

The Life Science Litigator

Like many sectors, it's an extremely challenging time for life sciences; from the increasing regulation to the pressure facing pharmaceutical, biotechnology and medical device companies to manage costs in order to both make a profit and remain competitive. What's more, in our increasingly global economy, life science companies that operate across international boundaries are increasingly subject to complex multijurisdictional patent litigation.

There are few industries in which patents play as important a role as they do in the life sciences sector and despite a company's best efforts or intentions, sometimes disputes simply cannot be avoided. When they do, it is absolutely crucial to have access to the best legal advice available to solve strategic problems and resolve the most contentious of disputes. Acquisition Internationals speaks to the experts.

Dierks+Bohle is specialized in advising national and international clients in the healthcare and life sciences. The firm particularly represent manufacturers and distribution companies of drugs and medical devices in product liability matters, competition law as well as anti-kickback or physician self-referral law. Dr. Ben Backmann is partner in the Berlin based health care and life science law firm Dierks+Bohle.

Biolato Longo Ridola & Mori Studio Legale Associato was established on the 1st January 1985 as a result of a split of former Studio Avv. Ercole Graziadei one of the first law firms in Italy organized to assist foreign

clients. Linda Longo is a lawyer partner at Biolato Longo Ridola & Mori Studio Legale Associato and has been working in the life science sector since her joining the firm in 1985 assisting pharmaceutical industries and medical devices companies in respect to regulatory, compliance and competition legal issues.

What gives you an advantage over local and global competitors in your areas of expertise?

Dr. Ben Backmann: "With 25 lawyers concentrated in one office we are capable to cover all legal aspects of our health care and life science clients. We are providing a long-tested network with partner law firms all over the world which enables us to represent our clients on an international basis. As we are working in a highly regulated field our proximity to politics in Berlin is of particular advantage."

Linda Longo: "It is a very specialised sector and experience and knowledge of the specific rules is very important to provide timely and cost effective advice."

Who is a typical client?

Dr. Ben Backmann: "We represent all kinds of health care providers but especially leading pharmaceutical companies and medical device manufacturers with a focus on biomedical technology and endoprosthetics."

Linda Longo: "Italian subsidiary of a multinational pharmaceutical group -; US and UK law firms specialised in the life science sector."

What are the most common types of life science disputes leading to litigation?

Dr. Ben Backmann: "The health care business is a competitive market that requires product innovations and intelligent marketing structures which in turn provoke unfair competition disputes and increases the risk of product liability."

Linda Longo: "In Italy mainly disputes before the Administrative Courts to challenge decisions of the Regulatory Authority in respect to pricing, marketing authorisation of medicinal products as well as disputes concerning public tenders for supply of products to Public Hospitals and Health structures."

What steps can be taken to avoid life science disputes in the first place?

Dr. Ben Backmann: "We place particular emphasis on effective risk management as key to reducing exposure to civil and criminal liabilities. ADRs like mediation are still on the development path in Germany."

Linda Longo: "Considering the nature of the litigations (mainly to obtain fair, appropriate and timely decisions by the Regulatory authority of by the local governments) the clients decide to start litigation only in very extreme situations when all the other remedies are not successful."

Why do patents play such a key role in the life science industry?

Linda Longo: "Because only with a full and adequately long patent protection

industry can recover the cost of the research and clinical trials necessary to develop the product."

How do you formulate a multijurisdictional patent litigation strategy? What methods do you use?

Linda Longo : "Since ordinary litigation in Italy may take an outrageous length of time, including patent litigation, the legal actions which can be taken to obtain an effective result are the request of urgency measures or recognition of a foreign judgment to be enforced in Italy.

Can you please highlight the key challenges in coordinating multijurisdictional product liability litigation?

Dr. Ben Backmann: "To coordinate successful multijurisdictional product liability litigations you need to understand all technical and scientific aspects of the products as well as the commercial concerns of your client. The sued company needs to speak with one voice worldwide while the legal specifics of each country and each single case need to be respected."

Can you please highlight the key challenges in coordinating litigation regarding public tenders?

Linda Longo : "Supply of medicinal

products to Italian Health structure is mainly subject to the public procurement rules. Several litigations regard the criteria for the classification of "equivalent" medicinal products and are aimed to avoid that innovative and more costly products are compared to less recent medicinal products. Timing to take legal actions before the Administrative Court against irregularities of the tender process is very strict: the client acting as claimant or as the defendant must receive prompt assistance in order successfully take legal action or defend his position."

What makes you the right life science litigator? How do you ensure satisfaction for your clients?

Dr. Ben Backmann: "Through a long international experience of advising and representing clients in cross-border product liability and competition law disputes and a highly focused team of regulatory experts, we are positioned to credibly articulate and advocate our interpretation of the applicable regulations as they relate to these matters."

How do you ensure satisfaction for your clients?

Linda Longo : "Providing cost effective and timely advice and assisting in analysing possible violations of the rules including EU Directives."

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