



Baker  
McKenzie  
Wong & Leow.

# Digital Health: *Are you Ready?*

Lim Ren Jun / Abe Sun | Baker McKenzie Wong & Leow



# Agenda

1

Digital Promotion To Consumers

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2

Virtual Engagement Of HCPs

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3

Patent Considerations

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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

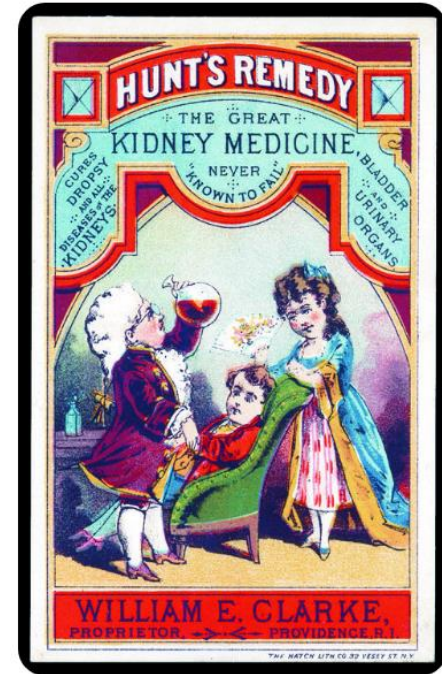
