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CLARITY IS KEY WITH 35 USC 112(F)

By Subaru Kanesaka

Grace Instrument Indus., LLC v. Chandler Instruments Co., LLC, Appeal No. 2021-2370 (Fed Cir., January 12, 2023, Chen, Cunningham, and Stark, precedential)

- ➤ Claim language should (1) be written clearly to avoid being interpreted in a detrimental way, and (2) avoid interpretation under 35 USC 112(f) unless the specification provides a corresponding structure.
- 权利要求语言应 (1) 书写清晰,以避免以不利的方式进行解释,并且 (2) 避免根据 35 USC 112(f) 进行解释,除非说明书中提供了相应的结构。
- ▶ 청구항 언어는 (1) 해로운 방식으로 해석되지 않도록 명확하게 작성되어야 하며, (2) 명세서에 해당 구조가 명시되어 있지 않는 한 35 USC 112(f)에 따른 해석을 피해야 합니다.
- ▶ クレームの文言は、(1) 弊害をもたらすような解釈がなされることを避ける ため明確に記載されるべきであり、かつ(2) 明細書中に対応する構造が開示 されていない限り米国特許法第112条(f)項下で解釈されることを避ける べきである。

Grace Instrument Industries, LLC (hereinafter "Grace") sued Chandler Instruments Company, LLC (hereinafter "Chandler") in the United States District Court for the Southern District of Texas, alleging that Chandler's Model 7600 viscometer infringed multiple claims of U.S. Patent No. 7,412,877 ('877 patent). The district court issued its claim construction order, finding that (1) the term "enlarged chamber" in independent claims 1 and 4 is indefinite, and (2) in regards to the feature "means for driving said rotor to rotate located in at least one bottom section" in claim 4, (a) "located in at least one bottom section" modifies "means for driving" and does not modify "said rotor", and (b) the corresponding

structure of "means for driving" is (i) magnetic coupling or (ii) a direct drive at the bottom of the cell body. The district court concluded that recitation of an "enlarged chamber" was indefinite because "enlarged" is a relative term and the '877 patent fails to disclose any reference for enlargement.

Grace appealed the district court's claim constructions. Applying the *Nautilus* standard, and reviewing intrinsic evidence of the meaning of "enlarged," the Federal Circuit agreed with Grace that the meaning of "enlarged" is explained in the patent as referring to a feature that addresses viscometer inaccuracy by minimizing contamination of tested samples, and that the district court's reliance on extrinsic information to construe the term was erroneous in light of the intrinsic evidence of the term's meaning. The reviewing court vacated the district court's holding that the term was indefinite and remanded for consideration of additional definiteness arguments.

The Federal Circuit affirmed the district court's construction of "located in at least one bottom section." Finding that "means for driving said rotor to rotate" should be read as a unit, based in part on use of the same phrase in a dependent claim, the reviewing court agreed with the district court that the skilled artisan would read the "means" as being "located in at least one bottom section."

The Federal Circuit also affirmed the district court's construction of "means for driving said rotor to rotate." The reviewing court rejected Grace's argument that the district court's construction is improper as being based, in part, Grace's improper interpretation of the recited "bottom section" as referring to the pressure vessel component of the viscometer, rather than to the viscometer as a whole. The Federal Circuit agreed with the district court that the intrinsic record, including recitation in dependent claims, comparison of usage in the independent claims, and description in the specification that the "means for driving" is a magnetic coupling, some components of which must be outside the pressure vessel, requires that the recited "bottom section" refer to the bottom section of the viscometer, not the pressure vessel.

