a license for use of the innovator's system. The FDA is expressly authorized (but not required) to "negotiate a voluntary agreement" for the use of the shared system.* It remains to be seen how this requirement will affect the approval and availability of generic versions of drugs subject to special distribution requirements.

Copyrighted Labeling

One innovator drug manufacturer attempted to block generic competition by copyrighting portions of its FDA-approved labeling and then seeking an injunction under federal copyright law against the ANDA sponsor on the basis that its copyright was being infringed. The court ultimately rejected this argument, concluding that the Hatch–Waxman requirement for the "same" labeling takes precedence over copyright law. However, that court recognized that use of the copyrighted materials in a context other than labeling (such as advertising) could well constitute copyright infringement.†

Antitrust Considerations

Agreements between competitors or potential competitors that have the effect of restricting competition may run afoul of federal and state antitrust laws and similar laws. Although a discussion of this area is beyond the scope of this chapter, it is worth mentioning that any generic company would be well advised to consult with antitrust counsel with expertise in pharmaceutical settlements as it develops its business and patent litigation plans.

The MMA requires that certain agreements (including oral agreements) affecting ANDAs (but not 505(b)(2) NDAs) be reported to the FTC and the Antitrust Division of the Department of Justice within 10 business days after they are executed. Specifically, the reporting requirement concerns agreements between the sponsor of a Paragraph IV ANDA and the brand-name drug company regarding the manufacture, marketing, or sale of either the brand-name drug or the ANDA drug or regarding the 180-day exclusivity period. Agreements between two Paragraph IV ANDA sponsors regarding the 180-day exclusivity period must also be reported. Purchase orders for raw materials, equipment and facility contracts, employment or consulting contracts, and packaging and labeling contracts are exempt from the reporting requirement. Information reported to the government is exempt from public disclosure under the Freedom of Information Act (FOIA). The failure to report in timely fashion can result in a civil penalty.‡ The FTC issues an annual report regarding all agreements filed with that agency.§

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* 21 USC § 355-1(i) (as added by FDAAA).

† *SmithKline Beecham Consumer Health Care, L.P. v. Watson Pharmaceuticals, Inc.*, 211 F.3d 21 (2d Cir. 2000) (involving nicotine gum).

‡ MMA, §§ 1111–1115.

§ The FTC FY 2011 report is available at http://www.ftc.gov/os/2011/10/1110mmaagree.pdf. Accessed June 13, 2013.