ABHAY H. PANDE

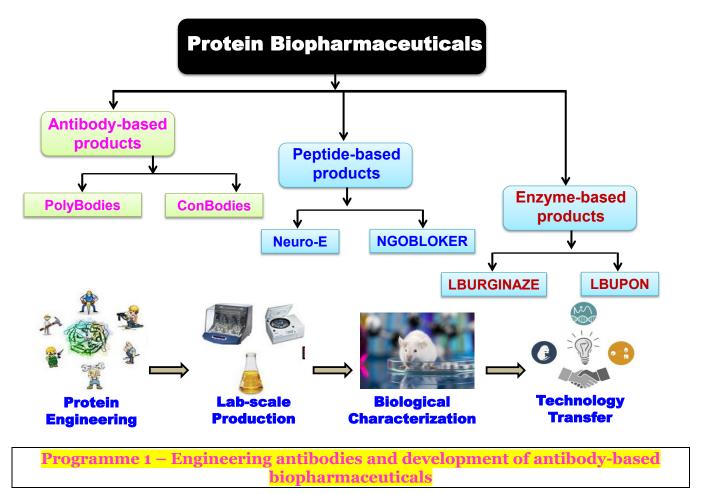
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Research experience (after PhD): > 24 years (PhD defended Feb 2000)

Research Area - Development of Protein Biopharmaceuticals

It is evident now that, in coming decade, the domestic as well as the international market for protein biopharmaceuticals will grow rapidly and will expand its share of the entire pharmaceuticals market. There is a dire need to develop NOVEL protein biopharmaceuticals and make them Available and Affordable to Jan-Manas (common man). My laboratory is involved in the development of Protein Biopharmaceuticals and the details of current research programs are summarized below:



In this program we are developing 2^{nd} generation antibodies (PolyBodiesTM) as well as conjugated antibodies (ConBodiesTM) for clinical use.

- BiSpekDAbTM, the first molecule we developed, is a bispecific antibody which targets both IL-23 & TNF- α and attenuates inflammation in animal models of inflammatory conditions (asthma, stroke, and others). (**patent # 17**). Detailed characterization of BiSpekDAbTM and other novel PolyBodies as well as ConBodies is currently going on in the lab (**patent # 12**, **15**, **16**).

- We are also engage in engineering and development of conjugated antibodies (ConBodies[™]) for therapeutic and diagnostic use.

Programme 2 – Engineering enzymes and development of enzyme-based biopharmaceuticals

In this program we are developing engineered enzymes, which are as follows:

- LBURGINAZE[™] is engineered human arginase 1 enzyme. LBURGINAZE exhibit enhanced *in vivo* pharmacokinetic as well as potent anti-cancer activity in multiple cancer models (**patents # 8, 10, 11**). We are developing this molecule for the treatment of Liver cancer.
- LBUPON[™] is an engineered human paraoxonase 1 enzyme that not only exhibits effective nerve agent-neutralizing activity but also possesses improved (*in vivo*) pharmacokinetic properties. Further characterization of LBUPON[™] is currently going on (in collaboration with DRDE, Gwalior & IRBA, France) (**patent # 1, 2, 9, 14**).
- We are also developing safe, effective, and environmentally friendly SsoPox enzymebased nanobioctatalyst for organophosphate decontamination. A panel of microbial enzymes is produced and immobilized on nanomaterials for efficient separation and reuse (**patent # 4, 5, 7**).

Programme 3 – Engineering peptides and development of peptide-based biopharmaceuticals

In this program we are developing engineered peptides, which are as follows:

- Neuro-ETM is apolipoprotein E-mimicking peptides which exhibit strong antiinflammatory and neurohealing properties. Neuro-E shows promising results in animal models of inflammation (pulmonary inflammation, cardiac inflammation and neuroinflammation) (**patent # 3, 6, 13**).
- NGOBLOKER[™] is engineered human endostatin molecule and has demonstrated desirable anti-angiogenic activity in the *in vivo* Chick Chorioallantoic Membrane (CAM) model. It is currently undergoing further characterization studies (**patent # 18**).

