1. 사안의 개요

(1) Gilead의 Truvada는 tenofovir disoproxil ("TD") + emtricitabine 복합제.

(2) Truvada SPC의 대상 특허는 EP 0915894, 청구항 중에서 복합제 청구하는 claim 27: "a pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients"

(3) 발명의 상세한 설명에 TD와 다른 유효성분 복합제에 관한 실시예 기재는 없었고, 특히 emtricitabine는 언급 없었음.
2. CJEU 판결 요지

(1) 결론: CJEU in Gilead Truvada case (C-121/17): no SPC for A+B unless “the claims relate necessarily and specifically to that combination”

(2) A combination product is protected by a basic patent, “where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination”.

(3) 판단기준 criteria: “for that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

A. the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

B. each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.”
(4) 구체적 사안에 대한 CJEU 의견 - Truvada SPC 인정 불가. “it does not seem possible that a person skilled in the art would be able to understand how emtricitabine, in combination with TD, necessarily falls under the invention covered by that patent.”