

Managing an IP Portfolio for In-house Counsel

ACC Alberta Luncheon

Thursday, November 21, 2019

Moderator and Speakers



Robert Holthus - **Moderator**
Counsel
Smart & Biggar

Speakers



Rob Fraser, PhD
President and Chief Executive
Officer
Molecular You



Jeffrey Gow
Intellectual Property Manager
Husky Injection Molding
Systems



Tom Trinh
Senior Associate
Smart & Biggar



Rob Fraser

President and Chief Executive Officer
Molecular You



Gartner

2019 'Cool Vendor' in Healthcare Artificial Intelligence

Named and positioned on four 2019 Gartner Hype Cycles for Precision Health

"MY's health assessment will help influence the metamorphosis of primary care services from reactive chronic care management into health, wellness and lifestyle coaching. "

Intellectual Property in Personalized Health

Rob Fraser, PhD
President & CEO

November 23, 2019

molecular
you PERSONALIZED
HEALTH

Real Need

Over 100 million people
in North America are on
medication

Payers are demanding a shift
to Value-based Care

Need to demonstrate value of care
solutions with real world outcomes

using..

Timely solutions and support
systems that are personalized
and complement treatments

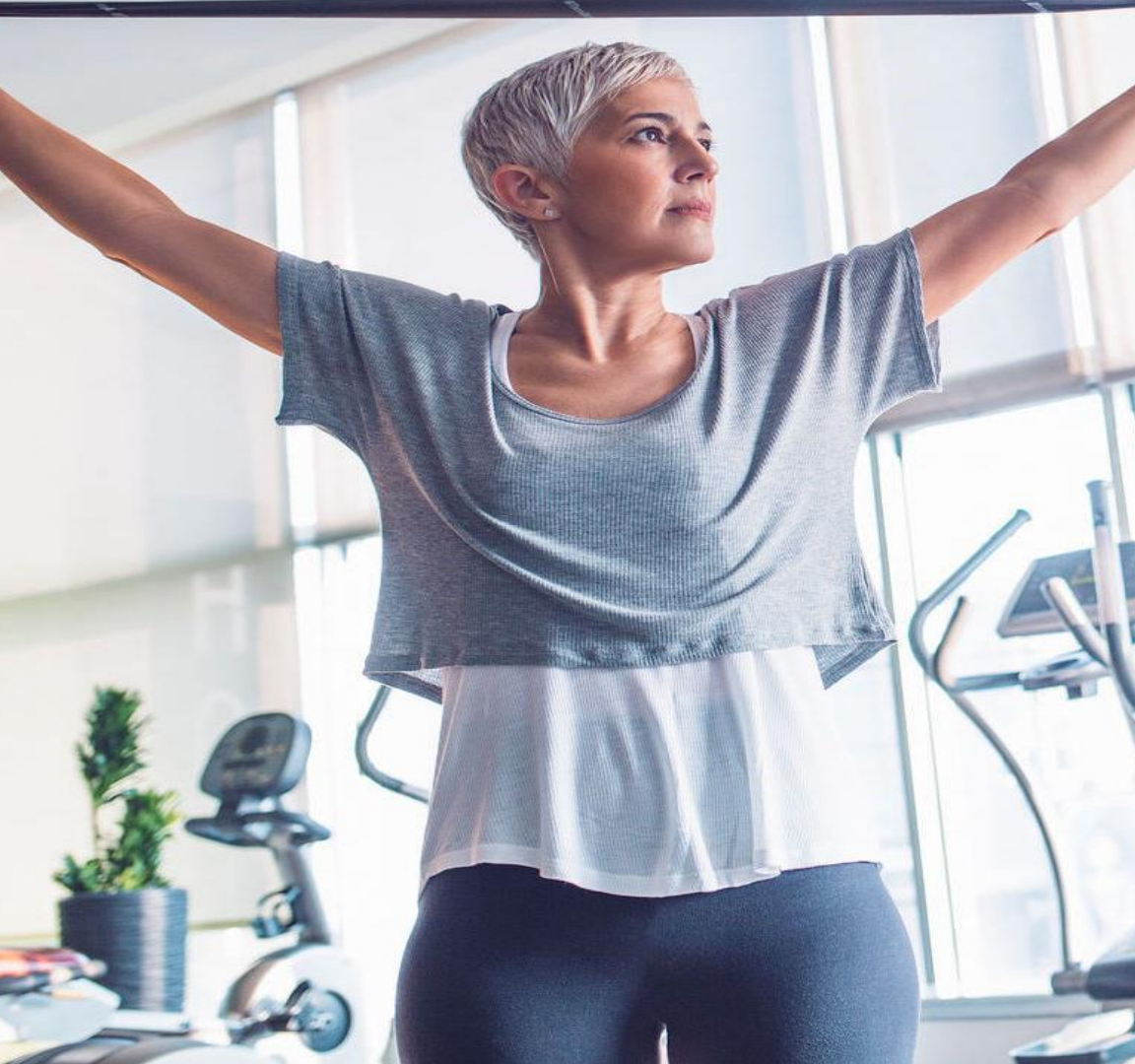
That empower the patient

And provide metrics throughout
the patient journey

molecular
you PERSONALIZED
HEALTH

“The best hospital bed is
an empty one”