# New Wine In Old Wineskins

- 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



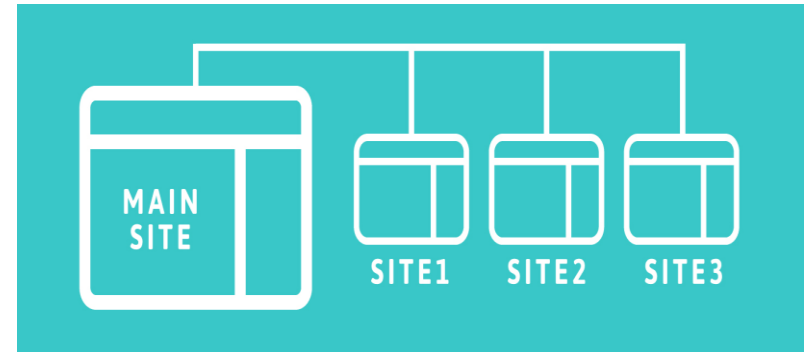
# Aggressive Claims

- 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

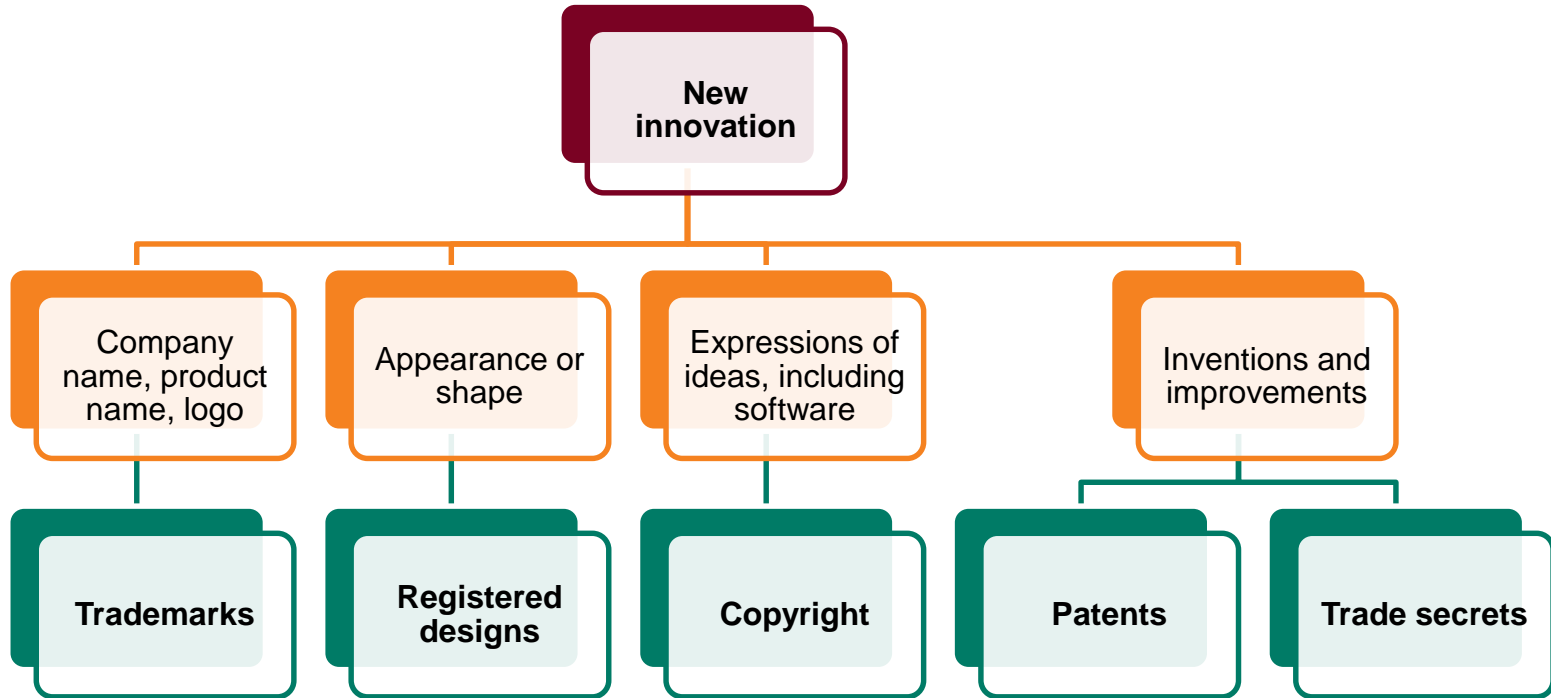




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# Patent Considerations

# Types Of IP Protection

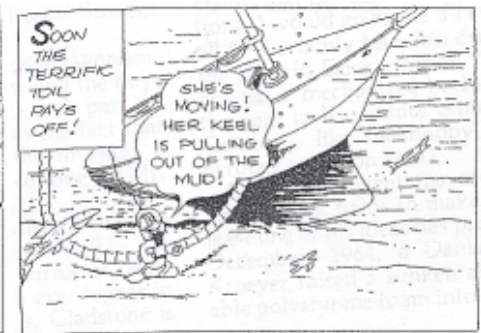
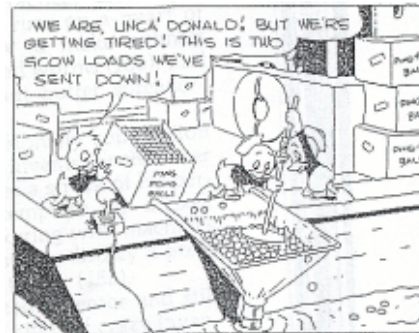
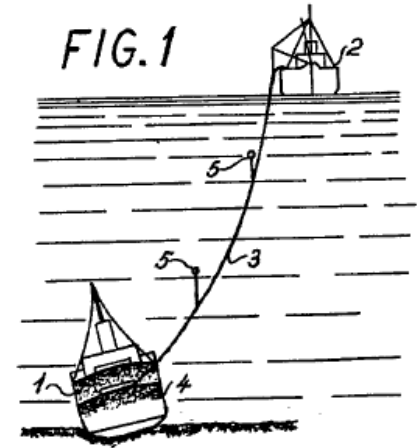


