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Takeaways from Our March 2016 Cincinnati Seminar

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On March 10-11, 2016 the Chisum Patent Academy held a small-group seminar at the 21C Museum Hotel in Cincinnati, Ohio to discuss and debate current developments in U.S. patent law. Our theme was "Obviousness in the Time of IPR." The roundtable seminar group was limited to ten persons; treatise authors and educators Donald Chisum and Janice Mueller led each of four discussion sessions. Our Cincinnati participants were experienced patent litigators and prosecutors from law firms and corporations in Cincinnati, Cleveland, Minneapolis, New York City, and Pittsburgh:



Here's a recap of our takeaways from the Cincinnati seminar:

Session One: "Blockbusters: Recent Supreme Court and Federal Circuit En Banc Decisions."

Starting the seminar with our traditional "Blockbusters" session, we agreed that Supreme Court decisions carry great potential to "bust" some of the established patent system's "blocks." *Alice* on "abstract ideas" was the best (or, rather, worst) example. But other of the Court's decisions have been sensible, including *Commil* (June 2015). Contrary to a Federal Circuit panel decision, the *Commil* Court held that a good faith belief in a patent's invalidity was not a defense to a charge of active inducement.

Next up from the Supreme Court will be its decisions regarding willful infringement (*Halo* and *Stryker*) and claim construction and judicial review in inter partes review (*Cuozzo*). The Court's grant of certiorari in *Cuozzo* (also discussed in Session Two) was extraordinary. The

Court usually waits for issues to "shake out" regarding a new area of law or procedure. The justices and their clerks must have gotten the word: inter partes review is a major new force in the U.S. patent system.

From the Federal Circuit, the latest en banc decision was *Lexmark* on patent exhaustion by authorized but conditioned sales and by foreign sales. We devoted Session Four (summarized below) largely to the intricacies of *Lexmark*. In our "Blockbusters" session, we discussed what the *Lexmark* opinion's approach might portend for the willingness of the Federal Circuit (especially in en banc cases) to look beyond general pronouncements and statements in Supreme Court opinions. The Circuit in *Lexmark* refused to accept at "face value" and in the abstract a generalized statement about exhaustion in a 2008 Supreme Court decision (*Quanta*). Instead, the Circuit looked carefully at the specific issues involved in the case and at prior case law.

Our seminar participants agreed that the Federal Circuit should apply the same contextual approach, that is, looking closely at the facts of a case in which the Supreme Court made broad statements, to other important issues. The scope of the *Alice* "abstract idea" exclusion would be a prime candidate for this more nuanced approach. The Federal Circuit had an opportunity to do that in the *Ariosa* case on "natural phenomenon," but unfortunately declined to do so by voting against en banc review in November 2015.

The Federal Circuit's next en banc opportunity to account for Supreme Court precedent is *Medicines Company v. Hospira, Inc.* The appellate court granted en banc review on November 13, 2015, to consider questions about the "on sale" bar. In the background looms the Supreme Court's most recent "on sale" decision, *Pfaff v. Wells Electronics* (1998), and its requirement for a "commercial offer for sale." *Medicines Company* does not directly involve the important but uncertain question about the meaning of "on sale" under the America Invents Act, but the Federal Circuit judges may be tempted to comment on that question.

Session Two: "Inter Partes Review Up Close--Current Status, PTAB Case Study, and Federal Circuit Appeals"

Since the Academy's seminars first began examining inter partes review (IPR) in detail two years ago, use of the new adjudicative proceeding for challenging issued patents in the USPTO has skyrocketed. IPR first became available (for attacking then-existing patents) on September 16, 2012. As of February 2016 (almost 3.5 years later), patentability challengers have filed over 4,000 petitions seeking IPR. Our seminar participants debated whether growth in petition filings will continue, or whether the numbers merely represent an initial offensive surge against the most "wounded wildebeests."

The statistics also show that *if* an IPR is instituted, the likelihood of at least some claims being cancelled is very high. Of the 2,600 IPR petitions completed as of February 2016, IPR was instituted in 50% of those petitions. Sixty-two percent (62%) of instituted IPRs went to trial and reached a final written decision (FWD), with the remaining cases terminated after institution due primarily to settlement as well as requests for adverse judgment and a handful of dismissals. In the 792 completed trials reaching a FWD thus far, 72% of *all* instituted claims were held unpatentable; at least *some* claims were held unpatentable in an additional 14% of the decisions.