Don Berwick, former administrator of the U.S. Medicare and
Medicaid programs



Establish the value of care

Precision exercise and
nutrition plans:
Preventive Health +
Adjuncts to care

Quantify the client/ patient
journey from beginning to end

With measurable outcomes

Complete the Care Package

molecular
you PERSONALIZED
HEALTH

myFitness_{FX}™

Optimized Health: Exercise + Nutrition

Fitness Insights

- Training and Recovery
- Fuel Selection & Availability
- Athletic signature
- Mitochondrial function
- Health benefits of exercise

Health Insights

- Vital Physiological Processes

Risk Insights

- UP to 16 Risks Assessed

Nutrition Assessment (Max):

- Vitamins and minerals
- Diet
- Environmental exposures

Action Plan

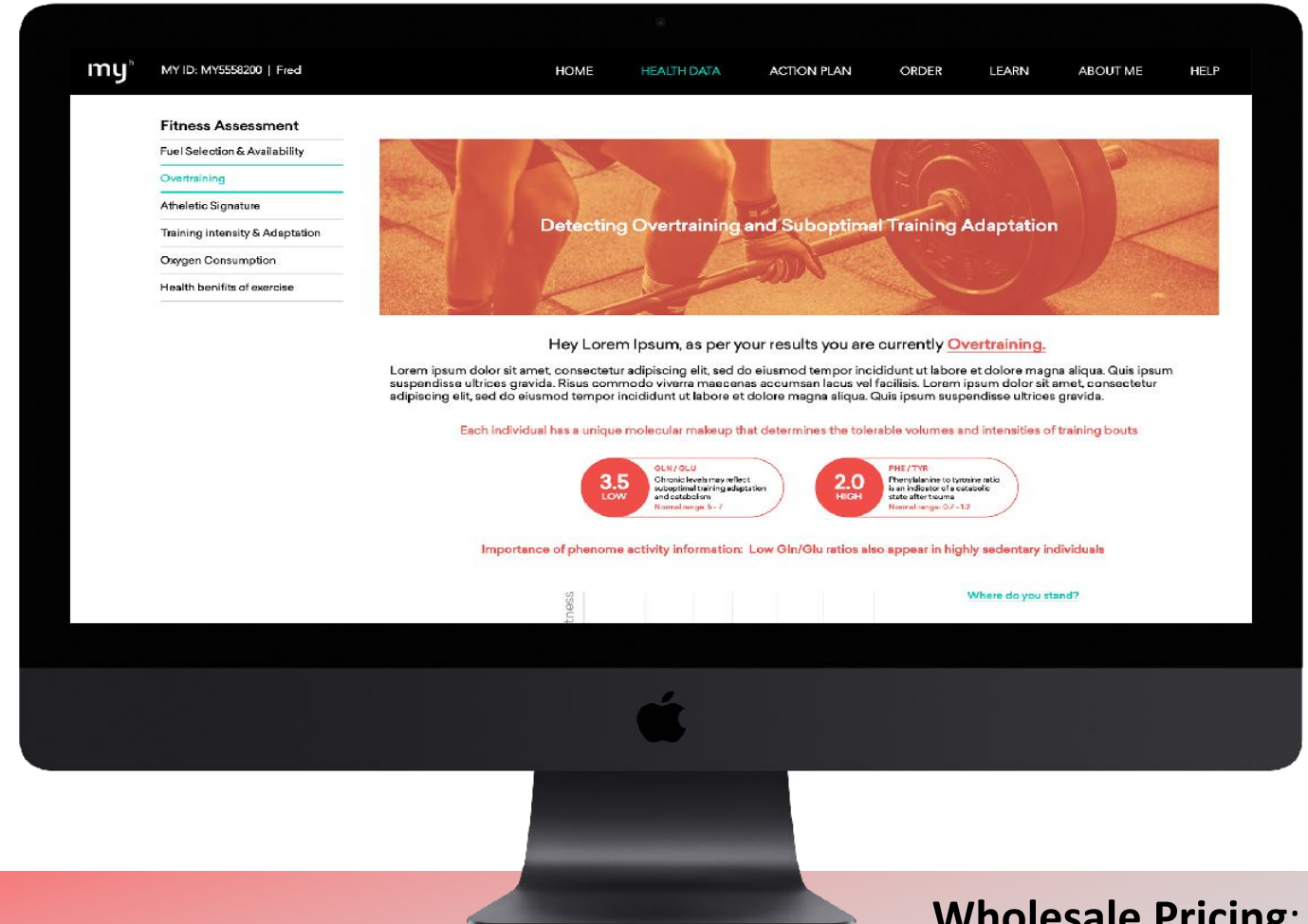
- Optimal Exercise Plan
- Optimal Diet
- Optimal Supplement

Interface

- Web Based
- Mobile App

Custody and Control (My PDx)

- Personal Health Data



Wholesale Pricing:
\$375-\$775

myNutrition_{FX}™

Optimized Diet + Supplements

Nutrition Assessment:

- Vitamins and minerals
- Diet
- Environmental exposures

Health Insights

- Vital Physiological Processes

Risk Insights

- 8 Risks assessed

Action Plan:

