

**Baker
McKenzie
Wong & Leow.**

**Digital Health:
*Are you Ready?***

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Agenda

1 Digital Promotion To Consumers

2 Virtual Engagement Of HCPs

3 Patent Considerations

4 Cybersecurity

5 Q & A



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1

Digital Promotion To Consumers

Threshold Approach

Product Categories

- Therapeutic Products
- Medical Devices
- Cosmetics
- Supplements
- Infant Formula
- Food Products
- Consumer Products

Digital Mediums

- Corporate Websites
- Social Media
- Mobile Applications
- Wearables

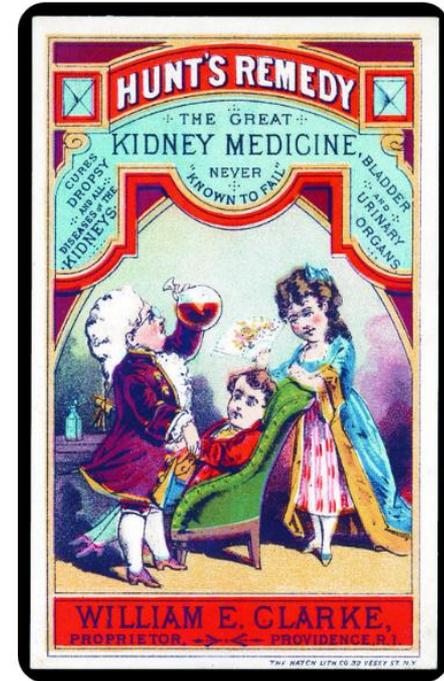
New Wine In Old Wineskins

- Traditional laws continue to apply
- Clear “no-go” areas
 - Prescription-only medicines
 - Pharmacy-only medicines require warnings
 - Professional use only medical devices
 - Restricted diseases / conditions
 - Off-labelling



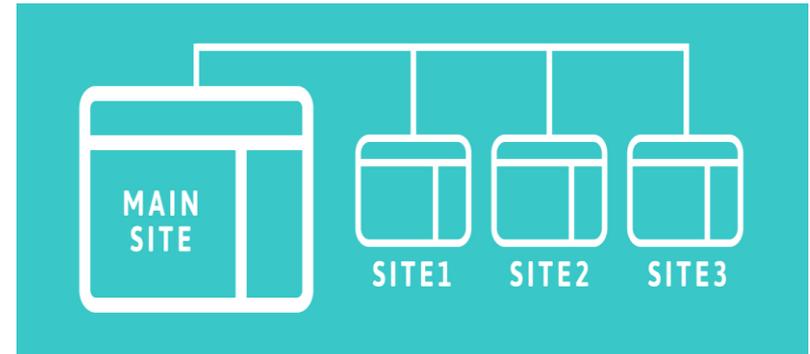
Aggressive Claims

- Heightened risk in digital world
- Key impression risks
 - Medical advice is not necessary
 - Encourage improper / excessive use
 - Misleading quality / efficacy
 - Endorsement by HCPs



Corporate Websites & Press Releases

- Informational statements allowed
- No promotional elements
- No discussion boards
- Corporate websites vs. microsites
- *C.f.* medical devices



Social Media

- Testimonials must be genuine
- Regulatory risks arising user generated content
- IP & defamation risks
- Personal data risks



Celebrities

- No medicinal product endorsement
- Captures persons of all fields
- *C.f.* medical devices
- Disclosure of commercial relationships



Borderless Internet vs Singapore Jurisdiction

- Local websites vs. regional / global websites
- Fact specific inquiry
- Connecting factors to Singapore audience



Indirect Promotion By HCPs

- Risk of attribution to product owners
- Risk of breaching clinic regulations / doctor ethical codes
- Negative publicity from MOH / SMC actions



2

Virtual Engagement Of HCPs

Digital Promotion To HCPs

- Restricting access to HCP-only ads for prescription-only medicines, pharmacy-only medicines and professional use only devices
- Laying paper trail with HCPs
- Disclaimers on unrestricted pages insufficient