PAST CONDUCT CAN PREDICT FUTURE BEHAVIOR IN HATCH-WAXMAN PROCEEDINGS

By Kien Le

<u>Genentech, Inc. v. Sandoz, Inc.</u>, Appeal No. 2022-1595 (Fed. Cir., December 22, 2022, Newman, <u>Lourie</u>, and Prost, precedential)

- ➤ Past conduct is relevant to what will happen in the future, and courts will consider all relevant evidence when considering induced infringement in a Hatch-Waxman suit.
- ▶ 발명의 상세한 설명이 청구항의 부정적 한정요소를 뒷받침할 때는 그 부정적 한정요소에 대해 명시적 또는 내재적 공개를 하고 있어야 한다. 아무런 언급이 없다는 것만으로는 충분하지 않다.
- ▶ 专利权利要求中对于否定性权利要求的书面说明支持必须包括对该否定性权利要求的的明示或固有披露。仅仅沉默是不够的。
- ▶ 特許クレームにおける否定的要件をサポートする記載には、その否定的要件の 明示するまたは内在する記載が含まれていなければならない。単に何の記載も ないということだけでは十分ではない。

This case involves pirfenidone - a drug used to treat idiopathic pulmonary fibrosis ("IPF") which is an irreversible lung disease. Genentech's patents at issue, Liver Function Test ("LFT") patents and Drug-Drug Interaction ("DDI") patents, do not claim pirfenidone or its use to treat IPF. Instead, the patents claim methods for managing certain side effects when using pirfenidone to treat IPF. The LFT patents are directed to methods for administering pirfenidone to a patient exhibiting an abnormality in a liver function biomarker, by temporarily discontinuing or reducing the dose of pirfenidone and then returning to the full dose or a reduced dose. The DDI patents are directed to methods for administering pirfenidone to a patient taking fluvoxamine (a drug for obsessive compulsive disorder), by either discontinuing fluvoxamine or modifying the dose of pirfenidone and continuing fluvoxamine, to avoid adverse interactions between the two drugs.

Sandoz submitted two Abbreviated New Drug Applications ("ANDAs") seeking approval from the United States Food and Drug Administration ("FDA") to market a generic version of pirfenidone. Genentech then brought this Hatch-Waxman suit, asserting that Sandoz's generic product would induce infringement of its LFT and DDI patents. The District Court found that the asserted LFT claims would have been obvious over the prior art and standard medical practices, and that Sandoz's product would not directly infringe the DDI patents. Genentech appealed. The United States Court of Appeals for the Federal Circuit ("CAFC") affirmed.

As to the LFT patents, Genentech challenged, among other things, the District Court's interpretation of the prior art. The CAFC reviewed the District Court's determination of what the prior art teaches, which is a factual question, for *clear error*. In a previous case, the CAFC had held that where there are two permissible views of the evidence, the fact-finder's choice between them cannot be clearly erroneous. Pursuant to that principle, and upon careful scrutiny of the record, the CAFC held that the District Court did not err in its prior art interpretation, and affirmed the District Court's holding that the LFT claims would have been obvious.

As to the DDI patents, to succeed on a theory of induced infringement in a Hatch-Waxman case, in which infringement is defined by filing an ANDA before the infringing product is marketed, the plaintiff is required to prove by a preponderance of the evidence (1) direct infringement, i.e., if defendant's drug was put on the market, it would infringe the relevant patent; and (2) that defendant possessed the specific intent to encourage another's infringement. The CAFC held that Genentech failed to prove the first prong, that Genentech's ANDA filing would directly infringe any of the asserted claims. More particularly, Genentech had not shown that any patient would be prescribed both pirfenidone and fluvoxamine as required by the asserted claims of the DDI patents. On the other hand, Sandoz submitted evidence including testimony from physicians that, in their decades of treating IPF patients, they had never prescribed pirfenidone to an IPF patient taking fluvoxamine; and were they to find themselves in that position, they would choose a non-infringing response, e.g., prescribing an alternative to pirfenidone. The CAFC agreed with Sandoz that past conduct is relevant to what will happen in the future. The CAFC then held that the District Court did not err, by considering all the relevant evidence including the physicians' testimony, in finding that Genentech had not met its burden to show that Sandoz's ANDA filing would directly infringe the asserted claims of the DDI patents. The CAFC affirmed the District Court's holding of non-infringement.