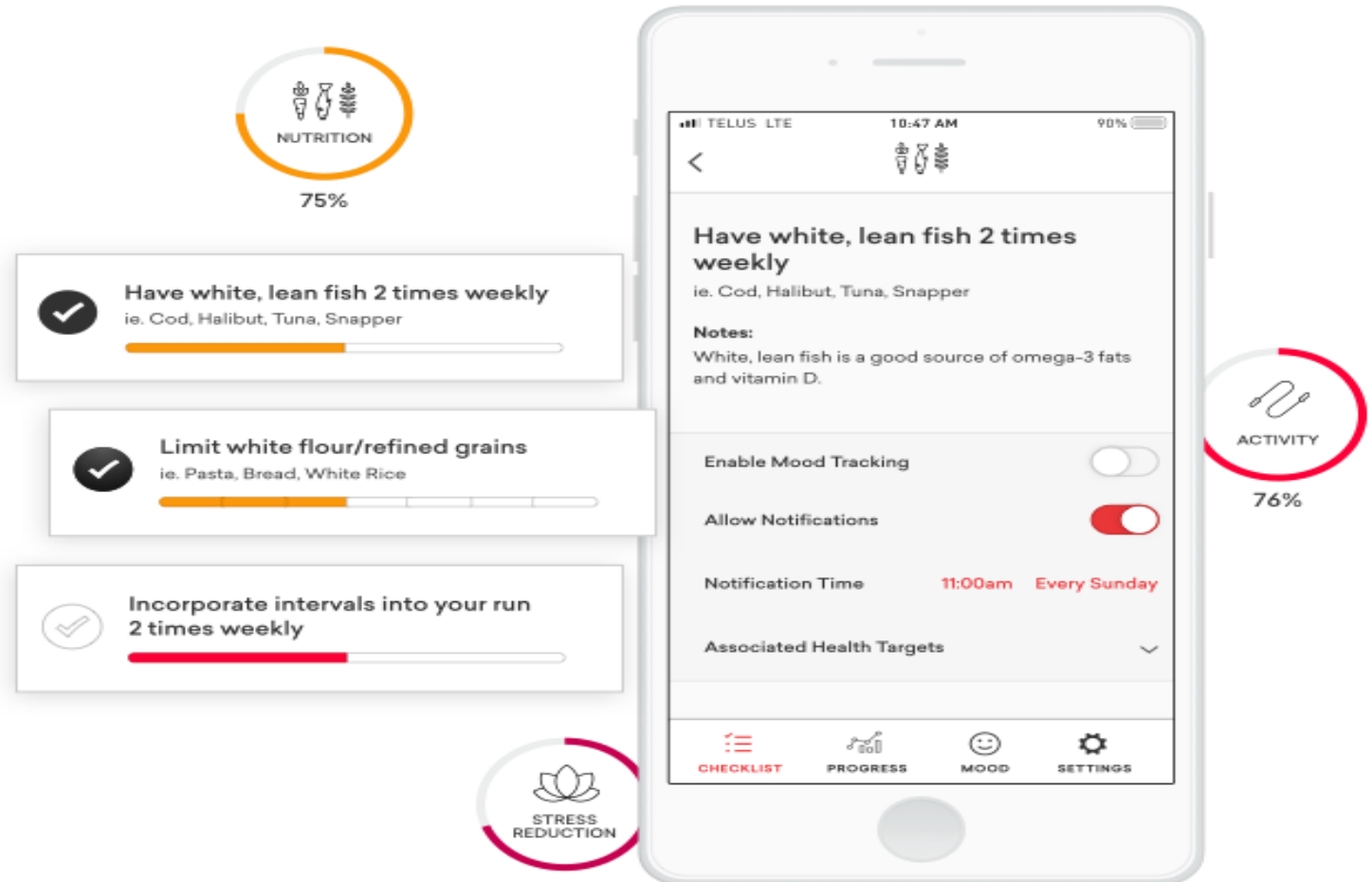
- Optimal Diet
- Optimal Supplements
- Exercise Recommendations

Interface

- Web Based
- Mobile App

Custody and Control (My PDx)

- Personal Health Data



Wholesale Pricing:
\$475

History



The discovery of the structure of DNA launched new industries...

...But it was discovery not invention

Genes are not patentable!



1 Genome
\$ 2.7B
13 years



1 Genome
\$ 1000
1 day

And now?

397-38

Patenting in the age of the whole genome

Human Genome Sciences:(GSK) est. 1992

- Attempted to patent genetic sequences as the genes emerged from the sequencer
- Genes as targets for their utility in drug discovery
- This was disallowed due to lack of demonstrated invention

Pharma and Biotech

- Assays for drug discovery as methods of use or trade secrets
 - New chemical entities- small molecule drugs
- Proteins- biologics therapeutic antibodies
- Predictive algorithms
- Trademarks
- Platforms for analysis and visualization

MY Personalized Playbook

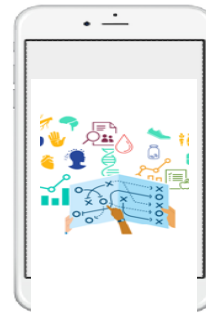
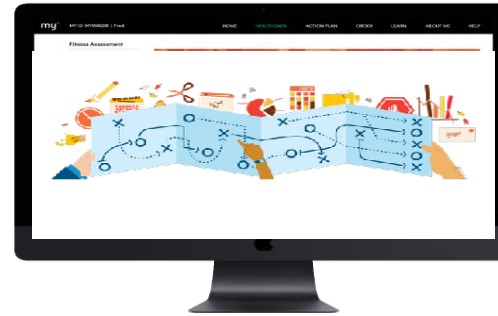
Data Driven::

comprehensive diverse blood markers
for increased insight and accuracy

- Metabolites
- Proteins
- Nutrients
- Toxins
- Genetics
- Pharmacogenetics
- Microbiome (optional)
- Self reported
 - Family and health history
 - Physical activities
 - Diet



