

공지 구성요소의 결합발명의 진보성 판단 – CR formulation 특허발명의 진보성 인정:

Purdue v. Depomed 사건 CAFC 2016. 3. 24 선고 2015-2029 판결



공지의약 Oxycodone Controlled Release 제형 발명으로서 그 제형의 구성요소도 각각의 선행발명(Shell formulation + Baveja formulation)으로 공지되어 있고, 그 공지요소를 결합한 특허발명은 신규성은 인정되지만 나아가 진보성이 인정되는지 여부가 쟁점인 사건입니다. 발명요지는 다음과 같은 제형발명 claim 1과 방법발명 claim 43을 보면 쉽게 알 수 있습니다.

Claim 1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20,

said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode [**“the swelling limitation”**],

that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid,

that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug within about eight hours after such immersion,

and that remains substantially intact until all of said drug is released [**“the substantially intact limitation”**].

Claim 43. A method of administering to a subject a drug that is therapeutic to said subject when absorbed in the stomach where said drug has at least one ionized group in the pH range 5 through 8,

said method comprising orally administering to said subject a dosage form of said drug while said subject is in a fed mode, said dosage form comprising a solid polymeric to said subject a dosage form of said drug while said subject is in a fed mode,

said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 0.01:99.99 to about 80:20,

said polymeric matrix being one that:

(a) swells upon imbibition of gastric fluid to a size large enough to promote retention in the stomach during said fed mode [**“the swelling limitation”**],

(b) releases said drug into gastric fluid by the dissolving of said drug by said gastric fluid and either erosion of said matrix or diffusion of said dissolved drug out of said matrix,

(c) retains at least about 40% of said drug one hour after such immersion in gastric fluid,

(d) releases substantially all of said drug within about ten hours after such immersion, and

(e) remains substantially intact until all of said drug is released [**“the substantially intact limitation”**],

thereby extending the release rate of said drug with time during said fed mode while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment.

USPTO PTAB 인정사실에 의하면 선행발명 Shell formulation에는 위 청구항에서 bold로 표시한 swelling limitation과 substantially intact limitation를 제외하고 모두 기재되어 있고, 위 추가된 한정요소는 Baveja formulation에 기재되어 있습니다. 따라서, 2건의 선행발명을 결합하면 특허발명의 구성이 모두 충족되는 상황입니다.

이와 같은 상황에서 미국 특허청 PTAB와 CAFC는 모두 등록특허의 유효를 전제로 결합 발명의 진보성 흠결로 특허무효라는 특허무효도전을 무효 입증 부족을 이유로 받아들이지 않았습니다. 전형적인 pro-patent 논리에 따른 진보성 판단 법리를 보여주는 것 같습니다.

CAFC 판결요지를 인용하면, "a patent challenger must demonstrate that a skilled artisan **would have had reason to combine** the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so."는 진보성 판단법리를 전제로,

당해 사안에서 “an expert opined generally on the interrelated teachings of those references, but **did not explain in sufficient detail how or why** a skilled artisan **would have been motivated to combine** the “swelling” and “substantially intact” features of the Shell formulation with the Baveja formulation to attain the claimed dosage form.”라고 판시하였습니다.

공지요소의 결합 가능성(could)을 넘어서 시도할 동기 내지 개연성(would)에 대해 충분하고 구체적인 이유와 방법이 설명되어야 한다는 취지입니다.

공지의약의 Formulation 특허발명은 유효성분이 공지되어 있을 뿐만 아니라 formulation 요소도 대부분 공지되어 있습니다. 그와 같은 상황에서 미국 USPTO PTAB과 CAFC에서 결합발명의 진보성을 어떻게 판단하는지, 특허도전자의 진보성 흠결 주장에 관한 입증요구 수준 등을 제시하는 판결입니다.

지재권분쟁, 침해대응/감정, 형사/민사소송, 손해배상, One-Stop service, A~Z 수행

T. 02-591-0657 E. kkh@kasanlaw.com H. www.kasanlaw.com