

# Respirator Innovation Challenges

Richard Gordon, Founder, Inventor, CEO



# The Airgami® Mask



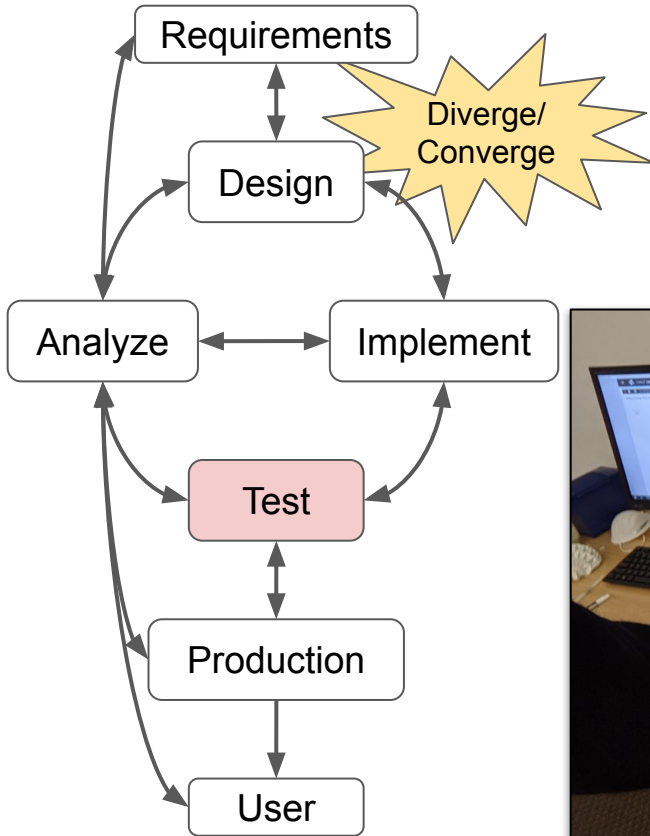
# Investment

Can you make, market, protect, exit? Even if you can, there is little investment!

- Government
  - Helpful competitions BUT ...
  - Mask Innovation Challenge: \$500 k total shared among 14 companies
- Dominant Mask Companies
  - Not acquiring startups
  - 10,341 active NIOSH respirator approvals, 104 NIOSH approval holders (4/28/2025)
- Venture Capital
  - Perceived mature industry
  - Boom-bust demand

