

Denying Patentability of Scientific Theories

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In general, intellectual property systems do not protect ideas but only their practical applications. To grant protection, patent law imposes stringent checks like novelty, non-obviousness, and utility, while copyright law involves a lower threshold of originality. Patentability determinations have undergone considerable disarray over the last few decades. The question to be answered is whether pure science has become patentable as against scientific development even as legal reforms have tightened the standards for patentability narrowing it to reduce the scope of patent-eligible subject matter and to make patents harder to acquire (thus easier to invalidate) based on obviousness. Can simple advances in science and its methods be regarded as patentable or should there be significant progress for satisfying patentability criteria is a question that needs to be answered.

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The present international tendency in the intellectual property system is undeniably toward improved minimum levels of substantive protection for intellectual property owners.¹ The possibility of obtaining strong patent rights has become a most sought incentive today.

While patent laws do comprise rigid standards such as novelty, non-obviousness, and utility that are assessed before grant copyright law involves a lower threshold of originality. But in all cases, no ideas are protected, only practical applications are protectable. Most patent systems assert that ideas are not patentable but only their practical applications.²

The original rules of patent law were set in a world in which inventions were mechanical and more homogenous than they are today. This author considers that commercialization has forced patent offices to award broad patents with the onus on courts to validate them. Nonetheless, this is not a uniform stand; European Patent Office (EPO) appears to be more restrictive than the US Patent & Trademark Office (USPTO) in allowing computer-related inventions. Overall, the term technology is construed more narrowly in Europe than in the US; the latter being known for taking a remarkably expansive approach towards patentable subject matter. Compared to Europe, for example, the US has been far readier to grant patents on business methods, medical diagnostic processes, and human genes.

There has been ambiguity with regard to patent scope, validity, and overlapping rights.³ Bringing patents more in line with scientific norms will help both patent law and the scientific community. While the most recent trend favours a stricter standard for patents⁴, patentability determinations have undergone considerable disarray over the last few decades as the US Federal Circuit moved towards less stricter standards for patentability.⁵

Patentability: Is the Line between Pure Science and its Applications Blurring?

The economic importance of patents have diminished the tendency towards dissemination and sharing among scientists.⁶ Patent disclosures have informational benefits across a broad range of technologies⁷ but has pure science become patentable as against scientific development is a question that begs answers. To that extent, courts have struggled to define the boundaries of the patent system focusing on attempts to identify generally applicable standards for identifying patentable subject matter.⁸

Current scientific progress has brought into the forefront various areas like biotechnology, nanotechnology, computer technology and so forth. Whether the principles of patentability can be effectively applied to these newer areas needs to be tested. Computer software and business patents are controversial since there is no common implementation of laws world over in what is and whether at all it is patentable. Also some countries

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grant copyrights while others allow patents on softwares. Several court decisions have tried to lay down principles, but the area remains ambiguous.

Biotechnology is a field that has the prospective to revolutionize society, the achievement of the sequencing of the human genome project and the ease with which nucleotides can now be sequenced, the next generation of inventions will take account of an increasing number of recombinant oligonucleotides and proteins and methods for using them. However, biotechnology portrays intricate challenges in defining the scope of new inventions because inventors can effectively apply for a patent, and yet not know the full scope of their innovation which indicates possible patenting of pure science and abstract ideas.⁹

Similarly, nanotechnology is a rising science that takes advantage of the unique properties of matter at the nanometer scale promising advances across a wide spectrum of applications, including electronics, pharmaceuticals, and industrial products. Nonetheless, products utilizing nanotechnology may portray exclusive problems to human and environmental health, in particular because, they do not work in the body or environment in the manner anticipated from conventional materials.

The aim of the analysis is the investigation of current developments regarding patentability, given the fact that there have been awards of patents even to abstract ideas or pure scientific theories. The analysis is based mainly on US law with reference to EU law with the core areas of software, biotechnology and nanotechnology patenting as the basis.

