

Brief Summary of Precedential Patent Case Decisions During October 2018

By Rick Neifeld, Neifeld IP Law, PC

I. Introduction

This paper contains summary abstracts of 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. Brief Summary Abstracts and New Points of Law

Bristol-Myers Squibb Company v. Aurobindo Pharma USA Inc., 17-374-LPS and 17-379-LPS (D. Del. 10/18/2018).

This is memorandum opinion by the D. Del. district court. Mylan moved to dismiss or transfer, alleging improper venue pursuant to 28 USC 1406(a). The district court granted the motion, and dismissed.

Legal Issue: 28 USC 1400(b), venue statute applicable to a patent infringement civil action filed pursuant to 35 USC 271(e)(2)(A) ("It shall be an act of infringement to submit ... an [ANDA] ...").

The district court held that 28 USC 1400(b), the patent specific venue statute, was applicable, and 28 USC 1391, the general venue statute was inapplicable, to ANDA patent infringement lawsuits.

Legal issue: 28 USC 1400(b), whether the residency of one entity may be imputed to another for purposes of satisfying 28 USC 1400(b).

The district court held that residency of one entity may be imputed to another for purposes of satisfying 28 USC 1400(b), but only by a clear and convincing showing of fraud, injustice, or unfairness.

Yeda Research and Development Co., Ltd. v. Mylan Pharmaceuticals Inc., 2017-1594, 2017-1595, 2017-1596 (Fed. Cir. 10/12/2018).

This is a decision on appeals from PTAB cases IPR2015-00643; IPR2015-00644; IPR2015-00830; IPR2015-01976; IPR2015-01980; and IPR2015-01981. The PTAB found Yeda's claims obvious. Yeda appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 311(b), whether the PTAB may consider non-prior art evidence, in considering the knowledge, motivations, and expectations of a PHOSITA.

The Federal Circuit concluded that the PTAB may consider non-prior art evidence, in considering the knowledge and motivations of a PHOSITA, but may not consider non-prior art evidence in determining the presence of an expectation of success.

Teva Pharmaceuticals USA, Inc. v. Sandoz Inc., 2017-1575 (Fed. Cir. 10/12/2018).

This is a decision on an appeal from the from the D. Del district court consolidated cases 1:14-cv-01171-GMS; 1:14-cv-01172-GMS; 1:14-cv-01278-GMS; 1:14-cv-01419-GMS; 1:15-cv-00124-GMS; and 1:15-cv-00306-GMS. The district court held all asserted claims of patents directed to COPAXONE® 40mg/mL (a product marketed for treatment of patients with relapsing forms of multiple sclerosis), to be invalid for obviousness. Teva appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 103, obviousness, post-invention evidence establishing

motivations and expectations of a PHOSITA reading the prior art at the time of the invention.

The Federal Circuit concluded that the district court did not err in relying upon post-invention documents, as evidence establishing motivations and expectations of a PHOSITA, at the time of the invention. The GALA reference was publication based upon Teva's own FDA Phase III clinical trial, and showed that Teva's FDA submission stated that a "natural next step [was] to reduce the dosing regimen."

Data Engine Technologies LLC v. Google LLC, 2017-1135 (Fed. Cir. 10/9/2018).

This is a decision on an appeal from the D. Del. district court case 1:14-cv-01115-LPS. The district court entered judgement on the pleadings that all claims were directed to patent ineligible subject matter. DET appealed. The Federal Circuit affirmed on some claims, reversed on other claims, and remanded.

Legal issue: 35 USC 101, patent eligibility, eligibility, at *Alice* step 1, of unconventional computer program user interface traceable to a real-world analogy, but which improves user's efficiency.

The Federal Circuit found that the claim to an unconventional user interface that improves user efficiency was not abstract (that it was patent eligible subject matter), at *Alice*, step 1.

Roche Molecular Systems, Inc. v. Cepheid, 2017-1690 (Fed. Cir. 10/9/2018).

This is a decision on an appeal from the N.D. Cal. district court case 14-cv-03228-EDL.

The district court granted summary judgement that the asserted claims were directed to patent ineligible subject matter. Roche appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 101, patent eligibility, primer claims corresponding nucleotide sequences.

The Federal Circuit reiterated that primer claims that "are indistinguishable from their corresponding nucleotide sequences on the naturally occurring DNA," regardless of whether it is selectively hybridizable to certain positions of naturally occurring DNA.

In response to arguments, the Federal Circuit noted that the primer claims were patent ineligible because "Roche's primers are indistinguishable from their corresponding nucleotide sequences on the naturally occurring MTB rpoB gene; *** It was undisputed that the primers in BRCA1 contain 3-prime ends and 3-prime hydroxyl groups, exactly as Roche's primers in this case *** [and thus, except for the [specifics of the] nucleotide sequences, the primers before us are not chemically or structurally different from the primers that we held patent-ineligible in BRCA1; *** the subject matter eligibility inquiry of primer claims hinges on comparing a claimed primer to its corresponding DNA segment on the chromosome—not the whole chromosome," concluding that "A primer that is otherwise patent-ineligible does not gain subject matter eligibility simply because it can selectively hybridize to a certain position of naturally occurring DNA, because a primer having an identical nucleotide sequence to naturally occurring DNA without further chemical modification is a natural phenomenon."

Legal issue: 35 USC 101, patent eligibility, *Alice* step 1, method of detection claims for detecting a "relationship between the signature nucleotides and [Mycobacterium tuberculosis] MTB."

The Federal Circuit, in *Alice* step 1, concluded that the method of detecting a relationship between signature nucleotides and bacteria were directed to a patent ineligible mental step (detecting) and a patent ineligible natural phenomena ("relationship between the signature nucleotides and MTB").

Legal issue: 35 USC 101, patent eligibility, *Alice* step 2, significantly new function sufficient to transform.

The Federal Circuit, in *Alice* step 2, concluded that the claimed method of detecting MTB did not define any "significantly new function," sufficient to transform the claim into patent eligible subject matter.

Natural Alternatives International, Inc. v. Iancu, 2017-1962 (Fed. Cir. 10/1/2018).

This is a decision on an appeal from PTAB case 95/002,001. The PTAB affirmed the examiner's rejections for anticipation and obviousness. NAI appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 120, burden of proof of entitlement to benefit.

The Federal Circuit concluded that "claims in a patent or patent application are not entitled to priority under § 120 at least until the patent owner *proves* entitlement to the PTO, the Board, or a federal court."

Legal issue: 35 USC 120, effect of amending an intermediate application in a benefit claim chain by removing its claim to benefit claim to prior applications.

The Federal Circuit held that amending an intermediate application by removing its claim to benefit of an earlier application cut off entitlement to the earlier application in later filed applications claiming benefit through intermediate application to the earlier application.

Legal issue: 35 USC 120, effect of disclaimer of benefit on patent term.

In dicta, the Federal Circuit concluded that disclaiming earlier benefit dates in order to extend patent term, was permissible.

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