AI-Assisted Analysis



MYhi
Connecting the dots

Strategies: Sensitive detection
Tactics: precision planning
Team: Patients, practitioners
and digital tools

Exercise

+

Nutrition

+

Supplements

+

Medications

MY Health IntelligenceTM

AI driven platform that delivers individualized healthcare solutions based on each user's data

About You:

High Level Report

- Fitness Insights
- Health Insights
- Risk Insights
- Interesting Insights

The screenshot displays the MY Health Intelligence user interface. At the top, a navigation bar includes the 'my' logo, user ID 'MY5558200 | Fred', and links for HOME, HEALTH DATA, ACTION PLAN, ORDER, LEARN, ABOUT ME, and HELP. Below the navigation bar, a welcome message for Fred states: 'Welcome Fred, Your October 25th report is ready for you. Check the status of your next report in the order page.' It also shows 'Report Date: Oct 25, 2018' and 'Package type: Premium Plus', with links to 'View another report' and 'Download Summary'.

The main content area features three tabs: 'About You' (selected), 'Molecular You', and 'Optimal You'. Under the 'About You' tab, there are four insight cards: 'Fitness Insights' (with a runner image and the text 'Eliminate the guess work from your workout'), 'Health Insights', 'Risk Insights', and 'Interesting Insights'.

Below these is a section titled 'Health Benefits of Exercise'. It contains the text: 'How big of an impact does exercise have on you? Health benefits of exercise extend to everyone, but your unique molecular makeup determines specific benefits of exercise for you.' and a 'Learn More' link. To the right of this text is an image of a person lifting a barbell with the text '6 of 10 biomarkers can be improved by exercising'.

The 'Fitness Metrics' section at the bottom is divided into three columns:

- At Risk** (red header): 'Congratulations, none of your biomarkers are at risk.'
- Needs Attention** (orange header):
 - Metabolic Flexibility**: 'Are your burning fats and sugar effectively?'
 - Training Tolerance**: 'Are you at the right level?'
- Optimal** (teal header):
 - Oxygen Consumption**: 'Are you using oxygen effectively?'

A 'Learn More' link is located at the bottom right of the Fitness Metrics section.