# What Are Patents?

- 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

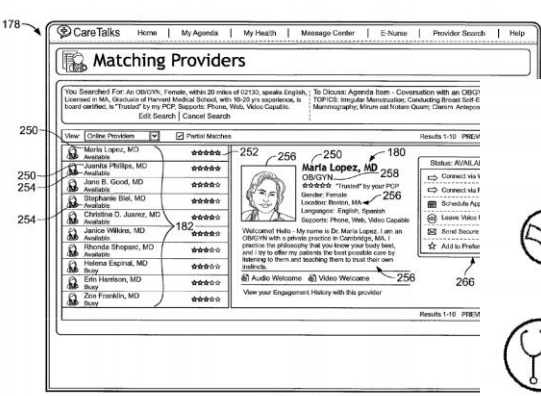


FIG. 5C

U.S. Patent

Fig. 10

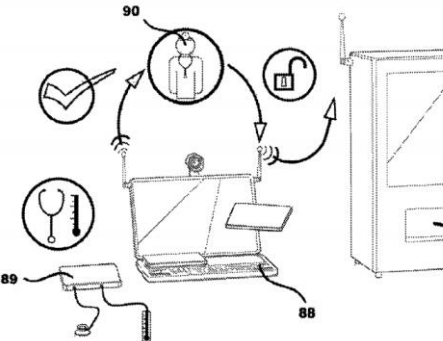
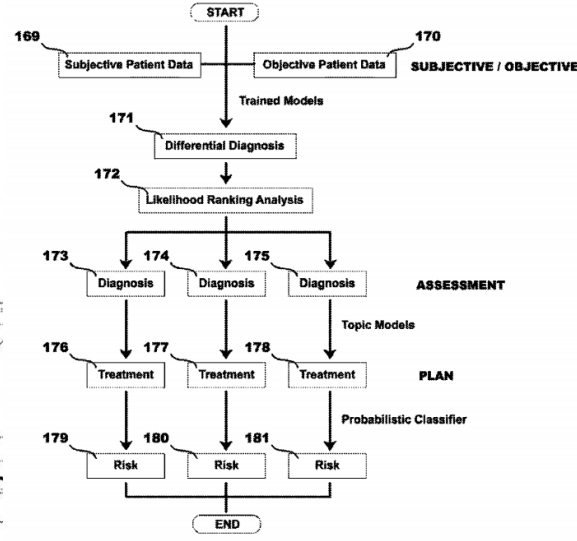


