International Issues in Biopharma Patent Litigation

This paper provides a short overview of certain international considerations in Biopharma Patent Litigation.

Issues arising in domestic US litigation have been addressed in the *Commentary on Patent Litigation Best Practices: Unique Aspects of Biopharma Patent Litigation Chapter* which provides Best Practice recommendations to counsel, parties, and the courts on how to navigate the relevant statutes and unique landscape involved in biopharma litigation.

When it comes to international practice, although systems may differ significantly between the US and Europe, similar issues in Biopharma patent litigation do arise.

Entry on the market of generics and biosimilar: regulatory, patent and competition law

Biopharma patent litigation is an area where there is still less uniformization than in other technical areas (like in Telecoms for instance). The main reason being that this sector contains a regulatory layer that frameworks or has an impact on litigation, in particular in terms of timing.

As it stems from the *Commentary*, The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") created an Abbreviated New Drug Application (ANDA) procedure regulated by the Food and Drug Administration (FDA), that in certain circumstances allows generic drugs to be approved based upon the same safety and efficacy test data earlier produced and used by the drug's originator to gain the first FDA approval of that drug. Among the circumstances addressed are those relating to whether the proposed marketing of the generic drug would occur after the patents pertaining to the original "brand name" drug expire, or if not, whether the ANDA applicant can certify that the proposed generic product would not infringe any valid claim of the originator's patents pertaining to the proposed generic product[1]. This Act also establishes a framework for addressing patent disputes when a generic manufacturer seeks to obtain FDA approval of the proposed generic product. The Act first requires the originator of each FDA-approved drug to list its patents pertaining to that drug in an FDA-maintained registry, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."[2] This framework then requires of each generic manufacturer filing with the FDA as part of its ANDA a "patent certification" in one of the following categories: (1) that the drug has not been patented; (2) that the patent has already expired; (3) that the generic drug will not go on the market until after the expiration of the relevant Orange-Book-listed patents; or (4) that each relevant Orange-Book-listed patent is not infringed or is invalid.[3] The fourth category of certification allows the originator to bring an infringement action and if such an action is commenced, approval of the ANDA is automatically stayed for 30 months while the litigation proceeds.

In the US, listing of drugs on the Orange Book is therefore an effective tool to limit launch at risk of generics or biosimilars. In the last two years, the US Federal Trade Commission ("FTC") has become much more active in seeking to police Orange Book patent listings. In 2022, in *Jazz Pharmaceuticals v. Avadel CNS Pharmaceuticals*, the FTC filed an amicus brief in relation to a potential abuse of the Orange Book listing process arguing that a patent listed by Jazz claiming a so-called REMS system for distribution of the reference listed drug distribution

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2 This publication lists all commercial drug products approved in the United States along with the patents relevant to the active drug ingredient, as well as formulations, inert ingredients, and uses. Typically listed patents include compound patents, formulation patents, and method of treatment or use patents.

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system did not to meet the Orange Book requirements. By statute, only patents claiming a drug or a method of using the drug may be listed in the Orange Book. In September 2023 the FTC issued a statement cautioning drug manufactures against improper listing of patents in the Orange Book. The FTC indicated that in its view such improper listings "may constitute an unfair method of competition in violation of Section 5 of the FTC Act" and "may also constitute illegal monopolization." The FTC further stated that it intends to take legal action against what it views as improper Orange Book listings, including potentially seeking criminal penalties against pharmaceutical company employees who sign the listing submissions. In November 2023, the FTC sent letters to around ten pharmaceutical companies asserting that approximately 100 patents had been improperly listed in the Orange Book, and demanding that they be delisted. These patents mostly pertain to drug delivery devices. The Panel in Munich will discuss these recent issues.

In Europe, application for marketing authorization of medicinal products is subject to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency. It provides 8 years of data exclusivity during which the marketing-authorisation holder benefits from the exclusive rights to the data. This means that a generic or biosimilar applicant cannot cross-refer to this data in support of its own marketing authorization. After that period it is possible to use the abbreviated application for a marketing authorization (based on the innovator's data). But it is followed by 2 years of market protection during which a generic or biosimilar cannot be placed on the market. One additional year of market protection can be obtained in a case of a new therapeutic indication which brings significant clinical benefit in comparison with existing therapies. Generics or biosimilars can therefore not come on the market before 10 to 11 years from the grant of the marketing authorization to the innovative product. After that period, and although patent rights may still be in force, generics and biosimilars can come on the market. With no more regulatory protection, the patentees are therefore relying on their patents and the possibility to obtain injunctions in order to have their IP rights respected.

But the EU competition authority is closely monitoring the activities of pharmaceutical companies and recently launched investigations against Teva for potential misuse of the patent system accusing Teva of trying to extend its patent monopoly through the filing of divisionals. The panel will address this issue.

In Europe, the possibility of filing Arrow declarations has also developed in order to avoid litigating over numerous divisionals by obtaining a decision saying that a specific intended commercial product or process would have been obvious at a specific date over the prior art. This practice is not available in all EU countries and it remains to be seen whether the UPC will offer that possibility to litigants.

Patentability: enablement (US) vs plausibility (EU)

In the Biopharma field, obviousness and enablement (or inventive step and sufficiency of disclosure in Europe) are often at the core of disputes when patentability / validity is at stake. In March 2023, the Enlarged Board of Appeal of the European patent office, in the G2/21 decision, gave some guidance as to whether post-filed evidence to prove a technical effect is admissible and the conditions thereof.

Takeaways from the first UPC decisions

Although no decision on the merits has been handed down yet, firsts decisions in preliminary injunction proceedings give some guidance on how to handle litigation and obtain immediate remedies as preliminary injunctions in front of the Unified Patent Court. The recent decision from the Court of Appeal of the UPC lifting a preliminary injunction also provides interesting aspects to consider.