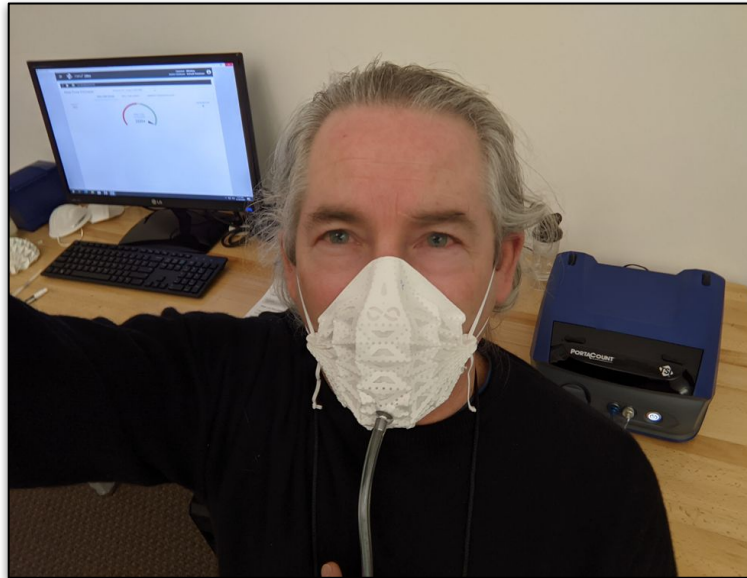


# Testing Bottlenecks

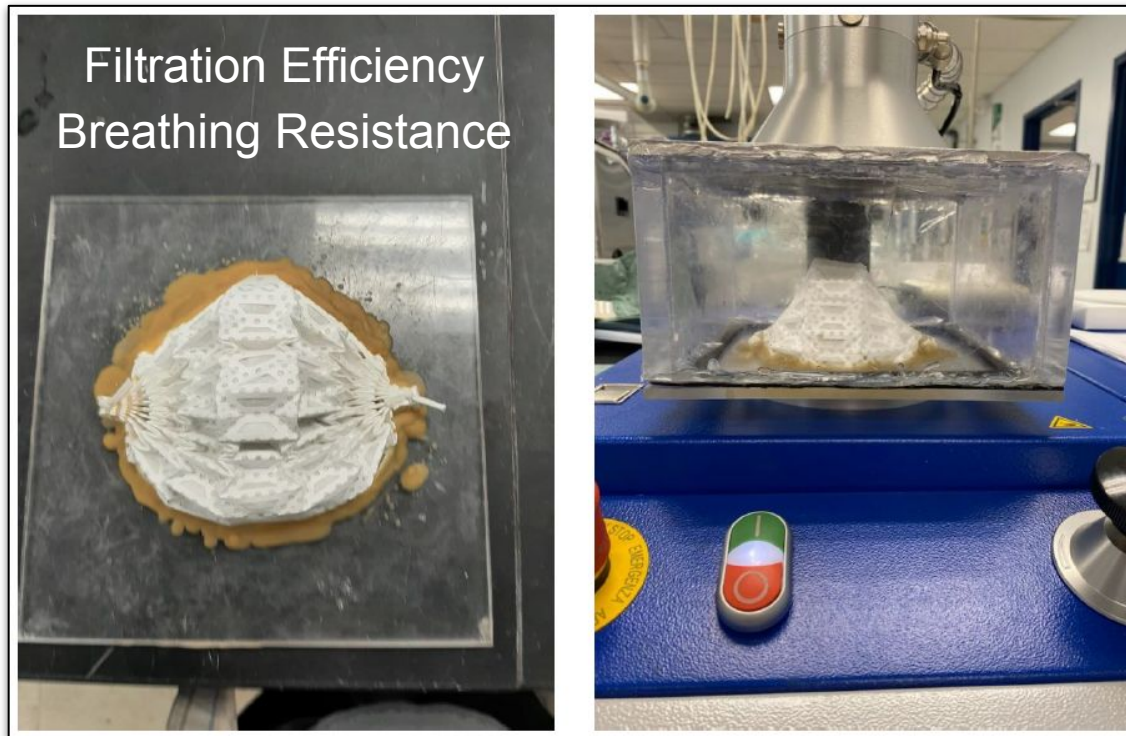


## Fit Testing

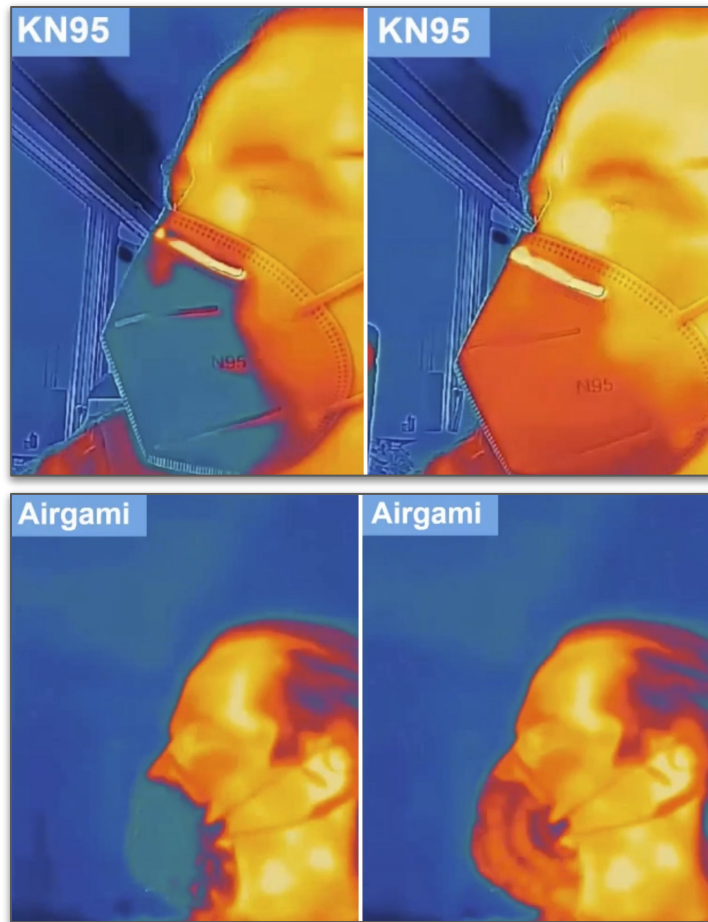
- Expensive equipment
- Time consuming
  - Multiple sizes (XL, L, M, S)
  - Multiple test subjects per size
- Expertise required especially for innovative designs