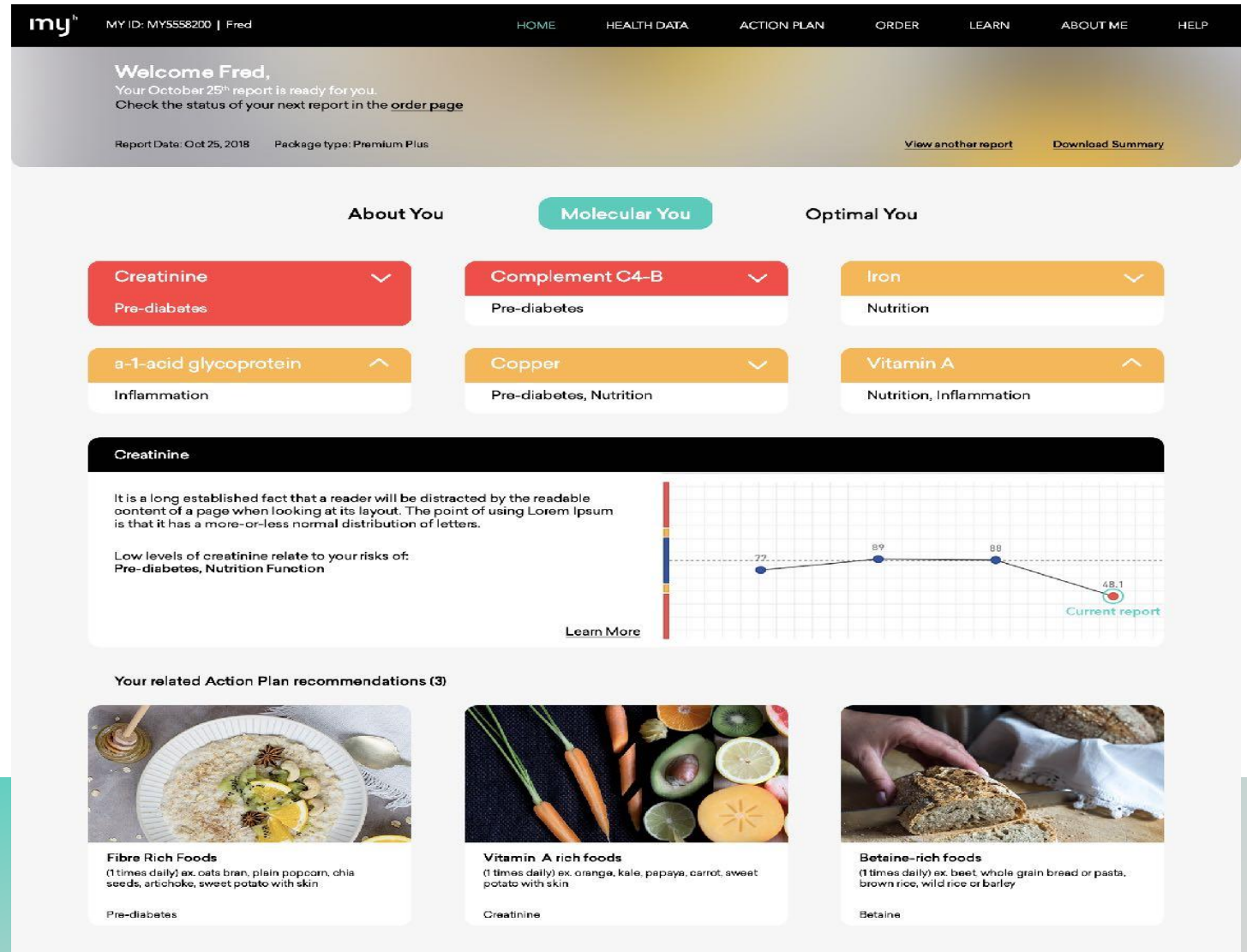
MY Health IntelligenceTM

AI driven platform that delivers individualized healthcare solutions based on each user's data

Molecular You:

A deeper dive into the details of the client's health status
Molecular Level Analysis

- Metabolites
- Proteins
- Nutrients
- Toxins
- Genetics



MY Health IntelligenceTM

AI driven platform that delivers individualized healthcare solutions based on each user's data

Optimal You:

A detailed lifestyle Action Plan for the client to achieve health goals based on their unique data set

- Diet
- Supplements
- Exercise

The screenshot displays the MY Health Intelligence user interface. At the top, a navigation bar includes the logo, user ID (MY ID: MY5558200 | Fred), and links for HOME, HEALTH DATA, ACTION PLAN, ORDER, LEARN, ABOUT ME, and HELP. Below the navigation bar, a welcome message for Fred states: "Welcome Fred, Your October 25th report is ready for you. Check the status of your next report in the order page." It also shows the report date (Oct 25, 2018) and package type (Premium Plus), with links to "View another report" and "Download Summary".

The main content area features three tabs: "About You", "Molecular You", and "Optimal You" (which is selected). Under the "Optimal You" tab, there are three sections: "Diet", "Supplements", and "Exercise".

The "Diet" section is expanded, showing "Diet recommendations (4)". It lists four recommendations based on the user's profile:

- Fibre Rich Foods** (1 times daily) ex. oats bran, plain popcorn, chia seeds, artichoke, sweet potato with skin. Associated with Pre-diabetes.
- Vitamin A rich foods** (1 times daily) ex. orange, kale, papaya, carrot, sweet potato with skin. Associated with Creatinine.
- Betaine-rich foods** (1 times daily) ex. beet, whole grain bread or pasta, brown rice, wild rice or barley. Associated with Betaine.
- Omega-3 fats-rich foods** ex. flaxseeds, chia seeds, salmon, mackerel, walnuts. Associated with Glycerophospholipids.
- Vitamin C rich foods** ex. tomato, pepper. Associated with Iron.
- Betaine-rich foods** (1 times daily) ex. beet, whole grain bread or pasta, brown rice, wild rice or barley. Associated with Betaine.

At the bottom right, there is a link to "See complete action plan".

Establish Agreements with Partners



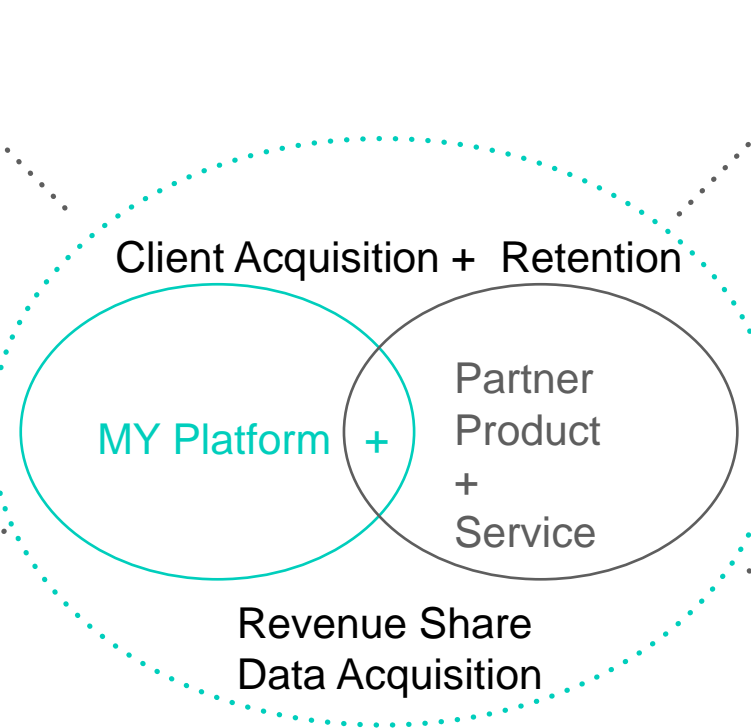
MY provides:

- Platform combining customer, partner and MY data
- Increased revenue opportunities
- Data sharing platform



Partners provide:

- Domain expertise and reach
- Complementary Products e.g. medicines, supplements
- Complementary Technology e.g. wearables



Partners gain:

- Added insights & guidance for customers
- Increased sales of complementary products
- Direct access to products via MY platform
- Content for marketing and training modules



