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A metaphorical history of DNA patents

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Abstract The aim of this paper is to retrace the history of genetic patents, analyzing the metaphors used in the public debate, in patent offices, and in courtrooms. I have identified three frames with corresponding metaphor clusters: the first is the industrial frame, built around the idea that DNA is a chemical; the second is the informational frame, assembled around the concept of genetic information; last is the soul frame, based on the idea that DNA is or contains the essence of the individual.

Keywords: DNA, DNA metaphors, patents, information

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1. Foreword: when law meets science

Science and law have a complicated relationship, and often face communication problems – if not quarrels – for example when trying to "bring together" psychiatric, and more recently neurosciences and criminal law (see for example GAZZANIGA 2008) or biotechnologies and food safety policies (see for example TAGLIABUE 2015).

Why this awkward situation? An easy answer is: because lawyers don't know science and scientists don't know law. This is true – in most circumstances – but it's also too simple. We must also say that in some situations the law must ignore science, because the aim of the law is to regulate human conflicts, contrasts that arise, and need to be resolved, using ordinary knowledge and thus ordinary language. For example, in the Nix v. Hedden case, the US Supreme Court decided that tomatoes should be classified as a vegetable rather than a fruit, using the ordinary meaning of the words "fruit" and "vegetable", instead of the scientific meaning.

Moreover, in law we may encounter legal fictions, which are facts assumed or created by courts in order to apply a legal rule. Legal fictions can be contrary to science, for example considering electricity – a flow of electric charge for physics – a material thing, and this in order to apply the law on goods.

In this complex picture, we have metaphors. Metaphors used in scientific research[1], metaphors used in the communication of science, metaphors used by lawyers in their argumentation. Metaphors that can facilitate communication between scientists, lawyers, and the general public, but that can also be misleading.

[1] The scientific language is highly metaphorical; see Hallyn 2014.

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In this paper, I will focus on a particular class of metaphors: those built around DNA[2] in the debate about genetic patents, with the aim of developing a brief metaphorical history of DNA patents from the 1970s to the Myriad case in 2013.

2. Before the molecular biology

This brief history starts in the 1970s with US patent number 3,710,511 (*Procedures for use of genic male sterility in production of commercial hybrid maize*), filed in 1971 and granted in 1973. But to understand the importance of this patent for our history, we need to go back in time to the beginning of the 20th century. At this time, the molecular basis of heredity was almost unknown and information theory – the importance of which will be specified later – was yet to come, and in order to avoid the taint of old hypotheses, such as Darwin's gemmules or Weissman's determinants, the Danish botanist Wilhelm Johannsen in 1909 introduced the new and, supposedly, theory-free word 'gene'. Perhaps as a consequence of the mysterious nature of the gene, we have the diffusion of the metaphor of gene-action (KELLER 2000): the gene is "something" whose action caused a specific trait in the organism (and the transmission of this trait to descendants). The trait caused by the gene in fact defined the gene, because the presence of the trait (in the individual or in her relatives) was the only thing that was known. This concept is often called, in contraposition to the *molecular gene* (i.e. a gene defined by properties of the DNA molecule), the *Mendelian gene* (HULL 1974, DUPRÉ 2004, CALVERT *et al.* 2011) or *operational gene* (BURIAN 2000); because of the dependency of this concept on the phenotype (the observable properties of the organism), in this paper I use the term *phenotypic gene*.

Before the discovery of the role and structure of DNA, we had only phenotypic genes; but we should not think that the advent of the molecular gene and the ability to discover the DNA sequence of a gene has obliterated the phenotypic gene: this concept is still present in all situations where the molecular nature of a gene is unknown or useless. This is true in particular for mendelian traits (such as, in humans, blood type or albinism) that depend on a single gene acting in accordance with the dominant and recessive rules taught in every school.

The genic sterility of the aforementioned patent refers to a phenotypic gene. In the description of the patent we read that «an understanding of the specific chemical nature and operation of the DNA which comprises the genes of chromosomes is not essential to an understanding of the present invention», and this because «it is sufficient to note that the DNA which comprises each gene of a chromosome is capable of directing cell metabolic functions in a particular manner» (PATTERSON 1971: 2).

So the first genetic patents were not, strictly speaking, DNA patents but phenotypic patents based on the gene-action metaphor.

