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2012 Pharma IP and FDA Law

Year in Review

Presented By:

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Highlights

- Review of some important pharmaceutical related IP and FDA cases
- Practical tips to implement
- 2013 in preview

About Us

Shashank Upadhye, a partner, joined Seyfarth Shaw in late 2012. He is the former VP – Global Head of IP for Apotex, Inc., VP of IP for Sandoz US, and VP of IP for Eon Labs. His practice specializes in life sciences IP and FDA regulatory law. He represents brand and generic companies in portfolio development, strategic life cycle management, corporate governance, FDA, and litigation.

Nigam Acharya is a Senior Counsel and he specializes in IP acquisition, portfolio strategy, opinions/counseling, and litigation. Nigam previously was a chemist investigating various organic chemistry and protein nucleic acid chemistry areas.

About Us - For more information

- You can visit our website at: www.seyfarth.com and can learn more about our life science group here: http://www.seyfarth.com/Pharmaceutical-Medical-Device

- Shashank is also pleased to announce the 2013 Edition of his leading book entitled, Generic Pharmaceutical Patent and FDA Law, an 800+ page book that details every aspect of patents, FDA, and Hatch Waxman law. The book is available in hard and e-book formats.

In Re Rosuvastatin (Patentee friendly) 703 F.3d 511 (Fed. Cir. 2012) [Crestor]

- No inequitable conduct for not presenting species claim in original patent; no I.C. in Reissue process that later added species claim

- No Structural Obviousness – yet again reaffirms “lead compound test” [Note: Apotex’s cert petition denied in Jan. 2013 re: aripiprazole challenging lead compound test]

Who is a Submitter of an ANDA?

- Court grappled with issue of difference between person who simply signs and files versus person who signs and gains benefit of the ANDA filing

- If Apotex Corp (USA) agent was not a submitter, then it could not be bound by Court judgment

In Re Rosuvastatin

Practice Tips:

- Int'l GRx companies who have named U.S. subsidiaries may want to consider using consultants or law firms as agents to administratively sign & file ANDA's to avoid encumbering U.S. subsidiary in the lawsuit

- If on Reissue, ensure that the proper statutory basis for Reissue is invoked. Dissent stated that Reissue here was improper and would have invalidated Reissue (GRx would have "won" if Reissue was indeed improper)

- GRxs and patent holders need to be aware that patents can be significantly altered by reissuance

In Re Staats (Patentee friendly) 671 F.3d 1350 (Fed. Cir. 2012)

Like Die Hard movies, they just keep coming…

- When is Reissue proceeding never over and can you always keep broadening claims outside of the 2-Year Rule?

- 35 U.S.C. §251 – governs Reissue process, applicant has 2 years from original patent date to file broadening reissue

Question: because applicant is allowed to file continuing applications off a pending Reissue, is there a time limit for filing broadening claims in Reissue continuations?

In Re Staats

01 Apr. 1996	Original patent application filed
17 Aug. 1999*	Parent patent issued (disclosing Embs: 1 & 2; claiming only Emb. 1)
17 Aug. 2001*	Timely filed (under 2 Yr Rule) RE#1 to broaden Emb. 1 claims
12 May 2004	RE#2 filed to Emb. 1 (broadening)
26 Oct. 2004	RE#1 reissued to claims Emb. 1
11 Aug. 2006	RE#3 filed, as CON of RE#2, to Emb. 1 [7 Yrs aft. parent iss., after RE#1 issued]
11 June 2007*	Added new broaden claims to Emb. 2 For first time, in 2007, Emb. 2 claims are added.

In Re Staats

- Issue – because the dedication to the public rule (disclosed but not claimed is dedication) requires some finality, is it “fair” to allow continuous reissues that broaden claims even to claims that are now unrelated to earlier presented broadened claims

- Staats Court held that because RE #1 was timely filed, continuations off of RE #1 still related back to RE #1 and broadened claims, even to different embodiments, are still permissible

- Practical Tip – patentees can use Continuations of timely filed Reissues to keep applications alive, to broaden, and to pivot claim scope, even during pending Para. IV litigation

Pozen Inc. v. Par (Patentee friendly) 696 F.3d 1151 (Fed. Cir. 2012) [Treximet]

It Lives …

What Lives?

