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Intellectual Property Alert

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Gut check: The FDA approves microbiome-based therapies, with future approvals expected

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Recent regulatory approvals create a path for a host of microbiome-related products to be developed, patented, and sold.

What's the Impact?

- The regulatory approvals of rCDI treatments Biomictra™, Rebyota™, and VOWST™ pave the way for companies to obtain FDA approval for other microbiome-related treatments.
- We anticipate that patent enforcement and challenges to those patents relating to approved products will lend certainty to the strengths of granted microbiome patent claims, spurring greater investment in microbiome-related products.

The commercial development of new drug therapies relies heavily on patent protection, and while Gut Check generally focuses on patent issues as they affect microbiome-related products, regulatory approval to actually sell the product is the linchpin for commercial viability for any drug. Much of the microbiome space is minimally regulated; in the US, the Food and Drug Administration (FDA) does not currently regulate foods and dietary supplements containing probiotics. However, if a company wants their microbiota therapy designated as a prescribable pharmaceutical and thus potentially covered by health insurance, they must conduct clinical trials and apply for approval by the FDA. In the maturing microbiome therapeutics arena, despite

a significant number of ongoing clinical trials, the entire field has been anxiously awaiting the first regulatory approvals.

That time has finally arrived. Australian regulators approved BiomeBank's Biomictra™ donor-derived fecal microbiota transplant (FMT) product for the treatment of recurrent *Clostridium difficile* infection (rCDI) in November of last year, marking the first approved human microbiome therapeutic in the world. In the US, shortly thereafter, on November 22, 2022, the FDA issued its first approval for a microbiome-based human therapy , for Rebyota™ from Ferring Pharmaceuticals Inc. Rebyota™ is a donor-derived, rectally-administered FMT product also approved for use in the treatment of rCDI, which affects 500,000 patients, leads to 30,000 deaths, and costs an estimated $1 billion to $6 billion annually in the US. Treatment with Rebyota™ is estimated to cost $9,000 per dose, which could be reduced to as low as $100 by insurance.

More recently, on April 26, 2023, the FDA announced the approval of Seres and Nestle's VOWST™ (also called SER-109) to treat rCDI after the conclusion of the ECOSPOR clinical trials. The VOWST™ capsules contain bacterial spores purified from healthy human donor feces, which have been pre-tested for pathogens. VOWST™ is the first fecal microbiota product approved by the FDA for *oral* administration. Seres announced that they plan to sell VOWST in June 2023 at $17,500 per course of treatment (4 capsules taken orally once daily for 3 consecutive days).

The regulatory approvals of Biomictra™, Rebyota™, and VOWST™ represent a watershed moment. While they are each directed to the treatment of rCDI, a varied pipeline of different microbiome-related drugs is in clinical trials for a variety of different indications. In the US, the FDA website lists at least 100 active or completed clinical trials that mention "microbiota." Maat Pharma recently started a Phase 3 trial of MaaT013, an enema-administered FMT therapy, for patients with acute Graft-vs-Host-Disease (GvHD). Therapies in the pipeline also include pharmaceuticals that comprise single species and defined consortia of microorganisms. Such products contrast with the currently approved FMT therapies, which comprise an undefined number of unspecified bacterial species manufactured from donor fecal samples. Although such fecal samples are screened for known pathogens before FMT manufacture, they present more health concerns than single species or consortia-based therapies, which are not isolated from feces and are manufactured using known lab-grown bacteria. FMTs also present issues regarding donor supply and microbiota uniformity and consistency compared to single species or defined consortia therapeutics. As but one example of a consortium therapeutic, Vedanta's VE202 is in a Phase 2 clinical trial for Ulcerative Colitis.

Where products are approved and beginning to be sold, we anticipate litigation enforcing microbiome patents to take off. Patent enforcement and challenges to those patents will lend certainty to the strengths (and potential weaknesses) of granted microbiome patent claims. Expect such certainty, combined with the recent and likely ongoing regulatory approvals, to spur greater investment in this space.

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