CONCRETE TECHNOLOGICAL ADVANCES INDICATE PATENT ELIGIBILITY By Nick Fan

ADASA Inc. v. Avery Dennison Corporation, Appeal No. 2022-1092 (Fed. Cir., December 16, 2022, <u>Moore</u>, Hughes, and Stark, precedential)

- ➤ If the focus of a patent claim is a specific and concrete technological advance, for example an improvement to a technological process or in the underlying operation of a machine, the claim is eligible for patenting.
- 如果专利权利要求的重点是特定且具体的技术进步,例如对技术流程或机器的基本 操作的改进,则该权利要求符合专利申请的条件。
- 특허 청구항이, 기술적인 공정의 개선이나 기계의 기본 작동과 같이 구체적이고 실체가 있는 기술 발전에 초점을 두고 있다면, 해당 청구항은 특허를 받을 수 있습니다.
- ▶ もしある特許クレームの焦点が特定のかつ具体的な技術的進歩に係るもの、例えば技術的な工程に対するまたは機械の基本的動作における改良に係るものであれば、そのクレームには特許適格性がある。

Background:

Avery Dennison Corporation appeals the district court's grant of summary judgment that claim 1 of U.S. Patent No. 9,798,967 is directed to eligible subject matter under 35 U.S.C § 101 and is not invalid under 35 U.S.C. §§ 102 and 103.

The '967 patent is related to systems and methods for commissioning RFID tags "on-demand" without the need for continuous connectivity to a central database. The '967 patent seeks to overcome challenges associated with the central database. Claim 1 of the '967 patent, which is the only claim at issue on appeal, is directed to an RFID transponder.

Holding:

The Federal Circuit affirmed the district court's holding that claim 1 is eligible for patenting under § 101. The Federal Circuit, however, reversed the district court's holding that claim 1 is neither anticipated nor rendered obvious by the cited references.

Discussion:

The Federal Circuit held that claim 1 is not directed to an abstract idea but it is directed to a specific, hardware-based RFID serial number data structure designed to enable technological improvements to the commissioning process. Claim 1 specifically recites portions of an RFID serial number that are used in different ways. To determine whether claim 1 is patent eligible, the Federal Circuit applied the two-step analytical framework set forth in *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014). In step one of *Alice*, the court determines whether the claims at issue are directed to a patent-ineligible concept. If the focus of the claim is a specific and concrete technological advance, for example an improvement to a technological process or in the underlying operation of a machine, the court inquiry ends, and the claim is eligible. Because the Federal Circuit finds claim 1 is eligible under step one of *Alice*, the court did not proceed to step two of *Alice*, which assess whether the elements of the claim both individually and as an ordered combination transform the nature of the claim into a patent eligible application.

The Federal Circuit rejected Avery Dennison's contention that claim 1 is directed to nothing more than mentally ascribing meaning to a pre-existing data field. The Federal Circuit concluded that claim 1 is directed to eligible subject matter as a matter of law and bolstered the conclusion about claim 1's eligibility by prior decisions finding similar claims eligible. In *Uniloc*, the eligible claims append an additional data field to a prior art data structure used for polling stations in a communication system. In *Enfish*, the eligible claims are related to a specific type of self-referential data structure designed to improve the way a computer stores and retrieves memory.

ADDITIONAL INFORMATION

2318 Mill Road, Suite 1400 Alexandria, VA 22314 USA Room B565, No. 5 building Huayangnian Meinian International Square Nanshan District, Shenzhen, China, 518067

Tel: +1 (703) 684-1111 Fax: +1 (703) 518-5499

Chiyoda Kaikan Bldg. 6F 1-6-17 Kudan Minami, Chiyoda-Ku, Tokyo 102-0074 Japan H-Business Park D 314, 26 Beobwon-ro 9-gil, Songpa-gu Seoul, Korea

Tel: +81 3 6256-8970 Tel: +82 (0)2 6412-0626 Fax: +81 3 6717-2845 Fax: +82 (0)2 6412-0627

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