Virtual Events

- Meal delivery services permissible under SAPI Code
 - Meal times
 - Company representative must be present
 - Formal educational activity
 - Not for one-to-one meetings
 - HCPs must be at workplaces
 - S\$30 limit
- *C.f.* medical devices under SMF Code



Gifts vs Donations & Grants

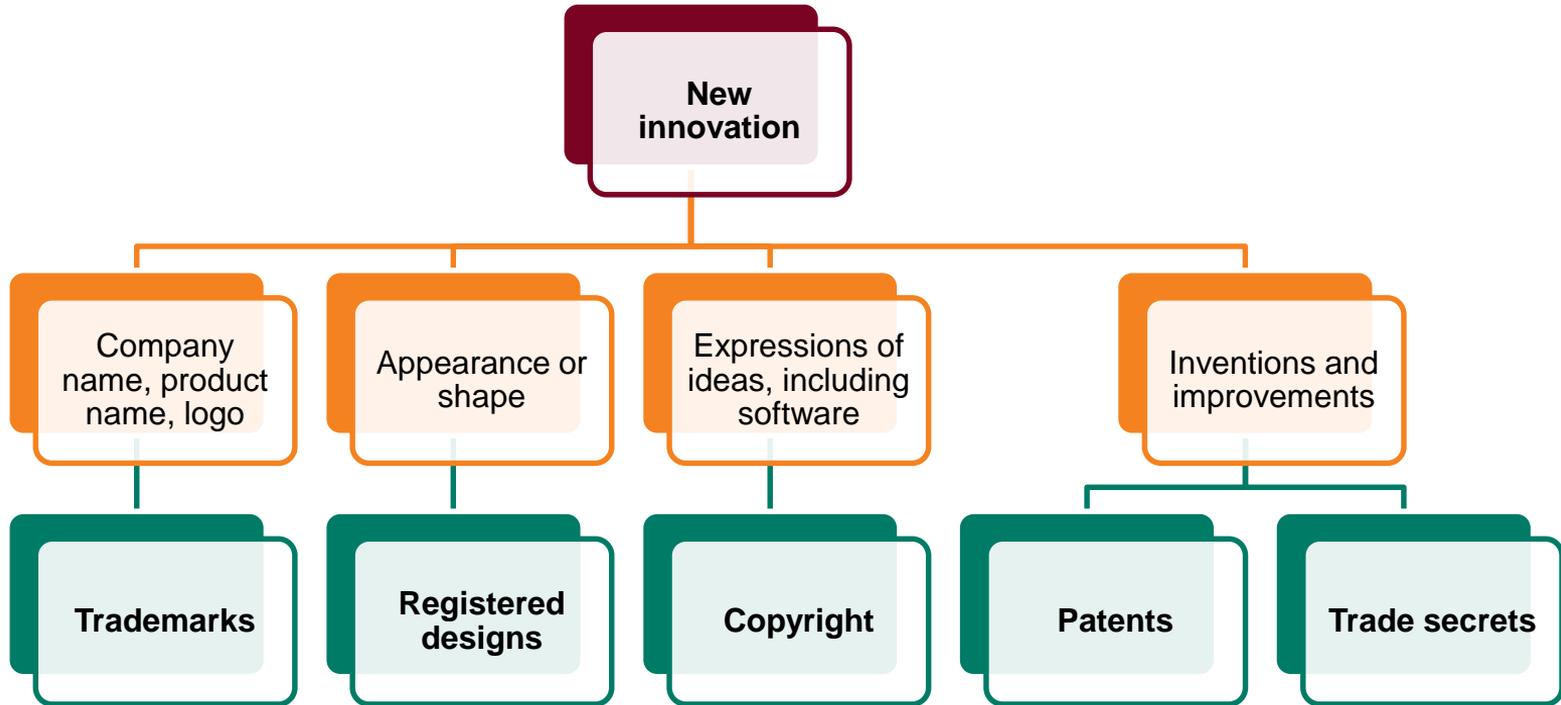
- No personal gifts even during COVID-19
- Consider donations / grants to institutions
 - Unsolicited
 - Unrelated to prescription / purchase
 - Paper trail
 - Withstand public scrutiny



