Top U.S. Patent Cases in 2019

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Return Mail, Inc. v. United States Postal Service (S.Ct., June 10, 2019)

Holding:

- The Federal Government cannot be a petitioner in a PTAB trial because it is not a "person" for the purposes of the relevant statutes.

Lone Star Silicon Innovations LLC v. Nanya Tech. Corp., No. 2018-1581 (Fed. Cir. May 30, 2019)

Holding:

- Assignee lacked standing to sue for infringement on its own because it lacked all substantial rights due to limitations included in the assignment.

Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc. (Fed. Cir., March 28, 2019)

Claims	Step 2A
1. A method of treating pain in a renally impaired patient, comprising the steps of: a. providing a solid oral controlled release dosage form, comprising: i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and ii. a controlled release matrix; b. measuring a creatinine clearance rate of the patient and determining it to be (a) less than about 30 ml/min, (b) about 30 mL/min to about 50 mL/min, (c) about 51 mL/min to about 80 mL/min, or (d) above about 80 mL/min; and c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief; wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL.	• "[T]he inventor here recognized the relationship between oxymorphone and patients with renal impairment, but that is not what he claimed. Rather, he claimed an application of that relationship—specifically, a method of treatment including specific steps to adjust or lower the oxymorphone dose for patients with renal impairment. The claims are thus directed to more than just reciting the natural relationship." • As a result, the Federal Circuit held the claims in *Endo* patent eligible under the first step of the *Alice/Mayo* framework (Step 2A in the USPTO' s subject matter eligibility guidance), because the claims "are directed to a specific method of treatment for specific patients using a specific compound at specific doses to a achieve a specific outcome."

Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc. (Fed. Cir., March 28, 2019)

Mayo	Endo
A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising: (a) **administering** a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) **determining** the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.	1. A method of treating pain in a renally impaired patient, comprising the steps of: a. providing a solid oral controlled release dosage form, comprising: i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and ii. a controlled release matrix; b. measuring a creatinine clearance rate of the patient and determining it to be (a) less than about 30 ml/min, (b) about 30 mL/min to about 50 mL/min, (c) about 51 mL/min to about 80 mL/min, or (d) above about 80 mL/min; and c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief; wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng·hr/mL.

AVX Corp. v. Presidio Components, Inc. (Fed. Cir. May 13, 2019)

Holding:

- Appeal against unfavorable PTAB decision on IPR requires standing. Without any current or nonspeculative infringement of the subject claims, Appellant suffers no injury and has no standing.

Other Cases

1. *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.,* (S.Ct. January 22, 2019)

2. *Regents of the University of Minnesota v. LSI Corp.* (Fed. Cir. June 14, 2019)

Takeaways

1. The federal government or its agencies cannot by themselves launch any post-grant review against any issued patent.
2. Assignee may lack standing to sue for infringement on its own if it lacks all substantial rights due to limitations included in the assignment.
3. To survive the Alice/Mayo 2-part test, a method of treatment must be directed to certain specific patients. A diagnostic step based upon certain correlation needs to be followed by a "administering" step based upon such correlation.
4. Any person can file IPR but may not have standing to appeal against an unfavorable PTAB decision on IPR.

Any Questions?

THANK YOU!

感谢您的参与

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