

Precedential Patent Case Decisions During January 2020

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I. Introduction

This paper abstracts what I believe to be the significant new points of law from the precedential decisions in patent cases this month. Cases captions relating to the PTAB are in **red** text. Case captions of extraordinary importance are in **blue** text.

II. Abstracts and New Points of Law

Hospira, Inc. v. Fresenius Kabi USA, LLC, 2019-1329, 2019-1367 (Fed. Cir. 1/9/2020).

This is a decision on appeals from the N.D. Ill. district court cases 1:16-cv-00651, 1:17-cv-07903. The district court held claim 6 invalid for obviousness. Hospira appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 102, inherency, reliance upon non-prior art data to find a property inherent.

The Federal Circuit concluded that it was not legally incorrect for the district court to rely on non-prior art data as evidence that a claimed limitation was inherent in the prior art.

As a threshold matter, we agree with Fresenius that the district court did not err in relying on data obtained after the priority date of the '106 patent in its inherency analysis. Extrinsic evidence can be used to demonstrate what is "necessarily present" in a prior art embodiment even if the extrinsic evidence is not itself prior art. *See Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1345 (Fed. Cir. 2018) (allowing "non-prior art data" to be used to support inherency); *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (finding that the prior art need not recognize the inherent property). Moreover, the work of the inventor or the patentee can be used as the evidence of inherency. *See, e.g., Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012) (analyzing inherency based on the disclosure of the "patent itself"); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1327-28 (Fed. Cir. 2001) (finding that features were inherent "as evidenced by [the patentee]'s own documents"). The later evidence is not itself prior art; it only helps to elucidate what the prior art consisted of. Therefore, it was not legally incorrect for the district court to rely on non-prior art data from Hospira's NDA and Fresenius's ANDA as evidence of the inherent stability of the 4 µg/mL preferred embodiment. [*Hospira, Inc. v. Fresenius Kabi USA, LLC, 2019-1329, 2019-1367 (Fed. Cir. 1/9/2020).*]

Legal issue: 35 USC 102, inherency, reliance upon disclosed but not claimed

manufacturing variables to show inherency.

The Federal Circuit held that using manufacturing variables disclosed in an embodiment in the patent to prepare samples to show inherency of a claimed property did not as a matter of law, preclude a finding of inherency.

Furthermore, we agree with Fresenius that the unclaimed manufacturing variables in Example 5 do not, as a matter of law, preclude a finding of inherency in this case. First, although Hospira faults the district court for looking only at samples prepared by the manufacturing process of Example 5, it is not entirely clear that Hospira actually argued below that the inherency analysis required stability data from samples prepared by manufacturing processes other than Example 5. But even assuming that Hospira preserved that argument by raising it to the district court, it is without merit. Claim 6 is directed to a composition of 4 µg/mL dexmedetomidine disposed in a sealed glass container. '106 patent col. 26 ll. 18-24, 41-43. Claim 6 is not a method claim, it is not a product-by-process claim, and there are no limitations in claim 6 regarding the manufacturing process by which the recited 4 µg/mL dexmedetomidine composition must be prepared. Importing such limitations from Example 5 into the claim, as Hospira seeks to do, would be improper. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). Thus, the district court did not misapply the law of inherency by considering the samples in the record without regard to the process by which those samples were prepared. [*Hospira, Inc. v. Fresenius Kabi USA, LLC*, 2019-1329, 2019-1367 (Fed. Cir. 1/9/2020).]

Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).

This is a decision on an appeal from the district court case 1:16-cv-03545. The district court granted a SJ motion that Molon was barred by a 2006-granted covenant not to sue. Molon appealed. The Federal Circuit majority consisting of judges Lourie and Hughes affirmed.

