This article deals with the latest technology to create major intellectual property problems for courts and legislatures, viz. biotechnology. It discusses the economic principles of intellectual property in the way these apply to the decision framework for new technologies. However, it is limited to patents leaving out copyright, trademarks, trade secrets and other forms of protection where other considerations come into play. The way the courts have handled core patent issues such as novelty, non-obviousness and utility in the biotechnology field is reviewed in order to explore more deeply the application of the economic principles of intellectual property, viz. incentive and access principles. It discusses the various issues in biotechnology patenting as an illustration of an economic approach to intellectual property law not limited to threshold issues.

**Keywords:** Biotechnology, patent, patent doctrine, intellectual property rights, *sui generis*, novelty, non-obviousness, utility, inventive step

The basic economic foundations of intellectual property are straightforward and increasingly recognized by the courts. The problems lie in applying them in particular situations which can be highlighted by considering how intellectual property deals with new technologies and in the present case biotechnology\(^1\).

In considering this new technology from the point of view of intellectual property rights, it is useful to keep in mind that there are in principle three options for each new technology. First, do not protect at all. Second, protect in principle while applying the rules in such a way as to balance incentive and access. A variant of this second option is to protect in principle but because of some societal judgement, to decide -often case by case - to emphasize access over incentive in particular situations\(^2\). Third, protect not through patent, but through a tailored, *sui generis* system. A related preliminary point is that new technology protection has evolved in somewhat different ways in the patent regimes. The pattern in patent law was completely different. The first patent statute set out to give protection to inventions of every kind. Today, the list of categories remains the same, substituting only ‘process’ and ‘product’ for ‘art’ to reflect contemporary usage. In principle, an invention has to satiate the requirements of novelty, utility, inventive step and a product or process or else no patent will accrue\(^3\).

---

\(^1\) Email: jideshkumar@justice.com
A caveat is, however, in order. Despite this rather clear positive direction on coverage, the courts took it upon themselves to declare that certain kinds of inventions were not patentable subject matter. Although some courts had declared that a ‘product of nature’ could not be patented because it was not in one of the patentable categories, the courts later took to declaring certain things not patentable without too much attention to the categories.

To summarize, patent protection for biotechnology did not require a ‘go/no go’ decision by either legislature or courts. The only question was under what circumstances biotech patents met the standards of novelty, utility, inventive step and non-obviousness. However, as we shall see, the courts did have to wrestle with some judicially created exceptions to patentable subject matter. Since Parliament did not undertake to protect biotechnology by copyright, protection has been sought and accorded only by patent despite the fact that Parliament also took no action under the patent code. This differential result of Parliament’s non-action in both fields is significant not just because there is a secondary literature suggesting copyright protection for biotechnology, but because at least some of the field would lend itself to copyright protection insofar as it has the equivalent of letters, words and sentences. The genetic code in DNA has only four letters, one for each of the building blocks (nucleotides) that comprise DNA. This is a remarkably efficient alphabet, indeed one in which all substantive ‘words’ are only three letters long with each different three-letter ‘word’ coding for an amino acid. With this language, cells are able to express thousands, probably hundreds of thousands of proteins, and - equally remarkably - to do so with only twenty naturally occurring amino acids. These amino acids are the ‘letters’ of protein ‘words’ and ‘sentences’. Be that as it may, patents, not copyrights, are the weapons of choice for biotechnology.

