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## Merck's NuvaRing Patent is Not Obvious

NuvaRing is a vaginal ring that is a drug-delivery device used for contraception. The ring releases a constant daily dose of two hormones - progestin and estrogen.

Merck's patent requires the two hormones to be released from "one compartment." The prior art taught release from two compartments. And, the prior art explained the disadvantage of one compartment - the release of different hormones cannot be adjusted independently.

In a non-precedential opinion, the Federal Circuit reasoned that the prior art did not make Merck's patent obvious.

The prior art disclosed a broad range of values for the relative size of the two compartments, as well as the concentrations of the compounds.

The Federal Circuit explained that "nothing in [the prior art] suggests picking these values out of the innumerable possible combinations of ETO concentrations, EE concentrations, and compartment length ratios. Instead, the only way to arrive at the hypothetical ring is by using the [Merck] patent as a roadmap to piece together various elements of [the prior art]. That represents an improper reliance on hindsight."

### COMMENTS:

Patent owners face the constant challenge of arguing against assertions that each feature of a patent claim can be found in the prior art and, therefore, the claim is invalid. Finding each feature, however, does not make the combination of features obvious.

## Boston Scientific Not Liable for Royalties on Coronary Stent

Dr. Jang assigned his patent to Boston Scientific (BSC), and BSC agreed to pay a royalty if BSC sold a stent covered by the patent.

Jang sued for royalties, and BSC asked the USPTO to reexamine the patent for invalidity.

The USPTO found the patent invalid and BSC argued in the district court that it did not owe Jang royalties that accrued before the patent was found invalid.

The Federal Circuit concluded that the jury had sufficient evidence to find no "literal" infringement by BSC.

### COMMENTS:

Jang also failed to convince the Federal Circuit that the district court improperly denied Jang's claim of infringement under the doctrine of equivalents (which can apply in the absence of literal infringement).

## Eli Lilly's Patent for Cancer Treatment Survives Challenge

Lilly's patent covered the use of vitamin B12 and folic acid to reduce the toxic events associated with the administration of cancer drugs - such as Lilly's Alimta drug.

The patent identified "pemetrexed" as the most preferred "antifolate" (i.e., cancer drug).

Neptune Generics and others sought to have the USPTO invalidate the patent.

The USPTO concluded that the prior art did not provide a "reason to pretreat with vitamin B12, along with pretreating with folic acid, before administering pemetrexed to treat cancer."

Also, the USPTO found persuasive the fact that FDA expressed doubt about the pretreatment efficacy.

### COMMENTS:

Though not explicitly stated, it appears that the USPTO gave considerable weight to the fact that the FDA doubted the claimed efficacy. If the FDA doubted the efficacy, then the claimed treatment must not have been obvious.

## Federal Circuit Throws Out Amgen Win Over Sanofi

The patent laws require that a patent contain a written description of the invention in "exact" terms. This ensures that the inventor actually invented the invention claimed - at the time of filing the patent application.

The Federal Circuit ruled that the written description requirement is "judged based on the state of the art" as of the filing date.

However, according to the Federal Circuit, evidence of post-filing "species" may be relevant to determining whether the patent discloses a sufficient number of species so that one can determine what species fall within a "genus" (i.e., the umbrella that includes the specific species).

If there are a sufficient number of species, then the patent can claim the broader genus.

The Federal Circuit determined that the district court improperly excluded evidence of post-filing species. Therefore, the Federal Circuit vacated the injunction ordered by the district court which prevented sales by Sanofi.

### COMMENTS:

It seems that is generally better to disclose in a patent application more species or examples, rather than fewer. Otherwise, the scope of the patent claims may be limited.

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