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patents and other intellectual property protection are only one of the ways to increase the incentive to invest in research and development. the european patent convention is now well established and allows a number of innovative options. in particular, it provides for the possibility of granting a patent on a plant variety or plant variety cultivar. such patents are considered by some as a useful tool to protect plants against the threat of genetic modification by the notorious biotechnology industry. the process of genetic diagnosis involves various steps: (a) the genetic material of a body is analysed to detect the presence of a disease-causing gene, (b) the genetic change detected is used to identify the affected individual and (c) the presence of the change is used to predict the future course of the disease and the risks for the patient and family. 21 however, genetic diagnosis is a complex process involving many steps. in general, the main steps are: (a) selection of a mutation to be screened in a patient; (b) selection of a method for analysis; (c) selection of a method for interpretation of the results; (d) identification of the mutation; (e) consultation; (f) counselling for family members; (g) genetic counselling; (h) genetic testing. the mutation can be identified either by the analysis of a parent or a test with a high sensitivity of detection. all steps are subject to medical and ethical limitations and involve a risk of erroneous diagnosis. in general, genetic diagnosis is expensive, time consuming and requires the availability of trained staff. genetic diagnostic services are available in approximately 25 000 laboratories worldwide. 22 the most widely used methods for mutation detection are based on the use of pcr primers to amplify dna fragments carrying the mutation of interest and to produce a diagnostic product for mutation detection. 21 a number of different techniques are available for detection of genetic disorders. the most commonly used are denaturing gradient gel electrophoresis (dgge), denaturing high performance liquid chromatography (dhplc), denaturing capillary electrophoresis (dce), dye-terminator chain reaction (docr), restriction fragment length polymorphism (rflp), the use of an oligonucleotide to detect dna single-nucleotide polymorphisms (snps), or sequencing. because of the complexity of the human genome, the need for reliable diagnosis, the costs and, in particular, the uncertain future of genetic diagnosis, some authorities have called for a moratorium on the patenting of genes and gene products. a moratorium on the patenting of genes and gene products was approved by the european court of justice in europe. in sweden, an amendment to the medical products act and patent law was proposed in march 2002, which would have precluded the patenting of human genes and gene products in vitro. the amendment was rejected by the swedish parliament in april 2002. the authorisation of the patent was, however, formally revoked in september 2002, and no new applications for patent were filed after january 2003. 23

Patenting In Biotechnology : A Laboratory Manual

This section may be useful, especially for a laboratory manual, as a simple example of a patent application that has been filed and granted by the US Patent Office. The case involves a company that owns a strain of genetically modified plants that produce therapeutic products. The strain was developed by genetic modification of the HNK2 potato cultivar in the United States. The inventor is a scientist at a university, Johnathan Dunbar. The application for the Patent (A/US/60.050), which relates to strain HNK2-23, is not to be assigned to a university, but rather a corporation, Dunbar Rice LLC. Dunbar Rice is a new company. The strain is a product of several years of research by the university scientist and the company. Both published the results of their research in scientific journals. The plant itself is now sold to seed companies. The company Dunbar Rice stands for, is an operating company of the Johnathan Dunbar Research Foundation, a private charitable foundation. The fund was originally formed in 1990 as a consortium of several universities, so the consortium of institutions of higher learning that founded the company. The company is now generating large sums of money from third parties that can be applied for this purpose. Educating the public is one of the goals of Biotechnology. Educators have to remember that increasing knowledge is not synonymous with understanding. For example, a student that knows the basics of genetics and the cell biology of DNA expression on E. coli bacteria will not understand gene-based biotechnology. To enable students to understand the basic concepts of biotechnology, they have to be introduced to the key elements, the essential relationships, and the crucial concepts in the biological sciences. 26 The same is valid for the legal environment of patenting in biotechnology in particular the pertinent legal acts and IPR policy in the United States. 5ec8ef588b

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