Pozen v. Par Pharmaceuticals

The Doctrine of Equivalents still lives

- The claim term “substantially all of the triptan in layer 1”
- Claim construction: “substantially all” meant at least 90%

→literal term was to at least 90% (GRx product had 85% of triptan in layer 1)

→ Court then allowed DOE to lower 90% range to 85% saying that difference between 85% and 90% was insubstantial difference

→ Evidence of DOE was also based on ANDA product functionality

Marine Polymer v. HemCon (Patentee friendly)
672 F.3d 1350 (Fed. Cir. 2012)(en banc)

- Can defendant get Reexamination intervening rights if the claims are not amended during Reexam?
- Marine sued HemCon and during trial, HemCon provoked Reexamination. Claims were rejected and some canceled, but remaining claims were not amended.
- Initially district court adopted narrower claim construction and Examiner, during Reexam, used broader construction. Marine argued that narrower claim scope applied. Examiner then agreed.
- HemCon argued that the claim scope was changed so that meant that Reexam intervening rights applied.

Marine Polymer v. HemCon

- Court said that simply arguing and canceling claims are not amendments or new claims that earn intervening rights

- Claim scope may change due to arguments, but change in claim scope is not a new claim or an amendment to a claim.

Practical Tip:

- Reexamination can be used to overcome prior art (as here)

- Reexamination can generate intervening rights but have to examine the nature of any rights

- Reexamination can be instigated by Defendant and with inter partes reexamination, Defendant has ability to cause amendments to happen

In Re Baxter International

698 F.3d 1349 (Fed. Cir. 2012)(en banc denied)
underlying case: 678 F.3d 1357 (Fed. Cir. 2012)

- Friendly to both sides

  Hypothetical: GRx loses in Para. IV litigation. GRx successfully provokes Reexamination process, ultimately invalidates patent claims. BRx keeps losing on appeal and Fed. Cir. affirms PTO decisions to invalidate claims?

Questions:

- what happens in the Para. IV case?
- Is verdict overturned?
- If GRx launched at risk and now liable, can GRx expunge verdict and damages?
- Is there Constitutional separation of powers problem with PTO as agency overturning an Article III court's powers?

In Re Baxter International

- Baxter court suggests that prior Para. IV verdict could be binding on the parties under principles of *res judicata*

- Here, Fresenius filed DJ against Baxter's patent in 2003. In 2005, Fresenius provoked reexamination. In 2007, trial court "validated" patent. Fed. Cir. affirmed patent validity in 2009. In 2010, BPAI "invalidated" claims. In 2012, Fed. Cir. affirmed BPAI invalidation.

  → does it matter that Reexam provoked 2 years after trial started

  → if Reexam filed as soon as lawsuit started, would trial court stay lawsuit pending Reexam outcome

  → if Reexam invalidated claims first, can trial court still go ahead with lawsuit

In Re Baxter & Reexam

- Lots being said about Reexam during or after Para. IV lawsuit (is it a good idea, bad idea, can it create a “court decision that triggers 180-Day?)
- Reexam should be carefully considered to understand the impact.
- Reexam success may simply allow later GRx’s to overcome patent but GRx #1 still stuck by patent under “res judicata” grounds → what value is there for GRx #1 to do Reexam?
- GRx will likely continue to provoke Reexams to explore contours of future law and impact on previous Para. IV “losses”

Hoffman LaRoche v. Apotex et al. 2012 WL 4829204 (Fed. Cir. 2012) [Boniva]