Patentability of Computer, Software & Business Methods Patents

Software Patents

Section 101 of the US Patent Act defines patent-eligible subject matter as ‘any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof’ meeting additional requirements including, *inter alia*, the requirements of novelty and non-obviousness as imposed by Sections 102 and 103 of the Act, respectively.

Although an invention directed at mathematical algorithms underlying the asserted claims in turn targeting a physical product to be used for a specific purpose has been found patentable¹⁰, it has to be taken into account that a claim that is not noticeably abstract

as to override § 101 may yet be unpatentable under § 112 if it lacks adequate disclosure to warrant a patent.¹¹ For instance, if the written description is so theoretical that a person of ordinary skill cannot replicate the invention or if the written description does not present enough particularity and precision to inform skilled artisans of the scope of the claims, the subject matter is not patentable. Even though a computer readable medium can be deemed a manufacture or machine under § 101, simply reciting data or instructions on a stored machine readable medium does not make it a claim statutory under § 101. (ref. 12).

Modern computer systems¹³ are complex assemblies of systems and subsystems operating under software control. The tendency toward integrating hardware and software functions portrays particular challenges to those protecting the intellectual property in such systems. Intellectual property protection of computer hardware and software generally takes two forms—patents and copyrights.¹⁴

Software¹⁵ is written in a form understandable by humans, but commercially distributed to the public in a form readable only by computers. Software is patentable in the United States; more accurately, the functionality embodied in software is patentable. The software itself (the code), the expression of the functionality, is not patentable. Courts have traditionally interpreted the patent statute that allowed the patenting of any new process as excluding mathematical formulas, mental processes, or algorithms. However, it was felt that software patents such as improvements in computer implemented technologies should receive the same level of protection afforded to inventions in other arts since it would encourage innovation in software.¹⁶

The first significant software patent decision came in 1972 when the Supreme Court deciding in *Gottschalk v Benson*¹⁷ held that a mathematical algorithm converting binary coded decimal numerals into pure binary code itself is not patentable as a process, because it is merely an abstract idea. In 1978, in *Parker v Flook*¹⁸, the Court conceded that a process is not unpatentable only because it contains a law of nature or a mathematical algorithm. In 1981, in *Diamond v Diehr*¹⁹, the Court again noted that the prohibition against patenting abstract ideas “cannot be circumvented by attempting to limit the use of the

formula to a particular technological environment (or by adding) insignificant post-solution activity.”

There was no *per se* exclusion of cyberspace-implemented methods from the sphere of patentable subject matter.²⁰ To that extent, a new standard, announced in *State Street*²¹ and *AT&T v Excel*²², expanded patentable subject matter to include processes that produce a “useful, concrete and tangible result.” Hence, software that constituted a useful application of a mathematical algorithm, formula, or calculation was immediately patentable.

Although in the earlier mentioned cases there seemed to be an inclination towards software patents in various courts, there are also some examples where some of the inventions were turned down. In *re Nuijten*, it was held that while a transitory signal made of electrical or electromagnetic variances is physical and real, it is not a “machine” as specified 35 USC § 101 because it is not made of parts or devices in the mechanical sense.²³ Whereas in *re Comiskey* it was held that a signal comprising a fluctuation in electric prospective or electromagnetic fields is not a chemical union, nor a gas, fluid, powder or solid and is for that reason not a composition of matter. The simple recitation of a practical application as a form of post solution activity does not turn an abstract idea into patentable subject matter.²⁴ Here the extent of protection to software applications was interpreted rather rigidly.

On the other hand, computer programs “as such” are excluded from patentability by Member States of Europe and the European Patent Convention (EPC), although the European Patent Office (EPO) and national patent offices have granted several patents for computer implemented inventions.²⁵

In EPO computer-implemented inventions are expected to display a “technical contribution” to be patent-eligible, but the tests employed in these jurisdictions have criticized for being ambiguous.