Technologies available for co-development:

BiSpekDAb[™]: Engineered Bispecific Antibodies for the Management of Multiple Inflammatory Conditions

1. Field: Chronic inflammatory diseases are significant burden on the global health. Recent scientific data suggest that targeting more than one cytokine (by one or more drugs) is more effective than targeting only one cytokine in controlling chronic inflammatory disease progression and associated symptom management.

2. Problem: TNF- α & IL-23 are key 'culprit' cytokines that are responsible for numerous inflammatory conditions. 06 TNF- α targeting biologics are approved and many more are being developed for <u>>35</u> <u>diseases</u>. The market size of TNF-blockers is expected to reach USD 47.32 bn (CGAR of 3.59% for 2024-2029). Similarly, 04 IL-23 targeting biologics are approved and >35 companies are developing 24 IL-23 Inhibitors for <u>36 diseases</u>. Market size of IL-23 blockers is 24.3 billion in 2023 and will grow at 12% CGAR, 2024-2032. While, the available TNF α and IL23 blockers are effective, they target only one cytokine (either TNF α or IL-23) and this limit their overall effectiveness. Thus, there is an urgent need to develop more effective agent(s) for the treatment and management of chronic inflammatory conditions.

 Need of the hour: Considering the success of TNF-α/IL-23 blocking biologics and their tremendous market size, there is an urgent need to develop biologic(s) that can target both IL-23 & TNF-α.

 Our solution: BiSpekDAb[™]: Engineered bispecific antibodies that target both IL-23 & TNF-α.

SPECIFICATIONS OF TECHNOLOGY:

1. Dual Action Mode: Novel engineered biologics that can target two different cytokines

2. Unique structural design: Permits good structural stability

3. Simple-n-cost effective production platform: High yield clone (*P pastoris*) and simple production process

 Superior efficacy: Target TWO pro-inflammatory cytokines (IL-23 & TNF-α) and effectively ameliorate inflammation by regulating IL-23/TNF-α signaling pathways

 Protected intellectual property: Indian patent filed; Freedom-to-operate (FTO) analysis ensures no infringement on existing products.

6. Made In India !!!

STATUS: Applied

PATENT

TRL STATUS: TRL3/4



BiSpekDAb™

LBURGINAZETM: Engineered Human Arginase 1 for the Treatment of Liver cancer

1. Field:

Liver cancer, the sixth most common cancer globally and the second-leading cause of cancer-related deaths, presents a critical public health threat. Diagnosis often occurs in advanced stages of the disease, aligning incidence with fatality rates.

2. Problem:

There are various treatment strategies available for liver cancer, including surgery, transplantation, and radiotherapy, which are typically used for early-stage cases. For intermediate and advanced stages, chemotherapy is commonly administered; however, it is associated with serious toxicity issues. Even at maximum doses, chemotherapy extends median survival by only 3-6 months. Thus, there is an urgent need to develop more effective agent(s) for the treatment and management of liver cancer.

3. Need of the hour:

The urgent need for safer, more effective treatments for Hepatocellular Carcinoma (HCC) is critical due to the high mortality and severe side effects of current therapies.

4. Our solution: LBURGINAZE[™], an engineered human arginase 1, is an effective anti-cancer biologic.

LBURGINAZE

PATENT STATUS:

Applied

TRL STATUS:

TRL3/4

SPECIFICATIONS OF TECHNOLOGY:

1. Fusion Protein Engineering: LBURGINAZE is an engineered human arginase 1 involved in arginine deprivation and manages liver cancer effectively.

2. Simple-n-cost effective production platform: High yield clone (*P pastoris*) and simple production process

3. Superior efficacy: LBURGINAZE has potential against broad spectrum of arginine auxotrophic cancers.

4. Protected intellectual property: Indian and International patent filed.

5. Made In India !!!

NEURO-E[™]: Engineered Human Apolipoprotein E mimetic peptide for the Treatment of Stroke

1. Field: Stroke is the 2nd most common cause of mortality globally. Each year, approximately 15 million people worldwide suffer from stroke. Of these, five million do not survive, and another five million are left permanently disabled, creating a significant burden on families and communities..