Thus, cumulatively as of February 2016, at least some claims have been cancelled in **86%** of the 2,600 instituted and completed IPRs.

The Federal Circuit is now grappling with the first wave of appeals from the PTAB's growing body of IPR decisions. The court's statistics show that as of February 2016, it was docketing more appeals arising from the USPTO than the federal district courts, a dramatic inversion of the historical numbers. In Sessions Two and Three, our seminar examined in detail a total of nine recent Federal Circuit decisions in appeals from IPR final written decisions. These represent just the tip of a speedily-expanding iceberg.

Session Two next took a close look at Covidien's IPR challenge of an Ethicon-owned surgical stapler patent to discern how the PTAB as adjudicator is dealing with obviousness (*see Covidien LP v. Ethicon Endo-Surgery*, IPR2013-00209, PTAB Final Written Decision dated June 9, 2014). Based on that case and others examined in Sessions Two and Three, our seminar participants concluded that the PTAB is thus far responding to obviousness challenges far more favorably would than lay jurors. For example, the PTAB in *Covidien* gave minimal weight to the patentee's secondary considerations evidence. We also observed that the PTAB was quite comfortable in construing a patentee's statements in foreign prosecution or litigation proceedings (parallel, related, or not) as admissions against interest, even when such statements did not appear to qualify as prior art. The PTAB was heavily influenced in *Covidien* by patentee concessions that all elements of the claimed invention could separately be found in the prior art (despite the lack of persuasive reasons for combining the prior art teachings).

Since our last seminar in September 2015, the Federal Circuit affirmed the PTAB's decision in the Covidien IPR (see Ethicon Endo-Surgery v. Covidien LP, 812 F.3d 1023 (Fed. Cir. Jan. 13, 2016)). In a divided opinion, the Circuit panel decided two primary issues. First, the majority (in an opinion authored by Judge Dyk) rejected patentee Ethicon's intriguing Constitutional Due Process argument that Congress did not intend to have the same three-judge PTAB panel decide to institute an IPR and then proceed to try the case and issue a Final Written Decision. Having the same panel render both decisions increases the risk of unfairness, Ethicon contended, because the panel may have pre-judged the case on the incomplete record at the institution stage. Although the Patent Act (35 U.S.C. §314) explicitly authorizes the "Director" to make the institution determination and the "Board" to render the final written decision, this statutory division of functions did not dissuade the Ethicon majority. A longstanding rule of administrative law grants agency heads the implied authority to delegate to officials within their own agency, even lacking explicit statutory authority. Moreover, Supreme Court precedent did not raise a "combination of functions" problem, and there was no evidence of actual bias on the part of the PTAB in the case at bar. In dissent, Judge Newman charged the majority with ignoring the AIA provisions that divide the functions of institution and trial into separate bodies within the USPTO in order to preserve "administrative objectivity." In her view, the Director could have properly delegated institution decisions to examiners or Solicitors, but not to the PTAB.

On the merits, the Federal Circuit's decision to affirm the PTAB in *Ethicon* turned on a lack of nexus for secondary considerations evidence. Despite the considerable commercial success of petitioner Covidien's allegedly infringing surgical stapler, the Federal Circuit did not

reach patentee Ethicon's contention that it deserved to benefit from a presumption of nexus between that commercial success and its claimed invention. Regardless of any such presumption, the court concluded (as had the PTAB) that the commercial success of Covidien's device was due to unclaimed features and features known in the prior art.

Our seminars have previously examined in depth the Federal Circuit's 2015 decisions in *In re Cuozzo*, as summarized <u>here</u>. The Supreme Court has now granted *certiorari* in *Cuozzo*, its first review of a Federal Circuit appeal from an IPR decision. (*See Cuozzo Speed Techs., LLC v. Lee,* 136 S. Ct. 890 (2016)). Oral argument at the Supreme Court is scheduled for April 25, 2016. The seminar's consensus view was that the Court's selection of *Cuozzo* for review was highly unfortunate given the case's peculiar procedural history. After issuing in February 2015 a divided panel decision broadly sustaining the PTAB's use of the "broadest reasonable construction" (BRC) rule for interpreting claims in an IPR, the Federal Circuit in July 2015 withdrew its earlier opinion and replaced it with another that essentially limited the court's approval of BRC to the atypical facts of the case; namely, that the PTAB denied Cuozzo's motion to amend his claims because he wrongly sought to *enlarge* their scope (a debatable issue and one that seems not likely to occur in many other IPRs). Also on *certiorari* is the Federal Circuit's second holding in *Cuozzo*: that under a plain reading of 35 U.S.C. §314(d), the PTAB's institution decisions are final and non-appealable, even as part of a Federal Circuit appeal challenging a PTAB final written decision.