Business Method Patents

Business methods are often related to software and consist of algorithms to carry out certain processes. The area has become very significant due to the remarkable increase in the number of applications for business method patents with regard to e-commerce, insurance, financial services and the like. The drastic increase in business method patents could also be attributed to the influence of technological advances in communications. Business method software is one

of the fastest-growing categories of new patents, and software patents represent 15 per cent of all patents.²⁶

The “machine or transformation”²⁷ test put forth by the Federal Circuit for determining whether a subject matter under is patentable 35 USC § 101 is very important in the context of business methods. The Supreme Court²⁸ said that its “precedents establish that the machine or transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101”. The alteration must be fundamental to the rationale of the claimed process and patentability depends on whether a process converts an article into a different state or thing.

A business method when carried out using conventional computer systems or office equipment is still a business method but the invention must make an inventive “technical contribution” over the prior art. In other words, the overall inventive effect of the invention must lie in a technical area, not just in a new business method or computer program. Hence, in the case of business method patents relating to software applications, the courts have been even more generous in allowing patents in areas customarily viewed as out-of-bounds.²⁹

Many new business methods rely on new software or computer systems, but these are usually excluded from patentability because the sole contribution of the software or system lies in implementing the business method. *Bilski v Kappos*³⁰ highlights judicial disagreement over whether business method is patent-eligible subject matter. Business methods are patentable in the United States provided they have “practical utility” and produce a “useful, concrete, and tangible result.”

The majority in *Bilski*²⁸ held that a business method is not unconditionally unpatentable and that the machine-or-transformation test, while a useful tool is not the exclusive test for determining the patent eligibility of a process claim. When the claimed methods were directed to the abstract idea of employing an intermediary to make possible instantaneous exchange of obligations in order to minimize risk³¹, this abstract idea, if patented, would prevent the use of an electronic intermediary to guarantee exchanges across an incredible swath of the economic sector and so the court concluded that such claims were not patent-eligible subject matter. Moreover, turning to the computer system and product claims, the district court said that these

claims, while drawn to a machine, simply represented an embodiment of the abstract idea on a computer without any further meaningful limitation and failed to recite patent-eligible subject matter.

Finally, it can be summarized here that ambiguity in claiming patent-eligible subject matter will continue, at least at the boundaries defining protectable subject matter³² but in order to achieve patentability in the computer/software industry it is not enough that it be a purely scientific or technical matter. Thus, “obvious to try” applies to software as well.

Patentability of Biotechnology

Patent law has a general set of legal rules to govern the utility and infringement of patents in a wide variety of technologies. The statute does not distinguish between different technologies in setting and applying legal standards.³³ It could be argued that patent law is technologically flexible, with significant adjustment points built into the system.³⁴ This very same flexibility has allowed abstract ideas³⁵ and pure science in the case of biotechnology, nanotechnology, and related areas where scientific theories can easily be presented as an invention due to the complexity of the technical field.

Patent law should be technology-specific because the industries it governs are not homogenous. Determining what constitutes statutory subject matter under Section 101 is the most tricky and controversial issue in patent law and the problem arises from the failure of most courts to understand the difference between the requirements of Section 101 giving rise to patent-eligibility, and the other sections' requirements of patentability.³⁶ In *Bilski v Kappos*³⁷, the Supreme Court held when determining patentability of processes under § 101, the “machine-or-transformation test” was not the exclusive test for patentability. Crouch & Merges³⁸ argue that Section 101 increases “the total cost of deciding validity issues” and decreases “respect for patent tribunals” but on the other hand nature cannot be patented by an oligarchy against society.

The uncertainty in predicting the structural features of biotechnological inventions renders them non-obvious, even if prior art demonstrates a clear plan for producing the invention. The uncertain nature of technology requires imposition of stringent patent enablement and written description requirements that are not applied to patents in other fields. If it is not possible to accommodate new technologies in the old

patent rules and their interpretation, it would be wise to modify the patent law to accommodate particular industries³⁹ and the enactment of Leahy-Smith America Invents Act was an effort in that direction.

Naturally occurring objects such as plants or minerals are, in general, ineligible for utility patent protection because they are viewed as belonging to the public domain. Portions of items found in nature are eligible for patent protection if their claimed form is different from their natural form.⁴⁰ The patentability is founded on the process or way of altering natural things into useful new items and not the natural item itself by mere extraction from a whole.