[2] "Built around" in the sense that – using the terminology of the conceptual theory of metaphors (LAKOFF *et al.* 1980) – I will consider not only metaphors where DNA is in the target frame (such as "DNA is the blueprint of the organism") but also metaphors where DNA is in the source frame (such as "Quality is in the firm's DNA").

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3. Patenting a chemical substance

The 1940s and 50s, with the discovery of the role[3] and structure of DNA[4], saw the development of a new gene concept based on a new metaphor: the genetic program.
This change was made possible by the development of information theory, namely the discovery that information is a measurable quantity that we can mathematically analyze, studying in particular how this information is transmitted from a source to a destination through an emitter, a channel, and a receiver[5]. The text signaling the birth of information theory was *The Mathematical Theory of Communication* (SHANNON 1948), published in 1948 by the mathematician and electrical engineer Claude E. Shannon. In this text there is no reference to genetics, but Shannon was interested in this new discipline: his PhD thesis of 1940 at MIT was entitled *An Algebra for Theoretical Genetics*, and in the summer of 1949 he annotated his notebook with estimates of the «bits storage capacity» of various items such as punched cards, phono records, and the «genetic constitution of man» (cited in GLEICK 2012: 230). With Shannon the genome became information measurable in bits or base pairs (bps), the unit now used in biology (for a critic analysis of this informational approach, see GRIFFITHS 2001 and LONGO *et al.* 2012).
Shannon was, of course, an outsider in biology; nevertheless the information language was adopted by geneticists, starting with James Watson and Francis Crick, discoverers of the double helix structure of DNA. Their discovery was announced in April 1953 in a famous article published in *Nature* (WATSON *et al.* 1953b); a month later, the two scientists published a second article dedicated to the genetic implications of the double helix structure, writing: «It follows that in a long molecule many different permutations are possible, and it therefore seems likely that the precise sequence of the bases is the code which carries the genetical information» (WATSON *et al.* 1953a: 965). So it's not surprising that the language of genetics is largely informational: DNA is *transcribed* into RNA and then *translated* into protein; we have a genetic *code* where every nucleotide triplet, or codon, corresponds to a specific amino acid, and if two triplets corresponds to the same amino acid, they are said to be *synonymous* codons, and so on.
The double nature, molecular and informational, of DNA – which in reality is a metaphor, and quite a problematic one, as we will see in the next paragraph – is ignored by US, European, and Japanese patents offices, which established in 1988 that DNA is no different from any other isolated biological material and «eligible for patents on the same basis as other chemical compounds»[6]. In other words, in the 80s there was no significant difference between DNA and a dye or a solvent. This attitude is coherent with, and perhaps a consequence of, the industrial metaphor of life developed in patent law in the 70s and culminating with the "life is largely chemistry" motto, as stated in the Chakrabarty case.
The industrial metaphor of life, a sort of evolution of material mechanisms of the

[3] In 1944 by a team guided by Oswald Avery.

[4] In 1953 by the Nobel Prize winners James Watson, Francis Crick and Maurice Wilkins, and the often forgotten Rosalind Franklin.

[5] For a good introduction to information theory, see Gleick 2012. For a philosophical analysis, see Floridi 2011.

[6] US, JAPAN, AND EUROPEAN PATENT OFFICES 1988, cited in Gold *et al.* 2010.

17th century, is connected with the development of genetic engineering.[7] When, in the early 1970s, it concretized the ability to manipulate the genome by inserting DNA fragments from other species, along with an attitude of caution there was also a strong interest in commercial exploitation. Stanley N. Cohen at Stanford University and Herbert W. Boyer at the University of California, San Francisco developed the recombinant DNA technique (The history of the Stanley-Boyer patents is reconstructed in HUGHES 2001). From the scientific point of view, this technique was an extremely powerful research tool, since it allowed for isolating a single gene, but the two universities also noticed the economic potentials of this technology – it is estimated that the revenue of the three patents granted in 1980 is over 200 million dollars (FELDMAN *et al.* 2007) – and in 1974 filed a patent application.

How to communicate to the general public, potential investors, and policy makers the importance and economic potential of recombinant DNA? William Carpenter, a Stanford student who was doing an internship at the Office of Technology Licensing, was appointed to investigate the possible commercial applications of the work of Cohen and Boyer. After meeting the two scientists, Carpenter presented a report that described the technology as a *gene transplant* able to transform bacteria in *genetic factories* for the production of substances otherwise difficult to obtain, such as insulin or viral proteins for the synthesis of vaccines. *Harvard Magazine* coined the term «bacterifacture» to indicate bacteria transformed in a factory.