Data Value Add:

- Combined MY & Partner data sets
- More accurate AI analytics and learnings
- Ecosystem of blockchain data share platform

IP Makes Molecular You Unique In the Market

Molecular-level insights into an individual's unique health needs

- Broadest range of biomarkers in the industry (know how)
- AI-driven web platform (Provisional filed)
- Mobile app

A personal game plan for healthy longevity

- MY is the only application that provides individuals and practitioners with an individualized playbook with action plan throughout the health journey. (Provisional filed)

MY Personal Data Exchange (My PDx)

- Blockchain wallet for personal data ownership (provisional in preparation)

MY Partnering Strategy

- Market access, shared revenue, complementary products and services and data enrichment (Partner Agreements)



The AI-Driven Playbook for Proactive and Personalized Health

Rob Fraser, PhD
President & CEO

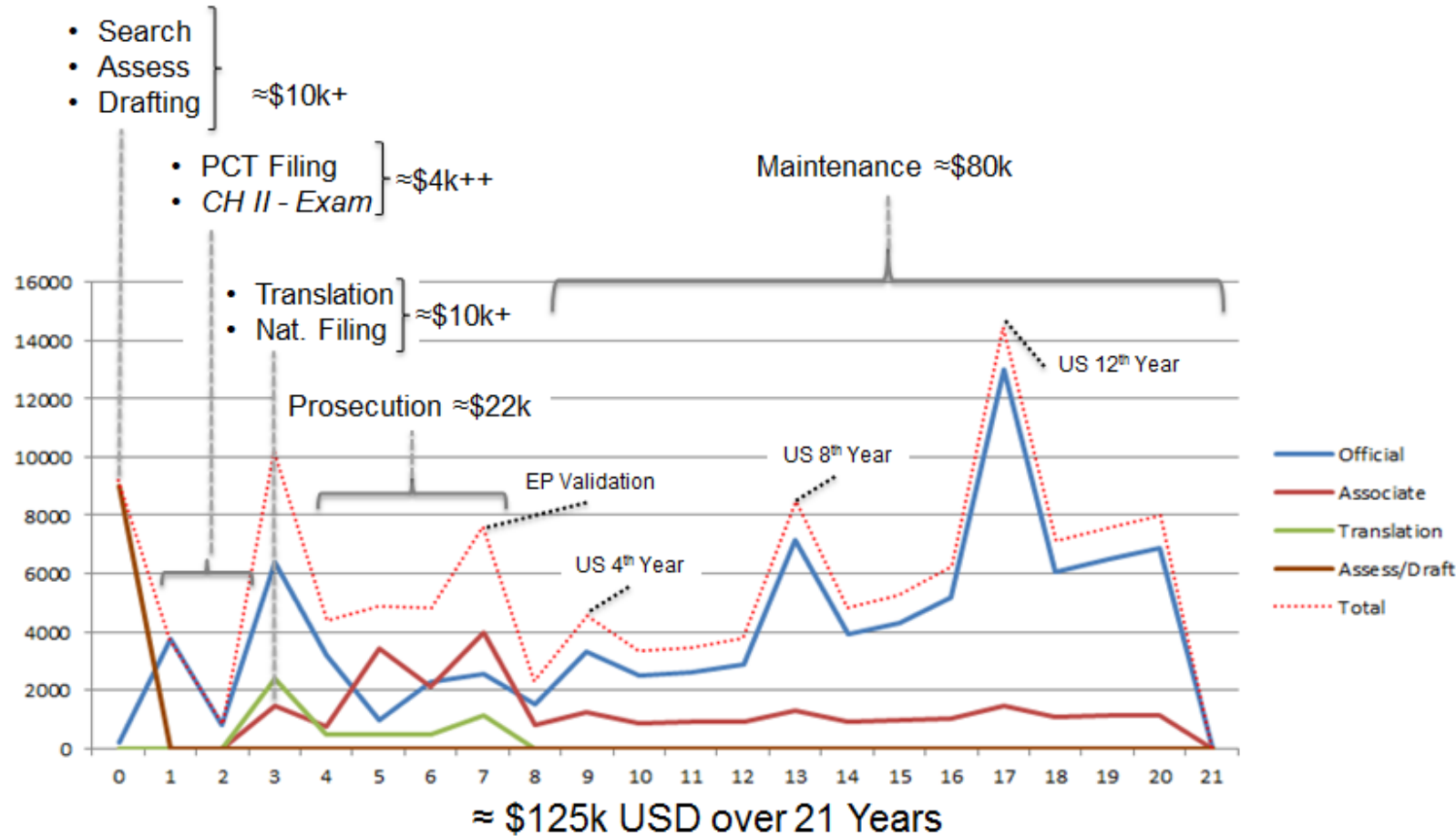
rob.fraser@molecularyou.com



Geoffrey Gow

Intellectual Property Manager
Husky Injection Molding Systems

Modest Patent Family Expense – US, CA, CN, EP



Challenges of Patent Portfolio Management

- Limited resources i.e. time and budget
- Imperfect information i.e. development, commercialization, market potential
- Abundant ideas and limited filing opportunities
- Ever changing products and services i.e. keeping patent portfolio relevant