The decisive case that was the starting point of biotechnology patent law was *Diamond v Chakrabarty*⁴¹ where the United States Supreme Court held that Congress meant for “anything under the sun” to be patented as long as it was useful and so a man-made strain of bacteria was patentable subject matter. Technically, DNA and protein sequences are complex chemical molecules which means for patentability, these sequences should fall within the higher scrutiny standards that apply to chemical compound inventions.⁴²

The Supreme Court, in *Bilski*,⁴³ stated that 35 USC §101 intended to identify an extensive and flexible domain for patentable subject matters to be adjustable to advances in new technology but this is not to imply that § 101 has no limits or that it includes every discovery because the laws of nature, physical phenomena, and abstract ideas have been held not patentable.⁴¹ The Supreme Court, in *Funk Brothers Seed Co v Kalo Inoculant Co*⁴⁴, stated that natural laws are “free to all men and reserved exclusively to none” and that the discoverer of an “unknown phenomenon of nature has no claim to a monopoly of it.” and invention from such a discovery “must come from the application of the law of nature to a new and useful end.” Moreover, the Supreme Court, in *Parker v Flook*⁴⁵, said that although “a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented.” In the 2010 decision of *Prometheus v Mayo*⁴⁶, the Federal Circuit stated that “transformative steps utilizing natural processes are not unpatentable subject matter” and that this holding was consistent with *Bilski*.

DNA patents do not claim to cover the natural behaviour or identity of any living organism, the entirety of the human genome, or the four-letter

'alphabet' of individual nucleotides that comprise DNA. Moreover, products of nature and discoveries in non-technological fields, such as pure mathematics and the liberal arts, are explicitly excluded from patentability.⁴⁷ Doctrinal support for the patentability of DNA is grounded in the structural and functional distinctions between an isolated, purified DNA molecule and its naturally-occurring, impure counterpart. A purified substance qualifies as a patentable 'new composition of matter' within the meaning of § 101 provided that the substance satisfies the novelty requirement of § 102 (ref. 48). The purification must produce an exclusively new utility that is specific to the purified substance. It could be argued that § 101 should be read to exclude not only naturally occurring substances, but also any invention whose disclosure provides no more information than could have been found by observing nature. Purification simply confers a change of context, not a primary transformation of biological function, on a naturally occurring DNA molecule in the same way as purification of natural proteins is 'merely a change of context. Artificial isolation and purification distinguish DNA molecules over products of nature. Compounds isolated and purified from nature are not found in the human body and have long been patentable. On the other hand, it could be said that genes are discovered, not invented, and that genes are products of nature. Isolated genomic DNA is not satisfactorily distinct from genomic DNA to be the subject of patent protection and a minor structural change is inadequate to outweigh the near identity of the two molecules to be contemplated "markedly different."⁴⁹ The isolated DNA sequence must code for a protein adequately dissimilar from that found in nature.

In re Bergstrom court accepted that 'purified', prostaglandins were patentable even though they occur naturally in every human being.⁵⁰ The most fundamental basis of biotechnology is often the discovery of preexisting building blocks of nature, with little emphasis on originality in terms of invention of products except at the level of applied biotechnology.⁵¹

The recent rulings in *AMP v Myriad*⁵² regarding BRCA1 and BRCA2 genes brought gene patents to the forefront of the debate over the scope of intellectual property protection. *AMP v Myriad* is the first trial on the patent eligibility of isolated genes.⁵² The Supreme Court released its opinion in *Mayo v*

*Prometheus*⁵³ overturning the Federal Circuit's decision that diagnostic method claims are eligible for patenting under 35 USC § 101. On the other hand, the court stated that "too broad an interpretation of this exclusionary principle could eviscerate patent law" and that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."