The industrial metaphor *the cell is a factory* spread rapidly, becoming one of the most common metaphors in science and in science communication (see REYNOLDS 2007). The source frame of this metaphor offers several elements that explain its success, such as the specialization and division of labor, or the importance of the exchange of substances between the various units (factories and cells). Another very important element of the metaphor relates to the economic importance of the industrial sector, which in those years was going through a deep crisis in the United States. To maintain economic supremacy, the Carter and Reagan administrations (also) pointed to biotechnology, and the cell factory metaphor allowed them to consider this conversion as a sort of natural evolution of the economy, from real factories to genetic factories (COLYVAS 2007).

If the cell is a factory, then we can patent it – with a product patent, not a process or use patent[8]. And this is what happened with US patent 4,259,444 for genetically modified bacteria invented by the Indian-American microbiologist Ananda M. Chakrabarty, a patent that arrived at the US Supreme Court which, in 1980, ruled in a 5 to 4 decision that «a live, human-made micro-organism is patentable subject matter» (Diamond v. Chakrabarty, 447 U.S. 303 [1980]). The man behind this case was the patent attorney for General Electric Leo I. Malossi, which also claimed – in addition to the new method used to produce it, and a compound formed of a support substance and the bacterium – the genetically modified bacterium itself. This was contrary to the practice followed by the patent office and accepted by biotechnology companies. But General Electric was not a biotechnology company: its main

[7] The term «genetic engineering» dates back to the 1950s: the term appears to have been coined by the fiction writer Jack Williamson in his novel *Dragon's Island* in 1951 – before the discovery of the double helix structure of the DNA (according to STABLEFORD 2004).

[8] A product patent is a patent on the product itself, regardless of how it has been obtained; a process patent is a patent on a method or process and is not infringed by a product made by another process; a use patent is a patent on the use of the product for a specific purpose.

activities were in the field of engineering; the interest in biology was recent, and signaled a strong diversification due to a contraction of investment in the aerospace sector[9].

After the refusal of the US Patent Office Board of Appeals – based on the fact that a living organism, even if artificial, is not patentable because is not a new composition of matter – the Chakrabarty case went to the US Court of Custom and Patent Appeals, where it crossed a similar case, Bergy, concerning a patent on a purified strain of fungus. The court, in a majority opinion written by Justice Giles S. Rich, decided that the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance (In the matter of the application of Malcolm E. Bergy *et al.*, patent appeal no. 76–712. US Court of Customs and Patent Appeals, 563 F. 2d. 1031 [1977], p. 1038).

The Solicitor General of the United States appealed the decision to the US Supreme Court, which vacated the decision and sent it back to the Court of Custom and Patent Appeals. In the new decision, Justice Rich was more explicit in applying the industrial frame to microorganisms, also using the aforementioned term "bacterifacture". The conclusion was clear-cut: «In fact, we see no legally significant difference between active chemicals which are classified as 'dead' and organisms used for their chemical reactions which take place because they are 'alive'. Life is largely chemistry» (In re Bergy, 596 F.2d 952 (C.C.P.A. 1979): 975).

The Solicitor General also appealed this new decision, and in 1980 the Supreme Court definitively closed the Chakabarty case, ruling, as mentioned, that genetically modified microorganisms – and in general living organisms – are patentable: «The relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions» (Diamond v. Chakrabarty, 447 U.S. 303 [1980]: 313).

DNA don't escape this "industrial framing", and this mechanistic metaphorization is apparent in one of the *amicii curae* sent to the Supreme Court: the Brief of Dr. George Pieczenik submitted on 29th January 1980. After describing the *dualistic property* of DNA, which is «definable like ordinary inanimate chemical compounds» and «capable of transforming susceptible host cells», Pieczenik used two interesting metaphors for the ability of DNA to alter the functional properties of cells: «analogously as an engine to its camshaft or an architect to his blueprints» (PIECZENIK 1980:7). Whether a camshaft or a blueprint, it is obvious that this frame is favorable to DNA patents.

