

LIFE SCIENCES PATENT NETWORK SPRING 2019



ADDRESSING SECOND MEDICAL USE
PATENTS AND INFRINGEMENT

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SECOND MEDICAL USE ISSUES

- **Importance of Second Medical Use Protection**
- **Patentability**
 - Patentable Subject Matter
 - Obviousness/Novelty Challenges
 - Sufficiency/Plausability (Europe)
- **Infringement**
 - Skinny Labels
 - Induced Infringement



TAKE-AWAYS

- **Validity and Infringement of Second Medical Use Claims are determined by national laws**
- **Courts in different countries may reach (and have reached) different conclusions**
 - Different aspects of national law on infringement
 - Different evidence or arguments presented to the court
- **Different approaches by the courts**
 - Important to consider the best place to bring initial lawsuits (but you may not have a choice)
 - Present considerable complexity in coordinating and addressing the differing approaches across key jurisdictions where multi-national litigation is involved

LESSONS FROM ABROAD

- Worthwhile to check alternative theories of bringing an action
- Expeditiously check & adjust portfolio in view of changing legal landscape
- In evolving area of law, even if a case is lost, it may set up the legal landscape for the future

SOME RECENT CASES

U.S. (New uses)

- *GlaxoSmithKline LLC v. Teva Pharm. USA, Inc.*, 313 F. Supp. 3d 582, 591-98 (D. Del. 2018) (Stark, J.) -carvedilol (granting JMOL of no infringement during skinny label (or full label) period, finding insufficient evidence of inducement *by Teva* and sufficient evidence of other factors influencing doctor's decisions)(on appeal)
- *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339-40 (Fed. Cir. 2019) (affirming district court's finding of no induced infringement where generic indication could include infringing and non-infringing treatment – for polyneuropathic pain (patented) or mononeuropathic pain (not patented))

SOME RECENT CASES

UK

- *Warner-Lambert Company LLC (Appellant) v Generics (UK) Ltd t/a Mylan and another (Respondents)* [2018] UKSC 56 – Lyrica (invalidity and non-infringement)

SOME RECENT CASES

France (Lyrica)

- First Instance Court of Paris, July 8th, 2016, *Generics U.K. and Mylan v. Warner-Lambert Company*, case No. 14/14370 - Lyrica (on the merits – validity only)
- First Instance Court of Paris, Presiding Judge Order, October 26th, 2015, *Warner-Lambert Company, Pfizer and Pfizer France v. Sandoz*, case No.15/58725 – Lyrica (summary proceedings on PI requests - no likely infringement)
- First Instance Court of Paris, Presiding Judge Order, December 2nd, 2016, *Warner-Lambert Company, Pfizer and Pfizer France v. Sandoz, Generic, Mylan, Teva Santé, Zentiva, BIOGARAN, Sanofi-Aventis France, Ranbaxy Pharmacie Generiques, Labo Laboratoires Eurogenerics, Hcs, Krka France, Arrow Génériques*, case No. 16/57469 - Lyrica (summary proceedings on PI requests - no likely infringement)

SOME RECENT CASES

The Netherlands

- District Court of The Hague, 5 April 2017, ECLI:NL:RBDHA:2017:3430, *Sun v. Novartis - Aclasta*
- The Hague Court of Appeal, 27 January 2015, ECLI:NL:GHDHA:2015:1769, *Novartis v. Sun - Aclasta*
- Supreme Court of the Netherlands, 14 April 2017, ECLI:NL:HR:2017:692, *Sun v. Novartis - Aclasta*
- The Hague Court of Appeal, 14 July 2015, ECLI:NL:GHDHA:2015:1899, *MSD v. Teva - Ribavirin*
- Supreme Court of the Netherlands, 3 November 2017, ECLI:NL:HR:2017:2807, *MSD v. Teva - Ribavirin*

SOME RECENT CASES

Germany

- Federal Supreme Court, 25 February 2014 –X ZB 5/13, GRUR 2014, 461 (German); IIC 2015, 470 (English) - Kollagenase
- Federal Supreme Court, 14 June 2016 – X ZR 29/15, GRUR 2016, 921 (German), IIC 2017, 208 (English) - Pemetrexed
- Hamburg District Court – 2 April 2015 – 315 O 24/15, BeckRS 2016, 9515; 2 April 2015 - 327 O 140/15, BeckRS 2015, 8822; 2 April 2015 - 327 O 132/15, BeckRS 2015, 8821; 2 April 2015 - 327 O 143/15, BeckRS 2015, 8691 (only German) – Lyrica
- Dusseldorf District Court, 5 July 2018 –4 c O 10/18, BeckRS 2018, 15603 – “estrogen blocker”*
- Dusseldorf District Court, 5 July 2018 – 4c O 47/17, BeckRS 2018, 15604 – “estrogen blocker”
- Dusseldorf District Court, 5 July 2018 – 4c O 46/17, BeckRS 2018, 15431 – “estrogen blocker”
- Dusseldorf Appeal Court, 5. May 2017 – W 6/17, GRUR 2017, 1107 – “Fulvestrant”
- Dusseldorf Appeal Court, 1 March 2018 – I-2 U 30/17, PharmR 2018, 306 - “Dexmedetomidin”**
- Dusseldorf Appeal Court, 9 January 2019, I-2 U 29/18 – “Fulvestrant” (not yet published, available at <http://eplaw.org/wp-content/uploads/2019/02/DE-AZ-Judgment-I-2-U-29-18.pdf>)
- *Fulvestrant (Faslodex®) from Astrazeneca for hormone therapy of metastatic breast cancer
- ** Dexmedetomidin (Precedex® or Dexdor®) from Orion for sedation

SOME RECENT CASES

Italy

- Milan Court of Appeal, 13 October 2014, *Giellepi Chemicals vs. Alfa Wassermann/Meda Pharma* (Alanerv)
- Court of Milan, 18 September 2015, *Actial Farmaceutica Lda vs. Mondelez Italia S.r.l.* (probiotic).

*Note: The Lyrica case did not go to court in Italy because the Italian Medicines Agency (AIFA) was cooperative and instructed physicians and pharmacists not to prescribe pregabalin for neuropathic pain. The measures that were taken forced the software used by pharmacists to show that Lyrica was the only permitted option for neuropathic pain, thereby substantially reducing the risk of an infringing off-label use.

DISCUSSION / QUESTIONS?

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