**Biotechnology and Patents**

Biotechnology has faced problems in achieving equal protection in the patent system. Nearly every principle of patent law has to be rethought and interpreted anew in biotechnology, which is a reason why so many leading patent law decisions of the last decade have resulted from biotech cases. For this reason and in order to explore more deeply the application of the incentive and access principles to contemporary patent law, it is worth reviewing not merely patentable subject matter, but also, how the courts have handled other core patent issues, such as novelty, non-obviousness and utility in the biotechnology field. With respect to the threshold issue of patentable subject matter, the underlying question is one of balancing the two grand economic principles of intellectual property - incentive and access. Under this economic approach, care should be taken to assure that principles of the biological sciences are not preempted through patents, but, rather, only specific technological applications, so that the basic scientific principles remain open to future innovators. Still the question whether biotech innovations are patentable subject matter has to be fought...
out in the courts. The Kolkata High Court has in the *Dimminaco* matter held that biotech innovations are patentable. However, there has been not much development in the Indian circuit after that. What has particularly bedeviled the courts and many opponents of biotechnological research has been the frightening notion that life itself might be patented. As usually argued, this is predominantly a religious or ethical concern, but it obviously relates to the question of what is being preempted if patents are granted. In the United States, the threshold issue was left to the courts and the issue was phrased as whether patentable subject matter was presented by the patent application. The breakthrough in the United States was the Supreme Court decision in the 1980 Chakrabarty case involving a patent on a living bacterium that could break crude oil down into its chemical components, a highly useful property in fighting crude oil spills. The Court simply concluded that the bacterium was ‘not nature’s handiwork’, but the inventor’s, and that Parliament had got it right in the 1952 patent codification when it said that patentable subject matter ‘include everything under the sun that is made by man’.8 Converting this approach, it can be summarized by saying that since neither naturally occurring bacteria nor the principles of life, but rather just a newly created bacterium was the subject matter from which the patentee could exclude others, the incentive principle clearly dominated any concerns about the access principle. Because of this decision, now there are patents on such things as the famous Harvard mouse, an oncomouse that rather perversely has the highly useful property that it is particularly susceptible to carcinogens and therefore lends itself to cancer research.9 The problem in that patent has nothing to do with mice, for one can invent any other kind of non oncomouse one pleases and so access is not compromised. Rather an access problem lurks in its broadest claims, including the claim to all transgenic, non-human mammals with increased susceptibilities to cancer. Not just mice, but elephants and whales are excluded too, so long as they show the same susceptibility to carcinogens.10 Of course, a new elephant can still be invented if it is made especially susceptible to say malaria rather than cancer. More important than transgenic creatures has been the fact that biotechnology inventions now enjoy patent protection without unnecessary squabbles about threshold life-related subject matter issues. The situation has been fundamentally different in some foreign countries that impose major restrictions on biotechnology patents, just as indeed some still do on pharmaceuticals11, though the TRIPS Agreement in the Uruguay Round should help because it is a violation of that Agreement to exclude any ‘field of technology’ from patent protection.12 One general point is that although Parliament has enacted two *sui generis* plant patent statutes to protect innovations in plants13, in part to avoid lurking doubts about the ‘product of nature’ exception to conventional patent coverage, the courts have wisely found that a *sui generis* approach is unnecessary for biotechnology. Indeed, new man-made plants, whether or not created by biotech methods, have been
held eligible for conventional patents, i.e., eligible for utility patents in order to distinguish them from plant and design patents14.

Biotech Patent Doctrine
In addition to the patentable subject matter issue, biotech product patent applications must face the four hurdles faced by all patents; the product must be novel, non-obvious, must have involved an inventive step and useful15. For commercial efforts in biotechnology, which at least initially were mostly concerned with using biotech methods to make what already existed in nature (say a human protein), one can readily see that these hurdles are not automatically cleared. The key in that context to meeting these four requirements lies in the fact that biotech provides the product in a form that is purer and easier to administer in the treatment of disease, while at the same time being cheaper to produce than through conventional pharmaceutical processes. Justice Sandra Panem has concisely summarized the early promise of biotechnology, “The power of this new technology lies in the ability to produce rare biological products in large quantity, with high purity, and at low cost”16.

Novelty
The courts have approached the biotech cases in the traditional patent law manner, which is to treat patent law as unitary and then to apply that law to the facts as if there were nothing extraordinary about the new technology. The novelty question, which is simply whether the naturally-occurring product is new, had already been answered in the pharmaceutical cases. Those cases held that if a protein is isolated and purified, then it is new for the purpose of the novelty test. This result not only solves a riddle inherent in the nature of biotechnology, but also, does so in a way that promotes the incentive principle17.