Talking of the "blueprint metaphor", it is interesting to note that this is one of the most common metaphors used in scientific communication – and perhaps one of the most misleading: first of all because the linear relation between the blueprint and the construction (or the architect, in the Pieczenik's version) is inadequate for the complex processes of genic expression, where only in rare circumstances do we see a perfect correspondence between one gene and one trait. Second, this metaphor has in its source frame concepts that are not intended to be projected into the target frame, but which are unlikely to be omitted by an inexperienced audience; most problematic is the idea that a blueprint has an author, a concept that if projected onto DNA conduct in line with the idea of intelligent design (on these limits of the blueprint metaphors, see PIGLIUCCI 2010 and PIGLIUCCI & BOUDRY 2010).

[9] The history of the Chakrabarty patent is reconstructed in Kevles 1994.

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4. Patenting the soul

The 1990s were the years of the Human Genome Project (HGP), the vast international initiative to sequence the entire genome of humanity started in 1990 and officially concluded in 2000 – though for some genes there was only a "working draft" – with a historic press conference at the White House.

A short glance at the speech of US president Bill Clinton is sufficient to get an idea of what had changed from the genetic factories of the firsts DNA patents. After a comparison between the map of the human genome and the first map of America – «a map that defined the contours and forever expanded the frontiers of our continent and our imagination» –, Clinton pointed to the figure of Galileo Galilei and his discovery that we can use «the tools of mathematics and mechanics to understand the motion of celestial bodies». Galileo «learned the language in which God created the universe» – and now, thanks to the HGP, «we are learning the language in which God created life […] gaining ever more awe for the complexity, the beauty, the wonder of God's most divine and sacred gift»[10].

This is a small example of what Dorothy Nelkin and Susan Lindee call «the DNA mystique»: the «spiritual imagery [that] sets the tone for popular accounts of DNA, fueling narratives of genetic essentialism and giving mystical powers to a molecular structure» (NELKIN *et al.* 1996:40). DNA is not simply a molecule or a blueprint, but the essence of the individual, the source of the boundaries of personhood. On this view, DNA is the soul, in the Aristotelian sense of psyche, the form or plan of the individual – the analogy between the two is acknowledged for example by biophysicist Max Delbrück, who suggested that Aristotle should be posthumously awarded a Nobel Prize «For the discovery of the principle implied in DNA» (DELBRÜCK 1976) – and perhaps also in the Christian sense of an immortal animating principle «that bears the marks of good and evil: a man my look fine to outside world, but despite appearances, if he is evil, it will be marker in his genes» (NELKIN *et al.* 2004: 41).

This reference to the *true self* of a person is one aspect of the social reception of genetic tests, often perceived as revelations of the real nature of a person, her past (with genealogical information) and future (with disease predisposition). In this regard, the soul metaphor is linked to the *blood rhetoric* that, in the 19th and 20th centuries, matched with class- and race prejudice and eugenics; but in the genomic era DNA is not only a factor of discrimination and segregation, but also an instrument of reconciliation and repair. Such is the case for the genetic test used by Las Abuelas de Plaza de Mayo (the grandmothers of Plaza de Mayo) to identify the children of the desaparecidos abducted by the military dictatorship in Argentina. Another interesting example is the ability of genetic ancestry tests – a consumer genetic test to find out the geographical origin of one's family – to construct a genealogy for African Americans families lacking a traditional ancestral narrative (NELSON 2016).

4.1. Genetic patents and slavery

If DNA is the soul of a human being, holding the intellectual property[11] of the human

[10] A transcript of the speech is available online at http://www.genome.gov/10001356/june-2000-white-house-event/.

[11] Intellectual property, which includes patents, copyright, trademarks, and other institutions, is a monopoly assigned by law; the idea of the possession of an intangible good is mostly metaphoric.

genome is equivalent to possessing a human being, i.e., slavery.
The slavery argument has been raised a few times (and immediately rejected). It has been presented to the European patent office by some members of the European Parliament in opposition to the patent granted for the gene that encodes a particular human hormone, relaxin, capable of relaxing the uterus during childbirth. The response has been quite dry: the patents of genes confer no rights on individuals (Howard Florey/Relaxin; Oppositions by Fraktion der Grünen im Europäischen Parlament; Lannoye; EPO 6/1995 388). A similarly harsh rejection came from the US Patent office (USPTO) during the consultation for the new guidelines of 2001, which introduced more stringent criteria for genetic patents. An anonymous petitioner asked the USPTO to not accept any patents covering human genes because these patents constitute a violation of the Thirteenth Amendment, and the reply was that patents have nothing to do with slavery (Federal Register/Vol. 66, No. 4).

