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Precedential Federal Circuit Decision Overturns Lack of Written Description Based on Later-Discovered Technology

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On January 10, 2025, the US Court of Appeals for the Federal Circuit issued a precedential opinion in *Novartis Pharmaceuticals Corp. v. Torrent Pharma Inc.*, reversing a lower court decision that claims of a Novartis patent covering its blockbuster drug Entresto were invalid for lack of written description, and affirming the lower court's decision that the claims were not proven invalid for lack of enablement or obviousness. An issue addressed in the opinion is the role of after-arising technology in the written description and enablement analyses – namely, that such technologies need not be described nor enabled, but may still be "covered" by the claims, and thus infringed, as was the case here. In addition, in reaching its written description conclusion, the court emphasized that claim scope is a separate issue from infringement, a distinction the court also drew in its recent precedential decision regarding Orange Book listings in *Teva v. Amneal*.

Background

Novartis sued a host of generic companies, including MSN Pharmaceuticals, in the US District Court for the District of Delaware under the Hatch-Waxman Act after receiving notice they were seeking US Food and Drug Administration (FDA) approval to market and sell generic versions of Entresto. These cases were consolidated in multidistrict litigation in front of Judge Richard G. Andrews.

Entresto is an oral combination of sacubitril and valsartan used to treat heart failure in various patient populations. Importantly, Entresto includes the two active ingredients – sacubitril and valsartan – in a form referred to as a "complex," which combines the two drugs into a single unit through noncovalent bonds.[1]

Novartis's US Patent No. 8,101,659 (the '659 patent) was the centerpiece of the case. The '659 patent explains the benefit of combination therapy of valsartan, a known angiotensin receptor blocker that reduces blood-vessel constriction, and sacubitril, which is a neutral endopeptidase inhibitor that also reduces blood vessel constriction but through another pathway. The patent explains that not every combination of drugs with these features will be advantageous, but that this specific combination therapy is effective and has less side effects.

Novartis asserted all four of the '659 patent's claims. Independent claim one recites:

1. A pharmaceutical composition comprising:

    (i) the AT 1-antagonist valsartan or a pharmaceutically acceptable salt thereof;

    (ii) the NEP inhibitor [sacubitril] or [sacubitrilat] or a pharmaceutically acceptable salt thereof; and

    (iii) a pharmaceutically acceptable carrier;

    (iv) wherein said (i) AT 1-antagonist valsartan or pharmaceutically acceptable salt thereof and said (ii) NEP inhibitor [sacubitril] or [sacubitrilat] or a pharmaceutically acceptable salt thereof, are administered in combination in about a 1:1 ratio.

Claim 2 specifies that the combination is used to treat hypertension or heart failure. Claim 3 recites that the NEP inhibitor in the combination is sacubitril, and claim 4, which depends from claim 3, requires the combination be in a capsule or tablet.

The parties disputed the claim term "wherein said [valsartan and sacubitril] are administered in combination." The district court agreed with Novartis and applied the term's plain and ordinary meaning. In rejecting MSN's construction that would require administration of valsartan and sacubitril "as two separate components," the court remarked that the specification "is silent" on whether the two claimed actives must be chemically distinct or if they may form a complex. The district court noted that "the absence of any indication in the written description that the patentee limited its invention solely to separate compounds means, in context, that a person of ordinary skill in the art [] would not read the claims as so limited." The district court also referenced Novartis's statement to the US Patent Office in its patent term extension application that the claims encompass Entresto, which is "non-separate, complexed valsartan and sacubitril."

Based on the district court's ordinary meaning construction, MSN stipulated to infringement. MSN raised multiple invalidity defenses, including obviousness, lack of written description and nonenablement.

The district court held a three-day bench trial on validity. [2] The district court rejected MSN's nonenablement theory that a "complex" of valsartan and sacubitril, which were covered by the claims, were not enabled. The district court reasoned that after-arising technology – such as valsartan-sacubitril "complexes" that were unknown at the priority date – may not be considered in the enablement analysis, relying on extensive case law, including *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004). Because of this, the district court held that the complexes need not be enabled by the specification.

