

BIOINSIGHTS



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We are pleased to share this latest issue of Wiggin and Dana's BioInsights Newsletter. We circulate this newsletter by e-mail periodically to bring to the attention of our colleagues in the biotechnology and life sciences industry reports on recent developments, cases and happenings at Wiggin and Dana. We welcome your comments and questions.

Emerging Antitrust Guidance on IP Licenses

On January 12, 2017 the Department of Justice ("DOJ") and the Federal Trade Commission ("FTC") (collectively the DOJ and FTC are the "Agencies") issued updated Antitrust Guidelines for the Licensing of Intellectual Property ("New Guidelines"). These new Guidelines modernize the FTC and DOJ's 1995 Guidelines on the licensing of intellectual property (the "1995 Guidelines").

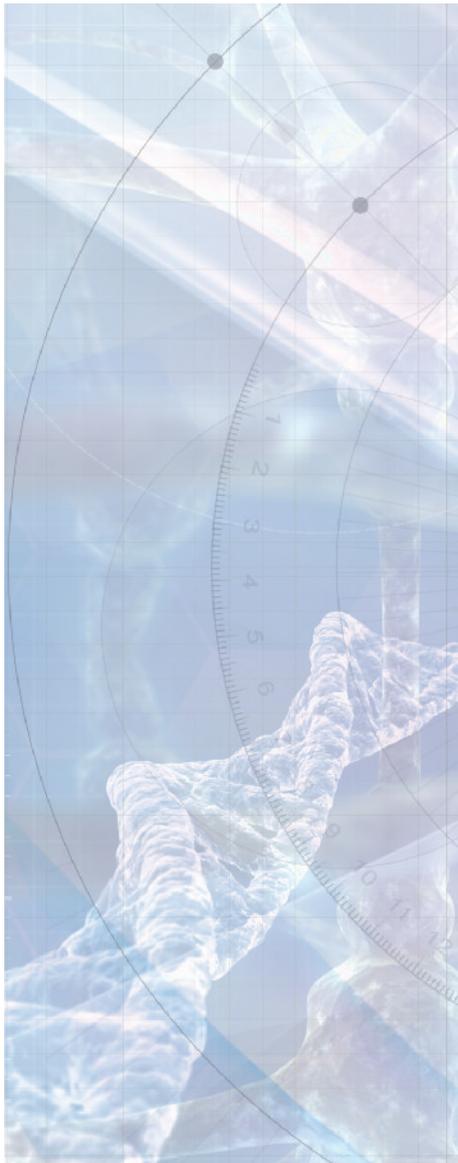
The New Guidelines revise the three pillars of the 1995 Guidelines. Briefly, they assert that:

- 1) IP licensing is neither particularly free from scrutiny under the antitrust laws, nor is it particularly suspect under the laws;
- 2) The Agencies will not presume that IP necessarily confers market power, especially if close substitutes are available; and
- 3) IP licensing may exhibit pro-competitive effects by facilitating the integration of the licensed IP with complimentary factors of production.

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IndustryNEWS



Emerging Antitrust Guidance CONTINUED

The Agencies' focus on an "effects-based analysis" will generally not result in enforcement action if an IP license: (1) facially lacks an anticompetitive restraint, and (2) the parties, in the aggregate, account for less than twenty percent of the impacted market. The Agencies will determine whether to apply either the traditional "*per se*" or "rule of reason" frameworks based on whether the restraint in question can be expected to contribute to "an efficiency-enhancing integration of economic activity".

Though fundamental philosophies of the New Guidelines and the 1995 Guidelines remain constant, there are significant changes. Importantly, the New Guidelines state that licenses comprising resale price maintenance provisions are not *per se* illegal but rather will be analyzed under a rule of reason analysis. Additionally, the New Guidelines state that though the Agencies reserve the right to review a unilateral refusal to share IP with competitors, such refusal does not generally result in antitrust liability

The New Guidelines address the impact of IP licenses on research and development markets, and acknowledge that analytical approaches to traditional markets may not adequately address anti-competitive effects when applied to research and development markets. As such, the Agencies will rely on specialized assets to independently identify pertinent facts including evidence of market participants' assessments of the significance of a particular research and development project.

Though non-exclusive IP licenses generally do not present antitrust concerns, exclusive licenses may be anti-competitive if there is a horizontal relationship between the licensor and licensee. Specific examples of IP license provisions that may be subject to agency scrutiny include grant-backs, patent pools, and cross-licensing amongst competitors that collectively possess market power. Depending on the licensor's market power, such provisions may also be 'hardcore restrictions' under the European Union technology transfer block exemption regulations.