- Patentee friendly dissent; GRx friendly majority
- GRx friendly in that it won denial of P.I. and won affirmance of P.I. denial on appeal
- Fed. Cir. panel used burden on patentee to prove infringement and that patentee will likely withstand any invalidity challenge

Practical Tip – BRx should rely on this Dissent

- Dissent – gives lots of flattery to BRx's innovations; credits all the R&D done; bore lots of risk
  - Dissent states that GRx only are slavish copiers
  - crediting any GRx development upsets the BRx's development efforts
  - equities will always lie with BRx and any equitable credit to GRx is wrong

Dey v. Sepracor (Infringer friendly) 847 F.Supp.2d 541 (SDNY 2012) [Brovana]

- Appeal pending 12-1428, oral argument 04 Feb. 2013
- Sepracor (Sunovion) argued that its own public use of clinical trials constituted a §102(b) public use
- Undisputed that Sunovion's own drug development was in traditional clinical trial formats, were Public Uses, and that its clinical trial product was ready for patenting
- Sunovion's clinical trials only had consent forms, no confidentiality forms, trials were in public, patients could take drugs at home, drug distribution was uncontrolled, any confidentiality with investigators irrelevant as patients were not under confidentiality

Practical Tip: could be used by GRx against BRx (but see other clinical trial non-public use cases)

Aventis v. Hospira & Apotex (GRx friendly) 675 F.3d 1324 (Fed. Cir. 2012) [Docetaxel]

- Obviousness and Inequitable Conduct affirmed
- First Federal Circuit decision post-*Therasense* that affirms inequitable conduct
- Materiality – because the very withheld references formed the basis for obviousness, they are necessarily material
- Intent – sufficient evidence on intent

Practical Tip = despite one court affirming I.C., still necessary to effectively plead I.C. in pleadings, and then prove it during proceedings. Also, prosecutors should not become complacent.

See, Cumberland Pharmaceutical v. Mylan, 2012 WL 6567922 (ND Ill. 2012)(pleadings sufficient)

Momenta v. Amphastar (Defendant friendly) 686 F.3d 1348 (Fed. Cir. 2012) [enoxaparin]

- Case concerned the scope of the "Bolar" exception and whether any post-approval activity is exempt under §271(e)(1)
- Section 271(e)(1) declassifies infringement if the activity is used to generate information submitted to the FDA
- Amphastar used MNTA's method of analyzing the enoxaparin to see if a 1,6 anhydro ring structure existed
- Amphastar would use that method even after ANDA approved as part of its Quality Control process
- Court ruled that exemption is wide/liberal interpretation and included certain post-approval activity

Momenta v. Amphastar

Court rejected argument that

1. §271(e)(1) only applied to pre-approval activity in drug investigation
2. if several other methods of doing the Quality analysis could be used, then exemption does not provide immunity to the infringing method (exemption should only apply if there is only one method)
3. only if the method produced information that was actually submitted would the exemption apply → if information is not required nor submitted, then exemption does not apply

- Dissent – implies that Amphastar is a thief who stole MNTA's labors and invention. Dissent would narrowly construe scope of §271(e)(1) safe harbor. Case cannot be reconciled with *Classen* case [659 F.3d 1057 (Fed. Cir. 2011)] that held that post-approval activity is not shielded.

Momenta v. Amphastar

Practical Tips:

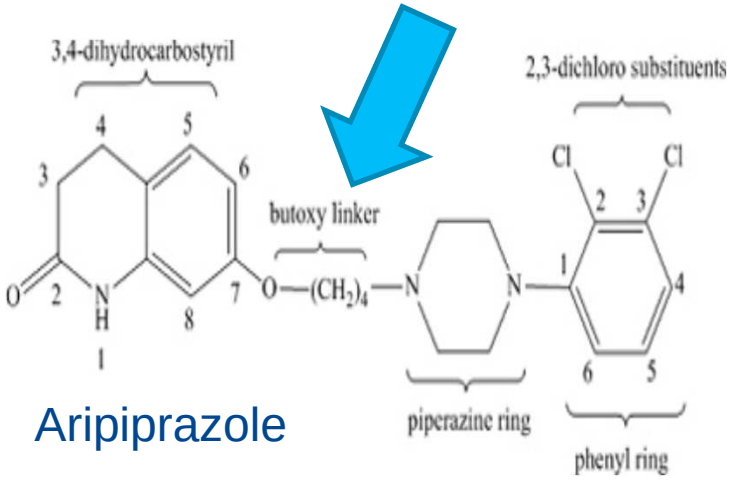
- Document the requirement to do the (infringing) activity by making parallels to the FDA statute, regulations, or guidances
- Document any discussions as to why a certain method was done and why that activity will create information that can be submitted to the FDA
- Seek independent legal advice as to whether the safe harbor applies
- Per Supreme Court in *Merck KGaA* case, what matters is the defendant's "reasonable basis for believing" that use of the patented method may generate information for submission [545 US at 207]

Obviousness

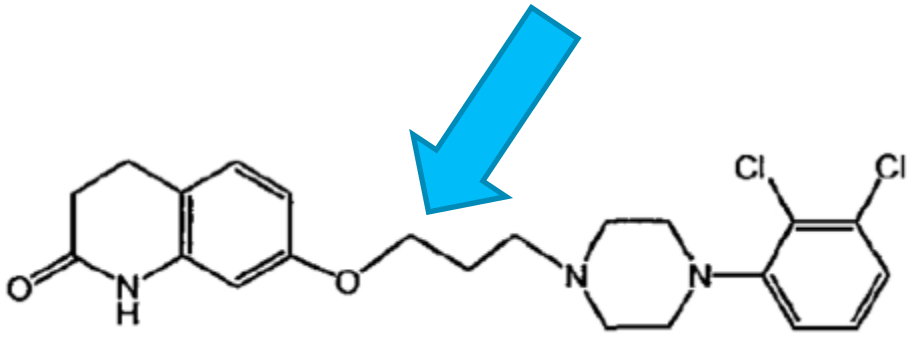
- Good news for patent holders in 2012
- TREND: patent applicants have been losing at the PTO on obviousness, but patentees are winning in court
- Pharma still an unpredictable art – Fed. Cir. provided guidance on “obvious to try” factors
- “Lead Compound” test is still the test, despite its rigidity and potential inconsistency with KSR that prohibits rigid tests

Otsuka v. Sandoz et al. (Patentee friendly) 678 F.3d 1280 (Fed. Cir. 2012) [Abilify]

- Court said GRx's arguments are the "Poster Child" for impermissible hindsight → Reaffirms lead compound test
- Court returns to pre-KSR language, "absent a reason or motivation for modifying [the prior art], mere structural similarity between the prior art and the lead compound does not inform the lead compound selection"



Aripiprazole



Prior Art

Other Cases

- Alcon v. Apotex, 687 F.3d 1362 (Fed. Cir. 2012)(olopatadine) – Overturned obviousness determination that claims directed towards treating human eye conditions were taught by animal studies.

- Santarus v. Par, 694 F.3d 1344 (Fed. Cir. 2012) - Overturned obviousness determination with regard to conventional oral dosage forms, despite prior art enteric coated PPIs, because it found that references taught away from formulating omeprazole with regard to the conventional forms.

- In Re Cyclobenzaprine XL, 676 F.3d 1063 (Fed. Cir. 2012) – in ANDA case, Overturned Obviousness determination with regard an extended release of Amrix basing it ruling on the fact that the prior art did not disclose the “pharmacokinetics/pharmacodynamics relationship” for the claimed drug.

- In Re Rosuvastatin – reaffirming the Lead Compound Test and clarifying when it is not obvious to try.