4.2. The common heritage argument

The slavery argument has been less important than the common heritage argument, the idea of which is to apply the common heritage of humankind doctrine to the human genome. This is a principle of international law which holds that defined territorial areas – such as outer space or the sea bed – should be protected from exploitation by individual nation states or corporations. This principle is stated in the first article of the UNESCO Universal Declaration on the Human Genome and Human Rights, adopted unanimously and by acclamation in 1997: «The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity».
The development of this idea is connected to the HGP, and became the most important argument against the filing of genetic patents from scientists involved in the project. The intellectual property of sequenced DNA became a conundrum and internal divergence on this topic lead, in 1992, to the resignation of James Watson as head of the project[12].
In the context of a publicly funded project (in fact the biggest publicly funded project ever) of basic research, it is difficult to disagree with this principle, but it's important to examine whether the common heritage reference is a serious claim (as affirmed in STURGES 1999) or just a plea to the importance of the genome – such that the real common heritage of humankind is the Human Genome Project.
The correct answer is the latter, at least when we read the aforementioned UNESCO declaration carefully: the genome is the heritage of humanity "in a symbolic sense". The reason for this, as stated in the report (Document 29 C/21) is very simple: DNA is not a territorial area, but a resource present in practically every cell of every human being, such that an international management of this resource could violate the rights of individuals and groups, with compulsory exploitation. If the (time-limited and partial) monopoly of a private company could be a problem, it's unlikely that the solution would be a (unlimited) monopoly of some supranational institution. There are other problems too: the "human genome" is an abstract concept (we have individual genomes, with unique or rare mutations, and large sections of DNA shared with other species, including unicellular organisms); a preservation approach, part of the common heritage doctrine, could imply the impossibility of genetic therapy; last,

[12] On Watson's resignation, see Roberts 1992; for an in-depth account, see Cook-Deegan 1996.

if the aim is to ban the intellectual property of DNA, this is the wrong approach, because the common heritage is compatible with private exploitation[13].
Given these difficulties, why is this argument so popular? Maybe because DNA is not only a chemical that embodies genetic information, but also the essence of the individual, what make me me and what make us humans and not chimpanzees.

5. Patenting DNA as information

The soul metaphor of DNA has shaped the opposition to genetic patents, with wide results in public opinion and research policies – many of the big research projects in genetics discourage patents (CONTRERAS 2011) – but small consequences for patents offices and courts, where the industrial metaphor of DNA remains standard and the idea of an untouchable genetic essence is largely unthinkable. Nevertheless, the development of bioinformatics and the widespread use of computers in the analysis of genetic sequences has led to some small digressions from this standard.

5.1. Copyright and computers

The scientific challenge is no longer the manipulation of the genome to create "genetic factories", but the understanding of complex genetic functions or diseases. So, next to *traditional* genetic patents for DNA sequences used in the production of improved or novel organisms, we find patents covering the DNA used in diagnostic tests. Without the fence of the industrial metaphor, the intellectual property space opens up to other possibilities, such as copyright[14].
The idea of the use of copyright – a legal right conceived for creative work and the original expression of ideas – for the genome was introduced by the Nobel prize Walter Gilbert, who in 1987 announced his intention to create a company, the Genome Corporation, for sequencing human DNA and selling the information obtained[15]. Lacking utility, these sequences cannot be patented, but for Gilbert «someone worked it out and wrote it down – so the order of the letters is copyrightable, like a string of letters in a book» (ROBERTS 1987).
Another analogy is drawn with pictures (a photo is copyrightable, though the scene in the photo is not) and, above all, computer programs; the common denominator is the idea that DNA is information. This reframing of DNA influenced, at least, one patent office: in 1995 we find an international patent application (number WO1996US05320) for the genome of the bacterium *Haemophilus influenzae* that does not concern the molecule, but the information of the sequence stored in an electronic format. The application, never approved, was withdrawn in 2005, so we can only speculate on what the consequences of this patent might have been. But it's very likely that, if approved, the patent would not have covered genetic tests nor the creation of a genetically modified organism with part of the genome of the

[13] For a critique of the common heritage argument, see Resnik 2004 and Ossorio 2007; for an apology (and a defense of genetic patents), see Queloz 2015.