Effective Patent Portfolio Management

- File wisely
 - Careful evaluation of opportunities – disclosure and patentability
 - Objective patent filing decisions (priority and national stage)
 - Assess the value – economic potential, other strategic considerations (e.g. license, blocking, etc.)
 - Identify markets and competitors – where to file
- Routine portfolio pruning
 - Objective patent maintenance decisions
 - Re-assess the value – economic, strategic
 - Cut under/non-performing patent families (i.e. abandon, license or sell/auction)
 - Trim unnecessary national patents from a family
 - Reinvest the money saved into patent procurement

Teamwork

- Build a cross-functional IP committee
 - Engineering management (technical insight)
 - Business management (product and marketing insight)
 - Executive oversight (effective decision making)
- Build a trusted network of IP Service Partners
 - IP research associates
 - Enable informed filing decision and focused patent drafting
 - Network of trusted legal associates
 - Keen understanding of technology and business needs

Essential IP Tools

- Committee tools (assessment, filing/maintenance)
 - Structured approach to facilitate objective decision making
- Robust docket system
- Secure file transfer (e.g. FTP)
- Online collaboration tools
 - Greatly facilitates complex technical discussions
- Patent search and analytic tools
- Patent quality checker
- Check terms, parts, references
- Portfolio expense modeling – existing portfolio
 - Model patent procurement expense – existing and planned portfolio
 - Run scenarios (e.g. filing programs, portfolio changes)

Committee Tools – Framework

- Innovation Assessment
 - Technical and prior art summaries
 - Proposed claim(s) in view of prior art
 - Indicators that may influence filing decision (inventor viewpoint)
- Filing and Maintenance Scorecard
 - Threshold considerations
 - Product coverage; other strategic considerations
 - Marketing and business considerations
 - Time to launch; duration; financial benefit; market importance; market geography; demand, etc.
 - Engineering considerations
 - Technical feasibility; development status; available alternatives
 - Legal Considerations
 - Claim breadth; Detectability; Remaining term
- Foreign filing guidance



Tom Trinh

Senior Associate
Smart & Biggar



Portfolio Management

Top 5 IP Mistakes

Why Mistakes Happen?

- IP is often...
 - **not straightforward**
 - an **afterthought**
 - (perceived as ..) **too costly** or **time consuming**

1. Failure to Monitor Competitive IP

How to Avoid?

Regular Reports of 3rd Party's + IP Review = **Formulate an IP Plan**
Published Appls + Granted (Legal, R&D
Patents (Orbit, Delphion Commercial)
or Patent Searchers)

Search Criteria

- Cooperative Patent Classification (CPC)
- Key Words
- Competitors
- Countries (PCT, EPO, US, etc.)

1. Failure to Monitor Competitive IP (cont.)

Why is it Important?

- Identify FTP issue early on – PROPORTIONALITY
 - Impact of the risk on the business
 - Likelihood of the risk occurring

- Option to Oppose/ Invalidate

Watch-outs:

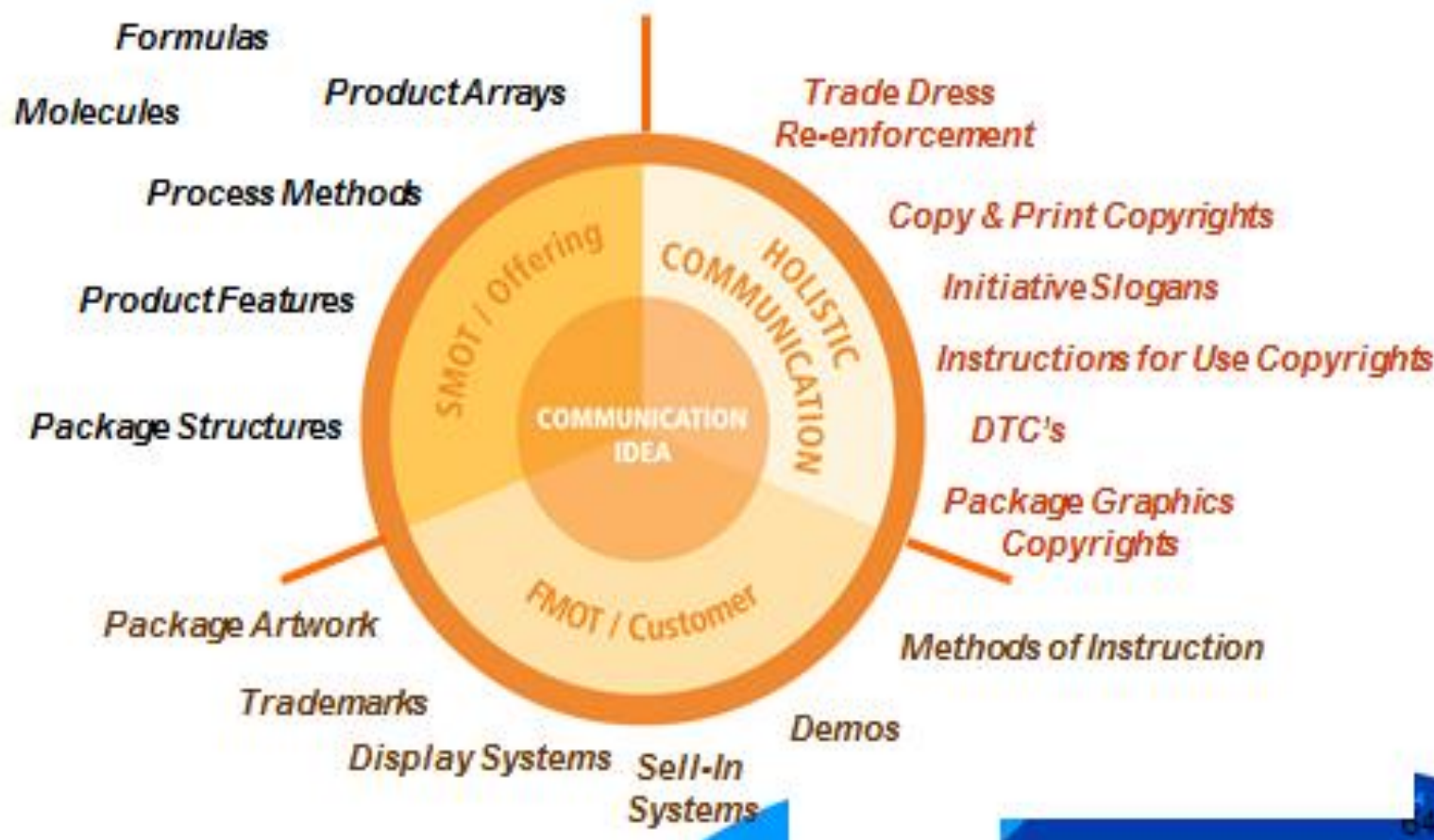
- Time limits EP (9 months)/ JP (6 months)
 - (i) Patent should have direct business impact or impact on plans; and
 - (ii) Establish up-front what a win looks like
- Opportunity to explore design around