3

Patent Considerations

Types Of IP Protection

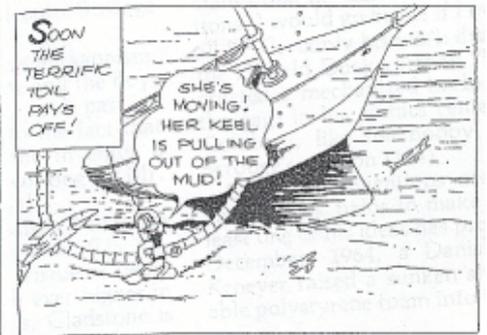
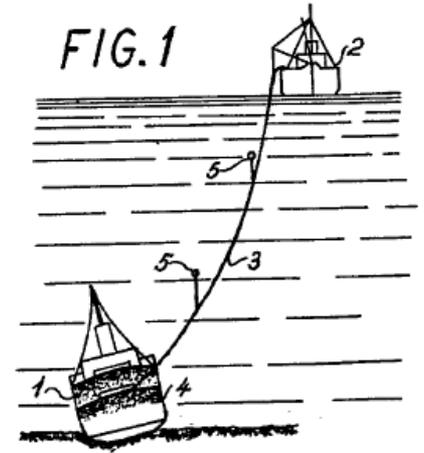


What Are Patents?

- Exclusive right
 - To make use, sell, offer for sale, import
 - Restricted geography & time (20 years)
- Patentable subject matter
 - ✓ System, device, product, method, process
 - ✗ Software, method of diagnosing/treating

What Are Patents?

- Substantive requirements
 - Novelty
 - Inventive step
 - Industrial application



Digital Health Patenting Trends

- Transformation of patient-doctor interactions e.g. telehealth, mobile health, real-time diagnostic tools