2. Problem: Currently tissue plasminogen activator (tPA) is the only approved drug for stroke treatment. However, its clinical use has serious limitations - *a narrow therapeutic window* of 3 - 4.5 h only and *neurotoxic & cytotoxic effects*. Furthermore, tPA can only dissolve clots (thrombolysis) and cannot heal or protect the affected tissues. Other medications used in stroke management are primarily supportive (e.g., blood thinners, anti-hypertensive agents) and serve mainly to reduce the risk of further stroke rather than address the immediate damage. Therefore, there is an urgent need to develop new agent(s) for the treatment and management of stroke.

 Need of the hour: The urgent need for safer, more effective treatments for stroke is critical due to the high mortality and severe side effects of current therapies.

 Our solution: NEURO-E[™], an engineered human apolipoprotein E mimetic peptide addresses these challenges

SPECIFICATIONS OF TECHNOLOGY:

1. Unique structural design NEURO-E is specifically designed to contain both LDL-R binding domain and the lipid-binding domain of native human ApoE, making it a highly efficacious to cross the blood-brain barrier, target brain cells, and promote repair.

2.Neuroprotective Properties: By mimicking ApoE natural role, NEURO-E[™] protects neurons from damage caused by ischemia, oxidative stress, and inflammation, which are major contributors to stroke injury.

3.Enhanced Neural Repair: NEURO-E[™] supports synapse formation, axonal growth, and neurogenesis in the hippocampus, all essential for cognitive recovery and motor function post-stroke.

4. Protected intellectual property: Indian patent filed.

5. Made In India !!!

PATENT STATUS:

Granted

TRL STATUS: TRL3/4

NEURO-E



Developmental stages of programs:

	Engine ering	Lab scale production	Animal Studies (PoC)	Improveme nt	Tech. Transfer	Pre-clinical data for IND filing
BiSpekDAb™						
Neuro-E [™]						
LBUPON™						
LBURGINAZE™						
NGOBLOKER™						

1. BISPEKDAB / POLYBODIES 2. LBUPON 3. APOEFRAG / NEURO-E 4. LBURGINAZE (Granted, TM # 5572164 /6168239; WIPO Int Appl # 1786205). (Granted, TM # 5572163). (Granted, TM # 5572165 / Application # 6168240). (Granted, TM # 5572162). (Application # 6168238)

Sequence Submission to GenBank:

5. NGOBLOKER

	>70	sequences	of	engineered	proteins	are	submitted	to	GenBank
(https:	<u>//www</u>	<u>.ncbi.nlm.nih.</u>	<u>gov/n</u>	<u>pande+ah</u>)					

Patents:

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- 4. Abhay H. Pande, Priyanka Bajaj, Rajan K. Tripathy, Ankita Jadhav Gaurav S. Chandak, Harsh D. Parikh. Recombinant and stable SsoPox enzymes, method of generation thereof and reusable nanobiocatalyst of the same. (Indian Patent no. 361919).
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- Abhay Hariram Pande, Suraj Hanumant Shinde, Sandeep. Polyvalent tumour necrosis factoralpha blocking domain antibodies and method of generation thereof (Indian Patent application # 202411012808).
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Google scholar – Citations =1350; h-index = 20; i_{10} -index =38 (as on 21.11.24)

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- 5. Hajela N, **Pande AH**, Sharma S, Rao DN and Hajela K (**1999**) Studies on a doubleheaded protease inhibitor from Phaseolus mungo. J. Plant Biochem. Biotech. 8, 57-60. [IF= 1.6]
- 4. **Pande AH**, Hajela N, Hajela K (1998) Biochemical characterization of a trypsin-chymotrypsin inhibitor from Vignaradiate. EAAP Publication 93 (1998): 47.
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Book Chapter