[14] A patent is a limited duration (usually 20 years) right relating to an invention, granted by a patent office in exchange for public disclosure of the invention; copyright protects original works of authorship including literary, dramatic, musical, and artistic works; copyright usually lasts for the life of the author plus 70 years.

[15] For the free flow of knowledge, the copyright of DNA will be a disaster: no utility requirement, no evaluation of novelty, at least 70 years of protection instead of the 20 of patents.

bacterium, for example for the production of a vaccine. It would, however, have granted something even more important: the ability to analyze, with a computer, the genome of the bacterium.

5.2. The European way: genetic information that performs its function

Another minor deviation from the industrial frame is contained in the European directive 98/44 on the legal protection of biotechnological inventions, approved on May 12, 1998 after intense debate and the first proposal of the Council of the European Union being rejected, in 1995, by the European Parliament.
Like almost all European laws, the directive is the result of numerous compromises, so article 5 establishes that «the human body […] and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions» unless «an element isolated from the human body […], including the sequence or partial sequence of a gene, may constitute a patentable invention» (Directive 98/44/EC, art. 5).
A similar strategy of balancing different interests and sensibilities is detectable in article 9:

> The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material […] in which the product in incorporated and *in which the genetic information is contained and performs its function* (Directive 98/44/EC, art. 9, emphasis mine).

The aim is to limit the extent of genetic patents – where too-wide protection can harm competition and technological innovation –, but it is interesting that this limitation is achieved using the concept of genetic information. And it is not only DNA is considered, for intellectual property, genetic information rather than a chemical, but also genetic information with a function – and, most importantly, a function that is active.
Practically, this means that the validity of a gene patent is limited to biologically active materials. For example, a Monsanto patent for a genetically modified soybean plant has no effect on the soybean meal produced by these plants, because the meal is «a dead material», as stated by the European Court of Justice (Monsanto Technology LLC v Cefetra BV and Others, Case C-428/08).

5.3. The American way: the Myriad case

The rules for gene patents were written, in Europe, by parliament; in the United States, conversely, the matter was established by judicial decision, in particular with the Myriad case[16], where the Association for Molecular Pathology challenged certain claims in issued patents owned or controlled by Myriad Genetics that covered the isolated DNA sequences of two genes, BRCA1 and 2 and their main mutations, connected with breast and ovarian cancers (BRCA stands for BReast CAncer)[17].
The patents of these genes are particularly unpleasant for several reasons: Myriad have stolen the march on public research; breast cancer is a very delicate and

[16] Association for Molecular Pathology v. Myriad Genetics, No. 12-398 (569 U.S. ___ June 13, 2013).

[17] In Europe, BRCA patent oppositions and appeals began in early 2001, but without worldwide attention and a real discussion about the patentability of the human genes. See Matthijs *et al.* 2013 for further details.

sensitive disease, and for some mutations, the BRCA test is highly predictive; not forgetting Myriad's business model of exclusively offering diagnostic testing services, without licensees, and sending cease and desist letters also to universities. The cost of testing for BRCA1 and 2 is perceived as an obstacle for many women to take control of their lives[18], so it is no surprise that standing alongside the plaintiff Association for Molecular Pathology is the American Civil Liberties Union.

The case was heard in 2010 in the Southern District Court of New York, which ruled that none of the challenged claims were patent eligible. Myriad then appealed to the US Court of Appeals for the Federal Circuit, which overturned the previous decision. As in the Chakrabarty case, there was an appeal to the Supreme Court, which remanded the case to the lower court, which did not change its opinion. So on September 25, 2012, the American Civil Liberties Union filed a second petition. On June 13, 2013, in a unanimous decision, the Supreme Court invalidated Myriad's claims to isolated genes maintaining those on complementary DNA[19].

Despite some reference to what we have called the DNA mystique – in particular in some *amicii curiae*, where we read that «genetic code is a divine gift» (SCARNECCHIA *et al.* 2013) or that «DNA's importance flows from its ability to encode and transmit the instructions for creating a human being» (WATSON 2013) – the key point of the case is whether isolated DNA is a patentable subject matter, i.e., if it is «made by man»[20]. The genomic DNA, present in the human chromosome, is of course natural and not patentable, but the isolated gene, artificially separated from the rest of the genetic material, could still be considered a natural phenomenon? And what about the complementary DNA (cDNA), that is, the sequence without noncoding sequences? The three courts, as stated, all answered differently: all natural (and thus not patentable) for the Southern District, all artificial (and thus patentable) for the Federal Circuit, isolated natural and cDNA artificial for the Supreme Court.