Isolated BRCA1 and BRCA2 genes are tool compounds in molecular biology research, while their parental chromosomes are carriers of biological information in human body. Isolated BRCA1 and BRCA2 genes seem to have different structures, different properties, and different utilities. Isolated genes are not products of nature even if their parental chromosomes are. Can isolated genes having in fact the same utility as natural genes deemed to be patentable? Also designing around DNA is not possible unlike in the case of chemical compounds.^{54,55}

Gene patents are the most upstream category of biotechnology patents and also the category that has attracted the most criticism because gene patents may potentially hinder access to technology for the purposes of further basic research and commercial exploitation of gene related inventions.⁵⁶

Sequencing an oligonucleotide is common and, in large part, automated.⁵⁷ Automation is the generally used process for the sequencing of molecules and it has become useful enough not to require purification for relatively long strands. Therefore, to include one or more sequences in a patent application classically is not difficult if an inventor can isolate it. The utility of an isolated gene is principally the function of its DNA sequence, and another DNA sequence would not have the same utility.⁵² However, it is important to distinguish whether the invention offers a new function for the isolated gene or merely discovers an isolated function that already exists.

Patents for isolated genes have been issued worldwide for many years and the USPTO has determined that an isolated gene is patentable subject matter⁵⁸ provided it satisfies other requirements of the patent law, such as novelty, non-obviousness, utility, and enablement. While DNA in the human body is combined with other genetic materials, isolated DNA has been chemically cleaved and exists as a free-standing molecule. The process of isolating DNA entails the breaking of covalent bonds, in consequence creating a molecule with a chemical structure dissimilar to the DNA found in nature.⁵⁹

USPTO granted Myriad a long list of patents for its applications claiming BRCA1 and BRCA2 genes, and their use as medical diagnostic tools for breast and ovarian cancers. Pure isolation and transplantation of parts of DNA are not patentable. Thus, while the isolated DNA is not patentable the technique to isolate DNA with a new utility could be patentable. To that extent, in Judge Sweet's⁶⁰ opinion, DNA was not patentable because proteins were "biological molecules of enormous importance" that "catalyze[d] biochemical reactions" and constituted "major structural materials of the animal body." DNAs, including isolated genes and their sequences, were too exclusive and primary in nature to be designed around. Judge Sweet stated that the "utility of the isolated DNA as a primer or probe is primarily a function of the nucleotide sequence identity between native and isolated BRCA1/2 DNA" and that "a different nucleotide sequence would not have the same utility because it would be unable to hybridize to the proper location in the BRCA1 gene." Moreover, Judge Sweet⁶¹ positively concluded that all genes isolated from nature were products of nature. A gene is a physical carrier of biological information, and an isolated gene carries the same biological information as the same DNA sequence embedded in its parental chromosome existing in nature. Because natural chromosomes are products of nature, all isolated genes are also products of nature. As a result, Judge Sweet concluded: "The preservation of this defining characteristic of DNA in its native and isolated forms mandates the conclusion that the challenged composition claims are directed to unpatentable products of nature." The claims towards isolated DNA should be held not patentable subject matter⁵³ and in fact in *Mayo v Prometheus* the Court held that the correlation between blood test results and patient health is not patentable. In *Mayo v Prometheus*, the Supreme Court underlined the concern over patents that unreasonably tie up the use of underlying natural laws, in that way inhibiting their use in the making of further discoveries, predominantly in fields not contemplated by the patentee.

Furthermore, the court held in *Mayo Collaborative Services v Prometheus Labs, Inc.* that one cannot patent an invention which simply applies known technology to natural phenomena vacating the ruling that isolated human genes are patentable subject matter.

