Prosecutorial Lessons of Recent Obviousness-Type Double Patenting Cases

Kimberly J. Prior
Hoffmann-La Roche Inc.
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We Innovate Healthcare

Obviousness-type Double Patenting

The doctrine of obviousness-type double patenting is intended to "prevent the extension of the term of a patent … by prohibiting the issuance of the claims in a second patent not patentably distinct from the claims of the first patent."
In re Longi, 759 F.2d 887,892 (Fed. Cir. 1985)

A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim."
Eli Lilly & Co. v Barr Labs, Inc., 251 F.3d 955, 968 (Fed. Cir. 2001)

ODP Standard for Review

As with statutory obviousness under 35 U.S.C. § 103, obviousness-type double patenting is an issue of law premised on underlying factual inquiries.
Otsuka Pharm. Co. v Sandoz, Inc., 678 F.3d 1280, 1290 (Fed. Cir. 2012)

Ultimate conclusion on obviousness-type double patenting is reviewed de novo, but predicate findings of fact reviewed for clear error

Sun Pharmaceutical Industries v. Eli Lilly Company (Fed. Cir. 2010)

Questions Presented

- Whether ODP applies to a method of use claim where the method was disclosed, but not claimed, as one of multiple methods of use in the specification of the reference patent
- Whether it is acceptable to use the specification of the reference patent in making an ODP rejection

Brief Facts

- GEMZAR® – gemcitabine, approved for treating various cancers
- 3 applications
  - '883 application described gemcitabine and antiviral activity
  - CIP added oncolytic activity and issued as US 4,808,614 with claims to gemcitabine & method of treating herpes viral infections (Exp. 5-15-10)
  - Separate application issued as 5,464,826 with claims to a method of treating cancer with gemcitabine (Exp. 11-7-12)

Brief Facts

- In 2006, Sun filed ANDA & ¶IV
- In November 2007, Sun filed a DJ action
  - '826 patent not infringed and invalid under ODP
  - Lilly counterclaimed for infringement of '614 & '826 patents
- District Court granted Sun's motion for SJ that '826 was invalid over '614 for ODP
- Lilly appealed

Process for Review

An ODP analysis "compares claims in an earlier patent to claims in a later patent or application." *Geneva Pharmaceuticals, Inc. v GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1(Fed. Cir. 2003)

An ODP analysis consists of 2 steps:

(1) The court "construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences"

(2) The court "determines whether those differences render the claims patentably distinct." *Pfizer, Inc. v Teva Pharmaceuticals USA*, 518 F.3d 1353 (Fed. Cir. 2008)

Decision – Method of Use

- Court held that *Pfizer* and *Geneva* control
- In *Pfizer* and *Geneva*,
  - Court held that a method claim is not patentably distinct from an earlier claim to the identical composition in a patent disclosing that use.
  - Does not matter whether the specification of the earlier patent discloses one or multiple uses

Decision – Use of Specification

- General rule is that the earlier specification cannot be used to show ODP
  (*Geneva*, 349 at. 1385)
- Limited exception
  - whether a claim "merely define[s] an obvious variation of what is earlier disclosed and claimed"
  - [T]o learn the meaning of [claim] terms
  - To "interpret[] the cover of [a] claim"
    In re Basell Piliolefine Italia S.P.A., 547 F.3d 1371, 1378 (Fed. Cir. 2008)

Thoughts for Prosecution

- To avoid ODP Rejections
  - Claim all disclosed uses in the original patent claims (§ 121 Safe Harbor)
  - Consider whether additional uses should be disclosed and claimed in original patent or in separate patents
    - may be able to show patentably distinct based on dosage, population, or route of administration, etc.
  - If later uses found, try to distinguish to avoid ODP

Eli Lilly & Co. v. Teva et al. (Fed. Cir. 2012)

Questions Presented

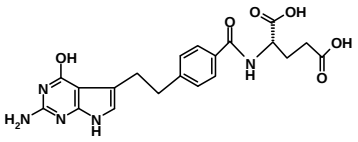
- Whether the claims of the '932 patent were invalid for ODP over claim to the '608 compound
- Whether the claims of the '932 patent were invalid for ODP over claim to the '775 intermediate