# Testing Bottlenecks



- Lack of access to affordable, rapid lab testing
- Lab testing may not reflect actual usage



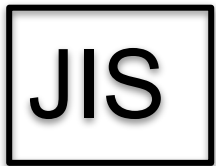
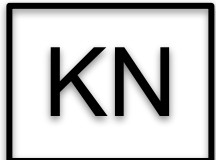
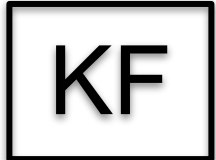
# Certification Standards

- Different test standards -> wildly different results
- Companies exploited such discrepancies to mislead

Table 3. [Study co-authored by NIOSH and Nelson Labs](#)

Filtration efficiencies for N95 FFR, surgical N95 FFR, and surgical mask models using the NIOSH NaCl, PFE, BFE, and VFE test methods.

| Type         | Model          | Sample Size | Efficiency (%) |      |           |      |       |      |       |      |
|--------------|----------------|-------------|----------------|------|-----------|------|-------|------|-------|------|
|              |                |             | NIOSH NaCl     |      | PFE (FDA) |      | BFE   |      | VFE   |      |
|              |                |             | Mean           | SD   | Mean      | SD   | Mean  | SD   | Mean  | SD   |
| N95 FFR      | A              | 5           | 98.87          | 0.20 | 99.88     | 0.16 | 99.90 | 0.00 | 99.90 | 0.00 |
| N95 FFR      | B              | 5           | 99.66          | 0.03 | 99.99     | 0.02 | 99.90 | 0.00 | 99.90 | 0.00 |
| N95 FFR      | C              | 5           | 98.15          | 0.21 | 99.74     | 0.11 | 99.62 | 0.24 | 99.80 | 0.12 |
| N95 FFR      | D              | 5           | 99.32          | 0.13 | 99.93     | 0.07 | 99.90 | 0.00 | 99.90 | 0.00 |
| N95 FFR      | E              | 5           | 99.31          | 0.18 | 99.94     | 0.05 | 99.90 | 0.00 | 99.90 | 0.00 |
| N95 FFR      | F              | 5           | 99.33          | 0.07 | 99.86     | 0.29 | 99.90 | 0.00 | 99.90 | 0.00 |
| Surgical N95 | G              | 5           | 98.93          | 0.20 | 99.97     | 0.02 | 99.80 | 0.12 | 99.88 | 0.04 |
| Surgical N95 | H              | 5           | 99.68          | 0.24 | 99.98     | 0.03 | 99.86 | 0.09 | 99.88 | 0.04 |
| Surgical N95 | I              | 5           | 98.27          | 0.37 | 99.84     | 0.05 | 99.90 | 0.00 | 99.90 | 0.00 |
| SM           | J <sup>a</sup> | 5           | 54.72          | 1.88 | 98.26     | 0.09 | 98.12 | 0.31 | 97.12 | 0.34 |
| SM           | K <sup>a</sup> | 5           | 88.40          | 1.48 | —         | —    | 99.80 | 0.10 | 99.88 | 0.04 |
| SM           | L <sup>a</sup> | 5           | 63.12          | 0.91 | 98.66     | 0.02 | 97.48 | 0.63 | 97.72 | 0.36 |



# Certification Challenges

- N95 Designed for Occupational Use
  - Need consumer standard
  - Need pediatric standard
  - Need reusability standard
- Certification Catch 22
  - Customers want N95 before ordering
  - Inventors need factories, stable processes (QMS) to get N95 certification
  - Factories need orders to start production
- Certification Process
  - Costly and time consuming
  - Inventors must freeze design and stop innovating to start certification
  - Redo certification if design changes (e.g. color)

# Production

- Ecosystem
  - Mask inventions need manufacturing inventions (e.g. machine-folding origami)
  - USA lacks manufacturing and automation expertise
  - USA supply chain is vulnerable
- USA Labor
  - Expensive, high turnover
- Pilot Lines
  - R&D needs a separate line from production
  - Innovating on stable production is too risky
- Mass Production
  - Inventor survival depends on cost reduction
  - Cost reduction needs automation
  - Automation needs CAPEX
  - CAPEX needs to be justified by predictable, high volume