Proponents of gene patents argue that such patents are essential to serve the key purpose of the patent system, namely to call forth new technologies that would not be invented without monopoly incentives.⁶² Critics respond that gene patents do more to hinder innovation than to advance it because monopoly control of genes obstructs the ability of scientists to engage in subsequent research and limits patient access to innovative medical technologies.⁶³

While the debate rages on the elements that are patentable in biotechnology, it is also necessary to understand that the non-obviousness requirements in this field are less stringent as compared to other technologies because of the flexible nature of the products. The prior art disclosure of a broad genus does not automatically render obvious a specific compound within the genus.⁶⁴

Furthermore, the non obviousness is a requirement that the claimed invention taken as a whole should not be obvious to one of ordinary skill in the art at the time the invention was made compared to the 'reasonable man' in tort law.⁶⁵ The lead compound rule is constructive, and has continued to play an important role in post-*KSR* chemical obviousness cases.⁶⁶ In assessing the common level of ordinary skills, courts take into account factors such as approaches found in the prior art, the sophistication of the technology involved, and the level of education typical of those in the field.⁶⁷ Initial biotechnology techniques are considered to be more predictable and are more likely to fall into the category of routine experimentation.

It should be taken into account that the functionality of biotechnology products is unforeseeable and involves a high degree of uncertainty and risk. Hence, biotechnology is less predictable than mechanics or electronics and biotechnological inventions need more incentive than other types of inventions if they are to make it to the market.⁶⁸ Thus, the less stringent legal requirements may well the incentive to the high risk biotechnology ventures.

Comparison with EU Laws

There are three sources of regulation that govern patent grants in Europe — the agreements of the EPC, Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of Biotechnological Inventions (Biotech Directive), and the national laws of the individual

European states.⁶⁹ The EPO follows the EU's Biotech Directive, which states that "biological material which is isolated from its natural environment" may be patentable "even if it previously occurred in nature." In the EU Case of *Monsanto Technology LLC v Cefetra BV*⁷⁰ it was specified that an interpretation of Article 9 of the Directive limiting the protection does not appear to conflict unjustly with a normal exploitation of the patent and does not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties, within the meaning of Article 30 of the TRIPS Agreement". There is a comparative convergence of the standards of exclusions from patentable subject matter and exceptions and limitations to the rights in connection with biotech subject.⁷¹

The EPO now interprets the Directive to allow patents on isolated and purified genes and other biochemicals on the theory that isolation and purification adds a significant mental step.

Biotechnology: Patentability Considerations

This author considers that medical discovery and new knowledge means a significant mental step as long as it develops artificially a new gene that can be used for treatment. Forbidding the patentability of discoveries of natural phenomena on the one hand but allowing patents to scientifically meaningless modifications to those same phenomena is a contradiction. Ingenuity or creativity is hardly ever a prerequisite to isolating or purifying DNA molecules using modern technology.⁷² An inventor must create a new product that is significantly different in function from the naturally occurring phenomenon.⁷³

Carriers of biological information are not automatically unpatentable. Gene patents allow the monopolization of scientific research and genetic testing on that particular gene.⁷⁴ When a novel isolated gene is discovered and claimed, the composition of matter is not the genetic information hidden in the sequence, but rather its novel configuration and distinctive properties represented by the structure. An isolated gene, however, has several utilities. The distinctive utility of those isolated genes based on detecting certain DNA sequences hidden in biological samples (natural chromosomes in a cellular environment) is patentable.⁷⁵

Artificially created chemical compounds are considered inventions.⁷⁶ Patents claiming isolated genes, modified or unmodified, are more

controversial due to the special properties of genes and their relationship to human life.⁷⁷ Courts treat biotechnology inventions as unpredictable and so an applicant has to disclose a plurality of sequences from within a genus, and if possible a super plurality that represents the genus as well as common features of species within the genus.⁷⁸

Sufficiency of Disclosure and Enablement

In 1999, the USPTO announced higher thresholds for utility and written description requirements of patent claims pertaining to DNA sequences.⁷⁹ The written description⁸⁰ requirement was separate from enablement.⁸¹

This heightened written description requirement (as well as a heightened enablement requirement) for biotechnological inventions has been a creation of the perception of courts of the level "of ordinary skill in the art," and the degree of unpredictability of biotechnology during the early years in which the patents were litigated.⁸² In *Ariad Pharmaceuticals Inc v Eli Lilly & Co*⁸³ the CAFC addressed the written description requirement in the context of a challenge to patent claims that were directed to gene regulation through the control of the transcription factor NF-kB. The CAFC verdict went in favour of Lilly, emphasizing that in order to comply with the written description requirement, the specification needed to "demonstrate that Ariad possessed the claimed [molecules] by sufficiently disclosing molecules capable of reducing NF-kB activity."⁸⁴ The lack of disclosure of any molecules for use in connection with the claimed invention meant that the application did not demonstrate that the inventors were in possession of what was claimed.