Because IP can be more easily misappropriated than tangible property, the Agencies recognize that certain restrictions may be permissible in IP licenses that might be deemed anti-competitive in other contexts. To that end, the Agencies will analyze both the pro- and anti-competitive effects in deciding whether to challenge a particular IP license. This analysis is necessarily qualitative as access

to alternative technologies, duration of restraints, expected market efficiencies, and the practicality of less restrictive alternatives vary greatly between industries, markets, and specific contexts.

The New Guidelines offer specific guidance on grant-back license provisions, typically understood to be a prospective grant from the licensee to the licensor with respect to licensee's future improvements in the licensed technology. Nonexclusive grant-backs are generally presumed to have pro-competitive effects. Where the licensor has market power with respect to the underlying technology, the Agencies will apply a rule of reason analysis in balancing the pro- and anti-competitive effects. The Agencies recognize that exclusive grant-backs may have anti-competitive effects, including reducing the licensee's incentive to further develop the underlying technology. This approach parallels the 2014 EU Guidance on technology transfer block exemption regulations that removes all exclusive grant-back obligations from their safe harbor provisions, including non-severable improvements.

Certain IP transfers such as exclusive licenses and asset sales will continue to be analyzed pursuant to the Agencies' merger guidelines including Section 7 of the Clayton Act, Sections 1 and 2 of the Clayton Act, and Section 5 of the FTC Act. IP licenses with exclusive license grants may be subject to the Hart-Scott-Rodino Pre-Merger Notification rules if the size-of-person thresholds and size-of-transaction threshold (recently increased to U.S. \$80.8 million) are met.

The New Guidelines do not clarify certain emerging issues, including standard-essential patents, reverse payment settlements, and activities by patent assertion entities (colloquially known as "patent trolls").

As noted by Assistant Attorney General Renata Hesse, the New Guidelines seek to support "procompetitive intellectual property licensing that can promote innovation." In all, the New Guidelines suggest an assertive approach by the Agencies - both in terms of geographic reach and subject matter scope - coupled with the implementation of a practical effects-based analysis intended to foster competition across all industries.



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FirmDEALS

Since 2015, Wiggin and Dana represented pharmaceutical, biotechnology and life sciences clients in partnering transactions totaling in the aggregate over \$6 billion. Exemplary transactions include:

- BioInvent International AB's collaboration and license agreement with Pfizer Inc. to develop novel immuno-regulatory antibodies to treat cancer. BioInvent will apply its unbiased translational drug discovery platform (F.I.R.S.T.TM) to identify therapeutics for tumor-associated myeloid cells. BioInvent will receive approximately \$10 million in early payments. Assuming five antibodies are commercialized, development milestone payments of more than \$500 million could be realized, as well as double digit royalties.
- Cormorant Pharmaceuticals AB's stock purchase agreement in connection with the sale to Bristol-Myers Squibb Company (BMS) of all of Cormorant's outstanding capital stock and in which BMS obtained full rights to Cormorant's lead antibody candidate, HuMax-IL8. HuMax-IL8 is a Phase 1/2 monoclonal antibody targeted against interleukin-8 (IL-8) that represents a complementary immuno-oncology mechanism of action to T-cell directed antibodies and co-stimulatory molecules. Payments by BMS to the Cormorant equity holders could reach a total of \$520 million if all clinical and regulatory milestones are achieved.
- Probi AB's (NASDAQ OMX) acquisition of the operations of TNTGamble, Inc. d/b/a Nutraceutix[®], a leading U.S. manufacturer and supplier of probiotics, headquartered in Redmond, WA, with operations in Lafayette, CO.
- Nuevolution A/S's collaboration and license agreement with Almirall S.A. to commercialize novel ROR t inhibitors for treatment of inflammatory skin diseases including psoriatic arthritis. Nuevolution will receive €11.2 million upfront and is eligible to receive up to €172 million in development and regulatory milestone payments and up to €270 million in tiered commercial sales milestones. Nuevolution would also be entitled to receive royalties on future sales.
- Nuevolution A/S's collaboration and license agreement with Amgen, Inc. to undertake a research collaboration to develop and commercialize novel therapeutics in the areas of oncology and neuroscience. Nuevolution will apply its Chemetics[®] drug discovery platform to discover and advance potential therapeutics of interest to Amgen. Amgen has an exclusive option to obtain all rights to successfully developed programs. Nuevolution is eligible to receive up to \$410 million in upfront and milestone payments per target for up to five targets, and would also be entitled to receive royalties on future sales.

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