- 1. Iyengar, A. S., Dobariya, P., &*Pande, A. H.*(2023). Paraoxonase 1 as a potential prophylactic against nerve agent poisoning. In Sensing of Deadly Toxic Chemical Warfare Agents, Nerve Agent Simulants, and their Toxicological Aspects (pp. 529-537). Elsevier (DoI: 10.1016/B978-0-323-90553-4.00006-8)
- 2. Sahni G, **Pande AH**, Angrish AK. Catalyzing and accelerating a new phase in Indian BioPharma. In a book 'Biotechnology in India Reworking A Strategy', Springer Nature <u>https://doi.org/10.1007/978-981-97-0896-3_12</u>.
- 3. Ahmed S., *Pande AH*, Sharma SS. ApoE Potential in CNS Drugs Targeting and as CNS Therapeutic in "Targeted Therapy for Central Nervous System: Formulation, Clinical Challenges and Regulatory Strategies" (DoI:10.1016/B978-0-443-23841-3.00005-4)

Conference Abstracts

- 13.Bzdrenga J, Khandave P, Soirot T, Belverge N, Taudon N, Nachon F, Brazzolotto X, **Pande AH** (2024) Recombinant human paraoxonase-1 variants depict hydrolyzing capabilities of A-series nerve agents in vitro CHEPON 2024, 15th International Meeting on Cholinesterases, 9th International Conference on Paraoxonases, Brdo pri Kranju, Slovenia, 15-18 September, 2024
- 12.Bzdrenga J, Khandave PY, Nachon F, **Pande AH**, Brazzolotto X. (**2022**) Evaluation of recombinant human paraoxonase-1 for hydrolyzing capabilities of G-series nerve agents, an in vitro study. 14th International Meeting on Cholinesterases and the 8th International Conference on Paraoxonases (ChePon2022), Bologna, Italy.

- 11. *Shebuski RJ, Joshi K, Pande A, Sharma R, Prashar Y, Kapeghian J and Sahni, G.* (2015) Preclinical safety and efficacy of a novel thrombolytic agent administered by rapid bolus injection: Clot Specific Streptokinase (CSSK/SMRX-11). **Circulation** 132 (Suppl 3), A12419-A12419.
- 10. *Aggarwal G and Pande AH* (2015) Understanding the catalytic mechanism of Human serum paraoxonase 1- Combined mutagenesis and Molecular dynamics study. FEBS J. 282, 334-334.
- 9. *Kar S, Tripathy RK, Patel MA and Pande AH*. (2012) Characterization of oxidized phospholipid containing reconstituted high density lipoprotein particle. **Biophys. J.** 102 (3), 494a.
- 8. Nemec KN, **Pande AH**, Qin S, Tatulian, SR and Khaled AR (2009) Bax C-terminal peptide-Insights into membrane interactions. **Biophys. J.** 96(3), 531a.
- 7. **Pande AH**, Qin, S., Nemec, K.N. and Tatulian, S.A. (**2007**) Real-time correlations between membrane binding mode, conformational changes, and activity of phospholipase A₂. **Biophys.J.** 338A-338A.
- 6. *Pande AH*, *Qin S and Tatulian SA* (**2005**) Membrane fluidity modulates interfacial activation of 5-lipoxygenase. **Biophys. J.** 88(1), 51A-51A.
- 5. *Pande AH*, *Nemec KN and Tatulian S.A.* (2005) Mechanism for enhanced activity of human group ha phospholipase A₂ upon V₃W mutation. **Biophys. J.** 88(1), 427A-427A.
- 4. *Qin S, Pande AH, He XM and Tatulian SA* (**2004**) Exploring the mechanism of secretory phospholipase A2 by protein engineering and biophysical approaches. **FASEB J**. 18(8), C187-C187.
- 3. *Qin S, Pande AH and Tantulian SA* (2004) Positioning a peripheral protein at the membrane surface. **Biophys. J.** 86(1), 102A-102A.
- 2. *Moe D*, *Pande AH*, *Qin S*, *Tan SH and Tatulian S.A*. (2004) Mechanism of interfacial activation of 5-lipoxygenase. **Biophys. J.** 86(1), 255A-255A.
- 1. *Hajela K*, *Pande AH* and *Sumati* (1997) Crosslinking of erythrocytes by lectin enhances susceptibility to superoxide radical damage. Eur J. Cell Biol. 74, 37-37.