In dissent, Judge Reyna wrote:

Resolution of this case should have been straightforward. In the 2006 Covenant, Molon granted Merkle-Korff a bare license to practice the '915 patent in any market. In the 2007 Settlement, Molon granted Merkle-Korff an exclusive license to practice the '915 patent in the Kinetek Exclusive Market only. Both licenses relate to the same subject matter—the right to practice the '915 patent. Thus, the 2007 Settlement's merger clause, which wiped away all prior covenants with the same subject matter, wiped away the 2006 Covenant. The majority's holding—that Merkle-Korff's successor, Nidec, can practice the '915 patent outside of the Kinetek Exclusive Market, despite the 2007 Settlement's clear prohibition of such practice—rewrites the terms of the 2007 Settlement and gives Nidec a windfall. Rewriting the key terms of an otherwise clear agreement is not the role of this court. For these reasons and those discussed below, I respectfully

dissent. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020)(Judge Reyna, dissenting).]

Legal issue: Contract interpretation, definition of contract clause merging prior agreements “concerning the subject matter,” whether an overlapping patent is sufficient to render two agreements to be “concerning the same subject matter.”

The Federal Circuit majority concluded that merely because a patent is referred to in earlier and later agreements, the two agreements are not necessarily “concerning the same subject matter,” such that the earlier agreement is merged into the later agreement. Consequently, in this case, the covenant not to sue on a particular patent provided in the earlier agreement was not extinguished by the failure to express that covenant in the later agreement.

The Federal Circuit majority looked to the relevant state law how to define the “subject matter” of contracts in the merger clause.

We first address the language of the merger clause in the 2007 Settlement, which limits its application to covenants "concerning the subject matter hereof." We consider whether the subject matter of the 2006 Covenant and the 2007 Settlement is the same, such that the 2006 Covenant was expressly merged into the 2007 Settlement. In comparing the subject matter of contracts, Illinois courts have cautioned against defining subject matter too broadly or too narrowly. For example, in *Ill. Concrete-I.C.I., Inc. v. Storefitters, Inc.*, the court rejected the broad view that two contracts had the same subject matter simply because both involved "using trucks." 397 Ill.App.3d 798, 337 Ill.Dec. 419, 922 N.E.2d 542, 546 (Ill. App. Ct. 2010). On the other hand, in *Midwest Builder Distrib., Inc. v. Lord & Essex, Inc.*, the court rejected an "extremely narrow view" of two contracts as having subject matter limited to "the specifications of the products to be delivered." 383 Ill. App.3d 645, 322 Ill.Dec. 371, 891 N.E.2d 1, 20 (2007). [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

The Federal Circuit majority “examine[d] the actual language of the agreements themselves... [and] consider[ed] how the language of each agreement conveys the substantive rights and obligations exchanged between the parties.”

We first address the language of the merger clause in the 2007 Settlement, which limits its application to covenants "concerning the subject matter hereof." We consider whether the subject matter of the 2006 Covenant and the 2007 Settlement is the same, such that the 2006 Covenant was expressly merged into the 2007 Settlement. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

We agree with Nidec and the district court that it is incorrect to define the subject matter of both agreements as the right to practice the '915 patent. Rather,

to determine the subject matter of each agreement, we must examine the actual language of the agreements themselves. We must consider how the language of each agreement conveys the substantive rights and obligations exchanged between the parties. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

The Federal Circuit majority found substantive differences between an earlier and a later contract, including the differences: in contract type (unilateral promise not to sue versus a bilateral contract sharing exclusive rights); in the patents covered (more covered by the later contract); in time of existence of covered products (preexisting patents in the earlier contract versus all product in the later contract); and in the specified market (limited set of entities in the earlier contract versus no limit in the later contract).

We thus find that there are important substantive differences between the subject matter of the 2006 Covenant and the 2007 Settlement. The 2006 Covenant is a unilateral promise by Molon not to sue Merkle-Korff (or its successor, Nidec) for infringement of two patents, one of which is the '915 patent. The 2007 Settlement, in contrast, is a bilateral contract through which Molon transferred to Merkle-Korff a share in the existing and potential exclusionary rights under more than a dozen listed patents and applications, one of which is the '915 patent. Moreover, the 2006 Covenant is limited to products existing at the time of its execution, while the 2007 Settlement includes both existing and future products. And the 2006 Covenant is not limited to any specific market, while the 2007 Settlement is limited to the Kinetek Exclusive Market. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

From these differences, the Federal Circuit majority concluded that the covenant granted in the earlier agreement was not “concerning the same subject matter” as the later agreement.

