

The exploitation of biotechnological inventions

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But what inventions are deemed moral or immoral from a public order perspective in Europe? For subject matters which come under the respective provisions for not granting a right to inventions of which the commercial exploitation would be contrary to ordre public or morality, the European Regime provided legislative guidance by issuing the EC Biotechnology Directive[2] which is reflected in the EPC 2000[3] and, despite some slight verbatim differences, is enacted in the statutes and schedules of the Patent Act 1977[4]. At the IPO, the threshold for moral issues goes beyond biotechnological invention, and thus, is broadly defined by the respective examination guidelines as to prevent the patent grant of an invention that would be expected to encourage offensive, immoral or antisocial behavior[5].

Nevertheless, the respective schedule focuses on biotechnology and sets out that processes for cloning human beings and modifying the germ line genetic identity of human beings[6] are clearly excluded on grounds of immorality, whereas the uses of human embryos for industrial or commercial purposes also come under inventions are currently not patentable[7] on moral grounds. Additionally, processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes[8] are not patentable due to moral issues. In case of plant breeding or biotech seeds, besides the fact that European Parliament called the EPO also to exclude from patenting products derived from conventional breeding and all conventional breeding methods, including SMART breeding (precision breeding) and breeding material used for conventional breeding,

and the critics' arguments that seed patents impose an abuse of the patent law by using it as a tool of misappropriation which turns agricultural resources into the intellectual property, the fact that Monsanto already owns 36% of the tomato seed varieties registered with the Plant Variety Office of the EU, as well as 32% of the paprika (sweet pepper) varieties and 49% of the cauliflower varieties, it seems to be not sufficient to argue ordre public or immoral behavior. In addition, the fact that the second biggest applicant in this field, Syngenta, owns 26% of the tomato varieties, 24% of the paprika (sweet pepper) varieties and 22% of the cauliflower varieties[9] doesn't bother the EPO to apply Art 53(a) in order to compel an alteration of the present filing strategies, but illustrates that for these subject matter the public policy of the EPO relies on the fact that plants and animals are regulated by EPC Art 53(b). But where is line draw to invoke such limitation on inventions? Hereto, the evaluation of Art. 53(a) at the EPO was centered on the Oncomouse[10] case.

which was ruled prior to and post the introduction of the EPC Rules in 2000[11], whereas in terms of animals as shown above, the EPO draws the line of morality by the application of the so-called utilitarian balance test in order to exercise balance between animal suffering, potential risks for the environment and beneficial usefulness to mankind. According to this narrative the necessarily cause of suffering[12] to the animals was sufficient to conclude immorality and render the invention for the process not patentable. However, it has to be highlighted that sharp line is drawn by the black letters of Art. 53(a) and Rule 28, since from an EU and UK perspective neither product claims, nor product-by-process claims will be affected by the

non-patentability of biological processes in the above scope[13]. Read about genetic alteration. Albeit the established cost-benefit-test with regard to Art. 53(a), in *Plant Genetic Systems* the EPO Opposition Division neglected to employ the test in the opposition proceedings, because there was no sufficient proof to quantify the reasons for the objection. Thus, albeit ethically questionable, the EPO's Technical Board of Appeal denied the opposition motion and upheld the patent grant because of the EPO's function to protect the deep rooted norms[14] of the European society but also to service both, public policy and science, respectively. Hence, the EPO took on the issues concerning public security, and physical integrity of individuals as part of society[15]. With regard to the above seminal cases, and in line with seminal decision in *Regina (in ex parte Quintavalle) v Secretary of State for Health*[16] that defined that the term embryo should not be restricted to a live human embryo produced by the fertilization of a female egg, but should be interpreted to include an embryo produced without such fertilization, such as one created by cell nuclear replacement[17], a further subject matter that was deemed immoral can be illustrated. Thus, with regard to stem cells to be retrieved with a destruction of a human embryo, the EU view on ethics clearly shows a prudent approach to deny patentability in this particular field of research, whereas the impeccable reasoning of the UK's position to the future of stem cells research that was conveyed to EPO Enlarged Board of Appeal Judgment in the *WARF*[18] case, shows an ethical balance to this issue.