Session Two finished with an examination of the Federal Circuit's February 2016 decision in *Nike, Inc. v. Adidas AG,* No. 2014-1719, 2016 WL 537609 (Fed. Cir. Feb. 11, 2016). In an opinion authored by Judge Chen for a unanimous panel, the court vacated the PTAB's decision and remanded the case. *Nike* is a detailed and important decision covering a number of procedural and substantive IPR issues. For example, the court confirmed that when a patentee files a motion to amend, the patentee (not the petitioner) bears the burden of proof to establish patentability of proposed substitute claims. In terms of the universe of prior art that the patentee must distinguish, the court blessed Nike's succinct statement that its proposed substitute claims "were patentable over prior art known to Nike, but not part of the record of the proceedings." Contrary to the PTAB's view, Nike was not obliged to specifically identify or discuss such art not part of the record. Rather, Nike's obligation to address the prior art was no broader in scope than its duty of candor to disclose known material prior art in the IPR, and there was no assertion that Nike had failed to comply with that duty.

Nike also illustrates a patentee proposing to substitute two new claims for one original/cancelled claim (going beyond the 1:1 presumption of the PTO's regulations). The court held that the Board erred by treating the two substitute claims as standing or falling together without first determining if one claim was patentably distinct over the other claim.

Lastly, the *Nike* court found that the PTAB erred by failing to acknowledge or analyze Nike's evidence of secondary considerations (including the declaration of an expert witness). Acknowledging the "stringent time constraints" on the PTAB, the court noted that the PTAB was not obliged to deal with "conclusory, unsupported arguments" about secondary considerations. But in the case at bar, the evidence deserved to be dealt with explicitly. It was not enough for the USPTO to argue (as intervenor) that the PTAB had "implicitly" considered but rejected the

patentee's secondary considerations evidence in the course of discussing whether a motivation existed to combine the teachings of the prior art references.

Our seminar participants discussed the implications of Federal Circuit remands (as in *Nike*) for the PTAB's caseload and expedited schedule for resolving IPRs. Oddly, neither the AIA or the USPTO regulations implementing IPR contemplate the remand scenario. Our participants agreed that this issue merits significant further attention as the Federal Circuit's docket of IPR appeals expands.

Session Three: "Obviousness: Comparing Inter Partes Review and District Court Litigation."

The current flow (or perhaps "flood") of Federal Circuit decisions on the merits of PTAB IPR decisions began in the latter half of 2015. In Session Three we looked at eight decisions on obviousness that the Federal Circuit issued in 2015. Along with the associated issue of claim construction, obviousness was and is likely to remain the predominantly appealed question. For comparison purposes, the first two decisions we examined in Session Three were appeals from federal court litigation; the remaining six were appeals from PTAB IPR decisions. (Full case citations are listed at the end of this section.)

Circuit Check involved a jury verdict favorable to a patent owner. A district court overturned the verdict, but the Federal Circuit reversed despite expressing "doubts" about the patent. Deference had to be given to presumed jury findings favorable to the patent owner, including a presumed finding that certain prior art was "not analogous" and that objective evidence supported nonobviousness. In our view, the evidence on those two issues was thin. A consensus of the seminar participants was that a PTAB panel would likely have reached a different result than the jury in *Circuit Check*.

The second case discussed in Session Three, *Allergan*, involved a pharmaceutical patent. The Federal Circuit held that a district court did not err in holding claims to a composition and related method for treating an eye disease (glaucoma) unobvious even though the claimed composition altered a prior composition only by decreasing the quantity of an active ingredient and increasing the quantity of a preservative. The district court found, first, that the prior art taught away from the claimed composition by discouraging increases in the preservative. Section, the composition achieved unexpected results in maintaining efficacy despite the decreased amount of the active ingredient.