Based on the substantial differences between the agreements, we conclude that the 2006 Covenant is not "concerning the subject matter" of the 2007 Settlement. We therefore conclude that the language of the merger clause in the 2007 Settlement did not expressly extinguish the 2006 Covenant. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

The Federal Circuit majority’s conclusion disposed of Molon’s argument that mere overlap of the asserted patent was sufficient to deem the two agreements to be “concerning the same subject matter.”

Molon criticizes the district court for allegedly requiring perfect congruity between the contracts. Appellant's Br. 19. But the district court properly considered the substantive differences between the agreements. Like the district

court, we reject Molon's argument that we should disregard those differences and instead focus entirely on the fact that the '915 patent appears in both agreements. And we find no legal support for the sweeping proposition that an overlapping patent is sufficient to render two agreements the same subject matter. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

The majority decision contains these restatements of law.

Contract interpretation, the four corners rule

Traditional contract interpretation principles in Illinois require application of the "four corners" rule. *Air Safety, Inc. v. Teachers Realty Corp.*, 185 Ill.2d 457, 236 Ill.Dec. 8, 706 N.E.2d 882, 884 (1999). In applying this rule, "[a] court must initially look to the language of a contract alone, as the language, given its plain and ordinary meaning, is the best indication of the parties' intent." *Gallagher v. Lenart*, 226 Ill.2d 208, 314 Ill.Dec. 133, 874 N.E.2d 43, 58 (2007); *Rakowski v. Lucente*, 104 Ill.2d 317, 84 Ill.Dec. 654, 472 N.E.2d 791, 794 (1984) ("Where a written agreement is clear and explicit, a court must enforce the agreement as written. Both the meaning of the instrument, and the intention of the parties must be gathered from the face of the document without the assistance of parol evidence or any other extrinsic aids."). [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

Definitions of nonexclusive and exclusive license

A covenant not to sue is equivalent to a nonexclusive or "bare" license, *see Ortho Pharm. Corp. v. Genetics Inst., Inc.*, 52 F.3d 1026, 1032 (Fed. Cir. 1995), which is a promise by the patent owner not to sue the licensee for practicing the patented invention, and under which the patent owner impliedly reserves the right to grant similar nonexclusive licenses to other entities. *See Intellectual Prop. Dev., Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333, 1345 (Fed. Cir. 2001). In contrast, an exclusive license is a license to practice the patented invention "accompanied by the patent owner's promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave." *Textile Prods., Inc. v. Mead Corp.*, 134 F.3d 1481, 1484 (Fed. Cir. 1998) (quoting *Western Elec. Co. v. Pacent Reproducer Corp.*, 42 F.2d 116, 118 (2d Cir. 1930)). We have characterized an exclusive licensee as "shar[ing] the property rights represented by a patent." *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1553 (Fed. Cir. 1995) (quoting *Weinar v. Rollform*, 744 F.2d 797, 807 (Fed. Cir. 1984)). [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

An exclusive license and a nonexclusive license do not concern the same subject matter

There are fundamental differences between an exclusive license and a nonexclusive license, particularly in the context of standing to assert a claim for patent infringement. *See Rite-Hite, 56 F.3d at 1552 (citing Independent Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 468-69, 46 S.Ct. 166, 70 L.Ed. 357 (1926))*. In essence, an exclusive licensee has an interest in the patent sufficient to establish an injury when a third party infringes, akin to an ownership interest, while a nonexclusive licensee has no such interest in the patent and merely enjoys freedom from suit. *See id.* Under this framework, it cannot be said that an exclusive license and a nonexclusive license necessarily concern the same subject matter, even though both licenses include the same patent. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

We thus find that there are important substantive differences between the subject matter of the 2006 Covenant and the 2007 Settlement. The 2006 Covenant is a unilateral promise by Molon not to sue Merkle-Korff (or its successor, Nidec) for infringement of two patents, one of which is the '915 patent. The 2007 Settlement, in contrast, is a bilateral contract through which Molon transferred to Merkle-Korff a share in the existing and potential exclusionary rights under more than a dozen listed patents and applications, one of which is the '915 patent. Moreover, the 2006 Covenant is limited to products existing at the time of its execution, while the 2007 Settlement includes both existing and future products. And the 2006 Covenant is not limited to any specific market, while the 2007 Settlement is limited to the Kinetek Exclusive Market.