These different evaluations are grounded in different visions of the nature of DNA, different conceptions that are manifest in the three decisions, all containing a short introduction of biochemistry that is very interesting to read in the search for metaphors.

The Southern District's decision focuses on the informational aspects of DNA, using a great many linguistic and essentialist metaphors, in particular in parts III-A and B and, of course, in the conclusion: «This informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as *no different* than other chemicals previously the subject of patents» (Association for Molecular Pathology v. U.S. Patent and Trademark Office, No. 09-cv-4515, 94 USPQ2d 1683 [S.D.N.Y. March 29, 2010]: 122-123).

If the only thing that matters is the meaning of the sequence of nucleotide, it is obvious that this meaning is the same in genomic DNA, in isolated DNA, and even in cDNA, where we have suppressed *meaningless* sequences.

For the Federal Circuit, DNA is a chemical: the informational dimension is simply dropped: «We recognize that biologists may think of molecules in terms of their uses, but genes are in fact materials having a chemical nature and, as such, are best

[18] See for example the testimony of Angelina Jolie on her mastectomy: Jolie 2013.

[19] The case also involved other claims that are not taken into account here.

[20] Patentable subject matter may include «anything under the sun that is made by man», as affirmed by the Supreme court quoting the testimony of Pasquale Joseph Federico, a high-ranking official of the US Patent Office, before a House subcommittee in 1951.

described in patents by their structures rather than their functions» (Association for Molecular Pathology v United States Patent and Trademark Office, 689 F 3d 1303: 45). And if it is a chemical, the isolation of the molecule from the rest of the chromosome is sufficient to consider it human-made and thus patentable.
For the Supreme court DNA is information, and confirmation of this is found in the patent's claims:

> Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes (Association for Molecular Pathology v. Myriad Genetics, No. 12-398 [569 U.S. ___ June 13, 2013]: 14)

Because the genetic information doesn't change with the isolation of a section of DNA, the claims on isolated BRCA genes are invalid.
However, cDNA is patentable, despite the fact that cDNA «contains the same protein-coding information found in a segment of natural DNA» (*Ivi*: 1). At first sight, it seems that DNA is information when it comes to isolated genetic material, but a chemical when it comes to cDNA (this is, for example, the interpretation of DOLIN 2013). But the problem could be the ambiguity of the term 'information', because cDNA contains the same "protein-coding information", but does not contain the same "raw information", because the (human-made) removal of noncoding sequences changes the text of the DNA.
Is interesting to note that the US patent office, in the new examination guideline, disregards the Supreme court's indication that DNA should be treated as information, interpreting the decision in the old frame of chemical substances[21].

6. Conclusion: and now something completely different

We have seen how the first economically important applications of genetics, in the industrial frame of genetic factories, has smoothly taken intellectual protection in the direction of industrial patents. This solution, with the development of biotechnology and a tendency to consider the informational aspect of DNA, has shown its limits – nevertheless without a true abandonment of the patent system.
A way of overcoming genetic patents could, however, come from the new field of synthetic biology, the design, or re-design, of new biological parts, devices, and systems. This field represents a puzzle when it comes to the question of intellectual property (RAI *et al.* 2007), not only regarding patent and copyright, but also *sui generis* database rights, the public domain, and the commons. All the currently available options come from the computer industry, because the most common metaphors used for synthetic biology come from this industry: the organism is a computer, DNA is the operating system of this computer, the biotechnologist is the software engineer who writes new code or hacks an old one, and so on (for a deep analysis of the metaphors used in synthetic biology, see HELLSTEN *et al.* 2011).
If we can learn something from the past, maybe it is that these solutions will have some limits. Perhaps what we need is something completely different: a new intellectual property right expressly designed for DNA, which accounts for the

[21] The same chemical frame is used by the Department of Justice in their *amicus curiae*, invoking a "magic microscope" able to look deep inside cells and find any natural molecule within them.

complex characteristics of genetic material and the various instances of stakeholders, from biotechnology industries to activist groups. In a similar, but perhaps more balanced way to what happened in the USA with the introduction of plant patents for asexually reproducing varieties of plants (KEVLES 2007). But at the moment this solution seems utopian.

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