Allergan might have come out the same way before the PTAB, but our seminar discussion of the six IPR appeals summarized below suggested that the PTAB panels were inclined to disagree with patent owner assertions that obviousness over close prior art could be avoided by a "teaching away" argument. Our view was best illustrated by *Merck*, apparently the first pharmaceutical patent to be invalidated by a Federal Circuit-affirmed PTAB decision (incidentally, USPTO statistics indicate that the number of pharma/bio IPR petitions is beginning to increase dramatically). *Merck* held that a supported finding of no teaching away also provided an implicit finding of the "reasonable expectation of success" required for obviousness.

Both patent owners and petitioners brought the six IPR appeals we considered in Session Three. The seminar participants identified a potential pattern. In two of the cases (*Belden* and *Redline*), the claims that the PTAB had upheld were ones that had been confirmed or added during a prior ex parte reexamination. We agreed that that made some sense. The PTAB judges were giving deference to their PTO reexamination colleagues. Thus, patent owners who have time to do so might be well advised to use reexamination to shore up the validity of claims in anticipation of a subsequent inter partes review challenge. However, the cases also suggested that the Federal Circuit may be less deferential than the PTAB to a prior reexamination. Only in one of the two cases (*Redline*) did it affirm the PTAB's decision.

Two of the six IPR cases involved appeals from a PTAB claim construction decision. The Federal Circuit reversed in *Straight Path*, noting that the PTAB was wrong in giving a phrase a broad meaning beyond the ordinary one, and emphasizing that it mattered not whether the standard was the broadest reasonable interpretation rule or the *Phillips* standard for claim interpretation in litigation. In *SightSound*, the Circuit affirmed a PTAB broad construction but only in part.

Of the six IPR cases, only *Redline* was an outright win for the patent owner. The petitioner's loss in that case traced mainly to its failure to file an expert declaration in a timely fashion. That left unrebutted the declaration of the patent owner's expert on a key point, whether a skilled artisan would have been motivated to combine prior art references. Other cases, such as *MCM Portfolio*, *SightSound*, and *Merck*, affirmed Board findings of a motivation to combine.

Redline illustrates the potential perils of a newly-implemented procedure such as IPR: early adopters can fall victim to a new, unexpected interpretation of a rule. The petitioner in *Redline* sought to file its expert declaration in a motion to submit supplemental information. The USPTO's Rule 42.123(a) can be reasonably read as giving an automatic right to supplement if a motion is made within 30 days of institution of an IPR and the supplemental information is "relevant to a claim for which the trial has been instituted." The petitioner plainly met those two "requirements." Yet the PTAB denied the motion, and the Federal Circuit affirmed, noting that the rule did not state *all* the requirements for a motion to supplement.

Session Three case citations:

Circuit Check Inc. v. QXQ Inc., 795 F.3d 1331 (Fed. Cir. 2015) Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293 (Fed. Cir. 2015) Belden Inc. v. Berk-Tek LLC, 805 F.3d 1064 (Fed. Cir. 2015) Straight Path IP Group, Inc. v. Sipnet EU S.R.O., 806 F.3d 1356 (Fed. Cir. 2015) (remand; claim construction error) MCM Portfolio LLC v. Hewlett-Packard Co., 2015 U.S. App. LEXIS 20848, 117 USPQ2d 1284 (Fed. Cir. 2015) SightSound Technologies, LLC v. Apple Inc., 809 F.3d 1307 (Fed. Cir. 2015) Merck & Cie v. Gnosis S.p.A., 808 F.3d 829 (Fed. Cir. 2015) (first IPR invalidating pharma patent) Redline Detection, LLC v. Star Envirotech, Inc., 811 F.3d 435 (Fed. Cir. 2015)

Session Four: "Exhaustion"

We concluded the seminar by analyzing recent exhaustion cases leading up to the Federal Circuit's en banc exhaustion decision, *Lexmark International, Inc. v. Impression Products, Inc.*, 2016 WL 559042 (Feb. 12, 2016).

Lexmark set forth two clear holdings, each running, to some extent, *against* the Supreme Court's description of exhaustion in prior cases.

