



#### PRACTICE AREAS

- · Access to Biodiversity
- Anti-counterfeiting
- Contracts
- Regulatory Data Protection
- Food & Drug Law
- Intellectual Property
- Licensing & Technology
- Litigation
- Patents
- Regulatory Law
- Trade Secrets & Regulatory
- Unfair Competition
- Counseling and Transactional
- · Life Sciences
- Science & Patent Specialists

#### LANGUAGES

- Portuguese
- English
- French
- German

# VIVIANE KUNISAWA

# Partner

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#### **BIOGRAPHY**

Viviane Kunisawa is a partner at Licks Attorneys and is one of our leaders at our Sao Paulo office. Ms. Kunisawa leads the life science regulatory compliance team including the protection of regulatory data and access to biodiversity. She has extensive expertise on intellectual property, unfair competition and regulatory law, by leading complex patent litigation and regulatory compliance cases. Viviane's solid experience includes nearly eight years as an in-house counsel at a multinational company in the agribusiness sector, where she managed intellectual property strategies and provided legal support to the government and regulatory affairs departments on the approval of products before the Brazilian government authorities, advising on risk mitigation and value capture, so as to ensure freedom to operate for the business, as well as led advocacy initiatives via industry associations.

# REPRESENTATIVE CASES

- Leadership of initiatives to ensure compliance of the legislation on access to genetic resources, that implements the Convention on Biological Diversity, establishing internal process in Brazil (even before a regional or global process is created) and, later, supported the global team responsible for the legal issues related to the company's germplasm;
- Managed legal strategy of the submission for registration and marketing of a product in Brazil (with revenue forecast of USD 90M annually), based on the protection of the regulatory dossier for 10 years without its use for registration by equivalence, despite the longstanding availability of the product in other countries. Protection confirmed by the ANVISA afterwards;
- Managed legal strategy of an agrochemical sold under authorization for emergency use to ensure compliance of the specific legislation, assessing risks and implementing mitigation measures;



- Supported advocacy activities for the express implementation of risk analysis in the registration process of agrochemicals into the Brazilian legislation;
- Managed legal strategy during the ANVISA's reevaluation proceeding of an agrochemical product, developing thesis according to which the undue use of agrochemicals for suicide should not be a ground for cancelling a product's registration.

# PROFESSIONAL HIGHLIGHTS

- Best Lawyers 'Recommended' Intellectual Property Law (2023);
- IAM Patent 1000- 'Leading Expert' in Patent Litigation (2022)
- The Legal 500 'Recommended' Life Sciences Practice (2022);
- 'EXCELLENT' Life Sciences (2021)

#### **AFFILIATIONS**

- Brazilian Bar Association Rio de Janeiro Section (OAB/RJ);
- Brazilian Intellectual Property Association (ABPI);
- Member of the Munich Intellectual Property Law Center MIPLC Alumni Network.

# **EDUCATION**

- Ph.D., Ludwig-Maximilians-Universität München (LMU) Munich, Germany, 2015;
- Research Fellow, Max Planck Instituto for Innovation and Competition (MPI-Munich) Munich, Germany, 2006-2009;
- Visiting Researcher, Chizaiken (Institute of Intellectual Property IIP) Tokyo, Japan, 2007;
- LL.M., Intellectual Property Law. Munich Intellectual Property Law Center (MIPLC) Munich, Germany, 2006;
- LL.B., Universidade do Estado do Rio de Janeiro UERJ, Rio de Janeiro, Brazil 2002.

# **PUBLICATIONS**

- "The TRIPS Agreement Implementation in Brazil Patents in the Pharmaceutical Area". MIPLC Studies, vol. 25. Nomos, Germany, 2015.
- "Protecting Plant Varieties under the Brazilian Intellectual Property Law System". In: Biotechnology and Life Sciences Sector: strategies for growth, survival and patent protection, Financier Worldwide, p.41-42, 2010 (co-authorship with Ricardo Dutra Nunes).
- "The Brazilian Patent System: Challenges in the Biotechnology Field". In: Shimanami, Ryo (ed.), The Future of the Patent System [Book celebrating IIP's 20th Anniversary], Institute of Intellectual Property IIP, Japan, 2009.
- "Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil". The Journal of World Intellectual Property, v. 12, n. 4, p. 297-316, 2009.
- "Brasilien Aktuelle Entwicklungen hinsichtlich der Rolle der nationalen Gesundheitsbehörde ANVISA im Erteilungsverfahren für pharmazeutische Patente". GRUR INT, Munich, n. 1/2009, p. 88-89, Jan. 2009.



- "O Direito de Informação do Consumidor e a Rotulagem dos Alimentos Geneticamente Modificados. Revista de Direito do Consumidor", São Paulo, n. 53, Jan./Mar. 2005.
- "O sistema de propriedade intelectual como fomentador da inovação tecnológica. Revista da ABPI Associação Brasileira da Propriedade Intelectual", São Paulo, n. 76, p. 16-21, May/Jun. 2005 (co-authorship with Luiz Leonardos).
- "Os transgênicos e as patentes em biotecnologia". Revista da AJUFE Associação dos Juízes Federais do Brasil, Brasília, n. 77, p. 315-344, Jul./Sept. 2004.

# **ARTICLES**

- The Amazon in the Limelight: An Opportunity for Biotech in Brazil, Genetic Engineering & Biotechnology News, 2023;
- OPL 6.299/2022 e a falsa dicotomia entre agricultura e meio ambiente, Conjur, 2022;
- Brasil ratificou Protocolo de Nagoya, mas não está claro como vai cumprir, Globo Rural, 2021;
- <u>Drones na agricultura: desafios da regulação atual e agricultura 4.0, Estadão, 2020.</u>
- O Protocolo de Nagoia e a sua esperada ratificação pelo Brasil, Estadão, 2020.