Non-obviousness
The novelty cases do not answer the obviousness question, the second hurdle to patentability. How can the isolated, purified form of a protein fail to be obvious if it is otherwise identical to a naturally occurring protein, which we already know about? This is a complicated question that the courts have struggled with18. But the courts have not tried to construct a separate biotechnology patent doctrine. Rather, they have used the traditional approach of comparing what is claimed with the prior art. The crucial point is that the prior art is not what is known to nature, but what is known to man. For example, if what is known to man is a protein and what is claimed is a gene and the gene has been isolated and purified so that it clears the novelty hurdle, then the obviousness question is not whether it is obvious that a particular gene having a particular nucleotide sequence exists in principle, but whether it would be obvious to one skilled in the art to identify and isolate it. The leading case of In re Bell held that while “it may be true that knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene,” nevertheless, the degener-
acy of the genetic code is such that there are more than 10^36 different possible nucleotide sequences in a gene that might code for that protein. This recognition of the special nature of the genetic code does not involve, however, any separate doctrine favouring biotechnology patents, but rather constitutes an application of the long-established principle applied across a wide range of technologies that simply because a new research approach is ‘obvious to try’ does not mean that a resulting product would be obvious. Thus, unless there is something in the prior art that would suggest to a researcher a particular gene in question, as opposed to the thousands or millions of other possible nucleotide sequences that might possibly encode the particular protein, the resulting isolated and purified DNA molecules are not obvious and may be patented. While the processes for looking for the right nucleotide sequence might be known, it is not obvious how to pick the right one out of this human haystack.

This approach seems eminently good common sense in the protein-to-gene case, but it does not provide a rule for the protein-to-protein situation where biotech methods are used to produce a protein identical to a protein found in nature. The patent application may meet the novelty test if the protein is isolated and purified, but does it meet the obviousness test? One possible, but inadequate, answer is that if the biotech process used to obtain the biotech form of the protein is new and non-obvious, then of course, the patentability standard is met. But the problem is that the inventor can obtain a process patent, not a product patent, and as the courts have recognized in the pharmaceutical cases, process patents may be so hard to enforce that they do not provide a sufficient property rights basis to finance the risky development and clinical trials necessary to bring a new drug to market. The effort to emphasize the incentive function through the isolation-and-purification rationale has created a problem of deterring future innovation. In the Scripps case, a patent involving a blood growth factor produced by a chemical purification process was held potentially infringed by the biotech version of the same product. The full impact of that decision on innovation over time becomes clearer when one considers that its doctrine could presumably preclude a subsequent biotech firm from producing the same growth factor through still newer and even more superior biotech processes. As biotechnology has progressed, the obviousness question tends not to arise in the simplistic way just discussed in which the applicant claims the biotech equivalent of the naturally occurring substance - for example, a protein or a gene -, but rather claims some new biotechnological half-way house. To the extent that biotechnology today creates substances that do not exist in nature, the obviousness issue rather becomes the generic issue of what would have been obvious to one skilled in the art.

Utility

The third hurdle to patentability, namely, the utility doctrine, has become in some ways the front line in the biotech patent wars. The threshold utility issue is whether any utility has been shown if a
substance simply does what the corresponding natural substance does. The essence of the issue is, however, that some major advances may not yet have a concrete use in medicine or agriculture or any other end use economic activity.

