歐洲專利規範中之 「公序良俗」條款檢驗標準:

以人類胚胎幹細胞專利爲例*

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目 次

壹、前言

貳、公序良俗條款與歐洲專利規範

- 一、公序良俗條款於專利法上之定義
- 二、公序良俗條款於歐洲專利規範中之現況
- 參、公序良俗條款與人類胚胎幹細胞
 - 一、公序良俗條款於人類胚胎幹細胞專利之適用
 - 二、G02/06 WARF 一案對於人類胚胎幹細胞可專利性 之見解

肆、結論

^{*} 本文為 99 年度國科會個別型研究計畫(編號 NSC 99-2410-H-029-062) 的部分研究成果,特此登謝。本文感謝二位匿名審稿教授細心審閱斧正, 所為指正與建議,本文已參照修正,併此致謝。

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2 中正財經法學 2011年1月

摘 要

由於胚胎幹細胞具有產出不同細胞型態的潛力,許多專家相信透過人類胚胎幹細胞研究將可帶來醫療上的重大革命。但胚胎幹細胞相關之法律及倫理議題,卻始終引發熱烈的討論與爭議。歐洲專利公約(European Patent Convention)第53條a款規定發明之商業利用違反公共秩序與道德者,不予專利。然而公序良俗的概念太過抽象,爲了確保所有歐盟會員國對於涉及生物科技的發明都能依照同樣標準有效保護,以維護法之安定性,歐洲生物科技指令(98/44/EC)指令試著將違反公序良俗之發明例示化,提供一參考準則。歐洲專利局上訴委員會與擴大上訴委員會,近年來亦試圖將公序良俗條款之檢驗標準具體化,並在其最新決定 G02/06中,對人類胚胎幹細胞之可專利性進行深入的討論。本文認爲公序良俗條款有存在之必要與價值,在維持法安定性的前提下,公序良俗條款及其例示規定雖爲例外條款,但並非表示適用更嚴格或者更狹義的解釋方式,仍須考慮條文上下文及其目的而進行一般性的解釋。而歐洲專利規範中所累積之見解,將可提供解釋公序良俗條款上之借鏡與參考。

關鍵字:公序良俗、可專利性、胚胎幹細胞、歐洲專利公約、歐洲生物科技 指令(98/44/EC)、生物科技相關發明 36 中正財經法學 2011年1月

Morality and *Ordre Public* criteria in European Patent Law:

Example of Stem Cells Patentability

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Abstract

Stem cell technology has the potential to bring the revolution to the way that certain diseases are treated. However, the use of embryos raises significant moral and ethical questions in many fields, including the patent system.

Article 53(a) of the European Patent Convention (the "EPC") 2000 excludes "inventions the commercial exploitation of which would be contrary to "ordre public" or morality" from patentability. In addition, there is a specific exclusion to the use of human embryos for industrial or commercial purposes which has been developed according to the principles set by EC Directive 98/44/EC.

The Technical Board of Appeals (TBA) and Enlarged Board of Appeals (EBA) at the European Patent Office (EPO) have tried in several decisions to establish the concrete standards for examining the *ordre public* and morality criteria in patent law to ensure legal security in Europe. The most recent focus has been the WARF case (G 02/06) decided by EBA in November 2008.

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This article attempts to analyze these recent decisions by considering the definition and the scope of the *ordre public* and morality criteria in the light of the *ratio legis* of Article 53 (a) EPC. By doing so, the application of these criteria in practice can be defined and the interpretation of those legal standards which is coherent and useful to the development of patent law can be introduced.

Keywords: Morality, *Ordre Public*, Stem cells, European Patent Law, Directive 98/44/EC, Biotechnological invention