Based on the substantial differences between the agreements, we conclude that the 2006 Covenant is not "concerning the subject matter" of the 2007 Settlement. We therefore conclude that the language of the merger clause in the 2007 Settlement did not expressly extinguish the 2006 Covenant. [Molon Motor and Coil Corporation v. Nidec Motor Corporation, 2019-1071 (Fed. Cir. 1/10/2020).]

Contract interpretation, the doctrine of merger

We agree with Nidec that the 2006 Covenant is a separate agreement that was not merged with the 2007 Settlement. It is telling that Molon's appeal relies on a clause that both parties repeatedly refer to as a "merger" or "integration" clause. Yet, neither party has invoked the merger doctrine in its traditional form as a doctrine of contract interpretation. *See Schweickhardt v. Chesson*, 329 Ill. 637, 161 N.E. 118, 122 (1928) ("The rule is, that when parties reduce their agreement to writing, all prior negotiations leading up to the execution of the contract are merged therein, and parol evidence is not admissible to explain, contradict,

enlarge, or modify the writing as it existed when executed."). The effect of the merger doctrine is to "preclude[] evidence of understandings, not reflected in a writing, reached before or at the time of its execution which would vary or modify its terms." *J & B Steel Contractors, Inc. v. C. Iber & Sons, Inc.*, 162 Ill.2d 265, 205 Ill.Dec. 98, 642 N.E.2d 1215, 1217 (1994); *see also Fuchs & Lang Mfg. Co. v. R.J. Kittredge & Co.*, 146 Ill. App. 350, 364 (1909) ("It follows legally that this [written contract] merged all prior negotiations, letters and telegrams in the written agreement thus formulated and signed; and all extrinsic evidence of oral or written negotiations became incompetent, immaterial and irrelevant for the purpose of contradicting or modifying the written agreement."). But here, neither Nidec nor Molon has argued that the 2006 Covenant was part of the negotiations for the 2007 Settlement and is thus relevant to interpret that later agreement. On the contrary, Nidec's position is that the 2006 Covenant is an entirely separate agreement unrelated to the 2007 Settlement, and Molon's position is that the 2006 Covenant should be considered extinguished. These positions reflect the parties' apparent concession that the 2006 Covenant was a separate agreement from the 2007 Settlement, and therefore outside the scope of what a merger clause is intended to cover. [*Molon Motor and Coil Corporation v. Nidec Motor Corporation*, 2019-1071 (Fed. Cir. 1/10/2020).]

Amgen Inc. v. Amneal Pharmaceuticals LLC, 2018-2414, 2019-1086 (Fed. Cir. 1/7/2020).

This is a decision on appeals from the D. Del. district court cases 1:16-cv-00853-MSG; 1:16-cv-00925-MSG; 1:17-cv-00183-MSG; and 1:17-cv-00713-MSG. The district court entered judgement that Amneal did not infringe certain claims and that Zydus and Piramal did infringe certain claims. Amgen appealed the judgement of non-infringement. Zydus and Piramal cross-appealed the judgement of their infringement. The Federal Circuit vacated and remanded the judgement that Amneal infringed and affirmed the judgement that Zydus and Piramal infringed.

Legal issue: 28 USC 1295, final judgement rule, undecided issue, waiver on appeal.

The Federal Circuit held that a party's abandonment at oral argument of a right to contest an undecided issue making the judgement non-final, cured that jurisdictional defect, preserving the appeal.