These R&D outputs, often the product of enormous R&D outlays, are more than basic research results, but may not, without further R&D, result in something of immediate concrete value to mankind. Still, they may be sold in the marketplace, particularly to pharmaceutical firms. While an economist might say that whatever commands a price in the marketplace meets an economic utility test, a conventional legal view has been that something that is useful only in further research does not meet the statutory utility requirement. For the purposes of emphasizing the factors at play it suffices to take just one hotly contested, indeed highly emotional, question now being fought out in the patent system. Suppose biotech methods are used to isolate not previously known partial complementary DNA sequences\(^2\), then these partial cDNA sequences may be patentable subject matter, but is the utility requirement met if we do not know for sure what they are useful for? Put in the language of the current debate, should we not wait until we at least know the function of these sequences? Or, to use the jargon of patent law, do the sequences have practical utility?\(^2\) In short, do they provide ‘some immediate benefit to the public’?\(^2\) One answer is to say that we should just wait until we have something truly useful - of ‘immediate benefit to the public’ before granting a patent\(^2\). Under this view, we should wait, for example, until we have isolated a useful protein using that cDNA sequence before considering patentability or until we have at least identified and located the cellular DNA or perhaps synthetically generated the full DNA sequences required to produce a protein. The essence of the policy argument for this wait-and-see approach is that issuing such cDNA patents would inhibit research leading to truly useful discoveries\(^3\).

The problem with this wait-and-see solution is twofold. First, given the progress in biotech methods, the method of identifying and locating the entire gene may be obvious from knowledge of the partial cDNA sequence. Second, the protein may be obvious from the gene or even from a complete cDNA sequence\(^4\). And so if there is no patent on the partial sequence, there may be no patent available at a later stage because of the non-obviousness requirement. Would such an outcome serve the incentive function of the patent system? As already mentioned, it is well known that pharmaceutical companies are reluctant to engage in R&D and unwilling to go through the expensive clinical trial process on new drugs unless patent protection can be relatively assured because otherwise commercialization will not be financially feasible\(^5\). Of course, if the firm that discovers the partial sequence neither publishes it nor sells it publicly, then it may later be able to patent the full gene. The result would, however, be later disclosure to the public and to that extent, perversely, serves neither the incentive nor the access function\(^6\).

Recognizing this simple fact of busi-
ness life, there has been considerable development in foreign lands. The US Commissioner of Patents, reacting to criticism from the biotech industry, adopted guidelines in 1995 making clear that a patent examiner should not reject biotech applications where the asserted utility ‘would be considered credible by a person of ordinary skill’34.

Guidelines on these lines might lead to patents being granted on cDNA sequences for their utility in construction of DNA probes or in new forensic applications or in tissue typing or in diagnostic applications35. Looking further ahead, cDNA sequences could be useful in some as yet unexploited ways based on the essential comparability of DNA in all of earth’s creatures. Some of these utility theories, especially those used in constructing cDNA probes to identify and locate the gene, have to confront the important principle of utility doctrine that frowns on any theory based on usefulness in further research36. This principle, which has its legal justification in the notion that an innovation useful only in further research is not of ‘immediate benefit to the public’, 37 is a somewhat dubious notion when biotech research itself has raised billions of rupees of capital from the public.

An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact ‘useful’ in a patent sense. If this view is sustained by the courts, the incentive function will be preserved in the biotech industry. But what will be the case of access for future innovation? We must recognize that the fight over partial cDNA sequences arises from the fear in academia, and also in some portions of the pharmaceutical industry, that access to the basic biological building blocks of the human body will be preempted by patents38. Here again the solution to this burning biotech patent issue lies in a clear recognition and discussion of the balance between the incentive and access principles.

**Inventive Step**

Inventive step is definable as the quality or step that makes an invention unique and new. However, there has been a great deal of controversy about what exactly comprises an inventive step. Every year, the Indian Patent Office deals with a great number of patent cases to determine whether or not an inventive step has been taken.

Inventive step can be best understood and interpreted by the Windsurfing Test39. Oliver L J proposed the following 4-point test to determine whether an invention involves an inventive step: (a) the court identifies the inventive concept embodied in the patent in suit; (b) the court will assume the mantle of the normally skilled, but unimaginative addressee in the art (the person to whom the patent is addressed) at the relevant date and impute to him what was at that date common general knowledge in the art in question; (c) the court identifies what, if any, differences exist between matter cited as known or used and the alleged invention, and (d) the court decides whether, viewed without any knowledge of the invention, those differences constitute steps which would have been obvious to the skilled
man or whether they required any degree of invention. A similar approach is applied consistently by the Boards of Appeal of the European Patents Office. Thus any invention satiating these requirements would pass the test of inventive step.

