

Client Name: Jane Doe / BT1001

Innovation Title: Application of Propionibacterium dermatum as a Skin Probiotic

Client Market Assessment (CMA™)

A function of the Innovation Commercialization Assistance Program (ICAP) for Assessing Innovations in Clean Technology and Modeling & Simulation



I. SWOT Analysis

Description Based on the Client Application and your knowledge and experience, analyze Strengths, Weaknesses, Opportunities and Threats relative to commercialization of the client's innovation.

Strengths

Internally focused. Positive, tangible and intangible attributes and advantages of the innovation and the client's team. Note how these strengths could be leveraged or built upon to further successful commercialization.

1. Use of Propionibacterium dermatum as a skin probiotic is a novel idea.
2. Bacterium is common, found on human skin, so less FDA safety concerns
3. Less frequency of re-application of the probiotic vs. antibiotic compounds
4. No known patented or commercial probiotic treatments for herpes simplex, warts, leishmaniasis
5. No patents known specific to this bacterium for anti-aging, anti-inflammatory, and anti-fungal probiotic therapies

Weaknesses

Internally focused. Tangible or intangible attributes of the innovation or client's team that require improvement and/or pose barriers to successful commercialization. Note whether and how these weaknesses could be resolved or remedied.

1. Bacterium is common, found on human skin, so natural bacterium may lack patentability. Careful review of expired patent for use of P. dermatum to produce antibiotics needs to be done to assure new patent for topical probiotic and anti-acne is viable.
2. Patents are known to be in place for two methods of synthesis of violacein; do careful review of those patents to verify that neither would be used.
3. Only laboratory animal data to date. No study of efficacy on non-moist, mammal skin; don't know ability to adsorb/penetrate nails
4. Method for using P. dermatum successfully as a skin probiotic in human clinical trials is lacking; must be defined and proven



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Description Based on the Client Application and your knowledge and experience, analyze Strengths, Weaknesses, Opportunities and Threats relative to commercialization of the client's innovation.

Opportunities

Externally focused. Factors and influences that enable market entry and/or improve sales and market share. Note how the client might strategically target, prioritize and exploit these opportunities.

1. Multiple, growing markets: Anti-Fungal: 10% annual growth, e.g., Athlete's foot \$385M. Anti-viral: e.g., warts ~\$125M. Antibacterials: OTC skin care ~\$3.3B, anti-acne \$560M, germicidals \$469M; Cosmeceuticals: skin care ~\$4.2B, anti-aging: ~\$2.5B, growing 17%; lip therapy OTC ~\$300M, growing 11%
2. Psoriasis, Atopic Dermatitis - effective topical medication needed for these chronic diseases. Test anti-inflammatory ability - not covered by existing Squibb patents.
3. Anti-parasitic: 1.5 million new cases cutaneous leishmaniasis per year.
4. Potential commercial enablers/licensees: Ganeden Biotech (17 patents in oral probiotics, nail antifungal), L'Oreal (recent patents in space); Probiomix, Ltd. (recent patents), Squibb (expired patents on antibacterials from P. dermatum)
5. Safety (likely since already on human skin) and non-allergenicity (early test to demonstrate)

Threats

Externally focused. Factors and influences that inhibit the innovation from getting to market or from growing sales and market share. Note how the client might avoid or mitigate these threats.

1. Competing antibiotic probiotic, prebiotic products. (Probiotic Lab Limited, Bacteriocin, Dr. Ohira's) Must determine where the P. dermatum has greatest efficacy against market-relevant targets (e.g., athlete's foot fungus?)
2. Violacein biosynthesis methods patented, but not known if in products. Mitigate: Probiotics offer ability to reduce # of re-applications
3. Insufficient funding to perform key early trials. Need plan to secure incremental funding, e.g., NIH SBIR/STTR funding
4. Adverse results from clinical trials. Unknown until done.
5. Productization - formulations will likely differ for varied applications. Focus formulation for efficacy in larger market applications.
6. Cultural resistance to application of live bacteria to skin. Education and increasing use of probiotics internally should mitigate this.



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II. Summary

Description Summarize in bullets your analysis of the client's innovation.

1. Novelty is in probiotic use as an antibiotic, anti-inflammatory. Some specific IP needs to be reviewed, but appears that there is opening for protecting P. dermatum use as a topical skin probiotic
2. Indigenous to human skin, so use as topical probiotic is plausible from safety standpoint
3. Multiple potential applications against fungal, viral, bacterial, parasitic targets, as well as anti-inflammatory diseases, representing large and growing markets, including growing use of probiotics
4. Need to answer key questions re: ability to colonize mammalian skin and produce the antibiotic.
5. Need to show clinically relevant efficacy against key targets in order to focus market strategy
6. Need incremental funding (preferably non-diluting, e.g., SBIR/STTR funding) to do #'s 4 and 5.

III. Grade

Description Based on your analysis, give the client's innovation a letter **grade (A to F)** representing your expert assessment of its viability.

C

Rationale:
Brief reasons
for grade.

1. Novel concept to use probiotics for topical delivery of antibiotic/anti-inflammatory
2. Variety of growing markets, but need to demonstrate clinically relevant (human skin) efficacy against specific targets (e.g. athlete's foot fungus) to focus on specific markets
3. Competing prebiotics, but also opportunity to bundle and partner with competitors
4. Funding needed to get key questions answered; SBIR/STTR may offer incremental solution

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IV. Recommended Next Steps

Description Suggest actions the client should take to get their innovation to market.

1. Secure incremental funding (SBIR/STTR) for early, critical tests (e.g., efficacy vs. key targets - fungal, bacterial, viral - on human skin, nails; anti-inflammatory properties; non-allergenicity clinical trials) to establish target markets
2. Review existing patents for production of violacein, and explore whether used in products. Review expired patent on use of P. dermatum for antibiotic, determine uses not covered to make new patent viable for topical antibiotic and anti-acne probiotic.
3. File provisional patent covering targeted (based on #1) uncovered uses
4. Secure funding to initiate scaling of manufacturing/formulation and clinical trials
5. Explore partnering opportunities with key commercial enablers