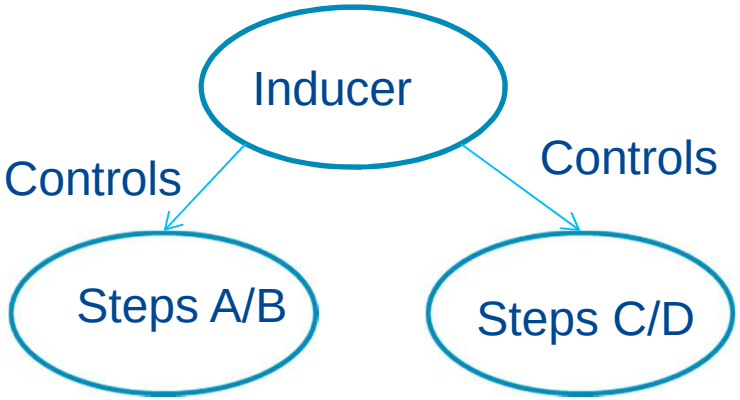
Practice Tips

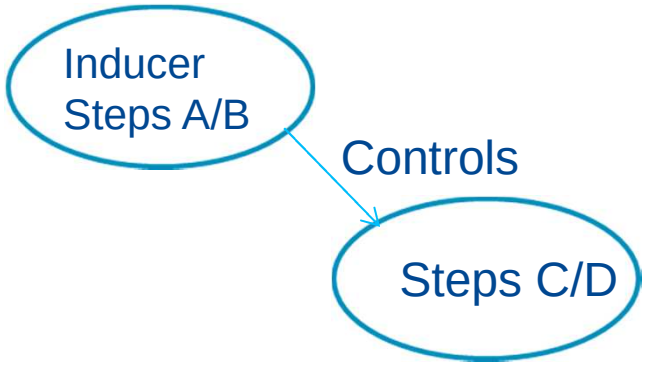
- Invalidating for obviousness, even when limited possibilities exist, is harder when secondary evidence exists and limited guidance on which, if any possibilities, will be successful
- Court is rejecting hindsight analysis
- BRx Tips: develop the record and secondary evidence; create nexus between commercial success and invention; get different experts to opine on different topics (avoid Daubert exclusion)
- GRx Tips: disconnect commercial success from actual claimed invention; have a lead formulation/compound
- Patent prosecution: claim the narrower ranges that cover the commercial embodiment

Akamai v. Limelight (Patentee friendly) 692 F.3d 1301 (Fed. Cir. 2012)(en banc)

- Induced infringement available even though no single actor performs all the method claim steps (overruling BMC v. Paymentech).

- Court allows “divided infringement” liability for inducer.





Mylan v. FDA (GRx friendly) 2012 WL 6705957 (DC DC 2012)

- Everyone thought that RBXY forfeited any exclusivity re: valsartan for failure to obtain TA in 30 Months
- FDA and Court ruled that the change in the USP monograph was a change of circumstance in the approval standards to save RBXY from forfeiture
- MYL challenged FDA decision but lost

2013 In Preview

- Based on Sup. Ct. denial of petition in aripiprazole lead compound case + Fed. Cir.'s insistence on lead compound test, what will Fed. Cir. do in Teva's trial court win on entacavir compound?
- En banc review of claim construction standard (revisiting Cybor's pure question of law) in *Lighting Ballast* case
- Supreme Court Cases: Bowman v. Monsanto (self replicating technology); FTC v. Actavis (pay for delay settlements); Myriad v. AMP (human gene patents); Mutual Pharma v. Bartlett (preemption of state tort claims for GRx drugs)
- Teva/Sun pantoprazole damages cases – should determine how patent damages are calculated

2013 In Preview

REMS cases

- Jazz v. Roxane re: Xyrem REMS patents and whether ROX can obtain FDA approval for separate REMS
- Actelion v. Apotex and Roxane re: REMS controlled drugs and access to the RLD to conduct BE trials, antitrust case

- Bystolic (nebivolol MDL) re: claim construction driving infringement case

The End

Thank you for your time and attention.

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