The foregoing discussion of the various issues in biotechnology patenting is not an attempt to lay down rules for its resolution in the manifold factual situations presented by the onrushing progress of the field, but rather is simply an illustration of an economic approach to intellectual property law that is by no means limited to threshold issues of whether or not to protect a new technology.

References

1 Biotechnology encompasses a variety of techniques such as selecting natural strains of organisms that carry desirable traits, making hybrids by fusing cells from different parental sources, using chemicals and radiation to create mutant strains, or genetically engineering plants, animals and microorganisms to contain specific phenotypic characteristics. At its most general level, biotechnology concerns techniques for using the properties of living things to make products or services.

2 A variant of this second option is to emphasize incentive over access. Although in the application of the second option, the balancing of incentive and access may have been done by some courts in such a way as to unduly emphasize incentive, no system appears to have explicitly downgraded the access principle.

3 Sec 2(j), Patents Act, 1970

4 Thomson Brandt v Controller of Patents and Designs AIR 1989 (Del) 249; Abid Kagawala v Edgar Haggley Co (P) Ltd 1984 PTC 234 (PO)

5 Merck & Co v Olin Mathieson Chemical Corp, 253 F.2d 156, 162 (4th Cir. 1958); Parke-Davis & Co v H K Mulford Co, 189 Fed. 95, 103 (S.D.N.Y. 1911)

6 For suggestions in the secondary literature that copyright be used for biotechnology, see, e.g., Burk Dan L, Copyrightability of recombinant DNA sequences, 29 Jurimetrics J 469, 1989, 492-512; Kayton Irving, Copyright in living genetically engineered works, George Washington Law Review, 50(2) 1982, 216-218

7 See Diamond v Chakrabarty, 447 US 303 (1980) (patentable subject matter); In re Bell, 991 F.2d 781 (Fed. Cir. 1993)(obviousness); In re Vaeck, 947 F.2d 488 (Fed.Cir. 1991) (enablement); Fiers v Revel, 984 F.2d 1164 (Fed Cir. 1993)(Conception)


12 Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Art. 27 (1). However, Article 27 (3) has certain exceptions with regard to biotechnology. See also the transitional provisions of Article 65. See Reichman J H, Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement, 29 Int’l Lawyer, 1995, 345, 352-353, 358-360

13 The two statutes are the Biodiversity Act and the Plant Variety and Farmers Rights Protection Act

14 Ex parte Hibberd, 227 USPQ 443 (Bd. of Pat. App.1985). See Animal Legal Defense Fund v Quigg, 932 F.2d 920, 923 (Fed Cir. 1991)

15 A further hurdle is the enablement requirement. 15 U.S.C. §112. See Amgen Inc
This requirement has the effect of narrowing the scope of biotech patents by limiting the ability of the applicant to make generic product claims covering more than the applicant has actually made, In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991), and thereby balances the incentive and access principle by granting the first innovator a narrow patent while leaving room for follow-on innovators to make claims for other species within the genus, assuming that the obviousness hurdle can be overcome. For a discussion of the significance of the enablement requirement to the biotech industry, see Burchfield Kenneth J, Biotechnology and the Federal Circuit 1995, 208-210.

To the extent that biotech innovation has expanded to include substances, not found in nature, the novelty requirement no longer presents a special barrier to patentability. The pharmaceutical cases used a variant of the purification rationale to deal with the obviousness doctrine as well. See Merck v Olin Mathieson Chemical, 253 F.2d 156 (4th Cir. 1958); In re Bergstrom, 427 F.2d 1394 (CCPA 1970).

The pharmaceutical cases used a variant of the purification rationale to deal with the obviousness doctrine as well. See Merck v Olin Mathieson Chemical, 253 F.2d 156, 164 (4th Cir. 1958) (“It did not exist in nature in the form in which the patentees produced it and it was produced by them only after lengthy experiments. Nothing in the prior art . . . suggested it.” (emphasis supplied)) 991 F.2d 781, 784 (Fed. Cir. 1993). See also In re Deuel, 51 F.3d 1552 (1995).

