Pharmaceutical Patent Litigation Basics and Discussion of Recent Cases and Trends

By

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I. INTRODUCTION

To the uninitiated, pharmaceutical patent litigation can seem wholly separate from patent litigation. The substantial interplay with the Federal Food, Drug, and Cosmetic Act[1] and claims commonly reciting chemical structures and formulas represent two such differences. However, once one moves past these initial differences and becomes familiar with pharmaceutical patent litigation, one will realize that pharmaceutical patent litigation is for the most part patent litigation. To help initiate the novice, we first provide a broad overview of pharmaceutical patent litigation, starting with the various approval pathways, exclusivities, and other frequently used terms. Next, we will discuss some recent cases and growing trends in pharmaceutical patent litigation.

II. PHARMACEUTICAL LITIGATION BASICS

As Hatch-Waxman litigation originates with a pharmaceutical company deciding to develop a generic version of a drug, this section will provide a high-level overview of the various approval pathways for a drug to be approved by the FDA, as well as the various regulatory exclusivities that the FDA provides to encourage drug development.

A. Pharmaceutical Drugs

1. Approval Pathways

a) New Drug Applications (NDAs)

[1] *See* FD&C Act § 505(j), codified as 21 U.S.C. § 355(j).

The first approval pathway is called a New Drug Application, or NDA.[2] An NDA is an application submitted by a pharmaceutical company seeking the FDA's approval of a new drug.[3] This pathway is generally very time and resource intensive, as the company must submit full reports of detailed investigations into safety and efficacy, among other things.[4]

b) Abbreviated New Drug Applications (ANDAs)

The second approval pathway is called an Abbreviated New Drug Application, or ANDA.[5] An ANDA is an application submitted by a pharmaceutical company seeking approval of a therapeutic equivalent[6] of a previously approved drug ("listed drug").[7] The ANDA must show: i) that the active pharmaceutical ingredients ("APIs") of the new drug are the same, or if not, they do not differ in safety and effectiveness from the listed drug[8]; ii) that the new drug's route of administration, dosage form, and strength are the same, or if not, they do not differ in safety and

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[2] *See* FDA's Determining Whether to Submit an ANDA or a 505(b)(2) Application, Guidance for Industry, May 2019, p. 2 ("ANDA or 505(b)(2) Guidance"), *available at* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM579751.pdf; *see also* FD&C Act § 505(b)(1), codified as 21 U.S.C. § 355(b)(1).

[3] *See* FD&C Act § 505(b)(1), codified as 21 U.S.C. § 355(b)(1).

[4] *See id.*; *see also* ANDA or 505(b)(2) Guidance, *supra* note 2, at 2.

[5] *See* ANDA or 505(b)(2) Guidance, *supra* note 2, at 2; *see also* FD&C Act § 505(j), codified as 21 U.S.C. § 355(j).

[6] *See* 21 CFR § 314.3 ("Therapeutic equivalents are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.")

[7] *See* FD&C Act §§ 505(j)(2)(A), codified as 21 U.S.C. § 355(j)(2)(A).

[8] *See* FD&C Act §§ 505(j)(2)(A)(ii), codified as 21 U.S.C. § 355(j)(2)(A)(ii).

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