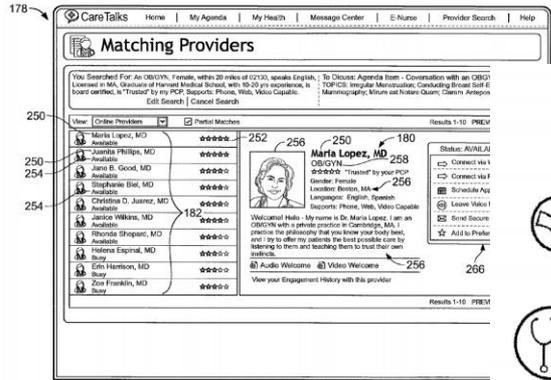


FIG. 5C

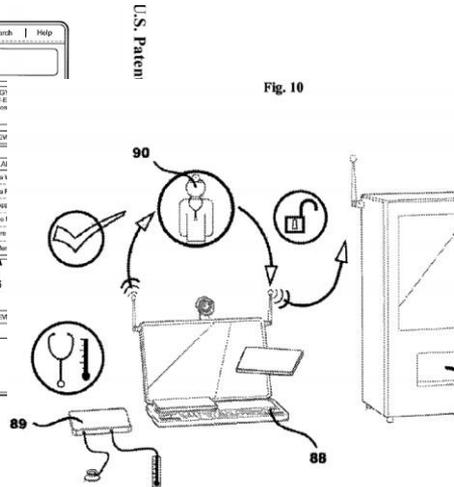


FIG. 10

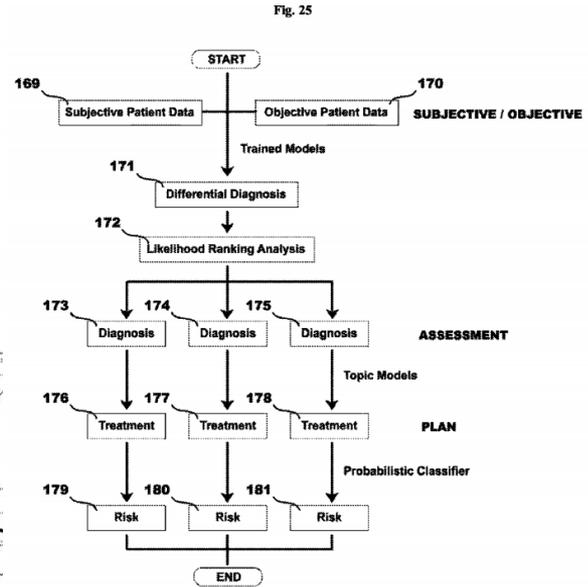


Fig. 25

Digital Health Patenting Trends

- Contact tracing

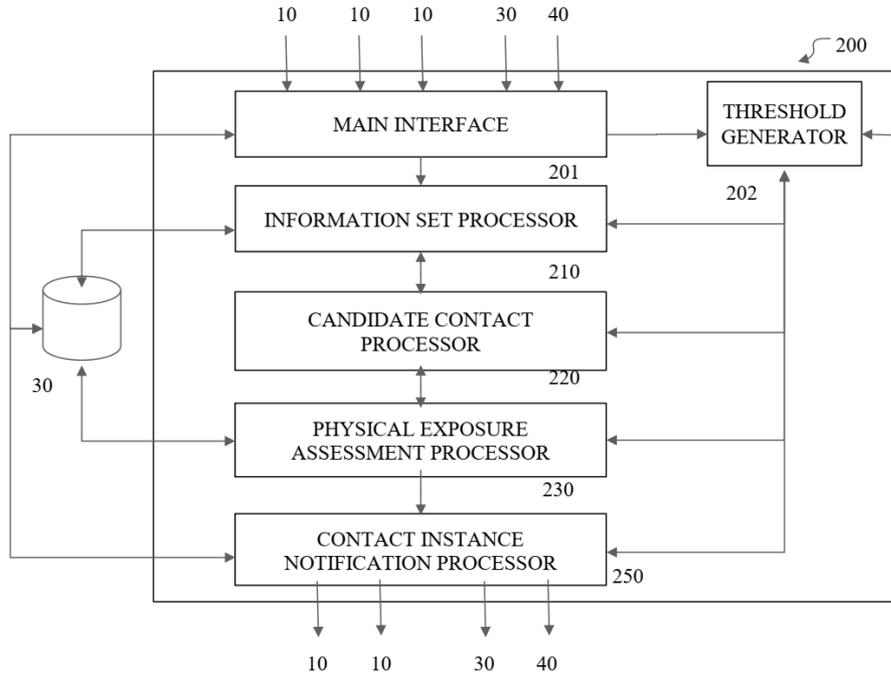


FIGURE 2

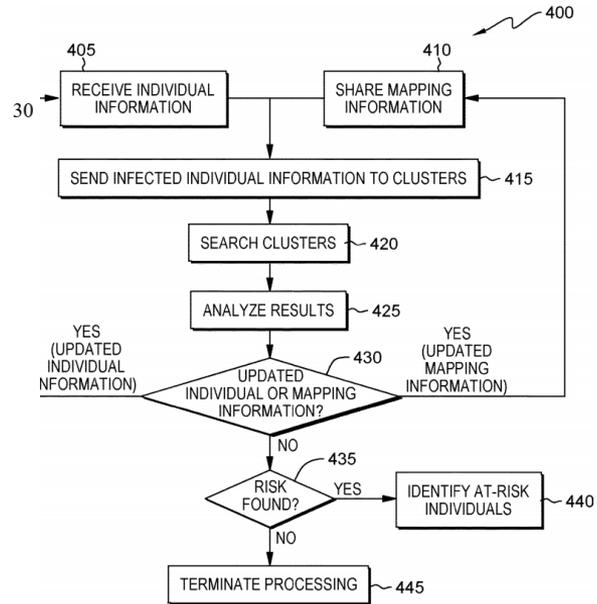
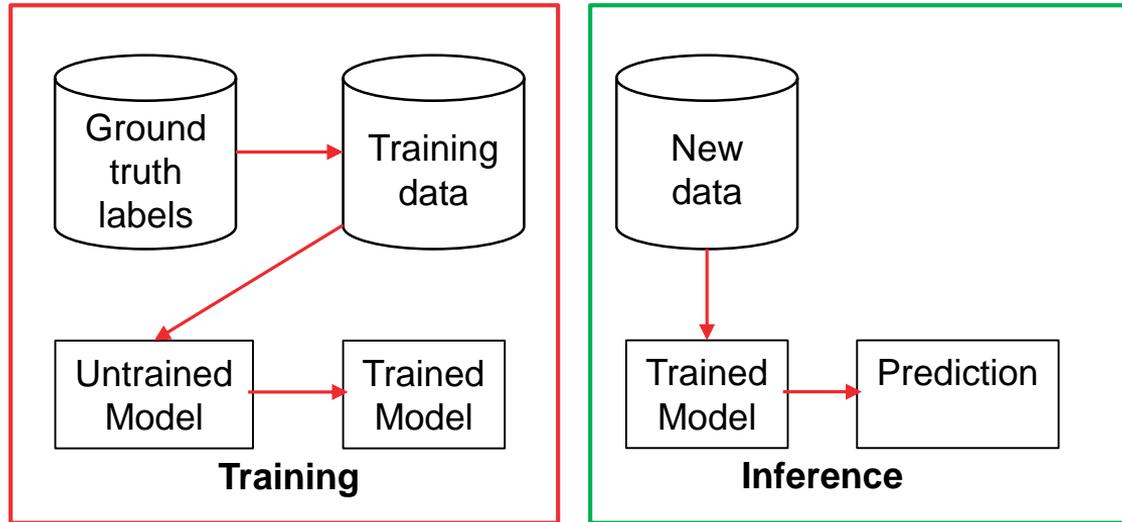


FIG. 4

Digital Health Patenting Trends

- Artificial Intelligence



Digital Health Patenting Trends

- Electronic health records
- Improving information flow
- Information security
- 3D printing applications
- Health insurance



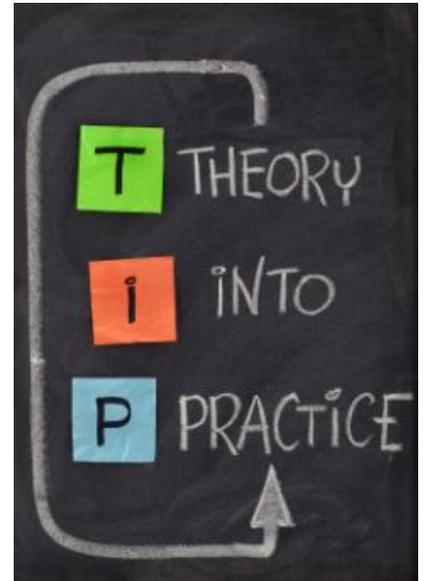
Key Issues

- Protect it
 - Which form of IP
 - Commercial value vs registration costs
 - Strategic reasons
- Protect yourself
 - Infringe on 3rd party IP
 - Jurisdiction-specific



Key Practical Tips

- Plan
 - Realistic timelines to pursue patent protection + assess infringement
 - Budgets should cater for IP costs
 - Involve internal legal teams early
- Disclosures
 - Do not publicly disclose
 - If 3rd parties are involved, ensure agreements in place
- Document
 - Written assignments / employee records



4

Cybersecurity

Why Cybersecurity Is Critical

- Healthcare tops list for cyberattacks
- Potential multiple heads of liability
- Cannot outsource liability to data intermediary
- May be data intermediary if data is processed
- Obligations *viz.* reasonable security arrangements
- Upcoming mandatory reporting obligations



Preparing For Attacks

- Put in place monitoring measures / tools
- Implement data breach management plan
- Review contracts
- Get cybersecurity insurance



Contact us



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