Process (or method) patents are of course also subject to the nonobviousness requirement. See In re O’Farrell, 853 F.2d 894 (Fed. Cir. 1988).

Sec 5 (1) (b) (explanation) included by the Patents (Amendment) Act, 2002.

See statement of Judge Rich, dissenting in Atlantic Thermoplastics Co v Faytex Corp, 974 F.2d 1279, 1280-1281 (1992), that the cost in 1990 of moving a new chemical entity from laboratory to market was over $230 million and that only one of 5,000 to 10,000 compounds discovered ever made it to market. Some attempts to find a solution to this problem have involved so-called product-by-process claims. Such claims have sometimes sought to give product protection where the essence of the invention is in truth a nonobvious process. However, the justification for such claims, which are not mentioned in the patent code, is to permit a patent on “an otherwise patentable product that resists definition by other than the process by which it is made.” In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985). Compare Atlantic Thermoplastics Co v Faytex Corp, 970 F.2d 834 (Fed Cir. 1992), holding that the process is a limitation on a product-by-process claim so that making the product by a different process would not constitute infringement with Scripps Clinic & Research Foundation v Genentech Inc, 927 F.2d 1565 (Fed. Cir. 1991).


See, however, Genentech, Inc v Wellcome Foundation, 29 F.3d 1555 (Fed. Cir. 1994), a doctrine of equivalents case, implicitly distinguishing the situation where an allegedly infringing protein was superior in therapeutic application to the patented protein. See In re Vaeck, 947 F.2d 488 (Fed Cir. 1991).

A complementary DNA sequence is one derived from messenger RNA, which may be thought of as a half-way house between cellular DNA and the protein expressed by that DNA within the cell. For an explanation,
see In re Deuel, 51 F.3d 1552, 1554 (1995)

27 On the patent law concept of utility, see Brenner v Manson, 383 U S 519 (1966)

28 Nelson v Bowler, 626 F.2d 853, 856 (CCPA 1980)

29 One can find an analogy in In re Joly, 376 F.2d 906 (CCPA 1962), which held that one cannot patent a chemical compound that is useful only because it is an intermediate in making another chemical compound in the absence of showing the utility of the latter compound.

30 Wuetherich Bernice, All Rights Reserved: How the gene-patenting race is affecting science, 144 Science News, 4 September 1993, 154

31 “Like mRNA [messenger RNA], cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA’s nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids.” In re Deuel, 51 F.3d 1552, 1554 (Fed. Cir.1995)


33 A recent development has been the effort of Merck to underwrite University laboratory sequencing of human cDNA followed by immediate deposit of the sequences in a public databank. This approach results in prompt disclosure to the public but also undercuts efforts by other to patent such sequences. See Columbia Shuns Profits from Gene Fragments, 268 Science 487 April 28, 1995. Since Merck is primarily a pharmaceutical rather than a biotech firm, the question of its motivation has arisen. Elliot Marshall, HGS opens its databanks - for a price, 266 Science 25 Oct. 7, 1994; and Bishop Jerry B, Plan may blow lid off secret gene research, Wall St J B1 Sept. 28, 1994


36 See Eisenberg Rebecca S, Symposium: A technology policy perspective on the NIH gene patenting controversy, 55 1994,633, 645-647

37 Nelson v Bowler, 626 F.2d 853, 856 (CCPA 1980)

38 On the possibility that the experimental use defense to patent infringement will satisfy the academic concerns, see Eisenberg Rebecca S, Patents and the progress of science: exclusive rights and experimental use, 56 U Chi L Rev 1989, 1017

39 See Windsurfing International Inc v Tabur Marine Great Britain Ltd [1985] RPC 59, 73

40 Yushiro Chemical Industry Co Ltd's Application, T0876-96 Technical Board of Appeal, 13 March 2001, 5