Brief Facts

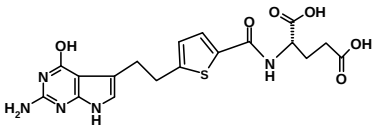
- ALIMTA® – pemetrexed, approved for treating mesothelioma & non-small cell lung cancer
- 3 Patents assigned to Trustees of Princeton University and licensed to Eli Lilly
  - US 5,344,932, claims pemetrexed specifically (claim 3) and generically (claims 1, 2, & 7) – Expiry 7-24-16
  - US 5,028,608, claims compound differing from pemetrexed by having a thiophene instead of a benzene – Expired
  - US 5,248,775, claims an intermediate used to make pemetrexed that differs by having a triple bond in the bridge and 3-protecting groups – Expired

Compounds at Issue

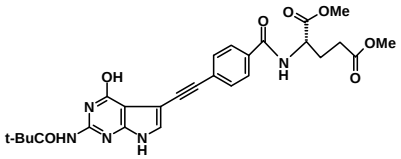
Pemetrexed



The '608 Compound



The '775 Intermediate



Brief Facts

- Generics filed ANDA & ¶IV
  - Not infringed or invalid and unenforceable
- Teva argued pemetrexed was obvious over '608 compound because the only difference was in the aryl portion and it would be obvious to substitute a thienyl group for a phenyl group
- Teva argued pemetrexed was a use of the '775 intermediate and was thus obvious over the *In re Byck*, 48 F.2d 665 (CCPA 1931) line of cases
- District Court rejected both arguments; Teva appealed

Decision – The '608 Compound

- Teva argued
  - under the *Amgen v. Hoffmann-La Roche Ltd*, 580 F.3d 1340 (Fed. Cir. 2009), court should look only to the differences in the compounds and that it would have been obvious to substitute a thienyl group for the phenyl group
- Court held ODP analysis is akin to an obviousness determination and must consider molecule as a whole
- Facts reviewed for clear error and there were none on the record

Decision – The '775 Intermediate

- Teva argued that pemetrexed was a method of using the '775 intermediate in the process described in the '775 application
- Court said no method of use – two compounds
  - *In re Byck* line of cases does not apply and teachings in specification are inapplicable
- Analysis is whether pemetrexed was obvious over the '775 intermediate compound and record below showed that it was not

Thoughts for Prosecution

- ODP analysis is the same as for obviousness
  - Consider differences between compounds of previous claims and present claims
  - What arguments are available to show nonobviousness
  - Should comparative data be included in the specification
  - Beware strained interpretations of the claims and/or the law

Boehringer Ingelheim International v. Barr (Fed. Cir. 2010)

Questions Presented

- Whether the filing of a retroactive terminal disclaimer after expiration of the earlier patent is effective
- Whether the Safe Harbor provision of § 121 precludes a finding of ODP where consecutive divisional applications are filed

Brief Facts

- MIRAPEX® – pramipexole, approved for treating the signs and symptoms of idiopathic Parkinson's disease
- BI owns 3 patents
- Mylan filed ANDA & & ¶IV
- BI sued for patent infringement of some claims of the '812 patent and Mylan counterclaimed for ODP
- BI attempted to overcome ODP by filing TD over the expired '086 patent
- BI argued § 121 safe harbor applied

The Applications

- The '947 Application contained 15 claims, restricted by USPTO into 10 groups
  - 5 compound groups based on diverse structures
  - 2 methods of making
  - 3 methods of treatment
  - Examiner required election of one group of compounds and one method limited to that group of compounds
  - Issued as US 4,731,374 on 3-15-88

The Applications

- The '197 Application, filed as DIV of '947 with original claims
  - No restriction
  - Amended after rejection to method claims demarcated from the claims in the '374 patent
  - Issued as US 4,843,086 (Expired 6-27-06)
- The '671 Application, filed as DIV of '197 with original claims
  - Claims amended – demarcated from both the '374 and the '086 patent
  - Issued as US 4,886,812 (Expiry 3-25-11)

District Court Opinion

- Found the compound claims of the '812 patent obvious over the method of use claims of the '086 patent
- Held TD was ineffective because it was filed after the '086 patent expired
- Rejected BI's safe harbor argument
- Held the '812 patent invalid for ODP
- … BI appealed

