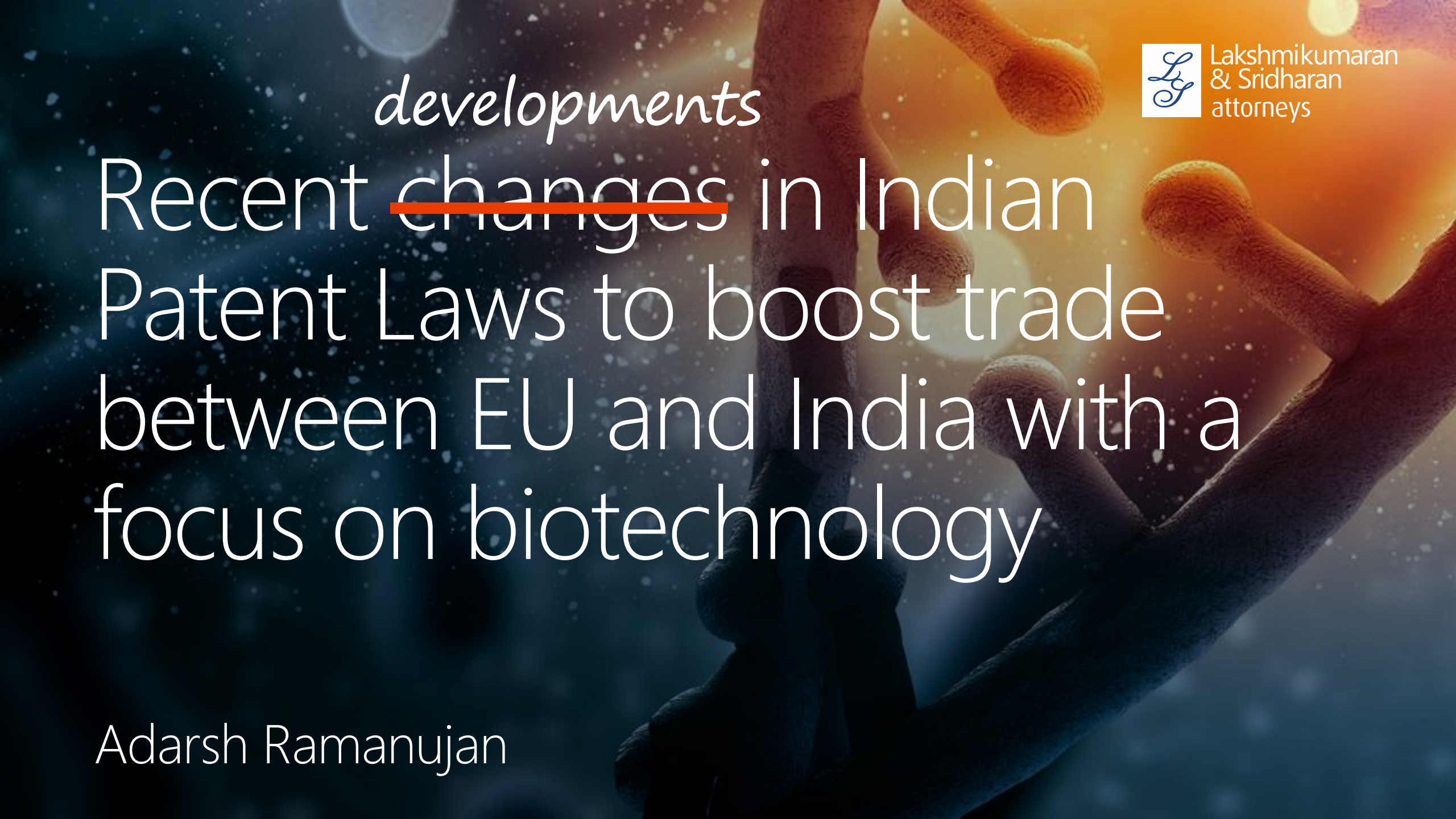

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developments

Recent ~~changes~~ in Indian Patent Laws to boost trade between EU and India with a focus on biotechnology

Adarsh Ramanujan

Agenda

Transparency and Reliability
Section 3(d)
Reducing Section 8 burden
Compulsory License

Transparency and Reliability

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Issuance of guidelines

- Open to public for comments
- Consistency across various patent offices;
- Pharma / biotech guidelines: reassurance of similar standards of patentability

IPR helpdesk

- Available on the IPO website
- Other capacity building and human resource expansion in the Patent Office

A vigilant IPAB and High Court

- Recent decisions of the IPAB and High Courts
- Clarifying open issues and keeps Patent Office in check

Section 3(d)

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Seek clarity

- Known substance?
- How is it a 'derivative'?
- What basis to assert same efficacy?

Support

- At least an assertion in specification
- Data produced later is being considered

What data?

- At least, animal studies (Supreme Court)
- Comparative data
- Supreme Court did not exclude BA in all cases

Patent Office considers TI and reduction in toxicity to be relevant evidence

May be, Quicker response, reduction in frequency and time-period of treatment?

The *GSK* decision (IPAB, 2013) emphasizes on the burden of proof on the challenger

"the position that emerges is that just increased bioavailability alone may not necessarily lead to an enhancement of therapeutic efficacy. [it must] be specifically claimed and established by research data."

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IPAB requires strict adherence

Delhi High Court suggests otherwise

Best Practice?

- High Court brings in materiality and intent as relevant considerations
- Conclusion seems logical, though approach may need re-visit
- Object to vague requests, citing *GSK* (IPAB)

Compulsory License

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Negotiate

- BDR Pharma case – requires CL applicants to also make effort

Have faith in Judicial approach

- Patentee's perspective's are always accounted (Nature of invention / industry and account for efforts of patentee)
- Applicant's ability to work the invention

Consider license manufacturing

- IPAB in *Bayer* did not rule out 'working' by importation
- IPAB in *Bayer* did not rule out license manufacturing
- Demand fulfilment is the key

Pricing Strategy

- Draft report of Committee on Pricing of Patented Products
- Provides a reasonable base-line

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Thank you.

adarsh.r@lakshmisri.com

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The firm has nine offices located across India in New Delhi, Mumbai, Chennai, Bengaluru, Hyderabad, Ahmedabad, Pune, Kolkata and Chandigarh. It specializes in the areas of Customs & International Trade, Taxation, Intellectual Property and Corporate law.

The firm has handled more than 40,000 litigation cases before various fora both in India and abroad including 2,000 cases before the Supreme Court of India.

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