On the other hand, the district court held that the claims lacked written description support, specifically with respect to the complex of valsartan and sacubitril. The district court reasoned that "the facts that helped [Novartis] with respect to enablement proved fatal for written description." It remarked that it was undisputed that the claimed complexes were unknown to a person of skill in the art, and therefore Novartis cannot satisfy the written description for those complexes.

The district court also rejected MSN's obviousness theories related to the combination of valsartan and sacubitril, finding they hinged on impermissible hindsight.

Novartis appealed the district court's findings regarding written description. MSN cross-appealed for the court's determinations on obviousness and enablement.

The Federal Circuit decision

The Federal Circuit's decision first addressed the written description issue and initially focused on the meaning and scope of the claim term "in combination." In doing so, it noted "[t]he issue is not whether the '659 patent describes valsartan-sacubitril complexes." Stating that, "[b]ecause the '659 patent does not claim valsartan-sacubitril complexes, those complexes do not need have been described." The court went on to explain how the '659 patent plainly describes its invention as referring to "combinations" and "combination therapy"; thus, the use of the two actives in combination, as expressly claimed, was supported by an adequate written description.

The complex of the two actives as utilized in Entresto, however, the Federal Circuit remarked was not discovered until four years after the priority date of the '659 patent, and that complex "is not what is claimed." The Court noted that by construing the claims to cover complexes of valsartan and sacubitril, "the district court erroneously conflated the distinct issues of patentability and infringement, which led it astray in evaluating written description." It noted that claim interpretation must be done "at the time of invention," and because the complexes at issue were unknown at the time of the invention, as a matter of law, the '659 patent cannot be construed as claiming them.

The court went on to affirm the district court's findings regarding nonenablement and obviousness. Regarding enablement, the court emphasized that a specification need only enable the **claimed** invention (here, sacubitril and valsartan administered "in combination"), and that later-discovered technology (such as the specific complexes of sacubitril and valsartan in Entresto) cannot be used to "reach back" and invalidate the claims.

The Federal Circuit also found the claims not proved obvious. In particular, the court found there was no motivation to combine valsartan and sacubitril with an expectation of success when sacubitril was one of many neutral endopeptidase inhibitors, it had never been administered to humans, and other neutral endopeptidase inhibitors presented discouraging results in humans. These facts distinguished other cases holding combination treatments obvious when both the claimed drugs were "together and individually considered promising …

treatments at the time [of the invention]."

What remains

The instant patent case is just one of many interesting issues involving Entresto that are relevant in the field. The '659 patent expired on January 15, 2025, but its life would be effectively extended for six months because the FDA awarded pediatric exclusivity. With the expiration date in mind, on January 13, 2025, Novartis requested a temporary restraining order and preliminary injunction prohibiting MSN from launching its generic product, which had received final FDA approval while the appeal was pending. Novartis is seeking relief under § 271(e)(4)(A) to effectively reset the date of MSN's final approval to coincide with the expiration of pediatric exclusivity.

On January 16, 2025, the Federal Circuit temporarily enjoined MSN from launching "until further notice." The next day, MSN requested that the Federal Circuit allow it to launch, challenging Novartis's reliance on pediatric exclusivity and stating that Novartis's entitlement to pediatric exclusivity is an "open and unresolved issue." The timing of the Federal Circuit mandate – and what the mandate means in terms of MSN's infringement position – are among the many issues raised by the parties in this hotly contested launch dispute. The pharmaceutical community will surely stay tuned for developments in and the outcome of this latest dispute involving Entresto.

Notes

1. See, e.g., Full Prescribing Information for Entresto at § 12.
2. MSN also asserted indefiniteness at the district court. The district court held the claims were not indefinite, but this argument was not considered during appeal.

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