Honours / Awards / Recognition / Fellowship received:

9) Honorary Fellow, Association of Biotechnology and Pharmacy (ABAP), India

8) **Distinguished Researcher in Biopharmaceuticals**, Venus International Research Award-2024.

7) Best Researcher Award, International Academic Excellence Awards 2024

6) One of our Technologies (BiSpekDAb[™] for Severe Asthma, defended by Sandeep) has won in the Grand Finale of "**National Bio Entrepreneurship Competition 2024 (NBEC 2024)**, BIRAC. Advance pre-clinical studies are going on.

5) One of our Technology has won in the Grand Finale of "**National Bio Entrepreneurship Competition 2022 (NBEC 2022)**, BIRAC. Advance pre-clinical studies are going on.

4) Visited to Shizuoka University, Japan (April, 2018) as a part of NIPER delegation for discussions on a memorandum of understanding (MOU).

3) **CSIR Technology Award for Life Sciences**: I was a part of the team receiving CSIR Technology Award for Life Sciences 2018 at Vigyan Bhavan on 26th Sep. 2018.

2) Humboldt Res Fellowship (2001) & The Wellcome Trust Fellowship (2003) [NOT availed]

1) CSIR Senior Research Fellowship: 1997-2000

Biotechnology Advocacy

Beyond my biopharmaceutical research, I am deeply committed to advocating for the vital role of Biotechnology in saving Biology. I believe biotechnology is crucial for addressing and mitigating the environmental impacts of human activity on mother Earth. It serves as a means to "save biology" by preserving and restoring the delicate balance of Life on Earth through the integration of science and innovation. By ethically applying various fields (colors) of biotechnology, we can not only repair the damage already caused by humans but also strive for a more harmonious coexistence with our planet, ensuring its beauty and diversity for future generations. To promote this perspective, we are engaged in numerous invited lectures/talks and published articles in esteemed magazines, emphasizing that biotechnology holds the key to addressing environmental challenges and mitigating the impact of human activities. By highlighting the transformative potential of biotechnology, we aim to inspire a greater appreciation for its role in preserving our planet and advancing human health.

- 8. **Pande AH**, Anakha J, Prasad YR, Angarish AK. Bharat, Bioeconomy and Biopharmaceuticals. (Communicated)
- 7. **Pande AH**, Anakha J. Brown Biotechnology A Science for Sustainable Landmass Utilization and Conservation. (Communicated)
- 6. Pande AH, Prasad YR, Anakha J. What are Biopharmaceuticals? **Explor Drug Sci.** (in press)
- 5. Pande AH, Prasad YR, Anakha J and Angrish AK. (2024). India's bio-economy's quest to be the global eco-system. Fortune India. (<u>https://www.fortuneindia.com/macro/indias-bio-economys-quest-to-be-the-global-eco-system/118662</u>)
- 4. **Pande AH**, Anakha J. (2024). The Impact of RED Biotechnology on Healthcare Advances. **The Science World.** 4(9), 3749-3757. <u>https://doi.org/10.5281/zenodo.13906501</u>
- 3. **Pande AH**, Anakha J (2024) Saving Biology with Blue Biotechnology. **The Maritime Executive**. <u>https://www.maritime-executive.com/article/saving-biology-with-blue-biotechnology</u>
- Pande AH, Anakha J (2024) DARK biotechnology-an emerging solution to CBRN emergencies. The Defence Horizon Journal Feb. DoI - 10.5281/zenodo.10701826
- 1. **Pande AH**, Anakha J. (2024) Biotech offers bright new future for the planet. **Innovators Magazine** (https://www.innovatorsmag.com/biotech-offers-colourful-new-antidote-tohuman-greed/)