In *Billups-Rothenberg Inc v Associated Regional and University Pathologists Inc*⁸⁵, the patentee's claimed methods were directed to detecting a predisposition to hemochromatosis. The specification failed to reveal the sequence of the gene or any explicit mutations that would result in the disorder. However, the CAFC disagreed, emphasizing the "immaturity and unpredictability of the science" during the relevant timeframe.

The Congress enacted the Biologics Price Competition and Innovation Act of 2009 which provides statutory exclusivity periods of 12 to 12.5 years for original biologics from the date of FDA approval overlapping with patent protection on the underlying biological result.⁸⁶ Statutory exclusivity regime in biologics could denote the beginning of a

new era in the protection and incentivizing of innovation and the emergence of a gradual replacement of the old patent system with modern idea of statutory exclusivities.

Patentability in Nanotechnology

Molecular nanotechnology is a very new form of technology with wide applications in medicine.⁸⁷ Nanotechnology involves the manipulation of matter at the level of individual atoms and molecules. By organizing individual atoms and molecules into particular configurations the molecular machines create works of complexity such as the human brain and a coral reef. Nanotechnology is an attempt to go beyond the capabilities of natural mechanisms, thus working for complete control over the physical structure of matter.⁸⁸

Nanotechnology products and inventions cross all scientific and technical areas raising questions in terms of patentable subject matter and laws of nature, physical phenomenon, and abstract ideas. The upsurge of nanotechnology is again challenging the criteria and practice applied by patent offices to inventions in ground-breaking sectors of technology. Nanotechnology is the technology of the infinitesimally small accompanied by at least one new technical effect directly resulting from nano size. It has to be taken into consideration that the patent developments analysed above are equally applicable to nanotechnology, bio-nanotechnology or biochemistry patenting as well.

Science and technology is systematically complex. Recent experiences with biotechnology and nanotechnology have only confirmed this. Nanotechnology is less about building nano-things and more about using nanotechnology as an enabling technology. For instance, nano-biotechnology or bio-nanotechnology is an area of scientific and technological prospect that applies the tools and processes of nanotechnology to develop devices for studying and interacting with bio-systems.

Conclusion

The functionality of computer/software industry, biotechnology, nanotechnology, bio-nanotechnology or biochemistry products is not foreseeable and involves a high degree of uncertainty and risk. Hence, these inventions need to be better incentivized than other types of inventions if they are to make it to the market.

Moreover, reforms have tightened the standards for patentability making it harder to acquire patents. With patent standards constantly in flux, it is essential that to have up-to-the-minute information on how best to protect inventions in upcoming technologies. There is widespread research activity in biomolecule⁸⁹ and biomimetic devices, biosensors, molecular motors, biomolecular fabrics, engineered enzymes and proteins, and drug discovery and delivery that are so new involving such impressive scientific advancement that even pure science can be awarded a patent.³⁵ It has to be examined if the complexity of theory in science can be regarded as an invention, thus preventing third parties from working on it. What level of scientific advance can be considered patentable is contentious. Gene patents for instance result in passionate debate because genes embody hereditary material and cannot be just a product in the hands of commercial companies. While many methods of medical diagnoses and medical treatment are now unpatentable, inventions that apply natural laws or natural phenomena are patentable and so one can patent a process for turning uncured rubber into moulded rubber products, even though the process uses a law of nature to ascertain when to open the mould. Finally, computer/software industry, biotechnology, nanotechnology, bio-nanotechnology and biochemistry bring forward new scientific theories and knowledge every day which means that it is essential to have something more than merely the scientific theory and knowledge in order to decide on patentability.

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