Decision – Retroactive TD

- A TD can be filed after a patent issues, even during litigation and even after a finding of invalidity based on ODP
- Permitting a later patent to remain in force beyond the date of the earlier patent's expiration wrongly informs the public that patentee has rights that it does not, giving patentee an unjust advantage
- Patentee cannot retroactively disclaim this later term because it has already enjoyed the rights it seeks to disclaim

Decision – Retroactive TD

- BI argued no unjustified advantage because it had obtained PTE under 35 U.S.C. § 156.
- Court disagreed because the scope of rights under § 156 is narrower than those enjoyed during the term of the patent
- Court held that a retroactive TD filed after the earlier patent expires cannot overcome an ODP rejection

Decision – Safe Harbor Provision

- The safe harbor provision states

… A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them …

Decision – Safe Harbor Provision

- "When the PTO requires an applicant to withdraw claims to a patentably distinct invention, § 121 shield those withdrawn claims in a later divisional application against rejection over a patent that issues from the original application.
  Geneva, 349 F.3d at 1378
- The court found that the safe harbor provision refers to patents issuing from any number of multiple divisional applications and precludes any of them from being used as a reference against any other.

Thoughts for Prosecution

- Retroactive Terminal Disclaimers
  - Review all members of a family before the earlier patents expire to avoid missing an opportunity to file a TD
- Safe Harbor
  - The key to be in a position to invoke the safe harbor provision of § 121 is to maintain consonance with the original restriction requirement.
  - Take care to maintain a demarcation between the claims of each divisional filed
  - Take care to avoid situations in which the PTO gives inconsistent restriction requirements in divisional applications

Otsuka Pharmaceutical Co. v. Sandoz (Fed. Cir. 2012)

Questions Presented

- Whether the analysis for ODP the same as that for obviousness
- Whether the test for ODP considers whether the prior art would have supplied a motivation to modify the earlier compound

Very Brief Facts

- ABILIFY® – aripiprazole, approved for the treatment of schizophrenia, bipolar disorder, and as an add on for depression
- Patent at Issue
  - US 5,006,528 issued 4-9-91 and has claims to aripiprazole, pharmaceutical compositions, and methods of treating schizophrenia, generically and specifically (Expiry 4-20-15)
- Sandoz filed and ANDA & Otsuka sued for infringement
- Sandoz asserted that the claims were invalid for obviousness & ODP

Similarities between Obviousness & ODP Analyses

Unless the earlier claim anticipates the later claim under § 102, ODP implicates obviousness, "which in the chemical context requires identifying some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success."

Takeda Chem. Indus., Ltd. v Alphapharm Pty., Ltd., 492 F.3d 1353, 1357 (Fed. Cir. 2008)

Differences between Obviousness & ODP Analyses

The patent principally underlying the double patenting rejection need not be prior art

No issue regarding selection of a lead compound because the focus is on the earlier compound whether or not it would be the lead compound

Otsuka Pharm. Co. v Sandoz, Inc., 678 F.3d 1280, 1290 (Fed. Cir. 2012)

Decision – Motivation

- In the context of claimed chemical compounds, an analysis of ODP – like an analysis under § 103 – entails determining whether one of ordinary skill in the art would have had reason or motivation to modify the earlier claimed compound to make the compound of the asserted claim with a reasonable expectation of success

Secondary Considerations

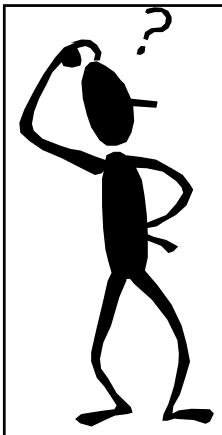
- *Geneva* Footnote 1
  - "…Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not"

  Geneva, 349 F.3d at 1377 n.1
  - *Geneva* was a case of anticipation, not obviousness
  - Cited as dictum in *Procter & Gamble*, which found no motivation to modify earlier compound, so no need to address secondary considerations

  Procter & Gamble Co. v Teva Pharm., USA, Inc., 566 F.3d 989 (Fed. Cir. 2009)
  - Keep an eye on *Ex parte Lee* (BPAI 2011)

Thoughts for Prosecution

- Review earlier filed patents to similar subject matter
- Consider whether there is a motivation to modify the prior compound(s) to achieve new compound
- Determine if there are any secondary considerations and consider including in specification



Questions?