Conditioned Sales. First, on conditioned sales, the Federal Circuit en banc majority in *Lexmark* held that a patent owner's sale of a U.S.-patented article under a restriction on resale and reuse that was communicated to a buyer at the time of sale and that was "otherwise proper" (that is, the restriction did not constitute misuse through a price-fixing or tie-in restriction, or an antitrust violation) did *not* exhaust its patent rights. The 1992 panel decision *Mallincrodkt* so held and was not undermined by the Supreme Court's 2008 *Quanta* decision.

At first blush, the *Lexmark* result on conditional sales was extraordinary given the Supreme Court's general description of exhaustion in *Quanta*:

"The longstanding doctrine of patent exhaustion provides that the **initial authorized sale** of a patented item terminates all patent rights to that item. ... Although the Court permitted postsale restrictions on the use of a patented article in *Henry v. A. B. Dick Co.*, 224 U.S. 1 (1912), ... that decision was short lived. ... [I]n *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 518 (1917), the Court explicitly overruled *A. B. Dick.* ... [I]t reiterated the rule that `the right to vend is exhausted by a single, unconditional sale, the article sold being thereby carried outside the monopoly of the patent law and rendered free of every restriction which the vendor may attempt to put upon it.'" (Bolding added).

The *Quanta* Court seemed to say, fairly clearly, that "postsale restrictions on the use of a patented article" were *not* permitted. Admittedly, the Court did reiterate the requirement of an "unconditional" sale, but that apparently meant a "title-passing" sale; the Court reiterated the rule as one in which an "unconditional" sale of an article rendered the article "free of" a restriction that a seller put upon the article.

But Circuit Judge Taranto for the en banc majority in *Lexmark* argued forcefully that such judicial statements must be taken in full context. Importantly, *Quanta* itself involved neither a conditioned sale nor a sale by a patent owner.

The *Lexmark* majority relied heavily on the Supreme Court's 1938 *General Talking Pictures* decision, which found no exhaustion when a licensee made a sale in violation of a fieldof-use restriction. The majority repeatedly asserted that it made no sense to distinguish patentowner restricted sales from licensee sales. Why give a "practicing" patent owner who makes and sell a patented article fewer rights to impose restrictions and conditions than a "nonpracticing" patent owner who, under *General Talking Pictures*, can impose those restrictions and conditions on a licensee? On that basis, the *Lexmark* majority distinguished Supreme Court cases stating the rule on exhaustion broadly, and limited Supreme Court cases that found exhaustion despite violation of restrictions to particular, "improper" restrictions; namely, tying and price fixing.

As an intermediate appellate court, the Federal Circuit was bound by *General Talking Pictures*. But the Supreme Court has greater freedom to resolve tensions and inconsistencies between and among its precedents. Our seminar participants theorized that the if the Supreme Court reviews *Lexmark*, it might agree that it was inconsistent to treat patent-owner sales and licensee sales differently, but go on to find that it was also inconsistent to distinguish reuse and resale restrictions from resale price restrictions. The Court could then resolve both inconsistencies by limiting, as well as expanding, *General Talking Pictures*. It might, for example, distinguish the field-of-use restriction in *General Talking Pictures* from the resale/reuse restriction in *Lexmark* (and *Mallincrodkt*). The Court could then impose exhaustion on an authorized, reuse/resale restricted sale but not on an authorized, field-of-use restricted sale, in neither instance distinguishing patent owner sales from restricted licensee sales.

Foreign Sales. On foreign sales, the *Lexmark* majority held that a foreign sale of an article, made or approved by a U.S. patent owner, did *not* exhaust U.S. patent rights even though the owner did not explicitly reserve those rights at the time of the foreign sale. The 2001 panel decision *Jazz Photo* so held and was not undermined by the Supreme Court's 2013 *Kirtsaeng* international copyright exhaustion decision. The patent owner could lose U.S. rights by foreign sale, however, through an express license or a licensed implied from the circumstances of the sale.

The *Lexmark* majority, the dissent, and the United States as amicus curiae all agreed that exhaustion by foreign sales should *not* operate as it does for domestic sales (or even as it does for international copyright exhaustion under *Kirtsaeng*). The seriously debatable question for potential Supreme Court consideration thus became: which is the better rule: (1) no exhaustion but allowing an infringer-importer to prove an implied license? (the *Lexmark* majority's holding), or (2) presumptive exhaustion but allowing the patent owner to prove the initial foreign was subject to an explicit reservation of U.S. rights (the position of the *Lexmark* dissent and the United States)?