# Legal



US010799728B2

## ● Patent

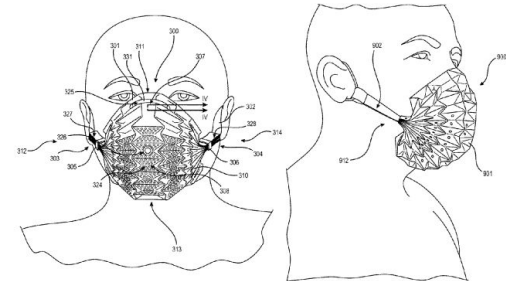
- Investment prerequisite
- Crowded IP landscape
- Slow and time consuming
- Expensive
- Domestic, international
- Arcane
- Zero ROI

## ● Litigation

- Historic product liability lawsuits (e.g. 3M)
- Illegal to export masks not certified to local standards
- Customer support risks
  - B2B: 1 customer, 10,000 masks each
  - B2C: 10,000 customers, 1 mask each

|                                                                                                                            |                                                                                                                                         |                                                  |
|----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| (12) <b>United States Patent</b><br><b>Gordon</b>                                                                          |                                                                                                                                         | (10) <b>Patent No.:</b> <b>US 10,799,728 B2</b>  |
|                                                                                                                            |                                                                                                                                         | (45) <b>Date of Patent:</b> <b>Oct. 13, 2020</b> |
| (54) <b>RESPIRATORS AND RELATED METHODS</b>                                                                                | D658,334 S 4/2012 Goranov et al.<br>8,439,038 B2 5/2013 Steindorf et al.<br>8,967,147 B2* 3/2015 Martin ..... A62B 18/025<br>128,206.19 |                                                  |
| (71) Applicant: <b>AIR 99 LLC</b> , Boulder, CO (US)                                                                       |                                                                                                                                         |                                                  |
| (72) Inventor: <b>Richard Gordon</b> , Boulder, CO (US)                                                                    | 2005/0096524 A1 5/2005 Cheng<br>2006/0130841 A1 6/2006 Spence et al.<br>(Continued)                                                     |                                                  |
| (73) Assignee: <b>AIR99 LLC</b> , Boulder, CO (US)                                                                         |                                                                                                                                         |                                                  |
| (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 272 days. | FOREIGN PATENT DOCUMENTS                                                                                                                |                                                  |
|                                                                                                                            | WO 2001089330 A2 11/2001                                                                                                                |                                                  |
|                                                                                                                            | WO 2014199378 12/2014                                                                                                                   |                                                  |
| (21) Appl. No.: <b>15/443,643</b>                                                                                          | OTHER PUBLICATIONS                                                                                                                      |                                                  |
| (22) Filed: <b>Feb. 27, 2017</b>                                                                                           | The International Search Report and Written Opinion for corresponding Int'l Application No. PCT/US18/19937 dated Jun. 29, 2018.         |                                                  |
| (65) <b>Prior Publication Data</b>                                                                                         |                                                                                                                                         |                                                  |
| US 2018/0243592 A1 Aug. 30, 2018                                                                                           |                                                                                                                                         |                                                  |
| (51) <b>Int. Cl.</b>                                                                                                       |                                                                                                                                         |                                                  |
| <b>A62B 18/08</b> (2006.01)                                                                                                |                                                                                                                                         |                                                  |
| <b>A62B 18/08</b> (2006.01)                                                                                                |                                                                                                                                         |                                                  |
| <b>A62B 23/02</b> (2006.01)                                                                                                |                                                                                                                                         |                                                  |
| <b>A62B 18/02</b> (2006.01)                                                                                                |                                                                                                                                         |                                                  |
| (52) <b>U.S. Cl.</b>                                                                                                       |                                                                                                                                         |                                                  |
| CPC ..... <b>A62B 18/084</b> (2013.01); <b>A62B 23/025</b> (2013.01); <b>A62B 18/025</b> (2013.01)                         |                                                                                                                                         |                                                  |
| (58) <b>Field of Classification Search</b>                                                                                 |                                                                                                                                         |                                                  |
| CPC .... <b>A62B 18/025</b> ; <b>A62B 18/084</b> ; <b>A62B 23/025</b>                                                      |                                                                                                                                         |                                                  |
| See application file for complete search history.                                                                          |                                                                                                                                         |                                                  |
| (56) <b>References Cited</b>                                                                                               |                                                                                                                                         |                                                  |
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20 Claims, 10 Drawing Sheets



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# Summary of Respirator Innovation Challenges

- Investment
- Testing Bottlenecks
- Certification Standards
- Certification Challenges
- Production
- Legal