Fig. 25



# Digital Health Patenting Trends

- Contact tracing

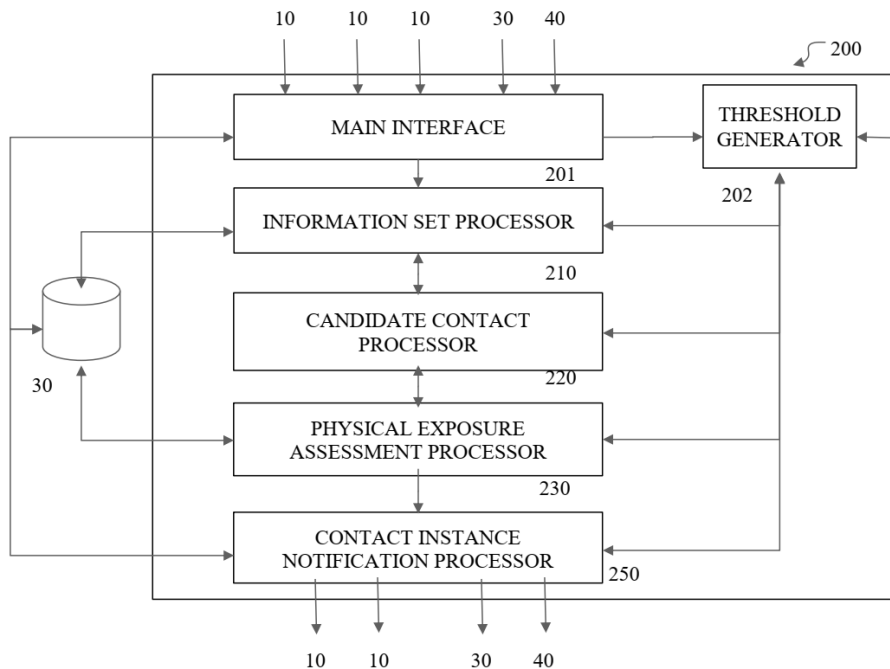


FIGURE 2

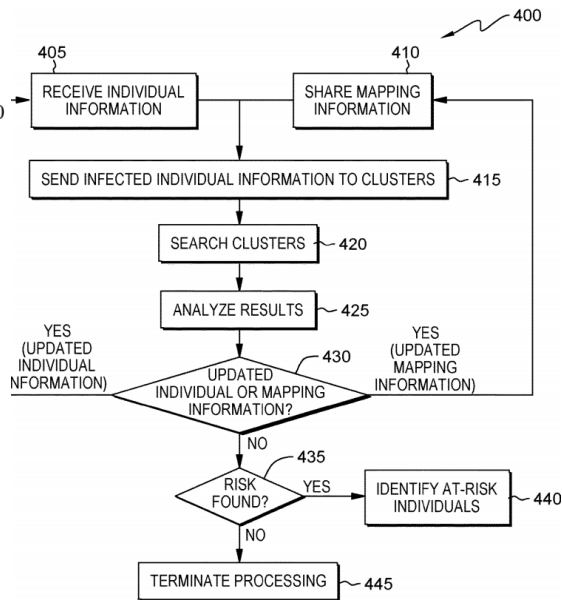
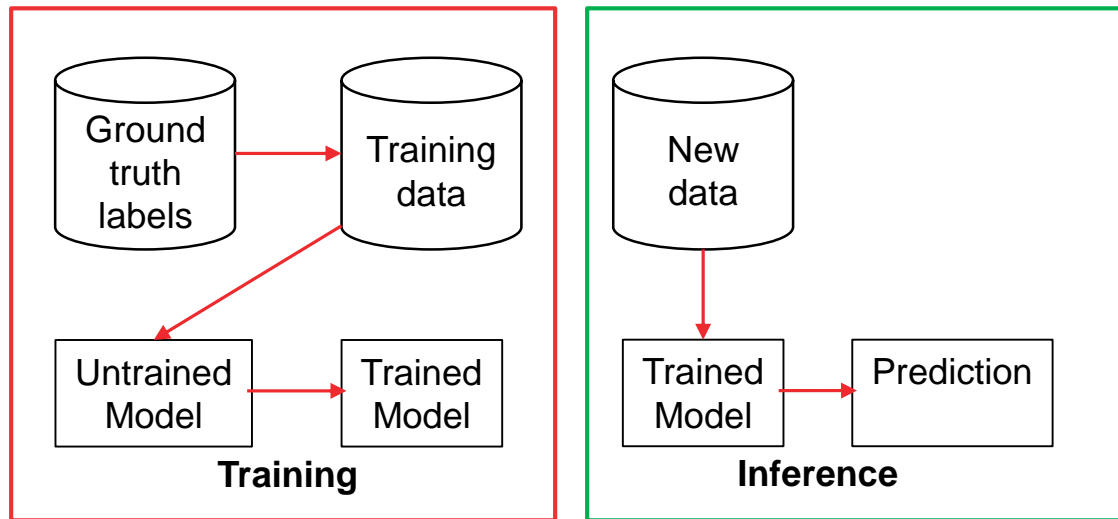


FIG. 4

# Digital Health Patenting Trends

- Artificial Intelligence





# Digital Health Patenting Trends

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



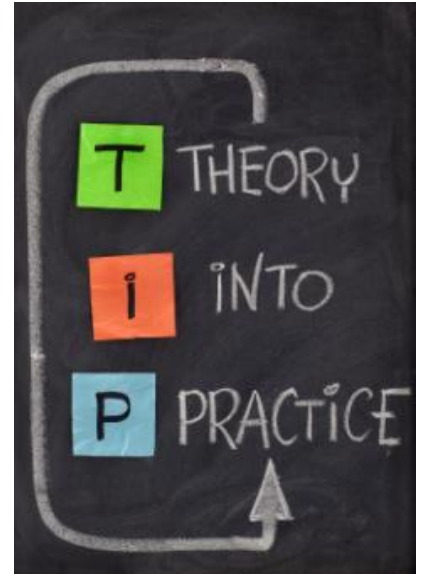
# Key Issues

- Protect it
  - Which form of IP
  - Commercial value vs registration costs
  - Strategic reasons
- Protect yourself
  - Infringe on 3<sup>rd</sup> 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 3<sup>rd</sup> 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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