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# TECHNOLOGY LAW UPDATE

*A report of the latest Federal Circuit updates brought to you by Preston Gates.*

## Geneva Pharms., Inc. v. GlaxoSmithKline, PLC

No. 02-1439 (Fed. Cir. Nov. 21, 2003)

***“[R]estriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121’s protections [against a double patenting challenge].”***

On November 21, 2003, the Federal Circuit affirmed the district court’s summary judgment that invalidated for nonstatutory double patenting six patents relating to the antibiotic clavulanic acid and its salts. One of these salts, potassium clavulanate, is an active component of GSK’s product Augmentin®. With respect to the district court’s holding concerning the invalidity of certain 2000/01 patents over a 1985 patent, the Federal Circuit stated:

In § 101, title 35 precludes more than one patent on the same invention. [A]n applicant may obtain “a patent” for an invention. Section 101, however, only prohibits a second patent on subject matter identical to an earlier patent. Thus, applicants can evade this statutory requirement by drafting claims that vary slightly from the earlier patent.

[The] doctrine of nonstatutory double patenting (also known as “obviousness-type” double patenting) [prevents] issuance of a patent on claims that are nearly identical to claims in an earlier patent. This doctrine prevents an applicant from extending patent protection for an invention beyond the statutory term by claiming a slight variant. With nonstatutory double patenting, a terminal disclaimer may restrict the slight variation to the term of the original patent and cure the double patenting rejection. . . .

Section 121 shields claims against a double patenting challenge if consonance exists between the divided groups of claims and an earlier restriction requirement. If a restriction requirement does not clearly set forth the line of demarcation, then challenged claims could not satisfy the consonance requirement. Therefore restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121’s protections.

GSK does not meet its burden to show that the record provides a clear demarcation of the allegedly restricted subject matter. In the first place, the record makes the substance of the documented interview uncertain. For example, the interview summary does not state what specific subject matter the allegedly restricted claims cover. The interview summary description refers generally to “simple  $\beta$ -lactamase inhibition compositions” and “method of use claims.” While the 1979 interview summary refers to “method of use claims” in the plural, GSK entered only one claim in the ‘035 application. This record provides no clear line of demarcation.

GSK took about a quarter-century to prosecute the 1985 and 2000/01 patents to issue. This record does not explain that delay. In any event, the effect of that delay could potentially extend patent protection for the invention in the original ‘007 application. For that reason as well, this thin and insufficient record simply does not operate to shield these patents under § 121 against double patenting rejections. Section 121 can extend the patent term for inventions that are not patentably distinct, as apparently would be the case here. Given the potential windfall such patent term extension could provide to a patentee, this court applies a strict test for application of § 121. Specifically, § 121 only applies to a restriction requirement that is documented by the PTO in enough clarity and detail to show consonance. The restriction documentation must identify the scope of the distinct inventions that the PTO has restricted, and must do so with sufficient clarity to show that a particular claim falls within the scope of the distinct inventions. In other words, § 121 requires a record that shows a discernable consonance.