company Eli Lilly & Co., who agreed to supply considerable finance against the promise of exclusive license for the commercialization of all therapeutic products developed in relation to the BRCA1 gene[72]. The BRCA1 gene was finally cloned and sequenced by Skolnick's group in 1994. In August of the same year Myriad lodged the first of a series of patent applications with respect to 47 mutations of the BRCA1 gene. The patent was issued by the U.S. Patent and Trademark Office in 1997. It was soon joined by others, specifically relating to the diagnostic methods for identifying the mutations, techniques of gene analysis and, above all, in 1998, the entire BRCA1 gene sequence[73].The results of the research had been published in *Science* in October 1994, a few months after the filing of the first patent application[74].

The results achieved in the field of the BRCA1 gene provided the stimulus to research on other tumour suppressor genes involved in breast cancer. Myriad embarked on a collaboration with the English geneticist Michael Stratton, of the Institute of Cancer Research in the UK, who in 1995 had identified a mutation in the gene to which the name BRCA2 would eventually be given. Such collaboration was suspended as soon as Stratton became aware of Myriad's intention to patent the gene. The British group were the first to attain the goal of sequencing[75], and published the sequence in the December 1995 issue of *Nature*[76]. However, the day before the article's publication, Myriad also announced that it had completed the sequencing and filed a patent application for biotechnological inventions with regard to BRCA2, its mutations and respective diagnostic methods. Such patents – opposed at this point

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[69] B. Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, cit., 129.

[70] R. Gold – J. Carbone, *Myriad Genetics. In the Eye of the Policy Storm*, cit., 41.

[71] B. Williams-Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, cit., 131; *Association for Molecular Pathology v. United States Patent and Trademark Office*, cit., p. 51.

[72] R. Gold – J. Carbone, *Myriad Genetics. In the Eye of the Policy Storm*, cit., 41.

[73] For details, see R. Gold – J. Carbone, *Myriad Genetics. In the Eye of the Policy Storm*, cit., 41.

[74] See Y. Miki et al., *A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene BRCA1*, in 266 *Science* 66 (1994).

[75] See *Association for Molecular Pathology v. United States Patent and Trademark Office*, cit., 53.

[76] R. Wooster – G. Bignell et al., *Identification of the Breast Cancer Susceptibility Gene BRCA2*, in 378 *Nature* 789 (1995).