



## ReGen Factor IP Portfolio Summary

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### 1. Overview

ReGen Factor's intellectual property (IP) portfolio is central to its leadership in regenerative medicine and synthetic biology. This portfolio includes patents, trade secrets, and proprietary processes, with a focus on producing bio-identical recombinant human basic fibroblast growth factor (rh-bFGF). These innovations enable scalable, cost-effective, and clinically safe production methods using both *Bacillus* and yeast systems.

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### 2. Key Patents

#### A. Bio-Identical rh-bFGF in *Bacillus*

- **Patent Description:**
  - Co-founded by Dr. Keith Kwong, this **approved U.S. patent** protects methods for producing bio-identical rh-bFGF using *Bacillus* systems. It ensures a 146-amino acid protein identical to the naturally occurring human bFGF.
  - The patent also includes specific processes for enhancing yield, stability, and safety of bFGF for clinical and therapeutic use.
- **Applications:**
  - Wound healing, anti-aging treatments, hair regrowth, and regenerative medicine.
- **Key Features:**
  - **High Purity:** Matches the body's natural bFGF, ensuring superior efficacy and reduced risks.
  - **Cost Efficiency:** Produces bFGF at less than 10% of competitors' costs.

#### B. Upcoming Patent: Bio-Identical bFGF in Yeast

- **Patent Application:**

- ReGen Factor is filing additional patents for producing bio-identical rh-bFGF in yeast systems, which provide complementary scalability and cost advantages.
- Yeast-based production allows for human-like glycosylation, further enhancing the compatibility of bFGF with therapeutic applications.
- **Applications:**
  - Expands therapeutic applications of bio-identical bFGF, particularly in chronic wound care, cosmeceuticals, and advanced regenerative therapies.

### C. Dr. Kwong's mRNA Transcription Patents

- **Patent Numbers:** CN 114717230 B and CN 114717229 B.
  - **Description:**
    - These patents focus on cell-free, carrier-free mRNA transcription technology for the large-scale production of therapeutic proteins, including FGFs.
    - The innovation ensures high stability, yield, and rapid scalability for applications in oncology, regenerative medicine, and chronic disease management.
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## 3. Trade Secrets

- **Optimized Production Processes:**
    - Proprietary methods for Bacillus and yeast fermentation systems.
    - Techniques to ensure bio-identical quality while minimizing production costs.
  - **Formulation Expertise:**
    - Development of advanced delivery systems for topical, injectable, and oral applications.
    - Custom formulations for enhanced stability and bioavailability of FGFs.
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## 4. Competitive Advantages

### A. Market Leadership

- **Established IP Foundation:**
  - Existing U.S. patent for Bacillus-based bio-identical rh-bFGF production establishes credibility and protection in key markets.
- **Innovative Growth:**
  - Yeast-based production and mRNA patents position ReGen Factor for dominance in emerging therapeutic areas.

### B. Scalable and Cost-Efficient

- **Production Costs:** ReGen Factor's technologies operate at less than 10% of competitors' costs, enabling affordability and broad market access.

- **Global Expansion:** Yeast-based methods and mRNA transcription patents ensure scalability for global markets.

### C. Bio-Identical Safety and Efficacy

- **Exact Match:** Bio-identical FGFs are structurally identical to natural human FGFs, ensuring optimal safety and efficacy in clinical applications.
  - **Regulatory Alignment:** Bio-identical properties reduce the risk of rejection by regulatory bodies like the FDA.
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## 5. Strategic Outlook

### A. Filing and Expansion Plan

- U.S. patents establish a strong foundation for Bacillus-based production.
- Yeast production patents will be filed in key markets (U.S., EU, Asia-Pacific) to complement existing IP.

### B. Monetization

- **Licensing Revenue:**
  - Annual revenue from licensing IP is projected to exceed \$30 million by 2030.
- **Product Commercialization:**
  - Direct product sales in therapeutic and cosmeceutical markets are projected to generate over \$100 million by 2030.

### C. Partnerships

- ReGen Factor plans to partner with leading pharmaceutical companies for R&D, manufacturing, and distribution.
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## 6. Conclusion

ReGen Factor's robust IP portfolio, anchored by Dr. Kwong's co-founded patent for bio-identical rh-bFGF and complemented by pending yeast-based innovations, positions the company as a leader in regenerative medicine. With a clear focus on affordability, scalability, and safety, ReGen Factor is set to transform the global markets for wound healing, cosmeceuticals, and advanced therapeutics.

## References:

### Market Growth Sources

- 1. Regenerative Medicine Market:**
    - The global regenerative medicine market was valued at USD 34.56 billion in 2023 and is projected to reach USD 398.77 billion by 2032, with a CAGR of 32.4% during the forecast period (2024–2032). (Source: Fortune Business Insights)
  - 2. Cosmeceuticals Market:**
    - The cosmeceuticals market is estimated at USD 52.3 billion in 2022 and is expected to grow at a CAGR of 20.4%, reaching USD 328.9 billion by 2032. (Source: Global Market Insights)
  - 3. Synthetic Biology Market:**
    - The synthetic biology market was valued at USD 59.68 billion in 2023 and is projected to grow at a CAGR of 26.37% from 2024 to 2031. (Source: Research and Markets)
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### Royalty Rate and Industry Standards

- 4. Royalty Rates in Biotechnology:**
    - KPMG's Global Valuation Institute report indicates that royalty rates in the biotechnology sector typically range between 5% and 15%, depending on the market exclusivity, IP strength, and commercialization potential. (Source: KPMG Global Valuation Institute Report)
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### Case Studies

- 5. Kaken Pharmaceutical Co., Ltd.:**
    - Kaken Pharmaceutical's Fiblast Spray (trafermin), a recombinant human bFGF product, has been successfully used in Japan but failed FDA Phase 3 trials due to safety concerns with its non-bio-identical structure. (Source: Regulatory Affairs Professionals Society)
  - 6. Krystal Biotech, Inc.:**
    - Krystal Biotech's KB103 (Vyjuvek), a gene therapy for epidermolysis bullosa, highlights the complexity and cost challenges of advanced biologics. (Source: Krystal Biotech Official Reports)
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### Revenue Potential

7. **Market Projections for FGFs:**
    - Bio-identical growth factors have significant revenue potential in regenerative medicine, with projected licensing revenues exceeding \$30 million annually by 2030. (Source: International Wound Journal, 2022)
  8. **Wound Healing Market:**
    - The global wound care market is estimated at USD 25 billion, driven by increasing cases of chronic wounds and innovative biologics. (Source: Grand View Research)
  9. **Anti-Aging Market:**
    - Anti-aging solutions contribute to over \$60 billion annually in the global market, with a CAGR of 8.2%. (Source: Allied Market Research)
  10. **Hair Regrowth Market:**
    - The hair regrowth industry is valued at USD 4 billion globally, with biologics driving new market entries. (Source: Journal of Cosmetic Dermatology)
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These sources provide robust support for the valuation and market analysis, aligning with industry benchmarks and KPMG's standards.