...The district court expressly conditioned its infringement judgment here on the claims being found "valid and enforceable." Trial Order, *Amgen Inc. v. Amneal Pharm. LLC.*, No. 1:16-cv-00853-MSG (July 27, 2018), ECF No. 376; J.A. 2. According to its own terms, the judgment did not resolve the parties' dispute and was thus not a "final decision." See Final Judgment, *Amgen Inc. v. Amneal Pharm. LLC.*, No. 1:16-cv-00853-MSG (Oct. 9, 2018), ECF No. 405; J.A. 5059-60. However, when questioned at oral argument about the jurisdictional defect in Zydus's appeal, Zydus represented that it would "give up" its invalidity defense and claim even if infringement was affirmed. Oral Arg. at 20:23-33, <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-2414.MP3>. Zydus's

representation effectively cures the jurisdictional defect in its notice of appeal because the contingency identified by the district court—Zydus's potential invalidity defense and claim—is nullified. Thus, the court's judgment resolves all claims for all parties and is a final decision within our jurisdiction. Accordingly, we have jurisdiction over both the appeal and cross-appeal under 28 U.S.C. § 1295(a)(1). [Amgen Inc. v. Amneal Pharmaceuticals LLC, 2018-2414, 2019-1086 (Fed. Cir. 1/7/2020).]

Legal issue: 35 USC 112, claim construction, “comprising: ...at least one [component having a function] selected from the group consisting of,” whether the claim excludes additional components having a similar function

The Federal Circuit held that a the presence of “an additional component ... functionally similar to the component identified in the Markush group limitation, unless there is a further basis in the claim language or other intrinsic evidence for precluding the presence of such additional components” does not avoid infringement of the claim.

For context, the claim at issue reads:

A pharmaceutical composition comprising:

(a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;

(b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof,

(c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and

(d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,

wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

The decisive issue in this case is critically different from any issue decided in *Multilayer* or *Shire*. The issue is whether all binders or disintegrants in the claimed formulation are subject to the specific binder or disintegrant limitations. The answer, we conclude, is no. There is no language in Amgen's claim indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups. Instead, the claim recites "at least one" binder or disintegrant "selected from the group consisting of" various excipients. And the limitations merely require that those particular binders or disintegrants meet the specified

weight-percentage requirements, which is not inconsistent with the overall composition containing other binders or disintegrants. The plain language of this claim requires "at least one" of the Markush members and certainly does not indicate that the only binders and disintegrants in the claimed formulation are those listed in the groups. And we do not see a sufficient basis for a different conclusion in the specification or in the prosecution history we have recited. [Amgen Inc. v. Amneal Pharmaceuticals LLC, 2018-2414, 2019-1086 (Fed. Cir. 1/7/2020).]

Importantly, we also have the "comprising" language. The term "comprising" is the standard transition term used to make clear that the claim does not preclude the presence of components or steps that are in addition to, though not inconsistent with, those recited in the limitations that follow. *See Wis. Alumni Research Found. v. Apple Inc.*, 905 F.3d 1341, 1348 n.8 (Fed. Cir. 2018); *Multilayer*, 831 F.3d at 1358. Here, for the reasons just stated, the language of the binder and disintegrant limitations is not inconsistent with the presence of binders and disintegrants beyond those identified in those limitations. Amgen's use of the "comprising" transition phrase reinforces the conclusion that the language of those limitations is best construed not to foreclose such additional binders and disintegrants. Thus, optional additional binders and disintegrants not recited in the Markush group may be included in the claimed formulation. [Amgen Inc. v. Amneal Pharmaceuticals LLC, 2018-2414, 2019-1086 (Fed. Cir. 1/7/2020).]

In short, this case involves a claim that uses a "comprising" transition phrase and one of the following limitations requires a component that "consists of" items listed in a Markush group and that meets the limitation's requirements for the component. Without more, such language is satisfied when an accused product contains a component that is from the Markush group and that meets the limitation's requirements for the component. It does not forbid infringement of the claim if an additional component is present functionally similar to the component identified in the Markush group limitation, unless there is a further basis in the claim language or other intrinsic evidence for precluding the presence of such additional components. There is no such basis here. [Amgen Inc. v. Amneal Pharmaceuticals LLC, 2018-2414, 2019-1086 (Fed. Cir. 1/7/2020).]