1. Failure to Monitor Competitive IP (cont.)

Why is it Important?

- Awareness of Competitors technology and future direction;
 - (e.g., highlight new competitive research areas, predicting competitive initiatives, understanding competitor's competencies)
- Source of inspiration
 - e.g., identifying white spaces
 - Identify new filing strategies (e.g., data support, technical problem definition)
- Offensive filing opportunities

2. Holistic IP Strategy (cont.)



3. Never Underestimate Value of Process IP

- Trade secret vs patent filing
 - General Guidance :
 - Broad applicability = Potentially disturbing to competition + risk of competitive filing (FTP!)
→ IP Right protection typical advisable
 - Very specific execution – narrow applicability = Probably not disturbing to competition + low risk of competitive filing
→ Trade Secret typical advisable

3. Never Underestimate Value of Process IP

- MNC are public companies with obligation not to knowingly infringe on 3rd party patents
- Require to conduct FTP searches and render clearance opinion
- Some local and smaller competition might behave differently

4. Comply with the 4'D's of Collaboration

- Collaborate Responsibly
 - Protect your company's IP and assets

✓ **D**etails

✓ **D**ocumentation

✓ **D**ata

✓ **D**istribution

4. The 4'D's of Collaboration (cont.)

- **Details**



- Share only what's necessary; avoid sharing "TMI" (Too Much Intel.)
- Limit to what's detailed in the agreement (collaboration field and scope)
 - Some agreements allow for more open discussions/collaboration (JDA vs CDA, etc.)
- Use very specific language in communications to avoid doubt or misunderstandings

4. The 4'D's of Collaboration (cont.)

- **Documentation**

- Document all relevant communications
 - Meeting summaries – appoint someone to take notes; share summaries in a timely manner
 - What was discussed?
 - What data, ideas, thoughts were shared and by whom?
 - What are the next steps (who is responsible for what, and by when?)
 - Email – save as a permanent record of communication
- Document samples received: what's the intended use, how much was used, sampled under which agreement?
 - Non-analysis agreements
 - Follow all TSCA requirements, etc.

4. The 4'D's of Collaboration (cont.)

- **Data**

- Preview

- Do not share raw data without first processing internally
 - Avoid confusion around unexplained results, test errors, etc.

- **Present**

- Whenever possible share charts, data tables, slides, etc. as a .pdf or .jpeg
 - Avoid formats that can be modified or 'tracked changes' viewed (.xls, .doc, etc.)

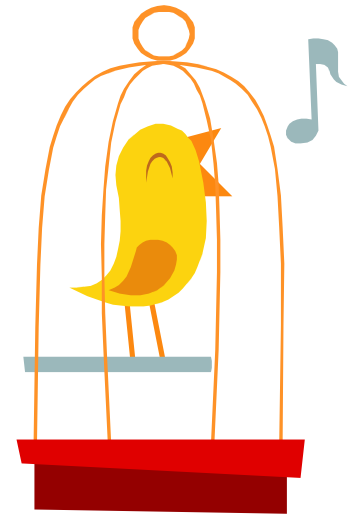
- **Protect**

- Label any shared information as “Confidential”, preferably include reference to agreement (often required by some agreements to include contract number)
 - Encrypt to prevent further sharing/modifying

4. The 4'D's of Collaboration (cont.)

- **Distribution**

- Share only what's needed to only those who need to see it
- Create teamspace or SharePoint site for uploading data, etc.
 - avoid email attachments (can inadvertently be forwarded)
 - Limited access to specific team members



5. Behaviours to Model

- Expectations on your teams to understand the IP space in which they work
- Encourage and offer IP training
- Ensure everyone is operating based on sound IP principles
- Encourage involvement of legal at appropriate timing
- Reward the amount of work required for quality IP



Questions

Thank you